RESIDUE DETECTION PROGRAM

OBJECTIVES

After completing this module, you will be able to:

1. List the names of the three federal agencies that are involved with residues in food animals.
2. Explain your role as a PHV in residue detection in the establishment
3. Describe the monitoring and receipt of laboratory results through LEARN.
4. Perform and accurately read FAST test.
5. Evaluate conditions which would lead to a decision by the PHV to perform an in-plant residue test.

Resource Materials

FSIS Directive 10, 800.1 Procedures for Residue Sampling, Testing, and Other Responsibilities for the National Residue Program

FSIS Directive 10, 200.1 Accessing Laboratory Sample Information via LEARN

FSIS Directive 10,220.3 Using the FAST Antimicrobial Screen Test to Detect Antimicrobial Drug Residues in Cattle and Swine

FSIS Directive 7355.1 Rev. 2 Use of Sample Seals for Laboratory Samples and Other Applications

Best available preventive practices are discussed in the Federal Register titled: Residue control in a HACCP environment dated November 28, 2000 (Vol. 65, No 229).

FSIS National Residue Program

The Food Safety and Inspection Service (FSIS) works with the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) to accomplish the 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. The United States has a complex residue control system, with rigorous processes for approval, sampling and testing, and enforcement.

Three principal agencies are involved in the control of residues in meat, poultry, and egg products: FSIS, FDA, and EPA. FDA and EPA establish tolerances (maximum

permissible levels) for chemical residues in foods, and FSIS enforces these tolerances through its various residue control programs.

FDA establishes tolerances for veterinary drugs and food additives under the statutory authority of the Federal Food, Drug, and Cosmetic Act (FFDCA). These tolerances are published in Title 21 of the Code of Federal Regulations (21 CFR). EPA establishes tolerances for registered pesticides under the statutory authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and FFDCA, as modified by the Food Quality Protection Act (FQPA). These are published in 40 CFR. Maximum permissible levels have also been established for residues that are the result of environmental contamination, such as cancelled pesticides that are no longer approved for use but persist in the environment (e.g., DDT), industrial chemicals (e.g., PCBs), and heavy metals. Tolerances for industrial chemicals and heavy metals are established by FDA and published in 21 CFR. For cancelled pesticides, action levels (similar to tolerances, but less formal) are established by FDA or FSIS, based on recommendations that EPA has published in the Federal Register.

Under the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA), FSIS acts to ensure that USDA-inspected meat, poultry and egg products do not contain illegal levels of chemical residues. The cornerstone of FSIS residue prevention activities is the FSIS National Residue Program (NRP), a multi-component analytical testing program for residues in domestic and imported meat, poultry, and egg products. The FSIS NRP, which has been in effect since 1967, provides a variety of sampling plans to prevent residues from entering the food supply, and develops national data on the occurrence of chemical residues to support risk assessment, enforcement and educational activities.

The range of chemical compounds evaluated for inclusion in the various NRP testing programs is comprehensive in scope. It includes approved and unapproved pharmaceutical drugs and pesticides known or suspected to be present in food animals in the U.S. and in countries exporting products to the U.S. It also includes any other xenobiotic or naturally occurring compounds that may appear in meat, poultry, and egg products and that may pose a potential human health hazard.

The NRP is designed to provide: (1) a structured process for identifying and evaluating compounds of concern by production class; (2) the capability to analyze for compounds of concern; (3) appropriate regulatory follow-up of reports of violative tissue residues, and (4) collection, statistical analysis, and reporting of the results of these activities.

When violative residues are detected in food-producing animals submitted for slaughter, FSIS notifies the producer and other parties involved in offering these animals for sale. Product found to contain violative levels of residues is considered adulterated and is subject to condemnation. If the product has been distributed into commerce, it may be subject to voluntary recall and/or other actions. In addition, FDA and cooperating state agencies may make on-site visits to these firms.

The purpose of the residue program is to maintain vigilance for non-permitted residues in food animals. The National Residue Program is the corner stone of FSIS residue prevention activities. The regulatory system that enforces U.S. food safety laws has been evolving since 1906.

There are three major aspects of the NRP:

1. the prevention of illegal chemical residues,
2. an analytical systematic testing program for the residues in domestic and imported products, and
3. verification that plants are fulfilling their responsibilities under HACCP for preventing violative residues. This is discussed more under "Residue in a HACCP environment".

An essential aspect of food safety in meat, poultry and egg products is the **control** of residues that may result from the use of animal drugs and pesticides, or from incidents involving environmental contaminants. The NRP is an example of interagency cooperation and teamwork between Food and Drug Administration, the Environmental Protection Agency and FSIS. Within FSIS there is extensive teamwork among the following offices and personnel, Office of Public Health and Science, Policy Development Division (formerly Technical Service Center), National Information Technology Center, District Offices, Laboratory support (Eastern Lab, Western Lab and Midwestern Lab), and most importantly, the FSIS in-plant personnel who review animals everyday, collect and submit the samples. This teamwork is what makes the National Residue Program a success.

