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

FSIS DIRECTIVE

7355.1 Revision 3 9/19/2022

USE OF SAMPLE SEALS FOR LABORATORY SAMPLES

I. PURPOSE

This directive provides instructions for the uniform use of sample seals to ensure the integrity of samples submitted to FSIS laboratories for analysis. The uniform use of sample seals and identity labels ensure that sample integrity and identity are maintained. FSIS is updating and clarifying inspection program personnel (IPP) and compliance investigator responsibilities regarding sample integrity.

II. CANCELLATION

FSIS Directive 7355.1, Rev. 2, dated December 3, 2002

III. BACKGROUND

- A. FSIS ensures that samples submitted for laboratory analysis are secure from the point of collection until the appropriate FSIS official receives the test results. Samples are to remain under direct FSIS control while in the establishment and at FSIS laboratories.
- B. During transport, samples are not under direct control of FSIS. The sealing of laboratory samples provides a measure of security whenever these items are not under direct FSIS control. Appropriate sealing of samples:
 - 1. Maintains the security and integrity of samples during shipment;
 - 2. Identifies samples where identity or integrity may have been compromised (such as in cases of suspected tampering); and
 - 3. Identifies and links samples with the information required for accurate analysis and reporting of test results.

IV. TYPES OF CONTAINERS

- A. Primary laboratory sample containers These are the containers that hold the actual sample, whether it be tissue, poultry rinsate, egg products, or swabs. FSIS laboratories may provide a sterile jar or a sterile sample bag for use as the primary container. The primary container may also be the retail package containing the product or a plastic bag obtained from an FSIS laboratory or at the collection site.
- B. Laboratory sample shipping containers These are the containers in which the primary laboratory sample containers are packed for shipment to FSIS laboratories. FSIS laboratories typically provide sampling supplies to IPP in cardboard boxes that are then used for shipping samples back to the laboratories. These boxes have a foam insert to protect the samples during transport and may contain one or more gel coolant packs to stabilize temperature during shipment.

DISTRIBUTION: Electronic OPI: OPPD

V. SEALING PROCEDURES

A. Laboratory Sample Seal and Labels

1. All samples submitted by IPP and compliance investigators to FSIS laboratories for analysis are to be labeled and sealed using the USDA sample seal packet (FSIS Form 7355-2A/2B) (Figure 1). It comes as a packet of multiple peelable seals on a strip and includes: one large "FSIS Laboratory Container Seal" (7355-2A) for the outer shipping box, one medium-sized "FSIS Laboratory Sample Identification Label" (7355-2B) for the plastic bag containing the primary container and the sample submission form, and several small barcoded labels to cross-reference one another.



Figure 1. The USDA sample seal packet for shipment to FSIS laboratories.

2. FSIS Form 7355-2A/2B is an accountable item and is to be handled as such. Once a component of a seal packet has been used, any unused barcodes, identification labels, or container seals from that packet should be shipped with the sample to the laboratory for disposal. Using one sample seal packet for more than one sample could jeopardize the sample identity.

B. Requesting Sample Packaging and Sealing Supplies

IPP are to follow instructions in <u>FSIS Directive 13,000.2</u>, *Performing Sampling Tasks in Official Establishments Using the Public Health Information System*, to request sample packaging and sealing supplies.

C. Labeling Laboratory Samples

IPP are to label sample packages shipped to FSIS laboratories in a manner that identifies and links the sample to its respective submission form and shipping container. When properly labeled, each laboratory sample package will have at least two separate, identically numbered/barcoded identification labels that match the shipping container seal.

- 1. IPP are to complete the sample submission form as follows:
 - a. Place one small barcoded label in the top center of the submission form so that it does not obstruct any printed information;
 - b. Verify the small barcoded label does not cover any sample identification information, whether

pre-printed on the submission form or provided by IPP; and

c. Place the completed submission form inside a plastic sleeve to protect it from moisture during shipping (Figure 2).

