

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 LIMS-Direct.
4. Perform and accurately read KIS™ test.
5. Evaluate conditions which would lead to a decision by the PHV to perform an in-plant residue test.

Resource Materials

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

FSIS Directive 10,100.1 FSIS Sampling for the National Antimicrobial Resistance Monitoring System (NARMS)

FSIS Directive 10, 200.1 Accessing Laboratory Sample Information via LEARN

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

FSIS Directive 13,000.2 Performing Sampling Tasks in Official Establishments Using the Public Health Information System

FSIS Notice 03-15 Sampling Project Codes for the Fiscal Year 2015 National Residue Program

FSIS Notice 60-14 FSIS Sampling Data Reporting Through LIMS-Direct

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 establishments 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 Staff, 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 Public Health Veterinarian (PHV) 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. This information is also in FSIS Directive 10,800.1. Surveillance sampling is a scheduled sampling designed to investigate 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 all animals that have passed ante-mortem inspection

without regard to whether the animal may or may not pass postmortem 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 establishment's HACCP system. This is inspector-generated sampling.

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 the Kidney Inhibition Swab® (KIS™) 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 KIS™ 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 FDA and EPA set tolerance limits of drugs, chemicals and pesticides.. A result is violative when this tolerance level is exceeded. When a violative result is reported to you by the Policy Development Division, 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 under the Slaughter HACCP Verification task. Also, if the establishment 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 establishment 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 establishment 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 establishment 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 establishment 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. Having said this, the Agency may take additional enforcement action against establishments that repeatedly purchase and slaughter animals with violative residue levels from the same source supplier. See the section headed "Multiple FSIS Laboratory Confirmed Residue Violations from the Same Source" on page 9 of this handout.

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.
- 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,
Iprnidazole, 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 PHIS and records the carcass owner's name, address, and other identifying information on the forms and in PHIS.
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 LIMS-Direct.
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 LIMS-Direct and the PDS 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 PDS when special sampling situations arise.
3. Cooperates with residue violation investigations that may involve FSIS, FDA, and EPA.
4. Cooperates with and aids the PDS in trace-back activities that may require contacting auction houses, brokers, establishments or PHVs in order to obtain information that the PDS 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 PDS and OFO Headquarters relating to field residue violations that require increased in-plant testing by the PHV.

OPPD, PDS Role in Residue Detection

The Policy Development Division 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 PDS 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 PDS also provides correlation as requested by OFO on residue results reported in LIMS-Direct, 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 PDS 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 PDS 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 PDS 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 PDS 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 specific producer's animals. 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 can find additional guidance on when to increase testing in FSIS Directive 10,800.1. If you have concerns, you should discuss them with the PDS Staff Officers. The FDA or the State may call the PDS 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 PDS, 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 ten times 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.

Multiple FSIS Laboratory Confirmed Residue Violation from the Same Source

When you are notified that your duty station has one or more FSIS laboratory – confirmed residue violations from animals purchased from the same source supplier, discuss this finding with the establishment at the next weekly meeting. Also, let them know that FSIS is implementing a more focused approach on the same source suppliers to ensure the establishment is notified of the residue history or its suppliers. Recommend that the establishment adopts corrective and preventive measures for chemical residues. Document the meeting in weekly meeting MOI and distribute copies to the establishment, FLS and District Office.

Review the establishment's residue control program, which may be addressed in the HACCP plan, Sanitation SOP or other prerequisite program. If the HACCP system is in

compliance, do not document a NR. If the establishment has a residue control program but has failed to take corrective actions, or the corrective actions are ineffective, issue a NR (for a prerequisite program, use 9 CFR 417.5(a)(1); for a Sanitation SOP, use 9 CFR 416.15; for a HACCP plan, use 9 CFR 417.3(a). If the establishment has not incorporated residue control into any of these programs, use 9 CFR 417.3(b) for a unforeseen hazard.