To have a better understanding of the role you will fulfill as an in-plant Veterinary Public Health Officer it is important to understand the four basic components of the NRP:

1. monitoring,
2. special projects,
3. surveillance,
4. and enforcement.

The monitoring plan covers both domestic and imported product. There is a "special project" component which encompasses projects such as the testing of show animals for Clenbuterol, FSIS Notice 45-01. This notice has expired but it is still useful as a guideline. This information is also in FSIS Directive 10,800.1. Surveillance sampling is a scheduled sampling designed to investigates and control the occurrence of residue violations in targeted animal populations. The fourth component is the enforcement testing. This is the testing for residue in animals or lots that appear suspicious to FSIS in-plant inspectors, based on herd history or antemortem /postmortem inspection.

Import residue sampling is part of the NRP and this program is where FSIS randomly samples meat, poultry and egg products for residues at the U.S. port-of-entry. However, as a PHV the main components of the NRP that you will be concerned with are the monitoring plan and enforcement testing.

There are some basic differences between the plans. For example, monitoring samples are ***directed samples***. You will receive direction and forms from OPHS (Office of Public Health Science), in Washington D.C., letting you know when to collect a sample and what sample to collect. The method of animal selection is also different. Monitoring samples are randomly chosen from animals that have passed inspection and been permitted entry into the food supply.

Enforcement testing is initiated by the in-plant FSIS personnel based on their judgment that an animal (or lot) may contain drug or chemical residues. This judgment can be based on ante-mortem findings, post-mortem findings and herd history. Herd history means that due to previous residue violations by a producer you may decide that in-plant screening for enforcement testing should be performed. The other reason to test is to verify the plant's HACCP system.

Regulatory Authority and Residue in a HACCP Environment

Because you are joining a public health regulatory agency it is beneficial to know the regulatory authority under which we operate. Regulatory residue authority for FSIS is in the US code Title 21 chapters 10 and 12, the Poultry Product Inspection Act and the Federal Meat Inspection Act. Under the FMIA, PPIA and EPIA, FSIS acts to ensure that USDA inspected meat, poultry and egg products do not contain illegal levels of chemical residues.

There are multiple regulations in the CFR 9 that give guidance on residue. These are parts 309, 310, 311, 318, 320, 381, and 417. Production classes for which FSIS has regulatory authority include: horses, bulls, beef cows, dairy cows, heifers, steers, bob veal calves, formula-fed veal calves, non formula-fed calves, heavy calves, sheep, lambs, goats, market hogs, boars, sows, young chickens, mature chickens, young turkeys, mature turkeys, ducks, geese, rabbits, and egg products (liquefied eggs and dried eggs).

Contained in the regulations above, that cover livestock and poultry, there are parts that should be clarified due to changes in practice. CFR 9 Part 310.21 specifically pertains to calves. You will notice that the regulation is written with CAST as the testing used. CAST is no longer used for federal establishments (we now use FAST for all bovine); however we still use the regulation as a guideline. You may disregard the definition of "certified calves" as that classification is no longer used. CFR 9 part 310.5 refers to carcasses or parts found to be adulterated; under FSIS definition (301.2 - adulterated), could mean with residues. The information regarding the increased testing that happens in calves when positive test results occur is still followed even though we use FAST instead of CAST.

The development and implementation of PR/HACCP introduced a new evolution to the residue control and avoidance responsibilities of the government and industry. Residue in a HACCP environment introduced the thinking that the establishment has a responsibility to address residue within their food safety system. It is made clear in 9 CFR 417.2 (a) (3) that violative residues present food safety hazards that may arise from chemical contamination, pesticides and drug residues. Using the principles of HACCP,

each establishment must perform a hazard analysis and determine if residue is a hazard that is reasonably likely to occur in that establishment.

The tolerance limits of drugs, chemicals and pesticides are set by FDA and EPA. A result is said to be violative when this tolerance level is exceeded. When a result is reported to you by the Policy Development Division (formerly Technical Service Center) as violative you need to determine if the establishment addresses residue in a HACCP environment. FSIS has told establishments that if their HACCP plans include residue controls that constitute the best available preventive practices, supply FSIS with information about violators, and follow appropriate corrective actions, then the Agency will not treat violative residue findings as a noncompliance (see CFR 9 part 417.3(a)). We will also follow these guidelines on FSIS monitoring and enforcement sample results.

However, when a residue result is violative and the establishment does not fully address residue in a HACCP environment a noncompliance record (NR) is generated. The O3J procedure code is used with the "verification" trend indicator. Also, if the plant does fully address residue in a HACCP environment, but they have failed to follow their plan, a noncompliance record should be generated.

