

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

FSIS PHIS DIRECTIVE

9900.2
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IMPORT REINSPECTION OF MEAT, POULTRY, AND EGG PRODUCTS

I. PURPOSE

This directive provides import inspection personnel with instructions on how to conduct import reinspection on shipments of imported meat, poultry, and egg products.

KEY POINTS

- *Outlines the process of how to perform the reinspection of imported meat, poultry, and egg products.*

II. CANCELTION

FSIS PHIS Directive 9900.2, Import Reinspection of Meat, Poultry, and Egg Products dated 5/24/12

III. REASON FOR REISSUANCE

FSIS is reissuing this directive because it has made changes in section VII. B. Table 1 and section XXIV. A., and Annex 1, Sampling Plan SP3, regarding the number of boneless manufacturing trimmings and similar products samples that import inspection personnel are to collect.

IV. REFERENCES

9 CFR parts 327, 381 subpart T, and 590.900-970

FSIS Directive 6420.2 Verification of Procedures for Controlling Fecal Material, Ingesta, and Milk in Slaughter Operations

FSIS Directive 9900.3 Pre-Stamping Imported Product

FSIS Directive 9900.8 Meat, Poultry, Egg Products, and Shell Eggs Refused Entry into the United States (US)

FSIS Directive 9900.5 Label Verification of Imported Meat, Poultry and Egg Products

FSIS Directive 9900.6 Laboratory Sampling Program for Imported Meat, Poultry and Egg Products

FSIS Directive 7530.1 Handling a Process Deviation or Abnormal Container of Thermally Processed, Commercially Sterile Canned Product

FSIS Directive 10,010.1 Microbiological Testing Program and Other Verification Activities for *Escherichia coli* O157:H7 in Raw Ground Beef Products and Raw Ground Beef Components and Beef Patty Components

The PHIS User Guide is available via the FSIS Intranet on the PHIS page under Resources

V. BACKGROUND

Import inspection personnel perform reinspection on all FSIS amenable meat, poultry, and egg products imported into the United States. They verify that the certification and application, whether printed or electronic data, is complete and accurate. They access the Public Health Information System (PHIS) and obtain the reinspection assignment. Import inspection personnel then follow the instructions in this directive on how to determine whether imported product meets FSIS standards and is not adulterated or misbranded. In order to complete the reinspection, import inspection personnel are to refer to the PHIS User Guide.

VI. PRIORITIZATION OF REINSPECTIONS

A. Prioritization. Each lot of meat, poultry, or egg products will be assigned at least a Certification and Label Verification type of inspection (TOI). When an inspection certificate/application contains more than one lot, import inspection personnel are to perform reinspection on the lots assigned additional physical TOIs with public health ramifications first (e.g., product examination, condition of container TOIs.) prior to those lots just assigned Certification and Label Verification TOIs.

B. Adding Unscheduled TOI's in PHIS. When a lot fails a physical TOI because of a food safety public health defect, and there are other lots on the inspection certificate in which the identified public health defects may be present, import inspection personnel are to add and perform an Unscheduled TOI. Import inspection personnel are to return to the PHIS Lot Manager, and for each lot on the inspection certificate, add a physical TOI as an Unscheduled TOI. The Unscheduled TOIs are only to be assigned to lots of product from the same processing establishment number and in the same process category and product group.

NOTE: In the PHIS Lot Manager, import inspection personnel are to add the Unscheduled TOIs rather than Redraw the Assignment from the remaining lots on the inspection certificate. This action will ensure that the Intensified Level of Reinspection is reserved for future inspection certificates and applications from the same processing establishment.

C. Import inspection personnel are to take samples from a lot when assigned a reinspection by the PHIS. These samples may be subject to destructive sampling procedures (e.g., thermal process product sample, pink juice test samples). When this occurs, the samples are not to be returned to the lot after reinspection.

VII. SAMPLING PLANS AND DEFECT TABLES FOR PHYSICAL INSPECTIONS

A. Physical Inspections - Import inspection personnel are to follow Table 1 (below) when determining the sampling plan and defect criteria for a specific product when a physical inspection has been assigned. Product examination is an organoleptic physical type of inspection in which import inspection personnel look for defects such as blood clots, bruises, bone fragments, fecal and ingesta, extraneous materials (wood, glass, chemicals, and insects), hair and wool, hide, stains, pathologic lesions, and off condition. The defects are classified either as a public health (PH) concern or as other consumer protection (OCP) concern (e.g. quality). The types of defects (Annex 2 attached to this directive) are described as:

1. Raw Intact and Raw Non-Intact products, excluding poultry and ratites (PE1);
2. Raw Intact and Raw Non-Intact poultry and ratite products (PE2); and
3. Further processed products of all amenable species, including egg products (PE3).

B. Import inspection personnel are to use the guidance in Table 1 when determining which Sampling Plan (Annex 1) and Defect Criteria Table (Annex 2) are to be used to determine the product's acceptability for physical inspections.

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

Product	Sampling Plan (Annex 1)	Defect Table (Annex 2) or Other
Beef, Equine (note below), and Veal Carcasses	SP1	Product Examination 1
Goat, Lamb, Mutton, and Pork Carcasses	SP2	Product Examination 1
All Red Meat Species – Primals/Subprimals, Cuts, Offals, and Miscellaneous Parts	SP3	Product Examination 1 as applicable for species
Boneless for Manufacturing (Trimming), Mechanically Separated, AMR, Finely Textured Trim and Bulk Ground Products	SP3A	Product Examination 1 or Product Examination 2, as applicable for species
Whole Birds and Poultry Parts	SP4	Product Examination 2
Ground, comminuted, processed, canned, packaged, and all other products not covered by Plans SP1 to SP4	Normal/Increased/Intensified SP5	Product Examination 3
Cooked Meat in Tubes (for Pink Juice Test only)	SP6	Product Examination 3
Condition of Container (COC) - Glass and Metal Containers with Double Seams	Normal/Increased/Intensified SP 7	Condition of Container Examination 1 (COCE1)
Condition of Container - Flexible Containers	Normal/Increased/Intensified SP 7	Condition of Container Examination 2 (COCE2)
Incubation	SP 8	Condition of Container, COCE1 or COCE2, as applicable for the type of container; FSIS Directive 7530.1
Net Weight	SP9	9 CFR 442.3 and 442.4.

NOTE: Currently the equine products that are imported as edible are destined for pet food.

VIII. PHYSICAL INSPECTION: CARCASSES, WHOLE BIRDS

A. Import inspection personnel are to use the following instructions when conducting a physical examination on all imported red meat carcasses (beef, veal, equine, goat, lamb, mutton, pork) or poultry (whole birds), including ratites:

1. Examine visually from top-to-bottom the inside and outside portions and surfaces,
2. Examine the body cavity of the carcass, and
3. For Hide-On Veal Carcasses, examine the back of the carcass, palpating and examining the surface to detect public health or other consumer protection defects.

