

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

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<b>FSIS DIRECTIVE</b>	7355.1 Revision 2	12/03/2002
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## Use of Sample Seals for Laboratory Samples and Other Applications

### I. PURPOSE

This directive provides for a unified system to ensure the integrity of samples submitted to laboratories for analysis or held for incubation in the establishment as agar plates. The uniform use of sample seals and identity labels ensures that sample integrity and identity are maintained. **(NOTE: THIS DIRECTIVE IS NOT EFFECTIVE UNTIL DECEMBER 16, 2002.)**

### II. CANCELLATION

FSIS Directive 7355.1 Rev. 1, dated 10-20-92

### III. REASON FOR RE-ISSUANCE

To update and clarify inspection program employees' responsibilities regarding sample integrity.

### IV. REFERENCES

9 CFR Chapter III  
FSIS 10,210.1, Amendment 3

### V. DEFINITIONS

**What are the terms used in this directive?**

**Primary containers** – These are the containers that hold the actual sample, whether it be tissue, poultry wash, egg products or swabs. A primary container may be provided to the

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**DISTRIBUTION:** Inspection Offices; T/A Inspectors; Plant Mgt; T/A Plant Mgt; TRA; ABB; TSC; Import Offices ;Compliance Offices; FSIS Laboratories      **OPI:** OPPD

inspector as a jar, a sterile sample bag, or sterile sample cup or may be the retail package containing the product. It could also be a plastic bag obtained from the laboratory, from FSIS Field Supply Center (FSC), or at the collection site.

**Shipping containers** – Shipping containers are usually cardboard boxes provided by the Agency for the shipment of laboratory samples. These boxes have a foam insert to protect the samples during transport and may contain a refrigerant pack to stabilize temperature during shipment.

**System-generated or directed samples** – These are samples requested by the Office of Public Health and Science (OPHS) as part of Agency sampling programs. The submission forms for these samples are generated at headquarters and distributed to the inspection program personnel. These forms have been accompanied by gummed sample identification labels. Once this directive is effective, labels will no longer be sent with forms. Instead, the sample identification label set, FSIS Form 7355-2A/2B, will be used to link the sample collection form (10,210-3 or 10,210-7) with the sample.

**Inspector-generated samples** – Inspector-generated samples are initiated by inspection program personnel.

**Scheduled samples** – These are samples collected as scheduled on the Inspection Procedure Schedule under O5BO1, O5BO2 and O5CO1.

## **VI. BACKGROUND**

### **A. Why must laboratory samples be sealed?**

FSIS must be sure that samples submitted for laboratory analysis and agar plates used for in-plant screening tests are secure from the time samples are collected until the appropriate FSIS official receives the test results. Samples remain under direct FSIS control while in the establishment and while in the FSIS laboratories. During transport, however, samples and products are not under direct control of FSIS. The sealing of laboratory samples and agar plates used for in-plant screening tests provides a measure of security whenever these items are not under direct FSIS control. Appropriate sealing of laboratory samples and agar plates should:

1. Maintain the security and integrity of samples during shipment;
2. Identify samples where identity or integrity may have been compromised (such as in cases of suspected tampering); and
3. Identify and link samples with the information required for accurate analysis and reporting of test results.

### **B. To which samples does this directive apply?**

This directive applies to samples submitted by inspection program personnel to FSIS laboratories (this includes all domestic and imported meat, poultry and egg product

samples) for analysis and agar plates held for incubation in the establishment during the performance of Fast Anti-microbial Screen Test (FAST), and Swab Test on Premises (STOP) tests. It includes the sealing and handling of Compliance Program Investigative Samples (STC-39). Code STC-39 Compliance samples will be sealed with the new Investigation Laboratory Sample Seal Packet following the same procedures detailed below for the use of FSIS 7355-2A/2B. Since the Investigation Laboratory Sample Seal Packets will not be available for several months **after** the issuance of this Directive, interim sealing instructions for code STC-39 samples are included under Section VII, H. of this document. All retail ground beef directed samples (project codes MT05 and MT06) are to be sealed using the FSIS Form 7355-2A/2B seal packet. These are not investigation laboratory samples and should not be sent as STC-39 samples.

## VII. SEALING PROCEDURES

### A. With what are laboratory samples sealed?

FSIS Form 7355-2A/2B is the new FSIS Laboratory Sample Container Seal. It comes as a set of seals on a strip, one large seal (7355-2A) for the outer shipping box, one medium-sized strip (7355-2B) for the plastic bag containing the primary container and the form, and several small seals, all bar-coded identically to cross-reference each other.