Best available preventive practices are discussed in the Federal Register titled: Residue control in a HACCP environment dated November 28, 2000 (Vol. 65, No 229). Several things happen with best available preventive practices. The plant must ensure all animals are identified for successful trace back to the owner of origin. Our concern is to prevent repeat violators from continually sending residue animals to slaughter. To do this we need to have the correct owner name and address. The plant needs to notify producers in writing of the residue findings and the company's future expectations of the producer. Future expectations may include the company's business practice of refusing to purchase more animals from a producer after several repeated violative results are confirmed by the FSIS labs. A company may have a policy where they send a representative to visit with the producer to make sure they understand residue avoidance.

Additional practices mentioned in the federal register discuss how some states may have a state-certified voluntary residue avoidance program. If this exists the plant may be able to add to their purchase specifications a requirement that suppliers participate in the program and supply certification to that effect. The establishment could explore live animal testing as a rapid and convenient verification tool. If the plant institutes the named best available preventive practices, when a violative residue occurs - they may not receive an NR (in general) as long as appropriate corrective actions are followed.

Residue Terminology

These are the basic "understood" definitions of violator and repeat violator.

- Violator: a person or organization that presents an animal for slaughter for food purposes (not including pre-clearance testing) which contains a violative tissue residue concentration of a drug, pesticide or other chemical.

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- Repeat violator: a violator who has had two or more violative tissue residues within the twelve months following issuance of an FSIS violation notification letter. (same thing as “residue notification letter”)

- AMDUCA: Animal Medicinal Drug Use Clarification Act - The AMDUCA establishes conditions for extra label use or intended extra label use in animals by or on the orders of licensed veterinarians of FDA approved new animal drugs and approved new human drugs.

  -There are a list of drugs that are prohibited for extra label use; Chloramphenicol, Clenbuterol, Diethylstilbestrol (DES), Dimetridazole, Ipronidazole, Other Nitroimidazoles, Furazolidone, Nitrofurazone, other Nitrofurans Sulfonamide drugs in lactating dairy cattle (except approved use of sulfadimethoxine, sulfabromomethazine, and sulfaethoxypyridazine) Fluoroquinolones Glycopeptides (example: vancomycin) Phenybutazone in female dairy cattle 20 months of age or older

Residue responsibilities for the Public Health Veterinarian

Public Health Veterinarians/Inspectors-in-Charge (PHV/IIC):

1. Identifies animals as suspect for residue testing at ante-mortem.
PHVs are to handle animals for slaughter with known violative residue levels in accordance with 9 CFR 309.16.

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

3. 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 the adequate control of supplies, incubators, and other equipment.

4. 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.

5. 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

.6. Selects carcasses or products for testing and ensures proper handling, labeling, processing, sealing, and shipping of the samples to avoid discard of any samples.

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

8. Documents noncompliance.

Frontline Supervisors/Multi In-Plant Performance System Assignment:

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

2. 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.

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

4. Operates in conjunction with the DO to ensure uniform and consistent implementation of the NRP.

District Office:

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

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

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

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

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

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

7. Verifies, through management information systems, 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.

8. May receive information from the PDD (formerly TSC) and OFO Headquarters relating to field residue violations that require increased in plant testing by the PHV.

OPPED, PDD Role in Residue Detection

The Policy Development Division (formerly 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 PDD (formerly 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 PDD (formerly TSC) also provides correlation as requested by OFO on residue results reported in LEARN, inclusive of carcass or part disposition.

Residue Violation Cases

All violative residue reports result in a residue notification letter being sent to the owner identified on the residue lab form. The PDD (formerly TSC) will send the original letter to the owner, and copies will be sent to FDA for their investigation efforts, and to the District Office of where the owner lives. There may be two District Offices informed of one case. For example when the PDD (formerly TSC) first receives the lab fax, the form with the written residue carcass disposition will then be faxed to the DO of where the establishment is located. This provides the IIC and that DO the information that a violation occurred. When the residue notification letter is completed a copy of it is sent to the DO of the residence of the identified owner. A case file is built at the PDD (formerly TSC) for each violator.

FDA, EPA and FSIS work in conjunction on the National Residue Program. An MOU spells out the information on violators that FSIS is required to provide to the other Agencies. In the spirit of teamwork and cooperation, FDA also provides FSIS with a final report (Called Attachment C) of their case investigation. The PDD (formerly TSC) reviews the final reports for any changes that should be made to the Residue Violation Information System.

Residue Follow Up Cases

There are different situations where you may be asked to increase your in-plant testing on a producer's animal. If you have knowledge that there have been previous violations by the owner, you may want to increase testing of those animals when they arrive. This is a judgment call on your part, you should discuss with the PDD (formerly TSC) veterinarians if you have concerns. The FDA or the State may call the PDD (formerly TSC) who will in turn contact you in cases where increased scrutiny is requested. If there

is a producer from that list bringing animals into your facility, you may also want to increase scrutiny and testing.

The PDD (formerly TSC), in conjunction with the labs and OPHS, review residue results for trends and unusual findings. In cases where an illegal drug, or a result of 10X over the tolerance or when a new drug shows up we will notify and work with FDA and EPA to determine the risks involved and if additional action is needed.

