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

# FSIS DIRECTIVE	10,800.1	7/12/07

PROCEDURES FOR RESIDUE SAMPLING, TESTING, AND OTHER RESPONSIBILITIES FOR THE NATIONAL RESIDUE PROGRAM

CHAPTER ONE – GENERAL

I. PURPOSE

This directive instructs inspection program personnel about how to perform residue sampling, testing, and verification procedures in accordance with the National Residue Program (NRP). This directive also:

- emphasizes the important role inspection program personnel have in the initial steps leading to the detection and control of residues in the nation's meat, poultry, and egg products;
- revises and combines instructions from previous FSIS directives;
- focuses on animal identification;
- familiarizes inspection program personnel with the detection of implants; and
- addresses the monitoring and receipt of laboratory results through LEARN.

II. CANCELLATIONS

FSIS Directives 8150.1; 10,001.1; 10,012.1; 10,100.1; 10,110.1; 10,130.1; 10,530.1; 10,600.2; and 10,620.1.

III. RESERVED

IV. REFERENCES

Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), Egg Products Inspection Act (EPIA), 9 CFR 300 to end, 417.3(a) and (b); FSIS Directives 5000.1; 5420.2; 7355.1; 10,200.1;10,210.1; 10,220.1; 10,220.3.

V. BACKGROUND

The Food Safety and Inspection Service (FSIS) works with the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) to accomplish its responsibilities under the National Residue Program. FSIS's primary mission under the NRP is to verify that establishments control animal drug residues, pesticides, environmental contaminants, and any other chemical hazards in and on meat, poultry, and egg products. The NRP also provides for the collection of national data on the occurrence of residues to support risk assessment, enforcement, and educational activities.

CHAPTER TWO – PROGRAM AREAS AND DUTIES

I. SPECIFIC PROGRAM RESPONSIBILITIES

A. Office of Public Health and Science (OPHS)

OPHS is the lead program area in the development and implementation of the FSIS NRP in that it provides scientific guidance in the planning, testing, and data analysis done for the program. OPHS also works in conjunction with the Technical Service Center (TSC), Office of Policy, Program, and Employee Development (OPPED), to respond to the Office of Field Operation's (OFO) questions and requests pertaining to the NRP.

Two components of OPHS play key roles in FSIS' residue program:

1. Residue Branch, Zoonotic Diseases and Residue Surveillance Division (ZDRSD):

a. Receives, evaluates, and provides residue-related information and scientific support to OFO, the Office of International Affairs (OIA), and OPPED regarding procedures and training for residue control activities.

b. Publishes the "FSIS National Residue Program Scheduled Sampling Plans" (Blue Book) and manages the publication and issuance of scheduled sample forms to OFO.

c. Summarizes the residue data published annually in the "FSIS National Residue Program Data" (Red Book).

2. FSIS's three laboratories:

a. Conduct laboratory tests and provide the results of those tests in accordance with Agency objectives and guidelines.

b. Assess and provide necessary modifications to laboratory methodologies in support of scheduled, inspector-generated, and other residue-related sampling.

B. Office of Field Operations (OFO)

1. Public Health Veterinarian/Inspector-in-Charge (PHV/IIC):

a. Identifies animals at ante-mortem inspection as suspect for residue testing.

PHVs are to handle animals for slaughter with known violative residue levels in accordance with 9 CFR 309.16.

b. Retains and tests carcasses with all pathologies and conditions listed in Section VI of FSIS Directive 10,220.3. If the in-plant screening test is positive, the PHV is to continue to retain the carcass and parts and submit tissue samples to the appropriate FSIS laboratory.

c. Understands how the establishment addresses residue control in its HACCP system.

d. Manages the duty station to ensure that it has proper equipment needed for the effective collection of samples and performance of in-plant tests and maintains adequate control of supplies, incubators, and other equipment.

e. Verifies that Consumer Safety Inspectors (CSIs) have been trained in residue testing sample submission procedures and in the appropriate identification of carcasses or products suspect for violative residues on post-mortem inspection.

f. Accurately completes FSIS Residue Sample Forms 10,000.2 and 10,210-3 in legible black ink and records the carcass owner's name, address, and other identifying information on the forms. See the Fast Antimicrobial Screen Test (FAST) and Swab Test on Premises (STOP) guidelines at the following link:

http://www.fsis.usda.gov/Science/Chemistry/index.asp

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g. Selects through random animal selection under the NRP surveillance program, carcasses or parts for testing to detect violators, and ensures proper handling, labeling, processing, sealing, and shipping of the samples to avoid discard of any samples.

h. Tracks the status of the sample and determines carcass/part disposition by reviewing LEARN.

i. Documents noncompliance.