Increase testing of the animals the establishment receives from this same source supplier subsequent to the initial violative finding. Test two or more animals each time the establishment receives animals from the supplier, up to 100% testing of animals from that supplier to ensure animals with violative residues don't enter the human food supply. Continue with this level of testing until tests for four consecutive, separate shipments from that supplier are negative.

After the initial violative finding, if there is another FSIS laboratory-confirmed residue violation from the same source supplier, issue a NR as described above and another NR citing 9 CFR 318.20, documenting the establishment's failure to prevent animals with violative residues from entering slaughter.

If there are multiple or recurring noncompliances, you may determine that the HACCP system is inadequate under 9 CFR 417.6 and further enforcement is warranted. Contact your supervisor and the District Office to discuss your assessment and determine if a NOIE should be issued.

Review FSIS Directive 10,800.1 for complete information on addressing repetitive residue violations from the same source supplier. The directive appendices include flow charts on enforcement actions.

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 LIMS-DIRECT

A. The Laboratory Information Management System (LIMS-Direct) is an information technology (IT) program that reports FSIS lab sample results directly from LIMS. It provides a close to real-time sample data electronically to FSIS program

personnel and other entities when applicable. FSIS Directive 10,200.1, (LEARN) System will be revised to reference LIMS-Direct.

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 LIMS-Direct 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 in PHIS 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 LIMS-Direct 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 LIMS-Direct

The PHV is to check LIMS-Direct 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 LIMS-Direct. LIMS-Direct indicates whether a tissue is "Not Detected", "Detected – non-violative", "Detected – violative", or "Detected but not Quantified, Violation". Follow the disposition guidelines to make the final disposition of the retained carcass and parts.

If there is no established tolerance (reported as "Detected but not Quantified, Violation) or there is a quantified violation for some part (such as organ tissue or fat) without a quantified muscle result:

- Condemn the carcass and all parts

If the residue test result is reported as "Detected – violative", use the following disposition guidelines:

- Violation **in muscle** – condemn carcass and parts
- Violation **in muscle and parts** – condemn carcass and parts
- Violation **in parts** but no violation in muscle – condemn parts, pass carcass

For NSAID or beta-agonist violation – call the PDS 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 PDS, 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 LIMS-Direct 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.

The PHV may see that LIMS-Direct reports a residue sample test result as either "Detected but not Quantified, Violation" or has a quantified violative result for some parts (e.g., organ or fat) without a quantified muscle result. This means that the identified compound does not have an established FDA or EPA tolerance for muscle. The PHV should not apply the mark of inspection to that carcass, and condemn the carcass and all parts.

Verification of Implant Usage in Pre-Ruminant 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 perform a Slaughter HACCP Verification task to verify 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.

In-plant Screening Tests

The only in-plant screening test currently used in federally inspected establishments is the KIS™ test. It only screens for antibiotics. Until August 2012, the FAST was also used as an in-plant antibiotic screen test. However, this test has been completely replaced by the KIS™ test and is no longer used. Please note that the FSIS Directives 10,800.1 and 10,220.3, addressing residues, have not yet been updated to reflect the change from FAST to KIS™ testing. Nevertheless, carcasses for sampling and testing by the KIS™ test are selected and handled in the same way as carcasses selected for the FAST.

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. Samples sent to an FSIS lab for confirmation testing because they are positive by an in-plant screen test are automatically tested for non-steroidal anti-inflammatory drugs such as flunixin or phenylbutazone.

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. A good example of this is testing for non-steroidal anti-inflammatory drugs (NSAIDs) such as flunixin or phenylbutazone. These drugs are used in older dairy cows and sows with arthritis as a means to prevent inflammatory conditions or prevent them from becoming non-ambulatory disabled. Such animals should be screened for flunixin; however, NSAIDs are not detected by the in-plant antibiotic screening tests. So, when the PHV or IIC suspects residues from NSAIDs, he or she must take samples and specifically request that the Midwestern Laboratory analyze for NSAIDs.

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.

