

**EXHIBIT 48**

# FSIS DIRECTIVE

10,220.3

8/23/06

## USING THE FAST ANTIMICROBIAL SCREEN TEST (FAST) TO DETECT ANTIMICROBIAL DRUG RESIDUES IN CATTLE AND SWINE

### I. PURPOSE

To advise inspection program personnel that the Fast Antimicrobial Screen Test (FAST) is replacing the Swab Test on Premises (STOP) in swine slaughter establishments. This directive also announces that because it is not efficient to support both FAST and STOP tests, the agency is moving to use only FAST tests in livestock, including sheep, goats, and horses. FSIS will phase out all STOP incubators and supplies. Inspection program personnel may only use the STOP test when testing is necessary and the FAST test is not yet available to them.

**NOTE:** This directive incorporates information from previously cancelled FSIS Notices 44-01 and 16-03.

### II. [RESERVED]

### III. [RESERVED]

### IV. REFERENCES

9 CFR 309, 310, and 311

### V. BACKGROUND

The United States has a complex residue control system, with rigorous processes for approval, sampling, testing, and enforcement activities. Three principal agencies are involved in the control of residues in meat, poultry, and egg products: FSIS, the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA). The FSIS National Residue Program (NRP) provides a variety of sampling plans to verify and ensure that slaughter establishments are fulfilling their responsibilities under the Hazard Analysis and Critical Control Point (HACCP) regulations, and in accordance with FDA and EPA regulations, to prevent the occurrence of violative levels of residues.

When inspection program personnel suspect, based on herd history or antemortem or postmortem examination, that the animals may have illegal levels of antimicrobial drug residues, Public Health Veterinarians (PHVs) are to conduct an in-plant screening

**DISTRIBUTION:** Inspection Offices; T/A Inspectors;  
TRA; TSC; Import Offices

**OPI:** OPPEd

test to determine whether they will need to submit a sample an FSIS Laboratory for further testing. PHVs use 2 screening tests, FAST and STOP, to detect individual animals with the presence of antimicrobial residues in kidney tissues. This testing is necessary in problem slaughter classes or subpopulations of these classes (those with a high prevalence of antimicrobial residue violations) and helps to detect carcasses with violative antimicrobial residues, so that they will not enter the food supply. It is also used to more closely monitor producers and others who are known to have marketed animals with violative concentrations of antimicrobial residues to determine whether the non-compliance has been corrected, and to verify the performance of an establishment's HACCP system in preventing or eliminating chemical (residue) hazards.

Because the FAST has been validated for use in testing swine, as well as cattle, for antimicrobial residue levels, inspection program personnel are to use FAST when possible for testing all slaughter classes of cattle and swine. If FAST is not available at the establishment, inspection program personnel may continue to use STOP when testing is necessary.

## **VI. PHVs' RESPONSIBILITIES**

A. At slaughter, the PHV will look for indications of illegal chemical use or exposure and collect tissue samples for residue analysis as part of verification of the food safety system. Observations of injection sites/signs of treatment, recent surgery (e.g., abomasal surgery), septicemia/pyemia, or animals identified at ante-mortem as "U.S. Suspect" will always indicate that residue testing is appropriate.

B. Depending on the slaughter class involved, there are pathologies that, if found, can also indicate residue testing is appropriate. The PHV should use professional judgment when selecting carcasses for chemical or veterinary drug residue analysis based on evidence of acute disease, production practices, herd history, environmental exposure, and threats to homeland security.

C. The list below contains descriptions of pathology and conditions that warrant retention and testing of carcasses. Symptoms are described to help PHVs determine when to test and retain carcasses. PHVs should test animals for residues when they identify them as U.S. Suspect during antemortem inspection. In addition, PHVs should conduct residue testing whether they have condemned or passed the carcass. The list of symptoms may also be useful when the PHV correlates with their CSIs about when they should retain a carcass for PHV review and disposition.

## **Pathologies and Conditions Warranting Sampling and Retention For In-Plant Testing**

- 1. Mastitis** –At antemortem animals identified with clinical signs of mastitis should be residue tested. At post mortem, carcasses found with inflammatory ventral edema in the perineal area or ventral hemorrhages and yellow serous exudates.
- 2. Metritis** – Carcasses with acute inflammation, including enlargement of the uterine body; distension of the uterus with a fetid brown, red brown, or black fluid; thinning of the uterine wall; and lack of evidence of normal uterine involution (no lines of contracture in the myometrium).
- 3. Peritonitis and surgery** – Carcasses with localized or diffused active peritoneal inflammation with fibrinous exudate or fetid ascitic fluid, with ventral abdominal cellulites secondary to percutaneous abomasal surgery. Findings of surgical devices (suture, toggles, fistula devices, etc.) are only significant if they are associated with active peritoneal or subcutaneous inflammation.
- 4. Injection Sites** – Carcasses with lesions associated with injections. Injection sites are likely to be found in a variety of locations including the neck, shoulder, thorax, axilla, ventral abdomen (along the subcutaneous abdominal vein), flank, hindquarter, pelvic area (perirectal), and tail. Also, look for cellulitis that is away from pressure points (e.g., tuber ischii, hip joint, and stifle joint). These are generally found in the semimembranosus and semitendinosus muscle.
- 5. Pneumonia** – Carcasses with acute, subacute and chronic active pneumonias and pleuritis resulting from reticulo peritonitis complex; or with embolic pneumonia.
- 6. Pleuritis** – Inflammation of the pleura lining the thoracic cavity and lungs.
- 7. Pericarditis** – Carcasses with fibrinous or fibrinosuppurative pericarditis.
- 8. Endocarditis** – Carcasses with endocarditis and acute pulmonary, renal or other embolic lesions.
- 9. Septicemia, pyemia or generalized disease** –Animals exhibiting any of the following conditions: Depression, an elevated or subnormal body temperature, hyperemic skin, congested mucous membranes, dehydration, or poor body condition, in association with an injury or inflammatory condition such as abscesses, arthritis, pneumonia, mastitis, metritis, or diamond skin.
- 10. Injury or inflammatory conditions** – Carcasses found with conditions not resulting in condemnation such as arthritis, pneumonia, mastitis, metritis, nephritis, cystitis, or diamond skin.

