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

FSIS DIRECTIVE

10,800.2 | 2/14/22

RESIDUE SAMPLING AND TESTING UNDER THE NATIONAL RESIDUE PROGRAM FOR MEAT AND POULTRY PRODUCTS

I. PURPOSE

This directive provides instructions to inspection program personnel (IPP) for completing sampling tasks for residue testing under the U.S. National Residue Program and for updating the Public Health Information System (PHIS) profile information related to residue sampling.

KEY POINTS:

- *In-plant residue screening (Kidney Inhibition Swab (KIS™)) tests are not performed in poultry, exotic animals slaughtered under voluntary inspection, or Siluriformes fish*
- *Tissues collected for residue testing do not need to be frozen prior to shipping to the FSIS laboratory*
- *Samples for residue testing are to be collected in a sanitary manner and do not require aseptic technique*

II. BACKGROUND

A. IPP conduct surveillance sampling of specified slaughter subclasses when scheduled in the Public Health Information System (PHIS). IPP randomly select carcasses within a given production class for sampling as part of a nationally representative sample.

B. IPP conduct inspector-generated sampling when they suspect livestock presented for slaughter may have violative levels of chemical residues. This sampling may include an in-plant screening test and confirmatory tissue testing. IPP may determine the need for this testing based on herd history, ante-mortem or post-mortem examination findings, and in slaughter classes with a higher incidence of violative chemical residues. In-plant screening tests are not performed in poultry, exotic animals or Siluriformes fish.

III. IPP RESPONSIBILITIES FOR COLLECTING SAMPLES

A. The Public Health Veterinarian (PHV) or IPP under the direction of the PHV are to collect kidney, liver, and muscle tissues from animals whenever there is reason to suspect that a violative level of chemical residue is present or when PHIS assigns a surveillance residue sampling task to the establishment's task list. IPP are to refer to FSIS Directive 10,800.1, *Residue Sampling, Testing and Other Verification Procedures Under the National Residue Program for Meat and Poultry Products,* and FSIS Directive 10,800.3, *Prioritizing Inspector-Generated Sampling under the National Residue Program* for additional instructions on situations that warrant residue testing and actions to take in response to test results. Residue sample collection cannot be delegated to establishment employees.

NOTE: The term "muscle, as used throughout this directive, refers to skeletal muscle, excluding tongue.

B. IPP are to ensure sample integrity when collecting, preparing, and packaging samples for chemical residue testing.

C. For Kidney Inhibition Swab (KIS™) testing and confirmatory tissue sampling, IPP are to retain the carcass and its parts (if not already condemned), pending test results. If the KIS™ test is positive, IPP are to continue to retain the carcass and parts (if not already condemned) and submit kidney, liver, and muscle tissues for further analysis to the appropriate FSIS laboratory. IPP are to document the retain tag number in PHIS for any inspector-generated sample submitted.

D. For surveillance residue sampling of livestock, IPP are to verify that the establishment holds or controls livestock carcasses selected for testing pending the test results. For surveillance residue testing of poultry, IPP are to recommend that establishments hold the specific poultry carcasses selected for residue testing pending the test results, however poultry establishments are not required to hold the sampled poultry carcasses.

E. IPP are to follow the instructions provided in FSIS Directive 13,000.2, *Performing Sampling Task In Official Establishments Using The Public Health Information System* for accepting, scheduling, and completing the residue sampling task in PHIS.

F. IPP are to ship residue samples to the FSIS laboratory as soon as possible after collection because residues in tissues can degrade over time, resulting in false negative results. IPP are to freeze samples if they need to be held overnight before shipping.

IV. ORDERING SAMPLING SUPPLIES FOR RESIDUE TESTING

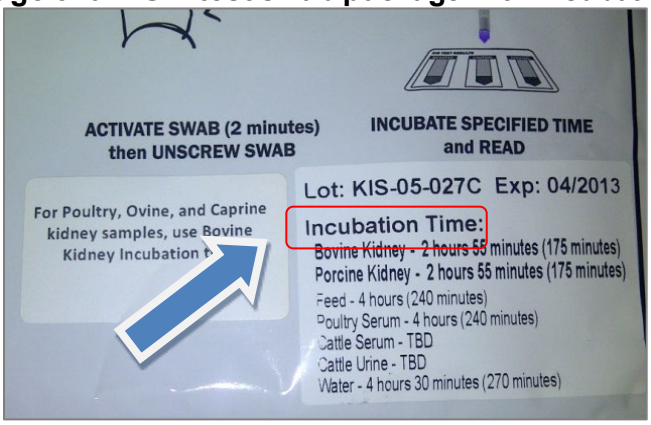
A. IPP are to use only sampling supplies provided by FSIS laboratories when conducting residue testing.