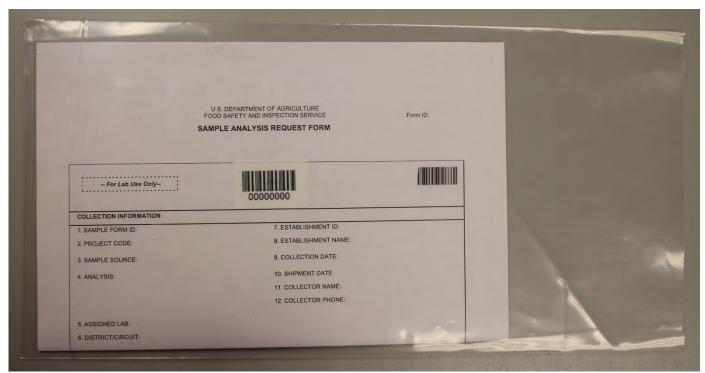


Figure 2. Placement of the barcoded label on the sample submission form and placement of the submission form in a plastic sleeve.

- 2. Unless otherwise directed by sampling program-specific instructions (see NOTE in Section V. Part D.), IPP are to label laboratory samples as follows:
 - a. Insert the sample (already in the primary container) and the submission form (in a plastic sleeve, as in Section V. Part C.1.) into a resealable bag;
 - b. Remove as much air from the bag as possible, and then close the bag;
 - c. Fold the top of the bag over if possible and place the medium-sized "FSIS Laboratory Sample Identification Label" (7355-2B) over the opening so the bag opening is secured while still allowing for the label to be scanned (Figure 3); and
 - d. Verify the barcode number on the submission form matches the identification label barcode on the bag.



Figure 3. Placement of the identification label on the resealable bag containing the sample and the sample submission form (which is protected in a separate plastic sleeve).

- 3. IPP are to retain a record of the seal packet used for each sample sent to the laboratory. An additional, small barcoded label may be placed on the IPP file copy of the submission form.
- D. Packaging and Sealing Shipping Containers
 - 1. If the FSIS laboratories provide a shipping container with self-sticking closures, IPP are to seal the shipping container as follows:
 - a. Place the packaged sample into the shipping container;
 - b. Close the inner flaps of the box;
 - c. Place the large "FSIS Laboratory Sample Container Seal" (7355-2A) (with the same identification number as the label on the form) across the closed inner flap of the box parallel to the edge of the closed flap (Figure 4); and
 - d. Fasten the outer flaps shut using the self-sticking closures.



Figure 4. Placement of the container seal on a box with self-sticking closures.

- 2. If the FSIS laboratories provide a shipping container without self-sticking closures, IPP are to seal the shipping container as follows:
 - a. Place the packaged sample into the shipping container;
 - b. Close the inner and outer flaps;
 - c. Place the large "FSIS Laboratory Sample Container Seal" (7355-2A) (with the same identification number as the label on the form) across the closed outer flaps of the box (Figure 5); and
 - d. Fasten the outer flaps shut with clear packaging tape covering the seal.

NOTE: IPP Help has a menu item, **Sampling**, that houses the **Handling and Packaging** guide. The **Handling and Packaging** guide addresses common questions about sample handling and provides examples of how IPP may package the various types of samples submitted to FSIS laboratories. IPP can access IPP Help by double-clicking the **FSIS Applications** icon from the desktop of their government-issued computer. The **Handling and Packaging** guide provides:

- A reference by Public Health Information System (PHIS) sampling task to the relevant <u>FSIS</u>
 <u>Directive</u> or <u>IPP Help</u> Topic (see Table 1 in the Handling and Packaging Guide);
- The corresponding FSIS Laboratory for special projects by special project (see Table 2 in the Handling and Packaging Guide); and

• A reference by sample type to best practices for handling samples after collection (see Table 3 in the Handling and Packaging Guide).



Figure 5. Placement of the container seal on a box without self-sticking closures.

NOTE: It is very important not to overfill any of the shipping containers, especially those containing heavy samples like chemical residue samples, some ready-to-eat samples, and multiple samples in the same box. The security seals are not designed to act as a closure device for the shipping containers. If boxes are overfilled to the point that pressure is placed on the self-sticking closure or seam, it is very likely that the seal will be broken during transport.

3. If the foam insert of a shipping container bulges upward, placing pressure on the self-sticking closure or seam, IPP are to place the samples back in the freezer, contact the appropriate laboratory (SamplingSupplies-EasternLab@usda.gov; SamplingSupplies-MesternLab@usda.gov), and request a larger box. Detailed instructions for requesting supplies via email are provided in FSIS Directive 13,000.2 and the IPP Help Handling and Packaging guide under the Sampling menu item.