Residue Violation Information System (RVIS)

Frequent communication between Agencies (FSIS, FDA, EPA, and states) and divisions of FSIS is vital to the NRP. The RVIS database is a nationwide, interagency computer information system designed to share pertinent data for regulatory enforcement on an open and regular basis. The system operates 24 hours a day to provide information on residue violations in livestock and poultry slaughtered in the USA. The RVIS has proven to be an excellent tool for supporting residue control measure in meat and poultry because it allows exchange of information among participating agencies regarding regulatory enforcement.

RVIS is a unique system and a successful example of interagency cooperation and teamwork. It was implemented in 1987, and since that time improvements have been made to increase the capabilities for its use. The goal continues to be to provide reliable, consistent, current and accessible source of information on residue violations.

Tracking the status of Residue Samples via LEARN

A. The Laboratory Electronic Application Results Notification system (LEARN) reports when the laboratory has received samples, whether the laboratory discarded them, and when the laboratory has posted the results. FSIS Directive 10,200.1, (LEARN) System, 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 discarded the samples, the PHV is to check the reason why as indicated in LEARN and make the necessary adjustments on how he or she collects, seals, and ships the samples to make sure the laboratory does not discard future samples because of improper handling.

1. If the PHV saved tissues from the original submission, the PHV is to send a replacement sample, prepare a 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.

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

Guidelines for carcass and parts disposition based on results posted 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;" "positive – non-violative," or negative.

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

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 PDD (formerly 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 PDD (formerly 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 tissue guidelines. 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.

Verification of Implant Usage in Pre-Ruminate Calves

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.

Ante-mortem verification activities in pre-ruminant calves:

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. 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

f. unusually heavy muscle development

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."

Post-mortem verification activities in pre-ruminant calves:

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.

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.

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.

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 as described in 9 CFR Part 311.

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

i. an implant

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.

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).

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

In-plant Screening Tests

These are the in-plant screening tests that are currently being used in federally inspected establishments. These tests only screen for antibiotics. Anti-inflammatory drugs, such as Flunixin, are used in older dairy cows and sows with arthritis to prevent downers and other inflammatory conditions. Such animals should be screened for Flunixin.

- FAST – this test is validated for all red meat species. If you are at a plant you should have the supplies and equipment for performing the FAST test.

Enforcement testing makes extensive use of rapid in-plant screening tests. In this way, only those samples that test positive by a screening test are sent to an FSIS lab for confirmation testing. However, if you feel the carcass may contain a violative level of a residue for which there is no official FSIS screening method, a sample taken from that carcass is sent directly to the lab for testing.

The in-plant screening tests provide a way to screen animals that are seen as suspicious based on their herd history, ante-mortem or post-mortem findings. They are used as a follow up on producers who have been known in the past to have residue violation issues, and also to verify the establishments HACCP system.

Animal Identification and Devices

When a residue sample is taken in the plant, USDA will request the producer/owner name and address from the plant. The USDA inspector will also request any external identification (back tags, ear tags, etc) numbers of that carcass from the plant.

By regulation and Law the plant is required to comply and provide the accurate identification requested.

Regulations pertaining to animal ID and connection with residue

FSIS, Department of Agriculture: Chapter III

9 CFR 309.16: Livestock suspected of having biological residues.
9 CFR 309.17: Livestock used for Research
9 CFR 309.18: operations must adhere to the defined use of U.S. Suspect and U.S. Condemn tags.
9 CFR 310.2 Animal trace back: all forms of identification are required to be removed and kept coordinated with the carcass until postmortem inspection is completed.
9 CFR 310.3: Carcasses and parts in certain instances to be retained.
9 CFR 310.21: carcasses suspected of containing sulfa and antibiotic residues; sampling frequency; disposition of affected parts.
9 CFR 311.30: Biological residues
9 CFR 318.20: Use of animal drugs
9 CFR 320.1(a): every person …within any of the classes specified ……is required by the Act to keep records which will fully and correctly disclose all transactions involved in his or its business subject to the Act.
9 CFR 320.3: Record retention period.
FSIS Notice 5-02: Animal Identification

Packers and Stockyards Act: Chapter II

9 CFR 201.49(a): Livestock weighed for purchase or sale must be serially numbered and scale tickets must be generated; if hot carcass weights are used for purchase, the scale must be linked to a printer to generate scale tickets with dates, names of buyers and sellers, number of head, kind of livestock, weights and the individual responsible for this task.
9 CFR 201.86(d): identity of the consignment is required until inspection has been completed.
9 CFR 201.94 and 201.95: Information and records described above must be made available to USDA.

9 CFR 71.19 -APHIS tattoos.

Animal Identification / Verification and Enforcement Activities when the Establishment fails to collect and maintain Animal Identification

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 310.2, 310.3, 310.21, 309.16, 309.17, 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, 9 CFR 310.2, 3, .4, or .21; 9 CFR 320.1, 310,23). NRs are to include a citation of the applicable regulation, the procedure code 06D02, and documenting "product, facilities" as the trend indicator.