B. CARCASS SHIPMENTS FROM CANADA

1. For hanging carcass shipments from Canada, under established procedures, generally the Canadian inspectors identify randomly selected samples by either numbering each carcass side or by marking the carcasses in such a way that they can be readily identified from the remainder of the lot. The selected samples are placed at the rear of the truck and sealed by the Canadian Food Inspection Agency (CFIA). The seal number will be identified on the inspection certificate.
2. When a product examination is assigned, import inspection personnel are to verify the CFIA seals are intact and have the CFIA marked samples unloaded and staged. If the samples are not properly identified, contact your supervisor for further guidance.

IX. PHYSICAL INSPECTION OF CUTS, OFFALS, AND MISCELLANEOUS PARTS

Import inspection personnel are to examine all external, internal, and cut surfaces of the product samples (Annex 1). Frozen product samples may need to be completely defrosted before examination (e.g. frozen boneless beef).

X. PHYSICAL INSPECTION OF FINELY TEXTURED TRIM, ADVANCED MEAT RECOVERY (AMR) PRODUCTS, BONELESS FOR MANUFACTURING (TRIMMINGS) AND MECHANICALLY SEPARATED PRODUCTS

The product samples (Annex 1) are to be removed from the container and then examined by import inspection personnel. It may be necessary to partially temper or completely defrost the samples to examine internal and cut surfaces during the examination.

XI. PHYSICAL INSPECTION OF COOKED MEAT FROM RESTRICTED COUNTRIES

A. For physical examination (not Pink Juice Examination as per FSIS Directive 9900.7), the sample unit for a product examination is to be taken by selecting:

1. a tube of cooked meat or;

2. approximately 12 pounds of product from the shipping container.

B. Import inspection personnel are to ask the import establishment to defrost the sample units and examine for bones or other defects.

NOTE: Import inspection personnel are to follow FSIS Directive 9900.7 if they find bones or under processing during a product exam of cooked meat from restricted countries.

XII. PHYSICAL INSPECTION OF PARMA, PROSCIUTTO, AND SERRANO HAMS

Import inspection personnel are to:

1. If packaged, ask import establishment personnel to remove the packaging and present with the sample;
2. Observe the outer surface of the sample unit;
3. Smell the outer surface for signs of off-condition;
4. Insert a trier or knife into the hole of the aitchbone;
5. If the bone is removed, make the insertion in the same location;
6. Remove the trier or knife quickly and carefully smell the trier or knife for evidence of off-condition or sour smell; and
7. Repeat this process on the stifle joint.

XIII. PHYSICAL INSPECTION OF MEAT EXTRACTS, BONE STOCK, BROTH, AND SIMILAR ITEMS

Import inspection personnel are to ask import establishment personnel to remove the sample from the container and place it on a sanitary surface for examination.

Import inspection personnel are to spread the product in a tray to examine it for color, odor, foreign material, and other defects.

XIV. PHYSICAL INSPECTION OF SEMI-SOLID PACKED PRODUCTS (e.g., canned hams, canned corned beef, taquitos, and other processed products)

Import inspection personnel are to:

1. If packaged, ask the import establishment personnel to remove the packaging and present with the sample (Annex 1);
2. Observe all outer surfaces and the inside of the can or package for possible defects;
3. Smell for possible off-condition odor;
4. Make at least one cut with a knife through the product; and

5. Observe the inner surfaces for off-color, which may be an indicator of under-processing.

XV. PHYSICAL INSPECTION OF NON-SOLID PACKED PRODUCTS (BEEF IN GRAVY, STEWS)

Import inspection personnel are to

1. Request that import establishment personnel remove the sample from the container and place it on a sanitary surface for examination
2. Spread product in tray to observe for defects;
3. Observe the inside of the can or package for possible defects; and
4. Smell for possible off-condition odor.

XVI. PORK SKINS LABELED FOR POPPING, RENDERING, OR GELATIN MANUFACTURING ONLY

Import inspection personnel are to request that the importer provide documentation that the intended use of the product is for popping, rendering, or gelatin manufacturing operation. Import inspection personnel are not to classify hair or hair roots as defects.

XVII. CONDITION OF CONTAINER EXAMINATIONS

A. For products imported in rigid metal or glass containers, semi-rigid containers that have double seams, and retorted pouches and trays, import inspection personnel are to sample and reinspect the condition of such containers. The reinspection is intended to determine whether the containers have any abnormal, critical, or major defects that may indicate under-processing of the products, or whether the defects themselves may substantially affect the integrity or usability of the containers. The primary methods for detecting container defects are as follows:

B. Metal Containers with Double Seams (Annex 2, COCE1 Table)

1. Examine the label (if a paper label) for stains that may be evidence of leakage or rust.
2. Apply slight end pressure on one end and observe for movement of the other end. Repeat on the other end.
3. Gently run finger along all double seams to detect any defects.
4. 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.
5. Check whether the container has a foreign establishment number embossed or lithographed on the container as required in 9 CFR 327.14 (b) (2).
6. Check whether the container, when required, is marked with a permanent, legible

identifying code mark as required in 9 CFR 318.301(e) and 381.301 (e).

7. Check any embossing impressions on container for metal fracture or stress.

C. Glass Containers (Annex 2, COCE1 Table)

1. Examine jar surfaces for obvious defects or crooked caps.
2. Examine the exterior of the jar closure for food particles or foreign materials.
3. 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.
4. Check the safety button, if present, on the cap.
5. If retorted, check whether the container is marked with a permanent, legible identifying code mark as required in 9 CFR 318.301(e) and 381.301 (e).

D. Flexible Pouches and Plastic Tray Containers (Annex 2, COCE2 Table): Visual defects of concern include misaligned seals, flex cracking, product contamination of the seal, non-bonding, seal creep, delaminating, or scratches.

1. All surface areas of the containers are to be examined for the presence of defects.
2. The edges of each seal are to be examined for any evidence of product in the seal area. No product (oil) should be visible.
3. Test the seals by grasping the unsealed area of the container and exerting a steady pressure. Observe the seals for signs of seal creep or delaminating (pouches).
4. If retorted, check whether the container is marked with a permanent, legible identifying code mark as required in 9 CFR 318.301(e) and 381.301 (e).

XVIII. INCUBATION OF HERMETICALLY SEALED CONTAINERS

A. When assigned by the PHIS, import inspection personnel are to select the appropriate number of containers for incubation, following the instructions below.