**11. Acute cellulitis or other acute inflammations** associated with a fibrinous or fibrinosuppurative exudate in any location on the carcass or viscera.

**12. Beta-agonist** such as Clenbuterol and ractopamine have been administered to show animals to give them a competitive advantage.

**13. Signs of Treatment** are indicated by leakage around jugular veins, subcutaneously, intramuscularly, or intra peritoneal or clinical signs indicative of treatment by mouth such as discoloration from particles found in any part of the digestive tract. These are important signs when examining veal calves for testing.

**NOTE:** Non-Steroidal Anti-Inflammatory Drugs (NSAID) (e.g. flunixin or phenylbutazone) are not detected by the in-plant screen tests. If the PHV suspects the use of NSAIDs, samples must be taken and carcasses retained until laboratory confirmation has been received. It has been found that dairy cows with inflammatory conditions (e.g. lameness, arthritis, acute pneumonia, etc.) are often treated with NSAIDs.

D. PHVs are to retain all carcasses and parts until they receive the results of the screening test.

**NOTE:** PHVs are to collect samples for antimicrobial residue testing even if they condemn a carcass because the use of veterinary drugs above the established limits and the use of prohibited veterinary drugs are violations of Federal law. The Food and Drug Administration may take regulatory action against the violator, and FSIS will place them on the FSIS Residue Information Center's repeat violator's list. Therefore, PHVs are to collect the appropriate tissue samples at the time they perform the in-plant rapid screening test on a condemned carcass and before the establishment disposes of the carcass and parts. This is necessary so that the tissue samples can be submitted to the FSIS laboratory if the result of the in-plant rapid screening test is positive.

E. PHVs are to follow the self-instructional guides for in-plant residue screening tests for the specific test that they are performing. See:

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

F. PHVs are to ask the establishment to provide any available information on the source or owner of the animal for traceback purposes.

## **VII. PHVs' RESPONSIBILITIES AFTER OBTAINING THE RESULTS FROM THE SCREENING TESTS**

A. If the rapid in-plant antimicrobial residue screening test result is positive, the PHV are to continue to retain the carcass and parts and submit appropriate tissue samples (liver, kidney, and muscle tissue) for further testing at the appropriate FSIS Laboratory. Carcasses that are condemned by the establishment or due to pathology need not be retained pending lab results.

B. If the rapid in-plant antimicrobial drug screening test result is negative, the PHV is to release the carcass and parts, unless in the professional opinion of the PHV there is reason to believe that residues other than antimicrobial drug residue exist that the in-plant rapid screening test will not detect (e.g., flunixin, phenylbutazone). In such cases, the PHV are to continue to retain the carcass and parts and sample the appropriate tissues (i.e., liver, kidney and muscle tissue) for submission to the appropriate FSIS laboratory for further testing.

**NOTE:** PHVs can find a current list of FSIS laboratories and the specific tests they perform on the Laboratory Electronic Application for Results Notification (LEARN) system.

## **VIII. PHVs' RESPONSIBILITIES AFTER RECEIVING THE LABORATORY RESULTS**

A. The PHV is to check LEARN for the laboratory results.

B. The PHV is to follow the disposition guidelines to make the final disposition of the retained carcass and parts.

### **Common Residue Tissue Guidelines**

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

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

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

d. Violation **in parts** but not muscle – release carcass and condemn parts

e. 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 should call the Technical Service Center, Technical Assistance/Correlation staff for answers to any questions.

## **IX. Obtaining FAST Test Equipment and Supplies**

PHVs may obtain the FAST test supplies and incubator from the Midwestern Laboratory (mailbox for sampling supplies:

[SamplingSupplies-MidwesternLab@fsis.usda.gov](mailto:SamplingSupplies-MidwesternLab@fsis.usda.gov) or

in Outlook: Sampling Supplies – Midwestern Laboratory).

**X. Special Instructions for FAST Supplies**

Refrigeration of supplies is very important in order to maintain proper growth of test organisms.

Direct any questions on this directive to the Technical Service Center at (800) 233-3935.



Assistant Administrator  
Office of Policy, Program, and Employee Development