E. Labeling and Sealing Pathology Sample Kits

- Pathology Sample Kits contain two formalin jars and two seal packets. IPP are to follow instructions provided in Section IX, parts B-C of <u>FSIS Directive 10,230.6</u>, <u>Submitting Tissue</u> <u>Specimens for Pathologic Evaluation to the Laboratory</u>, when collecting pathology samples. Two different pathology samples (samples from two different carcasses) may be submitted using one Pathology Sample Kit and both seal packets.
- 2. If submitting one sample (i.e., one carcass), IPP are to label and seal the Pathology Sample Kit as follows:
 - a. Label the formalin jar (or jars if submitting multiple tissues from one carcass) and

corresponding sample submission form with the small barcoded labels from one seal packet;

- b. Place the jars in the foam insert in the Pathology Sample Kit;
- c. Close the resealable bag containing the jars, removing as much air as possible;
- d. Place the identification label so the bag opening is secured while still allowing for the label to be scanned (Figure 6);

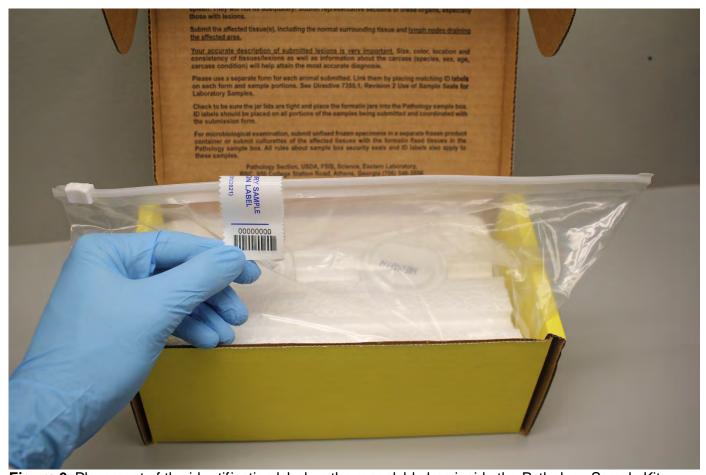


Figure 6. Placement of the identification label on the resealable bag inside the Pathology Sample Kit.

- e. Place the completed submission form in a plastic sleeve as outlined in Section V. Part C.1., and place it on top of the labeled bag containing the formalin jars; and
- f. Seal the Pathology Sample Kit with the container seal (Figure 7).



Figure 7. Placement of the container seal on the Pathology Sample Kit.

- 3. If submitting two samples (i.e., two carcasses) in one Pathology Sample Kit, IPP are to correctly indicate which submission form goes with each sample by using one seal packet per formalin jar and corresponding sample submission form. IPP are to label and seal the Pathology Sample Kit as follows:
 - a. Label the formalin jar and corresponding sample submission form with the small barcoded labels from a seal packet using a different seal packet for each sample;
 - b. Place the jars in the foam insert in the Pathology Sample Kit;
 - c. Close the resealable bag containing the jars, removing as much air as possible;
 - d. Place an identification label so the bag opening is secured while still allowing for the label to be scanned (Figure 6);

NOTE: The identification label from either of the two seal packets may be used to label the resealable bag.

- e. Place the completed submission forms in a plastic sleeve as outlined in Section V. Part C.1., and place them on top of the labeled bag containing the formalin jars;
- f. List the barcode numbers from both samples packed in that box on one container seal; and

g. Seal the Pathology Sample Kit with the container seal (Figure 7). Only one container seal (7355-2A) is needed per Pathology Sample Kit, even when the box contains more than one sample.

F. Shipping Samples to FSIS Laboratories

- 1. IPP are to include a FedEx billable stamp or airbill with all shipping containers.
- 2. If there is a missed pick up or shipping delay, IPP are to contact 1-800-GOFEDEX (1-800-463-3339) immediately with the confirmation or tracking number. If further assistance is needed, IPP are to discuss this issue with their supervisor.
- 3. IPP are to ensure the top of the shipping container is sealed as outlined in Section V. Part D.
- 4. IPP are to ensure that the bottom of the shipping container has remained sealed. If the bottom seam of the shipping container has become unsealed, IPP are to place a completed container seal (7355-2A) across the bottom seam and cover it with clear packaging tape before using the box.