B. Incubator Requirements –Import inspection personnel are to verify that official import establishments that receive shelf stable containers are able to provide an incubator. Import inspection personnel are to follow the Incubation Time and Temperature requirements identified in 9 CFR 318.309.

C. Selecting Samples – Import inspection personnel are to:

1. Randomly select 48 sample units from the lot. 24 of the sample units are used as the initial sample, and the remaining units are kept as the reserve sample. Incubation samples, including the reserve samples, are to be kept under FSIS control. Reserve samples are not to be secured in the incubator and are only used when a new incubation sample is needed for the involved lot.

2. Select only normal appearing containers.
3. Randomly select the incubation samples, when applicable, from those samples selected for a condition of container examination. The incubation samples may be selected after or during the container examination.

D. Record Keeping - Import inspection personnel are to:

1. Use FSIS Form 9550-1, Incubation Log, for documenting incubation start time, monitoring dates, and finish time, as well as results, and
2. Maintain, in the files, all recording charts used during the incubation.

E. Incubation Examination Procedures - Import inspection personnel are to:

1. Verify that only normal appearing containers are incubated.
2. Verify that the containers are placed in the incubator in an acceptable manner.
3. Verify that the recording chart is in place on the temperature-recording device.
4. Verify that the incubator and the recording charts are under FSIS control.
5. Check the sample containers in the incubator for abnormalities at least twice during the incubation period and at the completion of the incubation.
6. 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 to verify the incubator temperature has not exceeded 100^o F or gone below 90^o F. Request that the import establishment management adjust the incubator's temperature as needed. Refer to 9 CFR 318.309(d)(1)(ii) or 381.309 (d)(1)(ii) for additional requirements regarding the temperature for incubation of shelf-stable products.
7. Change the chart as needed to prevent overlap on the recording chart.
8. Inspect the containers for abnormal containers using the appropriate criteria (Annex 2, Table COCE1 or COCE2)
 - a. If abnormal containers are identified during or at the end of the incubation period, request that import establishment personnel remove the abnormal containers from the incubator and allow them to cool to room temperature for 24 hours under FSIS control.
 - b. After 24 hours, re-examine the containers. 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 laboratory as per FSIS Directive 7530.1, Handling a Process Deviation or Abnormal Container of Thermally

Processed, Commercially Sterile Canned Product.

- c. Disposition of the lot is determined when the laboratory results are forwarded to the FSIS subject matter expert (SME) who will interpret the laboratory results and ensure that the result is entered in the PHIS. Import inspection personnel are to take the action indicated by the SME. See Table B and C under Part XXIV of this directive, Results (“Pass” or “Fail” Criteria) 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.

XIX. NET WEIGHT REINSPECTION

A. Import inspection personnel are to follow these instructions when conducting a net weight reinspection.

1. Scales – Verify that the scales used by the import establishment in determining the net weight of meat poultry and egg products comply with 9 CFR 442.3 and 442.4.
2. Tare Weight – Verify that the tare weight is established using the National Institute of Standards and Technology (NIST) Handbook 133, checking the Net Contents of Packaged Goods.

NOTE: FSIS does not use the Wet Tare method.

3. Reinspection- Import inspection personnel are to use NIST Handbook 133, Tables 1-1, 2-1, and 2-9 in Appendix A (<http://ts.nist.gov/WeightsAndMeasures/h1334-05.cfm>) for net weight inspection on imported products.
4. Import inspection personnel are to:
 - a. Verify that the import establishment tests and certifies the scale, as per NIST Handbook 44.
 - b. Calculate the tare weight as per NIST Handbook 133.
 - c. Calculate the Maximum Allowable Variation (MAV) and record.
 - d. Weigh each sample unit and record the net weight.
 - e. Calculate total error and record.
 - f. Determine whether any containers are under or over the MAV and record.

XX. TANKER SHIPMENT REINSPECTION - (EDIBLE FATS AND OILS TRANSPORTED IN BULK TANKERS)

A. Import inspection personnel are to verify that inspection certificate or official letterhead documentation, official seals, and labeling of imported edible fats shipped in bulk tankers, either by railcar or truck, from approved foreign producers (countries and establishments) meet

all regulatory requirements.

B. Under 9 CFR 327.3, upon entry into the United States, tanker shipments of edible fats (tallow and lard) must be presented for reinspection at one of the following locations:

1. Official import inspection establishment; or
2. At a safe rail siding facility in close proximity to an official import inspection establishment. The responsible Regional Import Field Office (RIFO) is to be consulted for concurrence when this option is used.

C. Import inspection personnel are to verify that relevant required documentation has been presented to them before they perform reinspection the certification TOI.

D. Import inspection personnel are to perform a label verification procedure (LVP) and seal verification procedure for each tanker shipment of imported edible animal fat (e.g., tallow, lard, rendered fat) presented for re-inspection. When performing the seal verification, Import inspection personnel are to;

1. Verify that the seal numbers present on the tanker are the same as the numbers recorded on the inspection certificate or official letterhead documentation and application in PHIS.

NOTE: Import inspection personnel are to use extreme caution when performing this inspection task and to request that the official import establishment management facilitate the execution of this task in a safe manner. If the reinspection is at a rail siding, the inspection assignment will be known prior to leaving the import establishment.

2. Fail the Certification TOI and refuse entry the shipment when the shipment is non-compliant because the seals are missing, broken or incorrect.

E. If Import inspection personnel suspect that a physical inspection of the product is necessary; they are to:

1. Notify the RIFO, provide the basis for the request, and request that the shipment be transported to a FSIS official establishment capable of performing the reinspection.
2. If the RIFO concurs, contact the applicant to determine whether the applicant wants to forward the shipment for reinspection or not.
3. If the applicant does not want to forward for reinspection, access the PHIS, refuse entry as applicable, and monitor the disposition of the shipment that has been refused entry.
4. If the applicant does want to forward the lot for reinspection, the applicant will provide the Office of Field Operations (OFO) official establishment number to forward the lot to for reinspection.

F. The RIFO is to coordinate product movement for further inspection with the OFO District Office with authority over the official establishment and to provide a list of concerns about the

shipment.

G. Upon receipt of the inspection results from the OFO inspector, the lot disposition is to be completed by the assigned import inspector.

XXI. PHYSICAL INSPECTION OF EGG PRODUCTS

Approved foreign establishments exporting bulk packed egg products to the United States must adhere to the regulatory requirements as defined in 9 CFR 590.910.

FSIS requires that all egg products that are offered for import be presented for reinspection. The location of the reinspection will be as indicated on the FSIS Form 9540-1, Import Inspection Application.