FAST ANTIMICROBIAL SCREEN TEST

The Fast Antimicrobial Screen Test (FAST) is a biological screening test for the detection of antimicrobial residues in animal tissues. It is designed to be performed by a veterinarian or a designated food inspector in a slaughtering plant. FAST is an adaptation of the antimicrobial screening test that has been used in FSIS laboratories for years.

FAST is based on the principle that, if a carcass contains a residue from a previously administered antimicrobial drug, tissue fluid from the carcass will inhibit the growth of a sensitive target bacterial organism. With FAST, a cotton swab, saturated with tissue fluid from a suspected carcass, is placed on a culture plate seeded with a harmless organism. This organism, *Bacillus megaterium,* is sensitive to most commonly used antimicrobial drugs. The swab and plate are incubated to allow growth of *Bacillus megaterium.* Then the plate is examined for a zone of inhibited growth around the swab. The presence of a zone of inhibition is presumptive evidence that the carcass contains an antimicrobial drug residue. A presumptive positive carcass is retained and tissue is submitted to the laboratory for confirmation. A negative carcass is released provided all other inspection criteria are met.

The Inspector-in-Charge will determine when to perform the FAST on the collected kidney tissue samples. This determination will be influenced by the number of samples collected and the current staffing at the establishment. Once the FAST is started, a FSIS in-plant inspection person must be available to complete the FAST and a PHV to must be available to read the results 6 to 24 hours after the FAST was started.

If no FSIS in-plant inspection person will be available during that time, the kidney tissue samples must be held under refrigeration until a FSIS in-plant inspection person is available to complete the FAST and read the results.

If the test can be completed in the 6 to 24 hour time span, then some initial data entry on FSIS Form 6600-7 (10/96) is required.

Record initial information

Obtain a blank copy of FSIS Form 6600-7 and complete the heading. Enter the establishment number, establishment name, and the numerical codes for the District, Circuit, and State. Enter the numerical code for the District in the box labeled "REGION". Leave the box labeled "AREA" blank. The numerical codes for the District, Circuit and State can be found in the Meat and Poultry Inspection Directory.

Enter the date in the "DATE TEST STARTED" column and the retained tag number for the kidney tissue sample in the "RETAIN TAG NUMBER" column. Enter any information from other available carcass identification devices in the "BACK TAG OR TRACE BACK ID" column.

Enter the Species Code that best describes the species being tested in the "SPECIES CODE" column. The Species Codes can be found on the reverse of FSIS Form 6600-7 (10/96).

Enter the Reason Code . Enter the code for the primary reason that best describes why the carcass was retained for FAST in column "P" sub-column of the "REASON CODES" column. If a secondary reason for the carcass being retained for FAST for testing exists, enter this code in the "S" sub-column of the "REASON CODES" column.

FAST ANTIMICROBIAL SCREEN TEST WORKSHEET — SERIAL NO. 42904

ESTABLISHMENT NO	ESTABLISHMENT NAME	REGION	AREA	CIRCUIT	STATE
00000--M	Razorback Pack	DO25		2509	19

DATE TEST STARTED (mm/dd/yy)	RETAIN TAG NUMBER	BACK TAG OR TRACE BACK ID	SPECIES CODES	REASON CODES P	REASON CODES S	INCUB. TEMP (°C)	MILITARY TIME IN	MILITARY TIME OUT	ZONE OF INHIBITION (mm) NS	ZONE OF INHIBITION (mm) SWAB	TEST RESULTS (+ or –) h Hrs	TEST RESULTS (+ or –) h Hrs	DISP. CODE	FSIS 10,000-2 LAB REPORT SERIAL NO.	CASE #	INSPECTOR'S BADGE ID NO.	INSPECTOR'S INITIAL
02/22/01	34880602	93NF0366	15	14	01												

For information on completing FSIS Form 6600-7, go to FORMS.

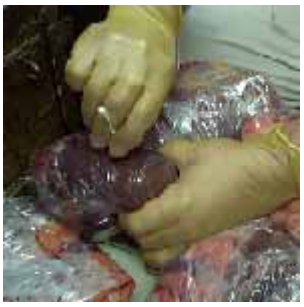
The FAST is performed using a cotton swab saturated with tissue fluid absorbed from macerated kidney tissue. Sterile technique is not required because the short incubation time rarely allows interfering growth of contaminating microorganisms.

However, your hands should be clean and dry whenever the cotton swab is handled to avoid contaminating the cotton swab with a substance that could interfere with growth of *Bacillus megaterium*. The cotton swab should never contact anything other than the sample kidney tissue and the FAST plate.