B. IPP are to submit requests for KIS™ test supplies to the Midwestern Laboratory via PHIS or Outlook (SamplingSupplies-MidwesternLab@usda.gov). The following KIS™ test supplies are available from the FSIS Midwestern Laboratory:

1. Digital Dry Block Heater (tests up to 20 units);
2. KIS™ Tests (in packets of 25 tests);
3. Negative Controls (four (4) tablets;
4. 15 ml Tube of De-ionized or Distilled Water (or equivalent);
5. Timer;
6. Transfer Pipettes (in packs of 25) or equivalent device for delivering 1 ml of water; and
7. Test Tube Rack (or equivalent device, to hold KIS™ tests).

NOTE: Upon receipt of KIS™ test supplies, IPP are to check the label on the KIS™ test package for the correct test incubation time based on the slaughter class and sample source (see Figure 1). IPP should note that incubation times may vary between different lots.

Figure 1. Image of a KIS™ test swab package with incubation time label



C. For surveillance residue samples, IPP are to request sampling supplies through PHIS by right-clicking on the scheduled residue sampling task on the Task Calendar, selecting "Order Supplies" and entering information in the fields provided.

D. For surveillance and inspector-generated tissue sample supplies other than KIS™ test supplies, IPP are to submit requests to any of the three FSIS Laboratories via Outlook, using one of the following e-mail addresses:

1. Eastern Laboratory: (SamplingSupplies-EasternLab@usda.gov);
2. Midwestern Laboratory: (SamplingSupplies-MidwesternLab@usda.gov); or
3. Western Laboratory: (SamplingSupplies-WesternLab@usda.gov)

E. IPP are to include the following information in their e-mail request for supplies:

1. The sampling project code;
2. The establishment number and establishment name;
3. The IPP's name and contact phone number; and
4. The specific supplies needed, including name and quantity to be ordered;

F. For tissue sample submissions, the shipping container should contain the following sampling supplies (Figure 2):

1. 1-gallon zipper lock bag (1);
2. 1-quart zipper lock bag (6);
3. Plastic sleeve or zipper lock bag for sample form (FSIS Form 8000-18) (1);
4. FSIS Laboratory Sample Container Seal (FSIS Form 7355-2A/2B);
5. Absorbent pad (1);

Figure 2: Residue Sampling Supplies

6. Gel coolant pack (1 or more);

7. Cardboard separator (1); and

8. FedEx pre-printed billable stamp (1).

V. COLLECTING ANIMAL IDENTIFICATION AND SUPPLIER INFORMATION

IPP are to obtain all man-made animal identification (ID) from the establishment for animals selected for KIS™ testing and for all surveillance and inspector-generated tissue samples submitted to FSIS laboratories for chemical residue testing. IPP are to refer to FSIS Directive 10,800.1 for additional information on animal identification collection.

VI. CONDUCTING IN-PLANT SCREENING TESTS (KIS™ TESTS)

A. The PHV, or IPP under the direction of the PHV, are to conduct a KIS™ test on any livestock carcass where there is reason to believe the carcass may contain a violative antibiotic residue, based on or ante-mortem or post-mortem inspection findings or herd history. IPP are to refer to FSIS Directive 10,800.3 for instructions on prioritizing pathological conditions that warrant residue testing. IPP are not to perform KIS™ testing on poultry, exotic animals slaughtered under voluntary inspection or Siluriformes fish.

B. IPP at livestock slaughter establishments that have historically recorded less than one (1) in-plant screening test per week, on average, will not receive KIS™ test supplies. This is to conserve laboratory resources and reduce situations where KIS™ test supplies go unused and expire. In this situation, IPP are to submit one (1) pound each of kidney, liver, and muscle tissue to the FSIS Laboratory for analysis as an inspector-generated sample, using the instructions provided in Section IX.

C. The Supervisory PHV (SPHV) or Supervisory Consumer Safety Inspector (SCSI) is to ensure IPP conducting KIS™ tests are properly trained. KIS™ test instructional materials are available on IPP Help.

D. IPP are to record KIS™ test results on the Daily Disposition Record page in the PHIS Animal Disposition Reporting (ADR) function using instructions in the PHIS Animal Disposition Reporting User Guide.

E. Information on actions to take based on KIS™ test results can be found in FSIS Directive 10,800.1. When indicated, based on KIS™ test results or other post-mortem findings, IPP are to submit tissue samples to the FSIS laboratory for further residue testing using the instructions provided in Section IX.

1. If the carcass and parts have been condemned and the KIS™ test is positive, IPP are to submit liver, kidney, and muscle tissue samples for confirmatory residue testing and document the carcass as "Condemned" in the Sample Collection – ADR Sample Management window in PHIS; and

2. IPP do not need to retain a condemned carcass and its parts pending residue test results.

F. For tissue samples submitted from the same carcass for both pathology and residue testing, IPP are to reference the pathology form number in the "Remarks" section of the PHIS Sample Collection Data tab in the Sample Collection - ADR Sample Management window.