NOTE: FSIS laboratories seal all shipping containers on both the top outer flaps and the bottom seam of the box with tamper-evident tape before shipping them to IPP (Figure 8). These seals are to ensure there has been no tampering with the sampling materials or shipping container when out of the direct control of FSIS personnel.

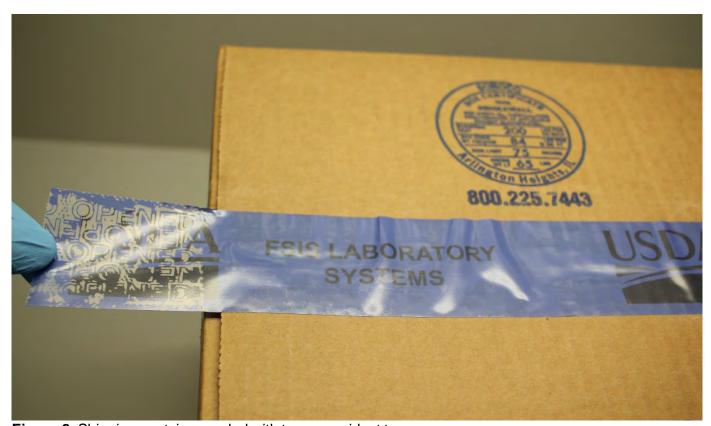


Figure 8. Shipping container sealed with tamper-evident tape.

4. If IPP receive sampling supplies where either the top or bottom tamper-evident tape is broken (Figure 9), do not use the container or sampling supplies. Instead, IPP are to:

- a. Reseal the container with a new container seal (7355-2A);
- b. Complete all the information required on the seal, except "Form No." On the blank marked "Form No.," place the words "seal broken"; and
- c. Ship the container back to the laboratory of origin for processing.



Figure 9. Shipping container where tamper-evident tape has been removed and seal broken.

- G. Labeling Samples and Sealing Shipping Containers with Multiple Samples
 - 1. If one sample consists of multiple individual primary containers, IPP are to:
 - a. Place all primary containers into one resealable plastic bag with the corresponding sample submission form;
 - b. Label the sample as outlined in Section V. Part C.2.; and
 - c. Seal the shipping container as outlined in Section V. Part D.
 - 2. If one sample consists of multiple individual primary containers that do not fit inside one resealable bag, IPP are to:
 - a. Use a small barcoded label to label an additional resealable bag; or

- b. Request an extra-large resealable bag from the laboratories as outlined in Section V. Part B.
- 3. If multiple samples, each with its own sample submission form, are to be shipped in one shipping container, IPP are to:
 - a. Package and label each individual sample with the corresponding sample submission form as outlined in Section V. Part C.2.;
 - b. Ensure each resealable bag is labeled with the identification label that corresponds with the sample contained inside;
 - c. Place each sample package into the box, being careful to not overfill the shipping container;
 - d. List the barcode numbers from all samples packed in that box on the container seal; and
 - e. Seal the shipping container as outlined in Section V. Part D. Only one container seal (7355-2A) is to be used per shipping container, even when the box contains more than one sample.

NOTE: Once a component of a seal packet has been used, any unused barcoded labels, identification labels, or container seals from that packet are to be shipped with the sample to the laboratory for disposal.

H. Sealing a Sample Shipment of Public Health Significance When no Seal Packet is Available

Rarely, a sample with potential public health significance (e.g., related to foodborne illness investigation) may be collected and the inspector may not have a seal packet available for use. In those rare instances, IPP and compliance investigators are to contact the appropriate laboratory (SamplingSupplies-EasternLab@usda.gov; SamplingSupplies-MidwesternLab@usda.gov; SamplingSupplies-WesternLab@usda.gov). The laboratory will issue a unique identification number and give detailed alternate sealing directions for that specific sample. IPP and compliance investigators are not to send unsealed samples without first contacting a laboratory and receiving a unique identification number and sealing instructions or the sample will be discarded.

VI. SAMPLE ACCEPTANCE POLICY

All non-investigative samples arriving at the FSIS Laboratories unsealed or with broken seals are to be discarded.

VII. QUESTIONS

Refer questions regarding this directive to your supervisor or if needed to the Office of Policy and Program Development through <u>askFSIS</u> or by telephone at 1-800-233-3935. When submitting a question, complete the web form and select **Sampling** for the Inquiry Type.

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

Assistant Administrator
Office of Policy and Program Development