A. Port of Entry Requirements

1. Pasteurized egg product. All pasteurized egg products must stop at an official import inspection establishment. The applicant must provide FSIS Form 9540-1 and the foreign inspection certificate (with microbiological testing results) to the import inspection personnel for data entry into PHIS. FSIS reinspection will occur at the official import inspection establishment or at the official establishment or the official egg plant designated on the FSIS Form 9540-1. Following reinspection at an official import inspection establishment, pasteurized egg products may also proceed to end user facilities.
2. Non-pasteurized egg products. Non-pasteurized egg products are not required to stop at an official import inspection establishment. Non-pasteurized egg products must always proceed directly to an official egg plant in the United States. PHIS Import implementation interim procedures require the applicant to continue to submit (email or fax), when the Customs entry is filed but prior to shipment arrival, the FSIS Form 9540-1 and the foreign inspection certificate for non-pasteurized egg products to FSIS, OIA, IID Headquarters for reinspection assignment in PHIS. FSIS reinspection will occur at the official egg plant designated on the FSIS Form 9540-1.

B. Bulk Packed Shipments (tankers and totes)

1. When egg products packed in bulk pack containers (tanker trucks or portable totes weight approximately 1,000 pounds or more) are presented at an official import inspection establishment, Import inspection personnel are to verify that:
 - a. The application information is accurate;
 - b. The inspection certificate complies with 9 CFR 590.915;
 - c. The seal numbers on the transport vehicle match the seal numbers that are identified on the inspection certificate or on official letterhead containing the exporting country's official seal;
 - d. The labeling on the product complies with 9 CFR 590.955;
 - e. For pasteurized egg products, the testing results for *Salmonella* are presented

with the shipment and identified as negative on the inspection certificate or on official letterhead for the production lot of pasteurized egg product that includes the product offered for entry; and

- f. The product matches information identified on the inspection certificate.
2. If the labeling or certification on the shipment does not comply with any of B. 1. above, import inspection personnel are to fail the appropriate TOI (Certification or Labeling Verification), refuse entry to the shipment (as per FSIS Directive 9900.8), and await a response from the applicant.

C. Product Examination

1. Import inspection personnel will receive egg product reinspection assignments through PHIS.
2. Import inspection personnel are to request that the import establishment management to remove the sample unit from the container and place it in a sanitary container for examination as required by 9 CFR 590.930(g).
3. When conducting a product exam, refer to Annex 2 (PE3) of this directive for classification of defects.

XXII. SAMPLING PROCEDURES FOR PHYSICAL INSPECTIONS

When a physical TOI is assigned, refer to Annex 1 of this directive for instructions on how many sample units are needed in conducting the reinspection. Randomly select samples of imported meat, poultry, or egg products from the staged lot.

1. Lot Size – The number of sample units necessary is based on the lot size. Depending on the TOI, the determination of the number of sample units may be based on the net weight of the lot or the number of containers in the lot. Verify that the lot size and sample units for the TOI to be performed are in accordance with the tables in Annex 1 of this directive.
2. Sample Size - Import inspection personnel are to take the correct number of sample units, as specified in Annex 1, for the TOI.
3. Random Numbers - Import inspection personnel are to obtain random numbers to ensure that the samples are randomly selected.
4. Sample Security - Import inspection personnel are to ensure that samples are under FSIS control from the time they are identified for removal from the lot until the reinspection is completed.
5. Sample Selection:
 - a. Import inspection personnel are to locate the sample cartons or locations in the lot and have them identified with “USDA Official Import Sample”.

- b. Import inspection personnel are to ensure that:
 - i. Sample units are numbered, and that sample units are identifiable to their original container when applicable.
 - ii. Exposed sample units are handled in a sanitary manner.
 - iii. Sample units are presented for reinspection on an acceptable surface or area.
6. Frozen Sample Preparation – As per 9 CFR 327.21 and 381.199, Import inspection personnel are to verify that:
- a. Official import inspection establishments collect and identify random sample units from the official import sample in a manner suitable to FSIS.
 - b. Establishments completely defrost frozen sample units. If all surfaces can be examined, complete defrosting is not required.
 - c. Defrosting and tempering is accomplished by the use of a rapid, efficient, and acceptable method.
 - d. Defrost/tempering procedures prevent product contamination. When defrost/tempering is accomplished by immersion in water, the establishments supply high quality, approved plastic bags or another acceptable means of preventing the defrost water from coming in contact with, and possibly adulterating, the sample units. If a sample unit does come into contact with the defrost water, the sample units are to be condemned, and a new sample is to be drawn from the same container as the original sample unit.
 - e. The temperature of the defrost water is not to physically affect the appearance of the product (i.e., give raw product a cooked appearance). If defrosted sample units have the appearance of being cooked, Import inspection personnel are to condemn the units and to draw new sample units from the same containers as the original sample units.

XXIII. IDENTIFICATION OF DEFECTS DURING PHYSICAL INSPECTION

A. Import inspection personnel are to perform reinspection on the specific type of product that has been identified for reinspection.

B. Import inspection personnel are to remove the sample defects from the applicable sample unit and are to classify and identify the defects.

- 1. Defects from passed lots are to be discarded in an inedible container.
- 2. 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. Hold the lot and refer to FSIS Directive 9900.6 when a pathological defect is identified.

NOTE: The RIFO may request defects be held for correlation purposes.

XXIV. RESULTS (“Pass” or “Fail” Criteria) BASED ON DEFECT IDENTIFICATION DURING PHYSICAL INSPECTION

A. Import inspection personnel are to record all defects as follows:

1. Food Safety or Public Health (PH) Defects: Record the PH defects in PHIS and ensure that the TOI result selected is “Fail.” Import inspection personnel are to refuse entry on the lot when a public health defect is identified during examination.
2. Other Consumer Protection (OCP) Defects: Record all OCP defects in PHIS. The OCP defects may result in a failed TOI, depending upon the rate of non-compliance and the effect on the product’s usability.

a. Sampling Plan 3A.

Sampling plan 3A provides for reinspection of additional samples when import inspection personnel are unable to make a “Pass” or “Fail” determination based on reinspection of the selected samples. When reinspection of the original samples is inconclusive, import inspection personnel will use the additional samples to determine the product’s usability.

b. All Other Sampling Plans.

The “Pass” or “Fail” determinations for OCP defects for samplings plans other than 3A are based on the results of the single sample set specified in the appropriate sampling plans.

3. Additional Instructions on OCP Determinations:

In order for import inspection personnel to provide their supervisor with a rationale for a failed TOI based on observation of OCP defects, they are to consider the rate of non-compliance and the effect on usability of the product. They are to determine, based on product examination, whether the defect is an isolated occurrence (e.g. a one time occurrence in the samples examined or one that is widespread), and whether the defect results in misbranded product or product that could not be further processed or consumed.