2. Frontline Supervisor/Multi In-Plant Performance System Assignment:

a. Evaluates and assesses in-plant residue control performance of PHV or inspection program personnel.

b. Evaluates and assesses in-plant staffing needs, sets priorities to

ensure that an adequate residue control system is in place, and provides feedback to the PHV.

c. Maintains current information on the NRP and apprises inspection program personnel of any program changes in a timely manner.

d. Operates in conjunction with the District Office (DO) to ensure uniform and consistent implementation of the NRP.

3. District Office:

a. Receives notification of residue violations and violators from LEARN and the TSC through the Residue Violator Information System (RVIS).

b. Coordinates residue-related activities and disseminates residue information to field personnel on an as-needed basis and operates in conjunction with the TSC when special sampling situations arise.

c. Cooperates with residue violation investigations that may involve FSIS, FDA, and EPA.

d. Cooperates with and aids the TSC in trace-back activities that may require contacting auction houses, brokers, establishments, or PHVs in order to obtain information that the TSC needs for residue management efforts.

e. Ensures that OFO staff and inspection program personnel enroll in appropriate training necessary to carry out NRP responsibilities.

f. Evaluates the performance of field personnel to ensure uniform and consistent implementation of the NRP.

g. Verifies, through RVIS, the degree and level of application of various residue-related activities conducted at the in-plant level by interpreting and analyzing operational reports, data, and other information to effect corrective actions in situations where the program failed.

h. May receive information from the TSC and OFO Headquarters relating to field residue violations that require increased in-plant testing by the PHV.

C. OPPED, Technical Service Center

The Technical Service Center coordinates residue violator activities and the dissemination of residue-related information among FSIS, FDA, and EPA in accordance with the existing Memorandum of Understanding (MOU). The TSC uses RVIS to manage violation cases. Case management includes communication with FSIS field

personnel, FSIS District Offices, FDA Districts, State officials, and the owners and establishment officials responsible for violations. The TSC also provides correlation as requested by OFO on residue results reported in LEARN, inclusive of carcass or part disposition.

CHAPTER THREE – ANIMAL IDENTIFICATION AND DETECTION OF IMPLANTS

I. ANIMAL IDENTIFICATION VERIFICATION AND ENFORCEMENT ACTIVITIES WHEN ESTABLISHMENTS FAIL TO COLLECT AND MAINTAIN ANIMAL INDENTIFICATION

Inspection program personnel are to verify that all animal identification devices remain associated with the carcass until FSIS completes the post-mortem examination.

A. FSIS verification activities:

1. Inspection program personnel are to verify that the establishment is collecting and maintaining animal identification until the completion of post-mortem inspection in accordance with 9 CFR 310.2.

2. Inspection program personnel are to collect all animal and owner identification from the establishment when they submit a sample for residue testing (e.g., livestock market or sale barn back tags, producer ear tags, feedlot identification tags, Canadian tags, and calf-hood tags [bangs]). (See: 9 CFR 309.16, 309.17, 310.2, 310.3, 310.21, , and 320.1 and FSIS Directive 10,220.3).

B. FSIS enforcement activities:

Inspection program personnel are to prepare a noncompliance record (NR) when the establishment fails to comply with the FSIS's regulations that apply to the identification, holding, and sampling of carcasses and parts for drug residues (9 CFR 309.16, 310.2, 310.3, 310.4, or 310.21, 310.23, and 320.1). NRs are to include a citation of the applicable regulation and the procedure code 06D02, and document "product, facilities" as the trend indicator.

II. VERIFICATION OF IMPLANT USAGE IN PRE-RUMINANT CALVES

A. PHVs are to condemn any pre-ruminant calf presented for slaughter that has an implant or evidence of implant use. PHVs do not need to collect tissue samples when there is an actual implant present.