VII. CONDUCTING INSPECTOR-GENERATED RESIDUE SAMPLING OTHER THAN THE KIS™ TEST

A. IPP are to collect and submit tissue samples for inspector-generated residue testing when:

1. A KIS™ test result is positive;

2. An animal is suspected of having violative levels of a chemical residue, other than an antibiotic;

3. A producer is a repeat violator as identified in the Residue Repeat Violator list for a chemical residue other than an antibiotic; or

4. Antemortem or post-mortem examination findings indicate a condition where violative residues may be present, regardless of KIS™ test results.

B. IPP are to create inspector-generated residue sampling tasks through the Daily Disposition page of PHIS using instructions in the PHIS Animal Disposition Reporting User Guide available in IPP Help

C. IPP are to retain the carcass and its parts pending residue test result reporting unless they are condemned by FSIS or the establishment elects to voluntarily discard the carcass. IPP are to enter the retain tag number into PHIS and indicate that the carcass and parts are "Retained" in order to elevate the sample analysis priority.

D. IPP are to collect and submit the following tissues for analysis:

Table 1: Samples to Submit For Inspector-Generated Residue Testing

Slaughter Class	Sample source and size
Cattle Swine	Muscle – 1 lb. Liver - 1 lb. Kidney – 1 lb.
Sheep Goats	Muscle – 1 lb. Liver - 1 lb. Kidney – both kidneys
Poultry	Muscle – 1 lb. Livers, Kidneys – From 6 carcasses
Roaster pigs	Liver – 1 lb.

E. IPP are to package, secure, and ship the samples to the FSIS laboratory using the instructions provided in Section IX.

VIII. CONDUCTING SURVEILLANCE RESIDUE SAMPLING TASKS

A. IPP receive notification of surveillance residue testing as a task added to the establishment's PHIS task list. IPP are to follow the instructions provided in FSIS Directive 13,000.2, for accepting, scheduling, and completing surveillance residue sampling tasks in PHIS.

B. IPP are to notify establishment management when scheduling a surveillance residue sample and provide enough time for the establishment to hold the sampled carcass.

C. To collect a surveillance residue sample, IPP are to:

1. Select from all animals that have passed antemortem inspection on the day designated for scheduled sampling for the livestock class indicated on the sample request;

2. Randomly select carcasses at the kill floor stage, regardless of post-mortem disposition. IPP are not to select animals condemned on antemortem because these animals are not permitted into the slaughter facility;

3. Collect and submit the following tissues for analysis from the carcass selected for surveillance residue sampling:

Table 2: Samples to Submit For Surveillance Residue Testing

Slaughter Class	Sample source and size
Cattle Swine	Muscle – 2 lb. Liver –1 lb. Kidney – 1 lb.
Sheep Goats	Muscle – 2 lb. Liver –1 lb. Kidney – both kidneys
Poultry	Muscle – 2 lb. Livers Kidneys } From 6 carcasses
Roaster pigs	Liver – 1 lb.

4. IPP are to collect residue samples in a sanitary manner; unlike samples collected for microbiological testing, aseptic technique is not required.

5. Package, secure, and ship the samples to the FSIS laboratory using the instructions provided in Section XI.

    a. For samples that are collected and shipped on the same day, IPP are to submit tissue as fresh (not frozen) samples on gel coolant packs.

    b. For samples that cannot be shipped on the same day as collected, IPP are to place the samples in a freezer overnight and ship them on the next available shipping day.

D. IPP are to inform the establishment that livestock carcasses selected for surveillance residue testing are to be held or controlled until the FSIS laboratory reports the results. IPP are to recommend that an establishment hold any poultry carcass selected for residue testing pending the test results. For chemical residue testing, a livestock slaughter establishment is required to hold or control only the sampled carcass and its parts because lotting is typically based on individual carcasses (unless there is evidence of flock or herd exposure).

E. When an establishment decides to voluntarily discard the carcass of a healthy-appearing animal selected for surveillance residue testing, IPP are to document that the carcass was "Passed and discarded by establishment" in the Sample Collection Data tab in the Sample Collection - Sample Management window in PHIS.

IX. SAMPLE PACKAGING AND SHIPPING

A. IPP are to use only the shipping materials provided by the laboratory and refer to FSIS Directive 7355.1, *Use of Sample Seals for Program Samples and Other Applications*, for instructions on the proper use of sample seals.

B. At least one (1) day prior to packing and shipping the sample, IPP are to pre-chill the shipping container in a refrigerator or freezer and place the gel coolant packs in the freezer.

C. Upon collection of the tissue samples, IPP are to:

1. Place each type of tissue collected into separate zipper lock sample bags. Do not commingle the tissues in the same sample bag even if they are from the same carcass. Expel excess air from the bag prior to closure. Close the bag using the zipper lock closure. Place each bagged tissue specimen in a second zipper lock bag.