Example 1: Import inspection personnel examine 12 twelve-pound samples of boneless beef primal/subprimal cuts using Product Examination 1 (PE1) as the defect criteria table in Annex 2 of this directive. In one sample unit, a single rib bone measuring 5 ½” long by 1 ¼” wide by ¼” thick is observed. No other defects are observed in the other sample units. The defect is classified as an OCP type under “Bone Fragments.” Since no other defects were found by import inspection personnel during reinspection, the TOI is recorded as passed. The rationale for not failing the TOI and refusing entry on the lot is that one bone defect out of 12 samples (144 lb), and the absence of other defects, is an indicator that the foreign establishment’s process is not out of control and does not warrant failing the TOI.

Example 2: Import inspection personnel examine 9 twelve-pound samples of boneless beef trimmings using Product Examination 1 (PE1) as the defect criteria from Annex 2. In two of the sample units, a small portion (2”x2”) of beef cheek meat is observed. In one of the other

samples, a portion of a beef cheek including lymph nodes and salivary glands (3"x3") is observed. No other defects are observed in the other sample units. Beef cheeks and beef cheek meat are restricted in certain products and cannot be mixed with beef trimmings except under their true name. These defects are classified as an OCP type under "Other." Import inspection personnel determine they cannot make a determination of "Pass" or "Fail" on these samples and decide to expand the reinspection to the three additional samples, finding no additional defects. Based on these findings, import inspection personnel determine the TOI is "Pass" as the additional samples contained no more defects.

Example 3: Import inspection personnel examine 15 twelve-pound samples of boneless beef trimmings using Product Examination 1 (PE1) as the defect criteria in Annex 2. In four of the sample units, a large portion (4"x5") of beef cheek meat is observed. In three of the other samples, a large portion (5"x6") of beef cheeks, including lymph nodes and salivary glands, is observed. No other defects are observed in the other sample units. Beef cheeks and beef cheek meat are restricted in certain products and cannot be mixed with beef trimmings except under their true name. These defects are classified as an OCP type under "Other." Import inspection personnel determine that the product is misbranded based on the amount of beef cheek meat present in multiple samples examined. Based on these findings, import inspection personnel are to recommend that the TOI is failed because the product does not meet the definition of beef trimmings. With supervisor concurrence, the TOI is failed, and the lot is refused entry.

B. Condition of Container Defects—Import inspection personnel identify defects according to the appropriate defect classification and enter the results in PHIS:

1. When an Abnormal Container Defect is recorded in PHIS, enter the TOI as "Fail". A follow-up Abnormal Container laboratory sample is assigned. Submit containers to the laboratory. Await further instruction.

NOTE: Abnormal containers (defined in 9 CFR 318.300(a) and 381.300(a)) are critical defects, and when identified, refer to 9 CFR 327.6 (j), 381.199 (b) and (d) and FSIS Directive 7530.1, Handling a Process Deviation or Abnormal Container of Thermally Processed, Commercially Sterile Canned Product for further guidance.

2. When Defective Container defects (Major or Critical) are recorded in the PHIS, the determinations, whether the lot is entered as "Pass" or "Fail," and whether the lot, if entered as "Fail", is sortable or not, are based on Tables A and B below. Refer to these tables when entering the results of the reinspection in PHIS.

Condition of Container – Lot Disposition

Table A – Disposition of Lots – Initial reinspection						
Sample Size (containers)	Abnormal Containers ¹		Critical Defects - Other		Total Critical and Major Defects	
	Pass	Fail ²	Pass	Fail ²	Pass	Fail ²
84	0	1	0	1	5	6
168	0	1	1	2	9	10
315	0	1	2	3	12	13
500	0	1	3	4	19	20

¹ Disposition of lot is determined after the laboratory results are returned

² See Table 2

Table B – Determining whether a lot may be eligible for sorting or is refused entry without the sorting option upon initial reinspection						
Sample Size (containers)	Hard Swells or Blown Containers		Critical Defects – Other ³		Loose Tins	Major Defects
	Normal Plan	Sort	No Sort	Sort	No Sort	Sort
84	0	1	6	7	No limit	No limit
168	1	2	10	11	No limit	No limit
315	2	3	18	19	No limit	No limit
500	4	5	27	28	No limit	No limit

³ Does not include loose tins

Table C – Disposition of Lots – Tightened reinspection						
Sample Size (containers)	Abnormal Containers		Critical Defects – Other ⁴		Total Critical and Major Defects	
	Tightened Plan	Pass	Fail ⁵	Pass	Fail ⁵	Pass
168	0	1	0	1	6	7
315	0	1	1	2	11	12
500	0	1	2	3	14	15
800	0	1	3	4	17	18

⁴ Includes loose tins

⁵ Ineligible for further sorting

Lots determined to be sortable may be sorted at the applicant’s request and presented for tightened reinspection (Table C, above), under reimbursable services.

XXV. COMPLETING DATA ENTRY

A. Import inspection personnel are to:

1. Enter all findings and results into PHIS;
2. Ensure that all of the information necessary to complete the assignment is entered into PHIS; and
3. Ensure that the assignment is properly completed and closed in the system.

B. Follow FSIS Directive 9900.8 for all refused entry instructions.

C. Consult the RIFO on any problems with data entry or questions related to completing the data entry and closing the case file.

XXVI. DATA ANALYSIS

Quarterly, the Data Analysis and Integration Group (DAIG) within the Office of Data Integration and Food Protection (ODIFP) is to review PHIS data on Port of Entry import reinspection of meat, poultry, and egg products. DAIG is to analyze the import data for potential trends that would lead to improvements in import inspection procedures or guidance to foreign countries,

starting 90 days after full implementation of Import PHIS. DAIG is to review these analyses with the Office of International Affairs (OIA) and the Office of Policy and Program Development (OPPD) to determine whether the findings suggest potential improvements that should be made in import reinspection procedures or guidance to foreign countries.

Refer questions regarding this directive through supervisor channels or askFSIS at <http://askfsis.custhelp.com>.

A handwritten signature in black ink, appearing to read "Rachel A. Edelstein". The signature is written in a cursive, flowing style.

Acting Assistant Administrator
Office of Policy and Program Development

ANNEX 1. SAMPLING DEFECT TABLES – INSPECTION - Import inspection personnel are to use the following sampling plans when performing product examination of imported product.