Figure 1. The new FSIS Laboratory Sample Seal Packet.



Note that FSIS Form 7355-2A/2B seal sets and the new Investigation Seal Packets are accountable items, and are to be handled as such. Once a component of a seal packet has been used, any unused bar codes, identification labels, or container seals from that packet should be shipped with the sample to the laboratory for disposal. Using one sample seal set for more than one sample could jeopardize the sample identity.

**B. Where do inspectors get sample packaging and sealing supplies?**

See Attachment 1

**C. How are the laboratory samples sealed?**

All sample packages (with the exception of investigation samples as noted previously) shipped to FSIS laboratories are to be sealed and identified using a three-part system. This system identifies and links the sample with the submission form and the shipping container. When properly sealed, each laboratory sample package will have three separate but identically numbered/bar-coded identification labels, as follows:

- 1) One small bar-coded label is affixed to the sample submission form. For *Salmonella* Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) samples, (FSIS Form 10,210-7), place a small, bar-coded label in the right-hand side margin (as shown in Figure 2) next to the Discard Condition Box, for directed samples requested on FSIS Form 10,210-3, place the bar-coded label in the top center so that it does not obstruct any printed information (other than the title of the form). For all other sample submission forms, place the bar-coded label in the upper-right or left corner. Make sure not to cover any sample identification information, whether pre-printed on the form or provided by the inspector.

Figure 2 –Placement of the bar-coded sticker on the HACCP and Unified Forms.



After completing the sample submission form and affixing the bar-coded label, place it inside a plastic bag to protect it from moisture during shipping (Figure 3).

Figure 3 – Protecting the submission form from moisture.



- 2) The medium-sized bar-coded label, the “FSIS Laboratory Sample Identification Label” (7355-2B) is to be placed on the plastic bag containing the primary container, as follows: Insert the sample (already in the primary container) and the submission form (in a plastic bag as in step 1 above) into a re-sealable bag. Express as much of the air out of the bag as you can, and then close the bag. Fold the top of the bag over if possible, and place the medium-sized bar-coded label so the top bag opening is sealed to the bag itself (Figure 4). Make sure the bar-code number on the label on the form matches the barcode number on the label on the bag (Figure 5).

Figure 4 – Placement of the bar-coded Identification Label on the zipper lock bag containing the sample and submission form.



Figure 5 – Assure that the barcode number on the form matches the barcode number on the sample bag.



- 3) The large bar-coded label, the FSIS Laboratory Sample Container Seal, (7355-2A) is to be placed on the shipping container as described in the next section.

The inspector should retain a record of the seal packet used for each sample sent to the laboratory. An additional, small bar-coded label may be placed on the inspector's file copy of the submission form or on a log sheet indicating to which sample this seal corresponds.

#### **D. How are shipping containers sealed?**

Place the packaged sample into the shipping container, with the ice-pack, if needed. Replace the foam insert lid, being sure that the insert fits entirely within the box. If the foam insert bulges up out of the box, the box is overfilled and a larger shipping container needs to be used. Close the inner flaps of the box. Place the large bar-coded seal (with the same identification number as the label on the form) on the shipping container as follows:

Shipping containers with self-sticking closures should have the inner flap closed. The bar-coded seal should be placed across the closed inner flap of the box parallel to the edge of the closed flap, as shown in Figure 6. The outer flap should then be closed over the seal.



Figure 6 – Correct placement of the container seal on a box with self-sticking closure.



Boxes without self-sticking closures should be sealed across the closed outer flaps as shown in Figure 7. The outside flaps should then be fastened shut with clear packaging tape.

Figure 7 – Placement of Container Seal on box without self-sticking closures.



Coolers for oversized samples should also be sealed with the bar-coded seal over the opening (Figure 8) and then securely closed with packaging tape by wrapping the tape all around the circumference of the cooler in each direction.

Figure 8 – Placement of container seal on a cooler for oversized samples.