B. Ante-mortem verification activities in pre-ruminant calves:

1. During ante-mortem inspection of pre-ruminant calves whose meat is to be labeled as "veal," inspection program personnel are to determine whether the animal has an implant.

2. Signs that an implant has been used are:

a. palpable implant;

b. missing ears;

c. ears with incisions indicating recent surgery;

d. mutilated ears;

e. atrophied testicles; or

f. unusually heavy muscle development.

3. If any of the above signs are present in a calf, inspection program personnel are to retain the animal and tag it as "U.S. Suspect." Inspection program personnel are to use their professional judgment to determine when the entire lot (i.e., all calves) from the same producer should be tagged "U.S. Suspect."

C. Post-mortem verification activities in pre-ruminant calves:

1. Inspection program personnel are to palpate the ears of the "U.S. Suspect" carcasses for implants. Inspection program personnel are to consult with their supervisor concerning adjustments in line speed that may be necessary to complete the inspection procedure.

NOTE: If necessary, the establishment may remove ears prior to hide removal, place them in a plastic bag, and attach the bag to the carcass. The establishment can also remove the ears when skinning the head and present them for review in a manner acceptable to the PHV.

2. If an implant is present, inspection program personnel will feel a linear, firm swelling under the skin when palpating the ear. The implant may feel like "beads on a string." The individual pellets that make up the implant are approximately 3 mm in size and about 2 mm apart.

3. Inspection program personnel are to retain the carcass of "U.S. Suspect" calves showing signs of having implants at ante-mortem inspection for the PHV to examine.

4. The PHV is to examine the rumen of the retained carcass to determine whether the rumen was functioning.

a. The PHV may pass the carcass for human food if the animal had a functioning rumen, and the carcass is not subject to condemnation under 9 CFR Part 311 because of the presence of disease.

b. The PHV is to condemn the carcass if the rumen was not functioning (pre-ruminant), and the animal had:

i. an implant; or

ii. missing ears, ears with incisions that indicate recent surgery, or mutilated ears to the extent that the PHV is unable to determine whether an implant was present. In the absence of the ear, the PHV cannot pass the carcass because there is no basis to find that it is not adulterated, and the PHV is to condemn the carcass.

5. If the PHV determines that a calf had an implant and a non-functioning rumen, he or she is to verify, using procedure code 03J, that the establishment takes the appropriate actions under 9 CFR 417.3(a) or 417.3(b).

6. If the establishment fails to take appropriate corrective actions, the PHV is to issue an NR and take the appropriate enforcement action as set out in FSIS Directive 5000.1, Revision 2, Amendment 1.

CHAPTER FOUR - PROCEDURES FOR SAMPLE COLLECTION AND TESTING

I. TISSUE SAMPLE COLLECTION AND TESTING FOR RESIDUES

There are two basic types of residue sampling: Scheduled Sampling on FSIS Form 10,210.3 and Inspector Generated Sampling on FSIS Form 10,000.2.

A. Scheduled Samples (FSIS Form 10,210.3)

1. Inspection program personnel will receive FSIS Form 10,210.3 from OPHS **with** all necessary information needed to collect scheduled samples. The form indicates:

a. when to take the sample;

b. what tissues to collect;

c. what slaughter class to sample; and

d. which FSIS laboratory is to receive the samples. (See FSIS Directive 10,210.1., Amendment 1)

NOTE: When one laboratory cannot conduct all the indicated analyses, inspection program personnel may need to collect split samples (i.e., the collection of extra tissue) and send samples to two or more FSIS laboratories. Inspection program personnel cannot make a disposition until all results from the split samples are in LEARN. For questions on split samples, contact the TSC at: 1-800-233-3935.

2. Inspection program personnel are to notify the appropriate plant official when they collect a sample and are to give the plant official the flyer “Residue Scheduled Sample Information,” which the laboratories provide in the sample box.

3. FSIS inspection program personnel should inform the establishment that the Agency recommends that industry hold these scheduled sample carcasses until FSIS reports the results to prevent a recall if the laboratory detects a residue as a violative level.