SP1

TABLE SP1 - SAMPLING PLANS FOR BEEF, EQUINE, AND VEAL CARCASSES

LOT SIZE (sides)	SAMPLE UNIT SIZE	NUMBER OF SAMPLES	DEFECT CRITERIA TABLE
< 100	1 side or 2 quarters; hide-on veal, 1 carcass	5	PE1
100 to 250		7	
>250 to 500		14	
> 500		22	

SP2

TABLE SP2 - SAMPLING PLANS FOR GOAT, LAMB, MUTTON, AND PORK CARCASSES

LOT SIZE (pounds)	SAMPLE UNIT SIZE	NUMBER OF SAMPLES	DEFECT CRITERIA TABLE
< 8,000	1 carcass	8	PE1
8000 to 24,000		12	
>24,000 to 60,000		30	
> 60,000		47	

SP3

TABLE SP3 - SAMPLING PLANS FOR NON-INTACT AND INTACT BEEF, EQUINE, GOAT, LAMB, MUTTON, PORK, AND VEAL PRODUCTS EXCEPT TRIMMINGS, MECHANICALLY SEPARATED, ADVANCED MEAT RECOVERY TYPE PRODUCTS, AND BULK GROUND PRODUCT OF ALL SPECIES

LOT SIZE (pounds)	SAMPLE UNIT SIZE	NUMBER OF SAMPLES	DEFECT CRITERIA TABLE
< 8,000	12 pounds	8	PE1 or PE2, as appropriate for the species
8,000 to 24,000		12	
>24,000 to 60,000		30	
> 60,000		47	

SP3A

TABLE SP3A - SAMPLING PLANS FOR NON-INTACT AND INTACT TRIMMINGS, MECHANICALLY SEPARATED, ADVANCED MEAT RECOVERY TYPE PRODUCTS, AND BULK GROUND PRODUCT OF ALL SPECIES

LOT SIZE (pounds)	SAMPLE UNIT SIZE	NUMBER OF SAMPLES	ADDITIONAL SAMPLES for OCP (if needed)	DEFECT CRITERIA TABLE
< 8,000	12 pounds	6	2	PE1 or PE2, as appropriate for the species
8,000 to 24,000		9	3	
>24,000 to 60,000		15	15	
> 60,000		22	25	

SP4

TABLE SP4 - SAMPLING PLANS FOR WHOLE BIRDS AND POULTRY PARTS

LOT SIZE (POUNDS)	SAMPLE UNIT SIZE	NUMBER OF SAMPLES	DEFECT CRITERIA TABLE
< 5,000	One (1) Whole Bird or 3 pounds of poultry parts	3	PE2
5,000 to 10,000		6	
>10,000 to 20,000		10	
>20,000 to 50,000		15	
> 50,000		21	

SP5

TABLE SP5 - SAMPLING PLANS FOR GROUND, COMMINUTED, PROCESSED, CANNED OR PACKAGED, AND ALL OTHER PRODUCTS NOT COVERED BY TABLES SP1 TO SP4.

LOT SIZE (POUNDS)	WEIGHT OF IMMEDIATE CONTAINERS (pounds)						DEFECT CRITERIA TABLE
	< 1	<1 to 2	<2 to 3	<3 to 4	<4 to 5	> 5	
	NUMBER OF SAMPLE UNITS						
< 5,000	10	9	6	5	4	3	PE3
5,000 to 50,000	20	18	12	9	8	6	
> 50,000	50	36	24	18	15	12	

NOTE: When the product is packaged in an immediate container > 5 pounds, the immediate container represents one sample unit. When product is bulk packed, the sample unit weight is 12 pounds.

SP6

TABLE SP6 - SAMPLING PLANS FOR FROZEN COOKED MEAT IN TUBES FROM AN APHIS RESTRICTED COUNTRY WHEN ASSIGNED WITHOUT AN ORGANOLEPTIC PRODUCT EXAMINATION (PINK JUICE)

LOT SIZE (pounds)	SAMPLE UNIT SIZE	NUMBER OF SAMPLES	DEFECT CRITERIA TABLE
< 8,000	Either the 6" center section of the tube or an entire tube	6	If other defects are observed while performing a pink just test, an unscheduled organoleptic product examination will be performed on the lot.
8,000 to 24,000		9	
>24,000 to 60,000		15	
> 60,000		22	

SP7

TABLE SP7 - SAMPLING PLAN FOR CONDITION OF CONTAINER EXAMINATION

LOT SIZE (No. of immediate containers in lot)	SAMPLE UNIT SIZE	NUMBER OF SAMPLES		DEFECT CRITERIA TABLE	
		Level of Inspection		Type of Container	
		Normal, Increased, Intensified	Tightened	Rigid	Semi-rigid and Pouches
< 6,000	One immediate container	84	168	COCE1	COCE2
6,000 to 12,000		168	315		
>12,000 to 36,000		315	500		
> 36,000		500	800		
Number of containers in each shipping container			Number of sample units to select from a shipping container		
< 6			All		
6 to 12			6		
13 to 60			12		
61 to 230			16		
231 to 500			24		
> 500			See below		
<p><i>A = Number of immediate containers in the lot</i> <i>B = Number of sample units required for Condition of Container inspection</i> <i>C = Number of pallets samples will be selected from (round up)</i> <i>D = Number of sample units selected from each pallet (round up)</i></p>					
<p><i>Example: A = 20,000</i> <i>B = 315</i></p>					
<p>Calculate: $B/100 = C (3.15) = 4$ $B/C = D (78.75) = 79$</p>					

SP8

TABLE SP8 - SAMPLING PLAN FOR INCUBATION EXAMINATION

LOT SIZE (No. of immediate containers in lot)	SAMPLE UNIT SIZE	NUMBER OF SAMPLES	DEFECT CRITERIA TABLE	
			Type of Container	
			Rigid	Semi-rigid and Pouches
< 48	One immediate container	All	COCE1	COCE2
≥48		48		
Selecting incubation samples when other examination TOI's are not assigned:				
Number of containers in each shipping container			Number of sample units to select from a shipping container	
< 6			All	
6 to 230			6	
> 230			12	

SP9

TABLE SP9 - SAMPLING PLAN AND CRITERIA FOR NET WEIGHT EXAMINATION

Inspection Lot Size (Individual cans, packages)	Sample Size (Immediate containers)	Sample Correction Factor	Number of Minus Package Errors Allowed to Exceed the MAV	Initial Tare Sample Size**	
				Glass and Aerosol Packages	All Other Packages
1	1	Apply MAV	0	2	2
2	2	8.984			
3	3	2.484			
4	4	1.591			
5	5	1.241			
6	6	1.050			
7	7	.925			
8	8	.836			
9	9	.769			
10	10	.715			
11	11	.672			
12 to 250	12	.635	0	2	2
251 to 3,200	24	.422			
More than 3,200	48	.291	1	3	
** If sample size is 11 or less, the initial tare sample size and the total tare sample size are 2 samples.					
Selecting net weight samples when other examination TOI's are not assigned:					
< 6			All		
6 to 230			6		
> 230			12		

ANNEX 2. DEFECT CLASSIFICATION – INSPECTION - - Import inspection personnel are to use the following defect tables when conducting reinspection of imported product.