2. If the sample will be shipped on the same day as the collection day, place the bagged tissue specimen in a secure refrigerator and allow a sufficient amount of time for chilling, if time permits, prior to packing the sample in the shipping container. If the sample cannot be shipped on the same day as the collection, place the bagged tissue specimens in a secure freezer until the sample can be shipped overnight on the next available shipping day.

D. On the day of sample shipping, IPP are to:

1. Retrieve the frozen gel coolant packs from the freezer and the pre-chilled shipping container;

2. Retrieve the tissue specimens from the refrigerator or freezer;

3. Place the cardboard separator and absorbent pad on the bottom of the shipping container and place the frozen gel coolant pack on top of the corrugated cardboard pad;

4. Place all bagged tissue specimens into the large zipper lock bag, expel the excess air from the bag, and close the bag using the zipper lock closure. Apply the medium sized bar-coded FSIS Laboratory Sample Identification Label (FSIS Form 7355-2B) to the zipper lock bag. Place the sample bag containing the tissue samples in the shipping container on top of the frozen gel coolant pack. When needed, place a second frozen gel coolant pack on top of the tissue samples, to ensure that the sample arrives at the laboratory at an acceptable temperature.

5. Review the information on the pre-printed FedEx billable stamp provided with the sampling supplies and select the air bill with the laboratory name and address that corresponds to the FSIS laboratory name and address printed on the FSIS sample form to ensure delivery of the sample to the correct FSIS laboratory. Enter the return address information on the air bill.

6. Place the completed, signed and dated sample form in the plastic sleeve provided. Place the completed sample form and any unused sample seals in the shipping container.

7. Insert the foam plug and press down to minimize the space between the sample and foam plug. If the shipping container does not have a foam plug, place the insulated lid on the container. Do not overfill the shipping container.

NOTE: Do not tape or wrap the samples or use any newspaper or similar material as packing material. Use of such materials may result in a sample discard by the laboratory.

8. Complete the information on the large bar-coded seal from the same FSIS Form 7355-2A/2B sample seal set and sign the seal. Apply the FSIS Laboratory Sample Container Seal (FSIS Form 7355-2A) to the inner flap of the shipping container as described in FSIS Directive 7355.1. IPP are to close the box flaps so that the container closure system is secure. IPP are not to tape the box if there are tapeless closure.

9. Affix the carrier shipping air bill on the shipping container and remove any old stamp receipts and carrier shipping bar codes from the container.

10. Place in the designated area for pick up by FedEx.

E. IPP are to ship samples on the day of collection or the next day. Do not ship samples on a Saturday, or the day before a federal holiday.

F. IPP are to return any unused shipping containers and sampling supplies after the sampling window closes, including the FedEx billable stamp, to the FSIS Laboratory that provided the IPP with these materials. IPP are to send a request to the FSIS Laboratory for a pre-addressed return FedEx ground-shipping bill, using the e-mail address provided in Section IV.D.

X. ACCESSING LABORATORY RESIDUE TEST RESULTS

A. IPP are to periodically check PHIS or LIMS Direct for the status of residue test results. IPP can access test results in PHIS through the Laboratory Sample data field on the Inspector Home page.

B. Sample discard: If the FSIS Laboratory discards a sample submitted for residue testing, IPP are to immediately contact their supervisor to determine the appropriate actions.

1. IPP are to review the reason for sample discard as indicated in PHIS and make the necessary adjustments in how the samples are collected, sealed, and shipped to ensure that the laboratory does not discard future samples because of improper handling or packaging.

2. For inspector-generated residue samples that are discarded:

    a. If any tissues (liver, kidney, muscle) from the original submission are available, IPP are to send replacement tissue samples from the same carcass. IPP are to complete the task in PHIS as an inspector-generated sample, enter all necessary information in the data fields in the PHIS Sample Collection window, note in the “Remarks” field that the sample submitted is “REPLACEMENT TISSUES” and reference the sample form number from the original submission.

b. If only muscle tissue is available from the original submission, IPP are to submit replacement muscle tissue samples from the same carcass. FSIS will use the results from the laboratory testing on the muscle tissue to determine whether there is a residue violation and the disposition of the carcass.

c. If the carcass and/or parts were condemned, there is no further action to take by IPP.

3. If the discarded sample was a surveillance residue sample, IPP are to release the carcass and its parts.

XI. IPP ACTIONS UPON REPORTING OF TEST RESULTS

IPP are to refer to FSIS Directive 10,800.1 for instructions on actions to take based on residue test results.

XII. QUESTIONS

Refer questions regarding this directive to your immediate supervisor or to the Office of Policy and Program Development through askFSIS or by telephone at 1-800-233-3935. When submitting a question, complete the web form and select Residue as 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