4. Once the plant makes a decision on whether it will hold the product, inspection program personnel are to document the decision by recording it in action block 22 on FSIS Form 10,210-3.

B. Inspector-Generated Samples

1. Inspection program personnel are to collect tissue samples every time there is reason to suspect that a violative residue is present.

NOTE: There are no exceptions to this direction. Inspection program personnel are to take a sample of any tissue that they believe may contain a violative level of a chemical residue.

2. The PHV is to conduct rapid, in-plant screening tests on any carcass that, based on herd history or ante-mortem or post-mortem inspection findings, there is reason to believe may have an illegal drug residue. The PHV is to retain the carcass while he or she performs the in-plant screening test.

a. The PHV is to perform in-plant screening tests on any animal that he or she suspects of containing an illegal drug residue. The PHV sends the liver, kidney, and muscle tissues, along with FSIS Form 10,000-2, for laboratory analysis when the in-plant screening test is positive.

NOTE: The PHV only needs to collect tissue for submission to the laboratory for confirmation testing. It is not required to collect additional tissue.

b. If the in-plant screening test is negative, the PHV is to determine whether there is reason to suspect that a residue exists that is other than an antimicrobial drug residue. In-plant screening tests are unable to detect anti-inflammatory drugs like flunixin or phenylbutazone, and, therefore, the PHV is to submit liver, kidney, and muscle samples to the appropriate FSIS laboratory for further testing with FSIS Form 10,000-2 if he or she has reason to suspect that an anti-inflammatory drug was used. PHVs are to retain the carcass and parts until the results are available in LEARN.

c. For descriptions of pathologic conditions that may warrant retention and testing of carcasses, see FSIS Directive 10,220.3, “Using the Fast Antimicrobial Screen Test (FAST) to Detect Antimicrobial Drug Residues in Cattle and Swine” in Section VI, “PHV Responsibilities.”

i. Unless there is clear evidence of a recent injection, bolus injury, or surgical intervention, the PHV is not to select animals with chronic conditions such as neoplasia, chronic pneumonia, chronic peritonitis, or chronic nephritis for residue testing.

ii. PHVs are to select animals with potential neoplasia or extensive complicated inflammatory conditions (e.g., pneumonias or peritonitis cases) for in-plant screening.

C. Residue Testing of Show Animals

1. When an establishment presents show animals, including steers, heifers, market hogs, mature sheep, and lambs, inspection program personnel are to perform in-plant screening tests for antibiotics (code 200) and sulfonamides (code 800) as follows:

a. On show animals that appear unhealthy or have unusually heavy muscle development. Excessive muscling may indicate Beta-agonist use or abuse. Inspection program personnel are to tag the animal as “U.S. Suspect” and perform inspector-generated testing.

b. When requested by a State health official or Fair Board because of reports of positive beta-agonist results on show animals, such as the Grand Champion. Inspection program personnel are to confirm whether testing is available by reviewing the LEARN web page “laboratory analysis” site or by contacting the TSC at 1-800-233-3935.

c. From the entire lot of show animals, provided the animals appear healthy, and they are from a single fair or livestock show. The PHV is to select animals for testing in the following manner:

i. randomly select and test a minimum of 1 animal if there are 1 to 10 animals in a lot;

ii. randomly select and test a minimum of 2 animals if there are 11 to 50 animals in a lot;

iii. randomly select and test a minimum of 3 animals if there are 51 to 100 animals in a lot; and

iv. randomly select and test a minimum of 4 animals if there are more than 100 animals in a lot.

d. Tissue and sample size requested for beta-agonist testing:

i. collect one pound of liver and one pound of muscle for Ractopamine; and

ii. collect one pound of liver and both eyeballs for Clenbuterol.

e. Required information for show animal lab forms:

i. complete FSIS Form 10,000-2 in the routine manner, including the following specific entries:

(a) Block 10: Project Name – Record "SHOW"

(b) Block 21: Enter Residue Class Code – 560 for Clenbuterol and Ractopamine, 200 for antibiotics, and 800 for sulfonamides. Send samples for Clenbuterol and Ractopamine to the Western Laboratory and send samples for antibiotics and sulfonamides to the Midwestern Laboratory.