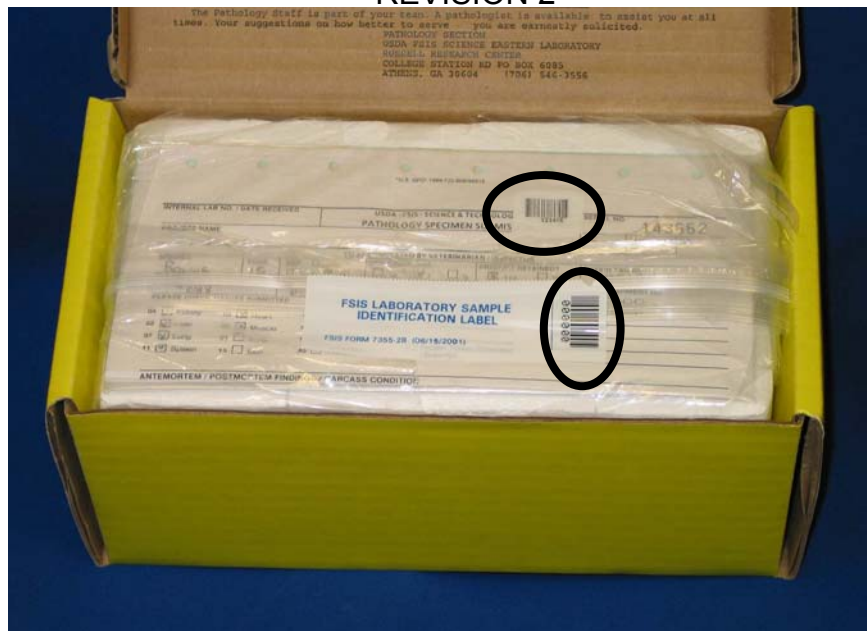


Each Pathology Sampling Kit will use one seal set. Once tissues have been placed in the jars, label the jars with the barcode label number and the serial number of the sample submission form accompanying that sample. Place the jars in the foam insert in the pathology sample box. Place the completed submission form in a plastic bag as directed in section C, and place it on top of the jars. Close the re-sealable bag containing the jars and form, making sure to remove as much air as possible. Seal bag with the medium-sized bar-coded label as previously described in section C2.



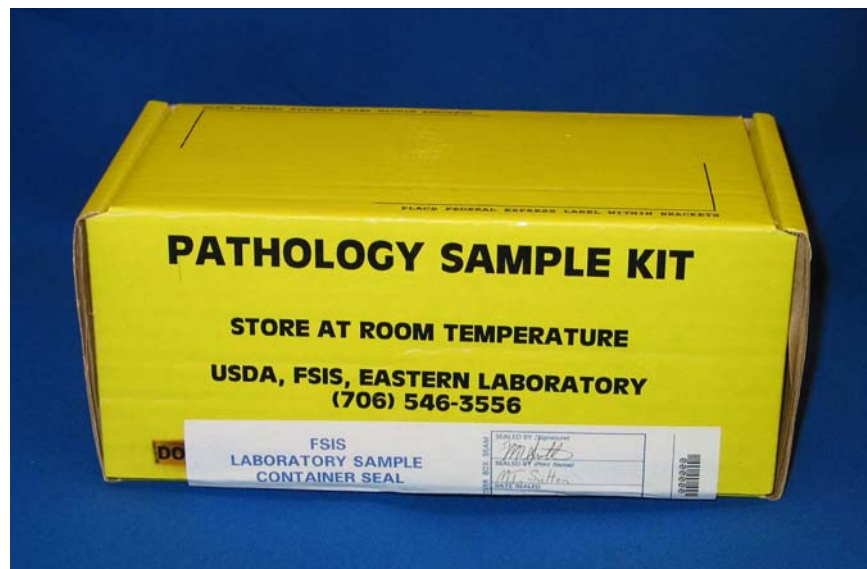
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Figure 9 – Placement of the identification label on the plastic bag inside the pathology box. Make sure the bar code on the form matches the bar code on the bag.



Then seal the box with the container seal as shown in Figure 10.

Figure 10 – Correct placement of the Container Seal on the Pathology Sampling Kit.



Remember, in addition to seals, all shipping containers **must** carry a Fed-Ex stamp or airbill. Both the top of the box **and** the bottom seam must be sealed. If the bottom seam of the shipping container you are using is not already sealed, place a completed FSIS Form 7355-2A across the bottom seam and cover it with clear packaging tape before using the box.

**It is very important not to overfill any of the shipping containers.** The security seals are not designed to act as a closure device for the shipping containers, and if boxes are

overfilled to the point that pressure is placed on self-sticking closures, it is very likely that the seal will be broken during transport.