PRODUCT EXAMINATION 1 (PE1)

DEFECT CRITERIA FOR RAW INTACT PRODUCTS AND NON-INTACT PRODUCTS OF BEEF, EQUINE, GOAT, LAMB, MUTTON, PORK, AND VEAL

1A. Food Safety or Public Health (PH) Defects		
TYPE	DESCRIPTION	CODE
SPECIFIED RISK MATERIAL (SRM) (BEEF ONLY)	SRM as listed in 9 CFR 310.22 (a) (1) or (2) from any country not designated as BSE free NOTE: System programming will not allow this defect to refuse entry of a lot from a BSE free country (as identified by APHIS).	PH
INGESTA	Any amount	PH
FECAL	Any amount	PH
MILK	Any amount	PH
OFF CONDITION	Any amount	PH
OTHER CHEMICAL OR PHYSICAL HAZARDS	An amount of any foreign and hazardous substance or material capable of causing injury or illness (e.g., poisonous or toxic chemicals, pieces of metal, glass, hard plastic, wood); or unidentifiable foreign material of size rendering the product unwholesome	PH
OTHER HARMFUL MATERIAL OR CONDITIONS	An amount of the following that renders the product unwholesome: Large insects, insects associated with insanitary conditions, or evidence of rodent activity Defects of a number or size seriously affecting product usability for slicing, chopping, or further processing in the manufacture of meat products	PH
PATHOLOGICAL AND PARASITIC LESIONS	Single or multiple lesions that seriously affect product usability, and renders the product unwholesome	PH

1B. Other Consumer Protection (OCP) Defects		
TYPE	DESCRIPTION	CODE
BONE FRAGMENTS	Bones or fragments of a number or size affecting product usability for slicing, chopping, or further processing in the manufacture of meat products	OCP
OTHER PATHOLOGICAL AND PARASITIC LESIONS	Any localized lesion that does not seriously affect product usability	OCP
BRUISES	Non-septic bruises of a number or size affecting product usability for slicing, chopping, or further processing in the manufacture of meat products	OCP
EXTRANEIOUS MATERIAL	Defects of a number or size affecting product usability for slicing, chopping, or further processing in the manufacture of meat products	OCP
HAIR, HAIR ROOTS, WOOL, SKIN	Defects of a number or size affecting product usability for slicing, chopping, or further processing in the manufacture of meat products	OCP
DETACHED CARTILAGE	Defects of a number or size affecting product usability for slicing, chopping, or further processing in the manufacture of meat products	OCP
STAINS, DISCOLORED AREAS	Defects of a number or size seriously affecting product usability for slicing, chopping, or further processing in the manufacture of meat products	OCP
OTHER	Defects that cannot be classified in another OCP category that affects product usability for slicing, chopping, or further processing in the manufacture of meat products	OCP

PRODUCT EXAMINATION 2 (PE2)

DEFECT CRITERIA FOR RAW INTACT PRODUCTS AND NON-INTACT WHOLE MUSCLE PRODUCTS OF POULTRY AND RATITES

2A. Food Safety or Public Health (PH) Defects		
TYPE	DESCRIPTION	CODE
FECAL	Any amount	PH
OFF CONDITION	Any amount	PH
OTHER CHEMICAL OR PHYSICAL HAZARDS	An amount of any substance or material capable of causing injury or illness (e.g., poisonous or toxic chemicals, pieces of metal, glass, hard plastic, wood); or unidentifiable foreign material of size rendering the product unwholesome	PH
OTHER HARMFUL MATERIAL OR CONDITIONS	An amount of the following that renders the product unwholesome: Large insects, insects associated with insanitary conditions, or evidence of rodent activity Defects of a number or size seriously affecting product usability for slicing, chopping, or further processing in the manufacture of poultry products	PH

2B. Other Consumer Protection (OCP) Defects¹		
TYPE	DESCRIPTION	CODE
BRUISES	Bruises of a number or size affecting product usability	OCP
FEATHERS	Attached feathers or protruding pinfeathers of sufficient amount affecting product usability	OCP
OTHER	Defects that cannot be classified in another OCP category that affects product usability for slicing, chopping, or further processing in the manufacture of poultry products	OCP
EXTRANEIOUS MATERIAL	<p>Specks of the following that individually or in the aggregate affects product usability:</p> <ul style="list-style-type: none"> (1) Ingesta (2) Unidentifiable foreign material (3) Grease (4) Unattached feathers (5) Bile remnants (6) Whole spleen (7) Gall bladder (8) Yolk (9) Stains 	OCP

1 IPP are to refer to 9 CFR 381.76 for complete definitions.

TRIMMABLE LESIONS, BENIGN INFLAMMATORY OR NEOPLASTIC CONDITIONS	<p>Defects that individually or in the aggregate affects the product usability</p> <p>Intestine</p> <p>Cloacae</p> <p>Whole or partial crop or portion which includes mucosal lining</p> <p>Tumors (whole or portion)</p> <p>Synovitis or airsacculitis</p> <p>Contamination</p> <p>Sores, scabs, or inflammatory process that measures greater than 1/2"</p> <p>Bursa of fabricius (rosebud) or any identifiable portion</p> <p>Esophagus</p> <p>Trachea > 1"</p> <p>Whole or partial oil glands</p> <p>Breast blister or inflamed, fluid or pus filled nodules</p> <p>Whole or partial lung including all or any portions of a second</p> <p>Compound fracture that has caused an opening of the skin</p> <p>Wingtip compound fracture: skin that has not broken</p> <p>External mutilation: Mutilation to the skin or muscle</p>	OCP
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PRODUCT EXAMINATION 3 (PE3)

DEFECT CRITERIA FOR GROUND, COMMINUTED, PROCESSED, IQF, COOKED BEEF IN TUBES, CANNED OR PACKAGED MEAT, POULTRY, AND EGG PRODUCTS