Establishments that slaughter certain categories of food animals must address chemical residues within their HACCP system. In establishments that slaughter cull dairy cows and/or bob veal calves, perform increased targeted testing for chemical residues if their hazard analysis does not demonstrate support for an effective residue control program. Some examples of lack of support are:

- the establishment repeatedly purchases cull dairy cows and bob veal calves from a producer without taking into account whether that producer has supplied to any establishment more than one animal with a residue violation in the last 12 months.
- an establishment does not have controls in place that address the possibility that it may receive animals from producers that are on the FSIS Repeat Residue Violator List (e.g., because it purchases animals at an auction barn that does not provide information on whether the animals are from a producer on the Repeat Residue Violator List)

If the increased rate of testing is warranted, IPP are to:

1. Test a minimum of two animals each time the establishment receives animals, and the establishment does not have a control in place that minimizes the possibility that the animals have an illegal residue,
2. Use professional judgment to determine whether additional sampling is necessary, up to 100% testing of the lot, based on the effectiveness of the establishment's residue control program at reducing or eliminating the occurrence of FSIS violative findings,
3. Continue increased testing rate on all dairy cows and bob veal as long as the establishment lacks an effective control program, and

4. Use the increased testing rate for dairy cows and bob veal from any unknown source, even if the animals appear to be normal, as well as on animals with pathologies listed in FSIS Directive 10,220.3. For bob veal, this increased testing rate is in addition to the rate described in 9 CFR 310.21.

Animal Identification and Devices

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

By regulation and Law, the establishment is required to comply and provide the accurate identification requested. In addition, FSIS has signed a Memorandum of Understanding (MOU) with APHIS detailing the specific types of animal identification collected to identify livestock and poultry slaughtered at Federal establishments. Collecting complete animal identification allows traceback to the animal production unit for disease surveillance and eradication.

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 specifiedis 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 (expired)

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- 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 documented in the Other Inspection Verification task.

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 semimembranosus and semitendinosus muscle.
- Pneumonia – carcasses with acute, subacute and chronic active pneumonias; with pleural cellulitis resulting from reticulo peritonitis complex; or with embolic pneumonia.
- Pleuritis – inflammation of the pleura lining in the thoracic cavity and lungs
- Pericarditis – carcasses with fibrinous or fibrinosuppurative pericarditis.
- Endocarditis – carcasses with endocarditis and acute pulmonary, renal or other embolic lesions.
- Signs of treatment – leakage around jugular veins; subcutaneous, intramuscular, or intraperitoneal signs of treatment; signs indicative treatment by mouth such as discoloration from particles found in any part of the digestive tract.
- Septicemia, pyemia or generalized disease – carcasses that are being condemned for septicemia, pyemia, or other inflammatory/infectious conditions. On antemortem or postmortem inspection – depression, elevated or subnormal body temperature, hyperemic skin, congested mucous membranes, dehydration, poor body condition, in association with an injury or inflammatory condition such as abscesses, arthritis, pneumonia, mastitis, metritis, or diamond skin
- Animals identified during ante-mortem inspection that were determined to be U.S. Suspect for residues.
- Injury or inflammatory conditions – carcasses with conditions not resulting in condemnation such as arthritis, pneumonia, mastitis, metritis, nephritis, cystitis, diamond skin
- Carcasses with acute cellulitis or other acute inflammations associated with a fibrinous or fibrinosuppurative exudate in any location on the carcass or viscera.

- Beta-agonist use – excessive or unusually heavy muscle development or hyperexcitability on antemortem inspection. Heavy muscle development or a “dark cutter” on postmortem examination.

WORKSHOP

1. The agency that establishes tolerances for veterinary drugs and food additives is:
 - a. OSHA.
 - b. FSIS.
 - c. FDA.
 - d. EPA.

2. For the following conditions, which would **both** lead to a decision by the PHV to perform an in-plant residue test:
 - a. Chronic pneumonia and acute fibrinous pericarditis.
 - b. Acute fibrinous pericarditis and septicemia.
 - c. Injection site and chronic mastitis.
 - d. Diamond skin not associated with septicemia and chronic bronchopneumonia.