#### **E. How are shipping containers with multiple samples sealed?**

1. If **one** sample consists of multiple individual primary containers, **all** primary containers should be placed into **one** re-sealable plastic bag, along with the corresponding sample submission form in its own bag, and sealed as indicated in section C.2. If all do not fit inside one bag, use a small bar-coded label to seal an additional bag, or request an extra large bag from the lab.
2. If **multiple** samples, **each** with its own sample submission form, are to be shipped in one sample shipping container, package and seal each individual sample and its own sample submission form according to section C.2. Be sure each plastic bag is sealed with the barcode seal that corresponds with the sample contained inside. Place each sealed sample package into the box, being careful to not overfill the shipping container. Only **one** seal (7355-2A) is needed per shipping container, even when the box contains more than one sample. All barcode numbers from samples packed in that container should be recorded on the one FSIS 7355-2A container seal used. **Note:** Once a component of a seal packet has been used, any unused bar codes, identification labels, or container seals from that packet should be shipped with the sample to the laboratory for disposal.

It is critical that shipping containers, especially those containing heavy samples like antibiotic residue samples, some ready-to-eat samples, and multiple samples in the same box, not be overfilled. If the foam insert bulges upward, placing pressure on the closure device, place the samples back in the freezer, e-mail the appropriate laboratory inquiry Outlook box (**Sampling Supplies – Eastern Lab, Sampling Supplies - Western Lab, or Sampling Supplies – Midwestern Lab**) and request a larger box.

#### **F. How should seals be placed to secure agar plates?**

When incubators cannot be secured, seals may be placed on agar plates to detect tampering (Species Identification Field Test (SIFT), FAST, and STOP tests or swab tests require the use of agar plates - petri dishes filled with sterile agar). Apply the sample seal to individual agar plates very carefully to avoid tipping or dislodging the disk or swab. Place a small FSIS Laboratory Sample Identification label (7355-2B) seal across the agar plate cover and fold each end down over the plate bottom. Avoid placing the label across the bottom of the plate.

To avoid handling the test plates, incubator doors or other enclosed areas where the plates are being incubated may be locked or secured **instead** of sealing plates as long as **only appropriate FSIS inspection personnel** have access.

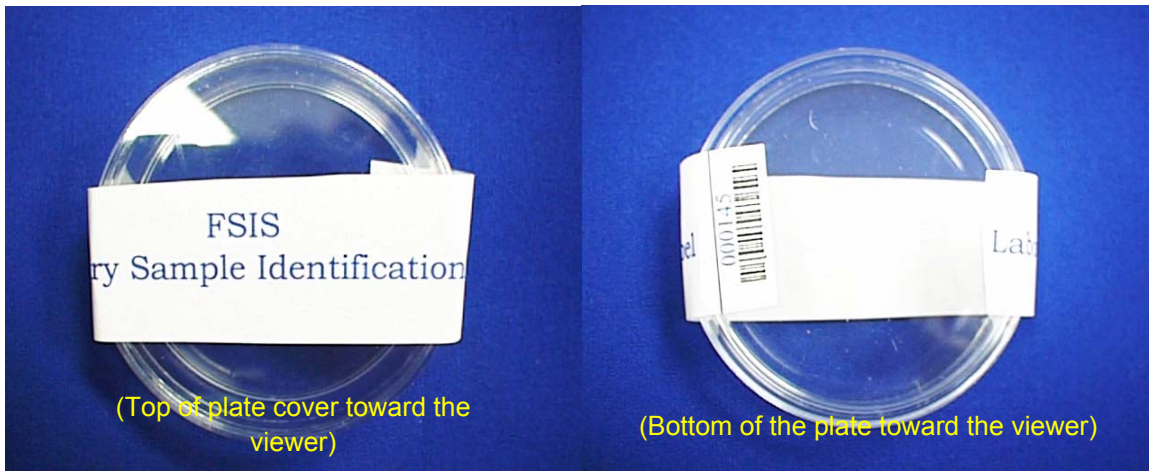


Figure 11 – Use of the Identification Label to seal agar plates.

**G. How are laboratory sample shipping containers secured when enroute from the laboratory to the establishment?**

1. Effective the issue date of this Directive, the FSIS laboratories will seal all shipping containers on both the top outer flaps and the bottom seam of the box with special sealing tape before mailing them to inspection personnel. These seals are to insure there has been no tampering with the sample materials when out of the direct control of FSIS personnel. If either top or bottom seal is broken, **do not open or use the container**. Instead reseal it with a new FSIS Form 7355-2A and ship it back to the laboratory of origin for processing. Complete all the information required on the seal, except "Form No.". On the blank marked "Form No." place the words "seal broken".