3A. Food Safety or Public Health (PH) Defects		
TYPE	DESCRIPTION	CODE
SPECIFIED RISK MATERIAL (SRM) (BEEF ONLY)	SRM as listed in 9 CFR 310.22 (a) (1) or (2) from any country not designated as BSE free. NOTE: System programming will not allow this defect to refuse entry of a lot from a BSE free country (as identified by APHIS).	PH
INGESTA	Any amount	PH
FECAL	Any amount	PH
OFF CONDITION	Any amount	PH
UNDER PROCESSED	Example: Pink Juices observed during examination of cooked beef from APHIS restricted country	PH
OTHER CHEMICAL OR PHYSICAL HAZARDS	An amount of any substance or material capable of causing injury or illness (e.g., poisonous or toxic chemicals, pieces of metal, glass, hard plastic, wood); or unidentifiable foreign material of size rendering the product unwholesome.	PH
OTHER HARMFUL MATERIAL OR CONDITIONS	An amount of the following that renders the product unwholesome: Mold ² ; Large insects, insects associated with insanitary conditions, or evidence of rodent activity; and Defects of a number or size seriously affecting product usability.	PH
PATHOLOGICAL AND PARASITIC LESIONS	Single or multiple lesions that seriously affect product usability, and render the product unwholesome.	PH
3B. Other Consumer Protection (OCP) Defects		
TYPE	DESCRIPTION	CODE
OTHER	Defects of a number or size affecting product usability.	OCP

2 Do not score mold or product where mold is part of the processing (such as dry cured sausages, Parma or Serrano Hams). Contact OPPD/PDD through AskFSIS (<http://askfsis.custhelp.com>) or at 800.233.3935 for assistance.

CONDITION OF CONTAINER EXAMINATION 1 (COCE1)

DEFECT CRITERIA FOR CANS AND GLASS –THERMALLY PROCESSED COMMERCIALY STERILE CONTAINERS

1A. Abnormal Containers (Critical Defects)	
TYPE	DESCRIPTION
SWELLS	Any container that is bulged by excess internal pressure. Also includes any burst or leaking containers.
FLIPPER	A rigid metal container that normally appears flat, but when its end is brought down sharply on a flat surface, one end will flip out. When pressure is applied to this end, it will flip in, and the can will again appear flat (i.e., normal).
SPRINGER	A container with one end permanently bulged. When sufficient pressure is applied to this end, it will flip in but the other end will flip out.
LOOSE TIN	A rigid container whose end or ends do not show evidence of full vacuum, thus allowing movement of either end.
OVERFILL	A can that appears similar to a flipper or slight springer but when pressure is applied to the distended end, the other end does not flip out. When shaken, the product does not slosh in the can due to the lack of headspace.

1B. Defective Containers (Major Defects)	
TYPE	DESCRIPTION
PUNCTURED CANS	A puncture through the plate of a metal container
DENTS	A substantial dent on the top, bottom, or side seam of a can or on the opening seam
IMPROPER SEAMS	Cut-over, cut seams, droops, lips, excessive countersink, jumped seam, false seam, long or short body or cover hooks, spinner (slip, skid, dead head), or similar defects that may compromise the integrity of the container.
BUCKLED SEAMS	A permanent distortion of the container end due to excessive internal pressures developed during heat processing which affects the integrity of the seam.
CABLE CUT	An abrasion at the top of the container double seam caused by the action of cable conveyors moving on stationary cans.
RUST	Rust that has pitted the tin plate of the can and cannot be wiped off with a soft cloth.
MISSING LABEL	All or part of a label of the immediate container has been removed or stained to such extent that the required features of the label are not present or cannot be read.
CUT-THRU	Occurs when the top of the glass finish has pushed completely through the gasket on the metal.
OTHER	Any other major defect in the container that compromises the integrity or usability of the container.

CONDITION OF CONTAINER EXAMINATION 2 (COCE2)

DEFECT CRITERIA FOR FLEXIBLE POUCHES AND PLASTIC TRAYS AND CUPS – THERMALLY PROCESSED COMMERCIALY STERILE CONTAINERS

2A. Abnormal Containers (Critical Defects)	
TYPE	DESCRIPTION
SWOLLEN PACKAGE	A package the shape of which has been altered due to gas formation within the package.
LEAKER	A container that is unsealed or exhibiting evidence of lost integrity.
2B. Defective Containers (Critical Defects)	
TYPE	DESCRIPTION
NON-BONDING	Failure of two sealant films to combine during the sealing process. This can be detected visually by the sealing bar impression on a pouch. If it is in only one area, there will be a faint void in the seal. If it is in the whole seal, the seal impression will be very faint.
CUTS	A mechanical slash or slice that penetrates the package, causing a loss of hermetic integrity. A cut will have a clean appearance on the edges of the material separated.
FRACTURE	A break through the packaging material.
NOTCH LEAKER	A leak at a manufactured notch used for easy opening.
HOLE/ PUNCTURE	A mechanical penetration of the package causing a loss of hermetic integrity. A hole or puncture is normally small in size.
CHANNEL LEAKER	A patch of non-bonded area across the width of the seal creating a leak. This defect can sometimes be detected by the absence of a portion of the seal impression in a seal.

2C. Defective Containers (Major Defects)	
TYPE	DESCRIPTION
ABRASION/ SCRATCH	A scratch partially through the surface layers of the package caused by mechanical rubbing or scuffing. The abrasion will appear as streaks, some darker in color, on the container.
BLISTER	A void within the bonded seal. This defect will appear to resemble a bubble in the sealed area.
COMPRESSED SEAL	A seal formed by excessive pressure or heat and evidenced by cracking and delaminating. A milky white appearance on the seal is an indication of excess heat and pressure.
CONTAMINATED SEAL	Foreign matter in the seal area such as, but not limited to, water, grease, or food that results in a seal width of less than 3mm (3/32"). A pouch with contamination will have a noticeable raised area in the seal where the bar has sealed over the contamination.
DELAMINATION	A separation of the laminate materials forming the package.
CROOKED SEAL SHORT SEAL MISALIGNED SEAL	A seal that is not parallel to the cut edge of the pouch. When on the edge of the pouch with a narrowing on one end, are not to be less than 3mm (3/32") wide. A hermetic seal that is on an angle with any amount of unsealed material above the closure seal will not be classified.
SEAL CREEP	Partial opening of the inner border of the seal. This problem is normally detected by applying some pressure upward toward the seal.
BURNING	A milky white appearance on the seal is an indication of excess heat and pressure. Some appear as delaminating or small blisters on the seal, caused by incorrect heat, pressure, or dwell time.
WRINKLE	A fold of material in the seal area. This problem is visual since the seal will have a pleated appearance from the fold-over of the pouch material and can be seen on the unsealed area above the seal. If the fold in the seal area leaves less than 3mm (3/32") continuous acceptable seal or if the fold-over wrinkle extends through all plies across the seal area score as major defect.
CRUSHED PACKAGE	Alteration of the package's original dimensions caused by force.
UNEVEN IMPRESSION	Impression from seal bar is uneven around the periphery of container. This could be due to uneven thickness of container flange resulting in uneven pressure during heat sealing.