(c) Block 24: Identify any related information

(1) The name and location of the livestock show.

(2) If FSIS receives a report that the animal tested positive for Beta-agonist, inspection program personnel are to collect and report the following information:

Positive "_____" test
Date of test
Name of facility performing the test
Name, title, and address of non-FSIS official reporting the test

II. IN-PLANT SCREENING FOR ANTIMICROBIALS AND SULFANOMIDES IN CALVES PRESENTED AS BOB VEAL CALVES

A. The Calf Antibiotic and Sulfonamide Tests (CAST) is no longer used in federally-inspected establishments for calves and has been replaced with the Fast Antimicrobial Screen Test (FAST). Changes as a result of the implementation of the FAST are:

1. The selection of carcasses for in-plant screening with a FAST test should include carcasses from apparently healthy bob veal calves, as determined by the PHV during ante-mortem inspection. The chart below (taken from 9 CFR 310.21) sets out the testing of healthy calves. For the purposes of this directive, a bob veal is a calf up to 3 weeks of age, or up to 150 pounds. Certified groups (calves) described in 9 CFR 310.21 no longer exist.

Testing of Healthy-Appearing Calves

Testing Level	Number of healthy-appearing animals to sample based on the percent of the day's estimated slaughter
	Healthy-appearing calves
A	100 %
B	50 %
C	30 %
(Start) D	10 %
E	5 %
F	2 %

2. Upon initiation of slaughtering non-ruminating (bob veal) calves at an establishment, the PHV is to begin the testing rate at Level D in the chart above. The PHV is to increase the testing rate to the next higher level on the following business day when three carcasses in 100 or less consecutively tested show a screen test result of presumptive positive for a drug residue. The PHV is to decrease the testing rate to the next lower level when no more than two calves show a screen test result of presumptive positive for a drug residue in 500 calves consecutively tested, or for all calves tested over a 60-working-day period. Tracking of calves tested should be on the back of the FAST sheets.

3. The PHV is to retain all carcasses and parts from the calves selected for in-plant screen testing until all test results are completed. The PHV may reduce inspection line rates when, in his or her judgment, the required testing cannot be adequately performed within the time available because the establishment's compliance history dictates a need for extensive testing.

4. A presumptive positive screen test for a bob veal calf is defined as a FAST zone size of 15 mm or greater. Negative screen test results are defined as zones less than 15 mm. When a screen test is presumptive positive, the PHV is to continue to retain only the carcasses testing positive on the FAST test and submit one-pound samples of the liver, muscle, and kidney to the designated FSIS laboratory for identification and quantification of the specific antibiotic or sulfonamide residue.

a. If the laboratory results do not indicate violative residue levels, the PHV is to release the carcass and parts.

b. If the laboratory results do indicate violative residue levels, the PHV is to condemn the carcass and parts.

III. COLLECTION OF IMPORT SAMPLES FOR RESIDUE ANALYSIS

A. When notified by AIIS to take residue samples, import inspectors are to:

1. Complete FSIS Form 9770-1, “Official Receipt for Samples of Foreign Products Collected for Laboratory Analysis” and provide it to the import establishment personnel.

2. Collect the sample as stated in AIIS and follow the directions in Tables 10 and 11 of the Import Inspection Manual to determine the sample size required and the address of the laboratory for each compound subject to testing.

3. Complete FSIS Form 9770-2, "Import Residue Program," and mail it with the sample to the appropriate laboratory.

B. Laboratory results are posted in AIIS and LEARN.

IV. NATIONAL SECURITY AND OTHER SPECIAL SAMPLES

A. In cases involving national security, severe threat conditions may dictate extra sampling and verification procedures. The DO, OFO Headquarters, or the TSC will contact inspection program personnel with specific instructions in the event of an emergency. (See FSIS Directive 5420.2, Revision 1)

B. The DO, OFO Headquarters, or the TSC will instruct inspection program personnel regarding other special sampling situations on an as-needed basis.