2. Inspection program personnel should **not** return shipping containers to the laboratories if they are already in inspection offices before the issue date of this Directive. You may want to prominently mark all the shipping containers currently under FSIS control with a piece of masking tape. Place your initials and the words "okay to use" on the tape. Use these boxes as soon as possible, so that the FSIS laboratories may process these containers and assure that they meet the security standards outlined in this Directive.

## **H. How are Investigative Code STC-39 samples to be sealed?**

Once the new Investigation Laboratory Sample Seal Packets are available, they will be used to seal Code STC-39 samples. Until then, Code STC-39 samples should be sealed with a FSIS 7355-2A/2B following the same procedures detailed in this directive for all other laboratory samples. Once the FSIS Laboratory Sample Container seal is completed and attached to the shipping container, a properly completed FSIS 8040-1 (current orange compliance seal) should be placed directly beside, but not overlapping, the FSIS 7355-2A on the shipping container. Place a piece of clear packaging tape over the orange compliance seal to assure that it does not come off of the box during shipment.

### **I. What happens if a non-routine sample is collected and the inspector has no seal packet available?**

Rarely, a sample with potential public health significance may be collected and the inspector may not have a seal packet available for use. In those rare instances, the inspector should contact the Eastern Laboratory via Outlook at Sampling Supplies-Eastern lab. If Outlook is not available, call the Office of the Director, Eastern Laboratory at (706) 546-3576. The Information Management Specialist (or designee) will issue a unique identification number and give detailed alternate sealing directions for that specific sample. **Do not** send unsealed samples without first contacting the Eastern Laboratory and receiving the unique identification number and sealing instructions or the sample will be discarded.

## **VIII. SAMPLE ACCEPTANCE POLICY**

### **What happens if the laboratory receives a shipping container with a broken or missing seal?**

Effective two months from issuance date of this directive, all non-Investigative samples arriving at the FSIS Laboratories unsealed or with broken seals must be discarded.

## **IX. FURTHER INFORMATION**

For further information, contact the FSIS Technical Service Center.

*Philip S. Derfler/s/*

Deputy Administrator  
Office of Policy and Program Development

**Where do inspectors get sample packaging and sealing supplies?**

**Contact the FSIS Laboratories via Outlook (See FSIS Notice 54-02) for:**

- **Sampling supplies for system-generated or directed samples**
- **Sample boxes** with sealed bottom seams
- **FSIS Form 7355-2A/2B**, Laboratory Sample Container Seal Sets

**Order from the Field Supply Center (FSC), Beltsville, MD**

*Follow established procedures for ordering Supplies from FSC\*. Be sure to use the Item Number and note the Unit of Issue for each item.*

- **Federal Express Airbills:**

<u>Laboratory</u>	<u>Item Number</u>	<u>Unit of Issue</u>
• Eastern Lab (Athens, GA)	FSIS-17EL	EA
• Midwestern Lab (St. Louis, MO)	FSIS-17MWL	EA
• Western Lab - (Alameda, CA)	FSIS-17WL	EA

- **Blank FSIS sample submission forms**

<u>Form Number and Title</u>	<u>Unit of Issue</u>
• FSIS 9770-2 - Import Residue Program	PKG100
• FSIS 10000-2 - Domestic Laboratory Report	EA
• FSIS 10,300-2 - Pathology Specimen Submission	EA
• FSIS 10600-1 - Domestic Chemistry Lab Report	EA

- **Plastic Bags**

<u>Description</u>	<u>Item Number</u>	<u>Unit of Issue</u>
• Resealable, Quart Size	FSIS-72-QT	PKG50
• Resealable, Gallon Size	FSIS-72-GAL	PKG50
• Resealable, Two-Gallon Size	FSIS-72-2GL	PKG50
• Flat, Open End, 6" x 12", 3 Mil	FSIS-14	PKG100

**\* - NOTE: Must have a FSC Customer I.D. Number to order.**

- If ordering by mail, send a completed CFPDC-1 to:

USDA, FSIS FIELD SUPPLY CENTER  
6351 Ammendale Rd.  
Beltsville, MD 20705

- If ordering on the FSC web page, follow the instructions on Page V of the Field Supply Center Catalog, November 2001 Edition.