Preparing Cotton Swab

Remove a sterile cotton swab from the pack and push the sharp end through the plastic bag and into the kidney tissue. Using the sharp end of the sterile cotton swab, widen the hole in the plastic bag to about ½" in diameter. The ½" diameter hole in the plastic bag will prevent squeezing tissue fluid from the cotton swab head when it is removed from the kidney tissue and pulled back through the hole in the plastic bag.

Push the sharp end of the cotton swab about ½" to ¾" into the kidney tissue. Move the sharp end of the cotton swab shaft back and forth several times to macerate the kidney tissue.



Remove the sharp end of the cotton swab, reverse the cotton swab, and insert the cotton end of the cotton swab through the hole in the plastic bag and into the kidney tissue.

Twirl the cotton swab shaft to ensure good contact between the end of the cotton swab and the macerated kidney tissue.

To ensure proper saturation of the absorbent end of the cotton swab, the cotton swab must remain in the kidney tissue no less than 30 minutes and no more than 2 hours.

Examine the FAST plate

An expiration date for the FAST plate is printed on the plastic wrapper and on the lid of the FAST plate. Check this date before using the FAST plate.

If the FAST plate has expired, call the Midwestern Laboratory, in St. Louis, MO. Tell them the expiration date on the FAST plate. The Midwestern Laboratory personnel will decide whether or not to extend the shelf life of the FAST plate.

The FAST plate should always be examined before use. The agar should not be dried out or cracked. Examine the surface of the agar for obvious contamination or bacterial/ fungal growth. Check for indications of freezing. If any of these defects are observed, the FAST plate should be discarded and a new plate used.

Always allow the plate to equilibrate to room temperature before using.

Mark the FAST Plate

Lift the FAST plate cover and mark an X on the outer vertical sidewall of the FAST plate.

On the bottom of the FAST plate, starting at the X, draw a straight line across the diameter of the plate so that the straight line divides the FAST plate into two equal sized sections.

Prepare the cotton swab with spore suspension

With the cap tightly screwed on, vigorously shake the vial of *Bacillus megaterium* spore suspension to thoroughly mix the spores. If particulate matter is present within the spore suspension or the spore suspension is cloudy or colored, the spore suspension must be discarded.

Remove the cap from the vial, being careful to avoid touching the inside of the cap or vial with your hands. Insert the cotton swab into the vial until the cotton swab is completely immersed in the spore suspension.

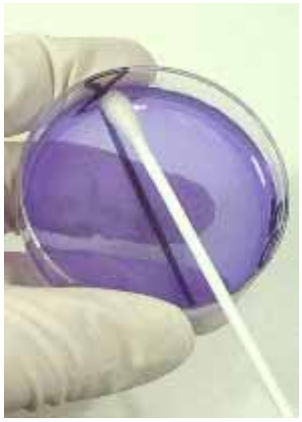
Before removing the cotton swab from the vial, gently touch the cotton swab tip to the side of the vial to remove excess fluid from the tip. Dip the cotton swab into the spore suspension only once. Replace the screw cap and set the vial of *Bacillus megaterium* spore suspension aside.

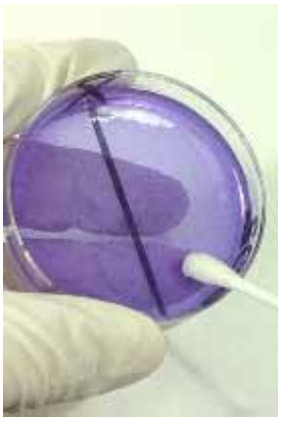
Streak the FAST plate

The *Bacillus megaterium* spore suspension must be applied to the agar surface of the FAST plate to create a "lawn" of bacterial growth. Avoid touching the cotton tip with your hands or allowing the cotton tip to touch another surface. If the cotton swab touches your hand or another surface discard the cotton swab and prepare another cotton swab with spore suspension.

The recommended method for streaking the plate is demonstrated in the following photos.

1. Remove the cover from the FAST plate and streak the spores over the surface of the agar by **starting at the reference mark** and gently streaking from top to bottom, back and forth, moving the swab to the right edge of the FAST plate.

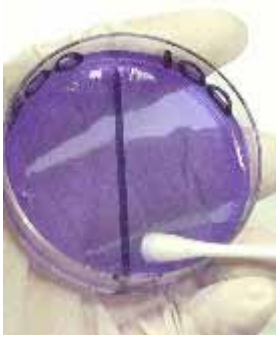




Be careful not to dig or plow the surface of the FAST plate.

2. Turn the plate 1/4 turn clockwise and repeat the streaking pattern, gently streaking from top to bottom, back and fourth, moving the swab to the right edge of the FAST plate. A left handed person may wish to swab the FAST plate from the reference mark to the left edge and turn the FAST plate counterclockwise.

3. Turn the FAST plate ¼ turn and repeat the pattern.



4. Turn the FAST plate ¼ turn and repeat the pattern.

5. Finally, turn the FAST plate ½ turn and repeat the pattern.

Replace the cover on the FAST plate and discard the used cotton swab.