CHAPTER FIVE – ACCESSING LEARN FOR SAMPLE RESULTS

I. TRACKING THE STATUS OF RESIDUE SAMPLES THROUGH THE LABORATORY ELECTRONIC APPLICATION RESULTS NOTIFICATION (LEARN) SYSTEM

A. The Laboratory Electronic Application Results Notification system (LEARN) reports: 1) when the laboratory has received samples; 2) when the laboratory discards them; and 3) when the laboratory has posted the results. FSIS Directive 10,200.1, Accessing Laboratory Sample Information via LEARN, provides complete information on how to access LEARN on the FSIS intranet.

B. The PHV is periodically to check the status of samples.

C. If the laboratory discards the samples, the PHV is to check the reason why as indicated in LEARN and make the necessary adjustments in how he or she collects, seals, and ships the samples to make sure that laboratory does not discard future samples because of improper handling.

1. If the PHV has any tissues from the original submission available, he or she is to send a replacement sample, prepare an FSIS Form 10,000-2 for each individual sample he or she submits, and enter all necessary information on the form. The PHV is to note in the “Remarks” block that the sample is submitted as a replacement.

2. If the PHV discarded all tissues, but the establishment has held the carcass from which he or she collected the original sample, the PHV **may** collect new tissue samples and resubmit them by using Form 10,000-2 and referencing the form number from the original scheduled sample submission. If only muscle is available, then the results from the lab on the muscle will be used to determine the disposition of the carcass and whether there is a violation.

D. PHVs are to print the LEARN screen of the positive residue results after making carcass disposition and maintain it in the office files as supporting documentation.

II. CARCASS AND PARTS DISPOSITIONS BASED ON RESULTS AS REPORTED IN LEARN

A. The PHV is to check LEARN and review the results of laboratory testing of residue samples already submitted. The PHV is to make final dispositions based on the results posted in LEARN. LEARN indicates whether a tissue is “violative;” “detected – non-violative;” or “negative.”

B. The PHV is to make the final disposition of the retained carcass and parts, in the following in the following ways:

1. Violation **in muscle** – condemn carcass and parts.

2. Violation **in muscle and parts** – condemn carcass and parts.

3. Violation **in fat** – condemn carcass and parts.

4. Violation **in parts** but not muscle – call the Technical Service Center for disposition of carcass and parts.

5. Flunixin violation – call the Technical Service Center for disposition of carcass and parts.

C. If any test results from the FSIS laboratory show violative levels of antimicrobial residues, the PHV may call the Technical Service Center, Technical Assistance/Correlation Staff, for answers to any questions.

D. When a carcass/part is retained (either by FSIS or the establishment), the PHV is to ensure that the carcass or part is released or condemned in accordance with the LEARN results and in conjunction with the above instructions. In a situation where the establishment did not elect to hold the carcass or part pending test results, the product may be subject to recall if the results are violative.

CHAPTER SIX - COMPLIANCE AND ENFORCEMENT ACTIVITIES

INSPECTION PROGRAM PERSONNEL ACTIONS

After the FSIS laboratories have reported the results for each tissue sample submitted, and the PHV has made the appropriate disposition, the PHV is to take any necessary regulatory enforcement actions.

A. In Compliance**:** Residue not detected; Positive but non-violative

1. If the PHV retained the product, he or she is to release it.

2. If the establishment held the product, the PHV is to inform the establishment of the “In Compliance” result.

B. Noncompliance: Residue detected at a violative level

1. The PHV is to notify the establishment of the violation and the final disposition of the carcass and parts.

2. The PHV is to verify the disposition of the carcass and parts with the establishment.

3. Noncompliance documentation:

a. The PHV is to review the establishment’s residue control program and perform verification of the establishment’s residue control program included in its HACCP plan or Sanitation Standard Operating Procedures (Sanitation SOP) or other prerequisite program.

b. If the establishment has not incorporated residue control in its HACCP system, the PHV is to document the noncompliance as an unforeseen hazard, 9 CFR 417.3(b), and use the “verification” trend indicator.

b. If the establishment does address residue control in its HACCP system, the PHV is to perform the O3J02 procedure. If the establishment has failed to follow its residue control program according to its HACCP plan or Sanitation SOP or other prerequisite program, the PHV is to issue an NR using the appropriate regulation and

trend indicator.

Refer questions to the Technical Service Center at 1-800-233-3935.

Assistant Administrator
Office of Policy, Program, and Employee Development