Do not reuse the cotton swab to streak additional FAST plates.

Use a fresh swab for each FAST plate prepared!

Identify the FAST Plate

After the FAST plate has been streaked with *Bacillus megaterium* spore suspension, the FAST plate must be accurately identified.

The FAST plate is identified with the last three digits of the kidney tissue sample retained tag number.

The last three digits of the kidney tissue sample retained tag number are written on the outside, vertical edge of the bottom half of the FAST plate. Each FAST plate can be used to perform two FAST tests. Therefore, it is important to write corresponding kidney tissue sample retained tag number on the half of the FAST plate where the corresponding cotton swab will be placed. If the other half of the FAST plate is used to perform a second FAST, identify that second half of the FAST plate to correspond with the second kidney tissue sample retained tag number for the second sample.

Accurate identification of the FAST plate is essential to ensure proper reporting of test results. The last three digits on the plate should match the last three digits of the retained tag number recorded on the FSIS Form 6600-7 (10/96).

Position the Neomycin Disc

Remove the cover from the FAST plate. Place the cover from the FAST plate open-side up beside the bottom of the FAST plate.

Dispense one neomycin disc into the cover from the FAST plate.

With the thumb forceps, pick up the neomycin disc by the edges. Select a point about ½" inch from the X reference mark and directly above the line dividing the FAST plate into two equal halves.

Carefully place the neomycin disc flat onto the agar. Do not try to reposition the disc if it is not exactly above the line. Use another plate if

the neomycin disc is badly out of position.

Lightly touch the neomycin disc with the thumb forceps tip to assure uniform contact. Be careful not to press hard enough to break the surface of the agar.

Position the Kidney Tissue Fluid Swab

After the neomycin disc has been placed on the FAST plate, break the cotton swab shaft off as close to the cotton tip as possible.

Place the cotton swab tip on the half of the FAST plate marked with the last three digits of the corresponding kidney tissue sample retained tag number.

The broken end of the cotton swab shaft should be near the neomycin disc and the cotton tip in the center of its section.

Avoid touching the cotton swab tip with your fingers when placing the cotton swab on the FAST plate! Sterile technique is not required, but fingers may transfer a contaminant to the FAST plate that could alter the result. Handle the cotton swab by the shaft only. Wash your hands and change gloves as often as necessary to avoid contaminating the FAST plate.

After the cotton swabs are correctly placed on the agar plate; lightly press down on the cotton swab shaft with your fingertip to ensure proper contact of the cotton swab head with the agar. Be careful not to break the agar surface when applying pressure on the cotton swab head.

Do not use the forceps! Forceps are contaminated with neomycin.

Incubating the FAST Plate

Place the FAST plate on the incubator shelf with the cover on top. Do not invert the FAST plate. The swabs can be dislodged during incubation. For optimum growth of *Bacillus megaterium* and clear zones of inhibition, the FAST plate must be incubated at $44^0 \pm 0.5$ Celsius for a minimum of 6 hours and a maximum of 24 hours.

Remove the FAST plate from the incubator after 6 hours of incubation. Otherwise, remove the FAST plate from the incubator within 24 hours.

Incubation in excess of 24 hours will allow the growth of interfering organisms, or the antibiotic activity of the neomycin disc can dissipate allowing the Bacillus megaterium to grow into the zone of inhibition. This creates false negative FAST test results. Tissues incubated longer than 24 hours should be retested, either by redoing FAST or submitting to the laboratory.

Using military time, record the "Time In" on the FSIS Form 6600-7 (10/96) in the "Military Time IN" column using the format HHMM.

MILITARY TIME	
IN	OUT
0600	

If FAST testing is performed early enough in the tour of duty to allow 6 hours of incubation time prior to the end of the work day, then FAST plates should be read prior to the end of the tour of duty. The appropriate time should be recorded in the "Military Time Out" column when the plates are removed for evaluation.

If FAST testing is performed late in the tour of duty, allow the FAST plates to incubate overnight and read the FAST plates after the start of the next day's tour of duty, up to a maximum period of 24 hours incubation. The appropriate time should be recorded in the "Military Time Out" column when the plates are removed for evaluation.

FSIS has begun using FAST testing for all bovine. This includes calves, when emergencies happen in the field STOP supplies can be used on the adult bovine – but only FAST can be used for the calves.

Using the N5 disc give you a reference point to use in determining if the supplies being used are working properly.

Observe the zone of inhibition around the disc. If the zone diameter is between 20-26 mm you read the rest of the plate.

- Zone less than 20 could mean;
  -N5 disc is outdated
  -too many spores on the plate (lawn issue)
  -incubator temp too high or low
  -too much moisture on surface of the plate

- Zone greater than 20 mm:
  -not enough spores on the plate
  -incubator temp too high or low

Observe the zones of inhibition around the swab heads

- present equals presumptive positive
- absent except for right under swab equals negative

If the zone of inhibition around the neomycin disc is greater than 26 mm or less than 20 mm, the FAST test result may be unreliable and the FAST test may have to be rerun or samples submitted to the laboratory. A decision to repeat the FAST or submit tissue to the laboratory depends on two factors:

1. Can changes be made that will result in a zone of inhibition around the neomycin disc zone that is not greater than 26 mm or less than 20 mm; and
2. what is the impact of waiting for FAST results versus submitting tissues now. If tissue is submitted to the laboratory, interpret the FAST as positive and record the result under the appropriate time column for the "Test Results" column. If the FAST is rerun, the FAST is inconclusive. Record "I" under the appropriate time column for the "Test Results" column. Do not place entries in both time columns!

If there is growth of *Bacillus megaterium* and the zone of inhibition around the neomycin disc is not greater than 26 mm or less than 20 mm, proceed with interpretation of the FAST.

The FAST worksheet is filled out as you take and complete FAST results. When a sheet is completed accurately and legibly you need to keep one copy for your plant files and send the top copy to the Des Moines Data Center. You may also be asked to send a copy to your District Office. If you have less than the full sheet filled out, you will still send it in on at least a monthly basis. These worksheets are scheduled to become all electronic in the near future, but the fields will remain the same.

After a presumptive positive FAST test the inspector will follow the unified sampling Directive 10,210.1 to process all the tissues collected. After freezing, all samples with the form are packaged for shipping to the Midwest Lab in St. Louis, MO. Before you send off the sample make sure to request the owner name and address from the plant and put it on the form.

The STOP test differs from FAST testing .in the incubator temperature settings and the spore species that is used.(*Bacillis subtilis*). Also for the STOP test the results are read the next day between 16 and 24 hours.

Residue Testing Procedures: Cattle and Swine

There are basic principles you should keep in mind when you are deciding whether or not a carcass may contain residues. The in-plant screening tests provide guidance and should be used as primary tools in the first step of the residue program.

The following is a list of the pathologies and conditions that warrant retention and testing of carcasses. Symptoms are described to help PHVs determine when to retain and test carcasses.

- Mastitis – carcasses with inflammatory ventral edema in the perineal area resulting from mastitis. Hemorrhages and yellow serous infiltrate, located ventrally, are typically present.

- Metritis – carcasses with acute metritis. Associated pathology includes enlargement of the uterine body, distension of the uterine horns 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).

- Peritonitis and surgery – carcasses with active peritoneal inflammation associated with fibrinous exudate or fetid ascitic fluid, no matter how limited the extent of the lesions or with ventral abdominal cellulitis secondary to percutaneous abomasal surgery. Findings of surgical devices (suture, toggles, fistula devices, etc.) are only significant if they are associated with active (i.e. the presence of fibrin as opposed to chronic peritonitis with fibrous adhesions) peritoneal inflammation.

- 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., tubor isschii, hip joint, stifle joint). These are generally found in the semimembranosis and semitendinosis muscle.

- Pneumonia – carcasses with acute, subacute and chronic active pneumonias; with pleural cellulitis resulting from reticulo peritonitis complex; or with embolic pneumonia.

- Pericarditis – carcasses with fibinous or fibrinosuppurative pericarditis.

- Endocarditis – carcasses with endocarditis and acute pulmonary, renal or other embolic lesions. Also, test carcasses that are condemned due to septicemia, pyemia, or other reasons.

- Abomasal disease – carcasses with recent abomasal displacement and torsions or with intussusceptions, mesenteric torsions, and cecal torsions.

- Septicemia and pyemia – carcasses that are being condemned for septicemia, pyemia, or other inflammatory/infectious conditions.

- Animals identified during ante-mortem inspection that were determined to be U.S. Suspect for residues.

- Carcasses with acute cellulitis or other acute inflammations associated with a fibinous or fibrinosuppurative exudate in any location on the carcass or viscera.

The following is a list of symptoms and conditions that may warrant collection of samples from swine carcasses for rapid in-plant antibiotic drug residue screening during post-mortem inspection:

- Animals that are identified during Ante mortem inspection as U.S. suspects for antibiotic drug residues
- Carcasses that are condemned for septicemia/pyemia
- Carcasses with lesions suggestive of injection sites
- Diamond skin or other skin conditions associated with septicemia
- Pneumonia/pleuritis
- Pericarditis/endocarditis
- Nephritis/cystitis
- Metritis
- Mastitis
- Peritonitis
- Arthritis

WORKSHOP

1. The agency that establishes tolerances for veterinary drugs and food additives is:

    a. OSHA.
    b. FSIS.
    c. FDA.
    d. EPA.

2. The following conditions would lead to a decision by the PHV to perform an in-plant residue test are;

    a. Chronic pneumonia, acute fibrinous Pericarditis.
    b. Acute fibrinous Pericarditis, septicemia.
    c. Injection site, chronic mastitis.
    d. Diamond skin not associated with septicemia, chronic bronchopneumonia.