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FSIS National Residue Program for Cattle

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DATE: March 25, 2010

REPLY TO
ATTN OF: 24601-08-KC

TO: Alfred V. Almanza
Administrator
Food Safety and Inspection Service

ATTN: William C. Smith
Assistant Administrator
Office of Program Evaluation, Enforcement and Review

FROM: Gil H. Harden /s/
Acting Assistant Inspector General
for Audit

SUBJECT: FSIS National Residue Program for Cattle

This report presents the results of our audit concerning FSIS management of the national residue program, especially as it relates to cattle. Your response to the official draft report, dated March 2, 2010, is included at the end of the report. Excerpts of the response, along with Office of Inspector General's position, are incorporated into the Findings and Recommendations section of the report. Based on your responses, we were able to reach management decision on all of the report's 14 recommendations. Please follow your agency's internal procedures in forwarding documentation for final action to the Office of the Chief Financial Officer.

We appreciate the courtesies and cooperation extended to us by members of your staff during this audit.

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Executive Summary

One of the public food safety issues facing the United States is the contamination of meat with residual veterinary drugs, pesticides,[1] and heavy metals. "Residue" of this sort finds its way into the food supply when producers bring animals to slaughter plants while they have these residual contaminants in their system. When the animals are slaughtered, traces of the drugs or pesticides contained in these animals' meat is shipped to meat processors and retail supermarkets, and eventually purchased by consumers. In order to safeguard the Nation's food supply from harmful residue, the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) administers the national residue program. FSIS inspectors sample meat processed through slaughter plants for residue testing and compare the results with tolerances established by the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) to prevent adulterated meat from entering into commerce.[2] The Office of Inspector General (OIG) initiated this audit to evaluate the effectiveness of the national residue program and to assess how well FSIS, FDA, and EPA were coordinating to accomplish the program's objectives.

Based on our review, we found that the national residue program is not accomplishing its mission of monitoring the food supply for harmful residues. Together, FSIS, FDA, and EPA have not established thresholds for many dangerous substances (e.g., copper or dioxin[3]), which has resulted in meat with these substances being distributed in commerce. Additionally, FSIS does not attempt to recall meat, even when its tests have confirmed the excessive presence of veterinary drugs.

To address these serious shortcomings in the national residue program, FSIS, EPA, and FDA need to take steps to improve how they coordinate with one another to accomplish the program's mission. Recognizing that they needed to work together to prevent residue from entering the food supply, the three agencies established the Surveillance Advisory Team (SAT) and the Interagency Residue Control Group (IRCG) as a way of coming together to communicate and coordinate.[4] We found, however, that there were a wide range of problems with relying on this process: not all agencies were equally committed to the SAT and IRCG; essential participants were not required to attend; and no one agency had authority to ensure that necessary actions were taken to deal with disagreements. Due to problems with how the SAT and IRCG were established and were functioning, we identified four issues relating to coordination between FSIS, EPA, and FDA. The three agencies involved need to: 1) expand the substances they test

[1] Pesticides are any substance intended for preventing, destroying, repelling, or mitigating any pest (e.g., insects or mice) or any substance intended for use as a plant regulator, defoliant, or desiccant.

[2] When violative levels of residues are detected in food-producing animals submitted for slaughter, the product found to be contaminated with violative residues is considered "adulterated" and is subject to condemnation and disposal. If the product has already been released into commerce, then FSIS evaluates the hazard the product poses to the public and, based on this analysis, determines whether to request a product recall by the firm that manufactured the adulterated product.

[3] Dioxins are formed as a result of combustion processes, such as waste incineration and the burning of fuels (e.g., wood, coal, or oil). Exposure to large amounts of dioxins may cause skin diseases, mild liver damage, cancer, reproductive problems, or developmental effects.

[4] The SAT meets annually with the primary function of establishing the sampling plan for the national residue program's scheduled sampling for the next year. The IRCG meets monthly to address ongoing issues concerning the national residue program.

for, 2) improve their methodology for sampling hazardous residues, 3) determine more efficient ways of approving newer methods of testing for drug residues, and 4) collaborate to set tolerances for additional residues.

FSIS, EPA, and FDA Need to Expand the Substances They Test For

Each year, the SAT brings together representatives from FSIS, EPA, and FDA to decide which residues they will include in the approximately 120 substances they test for annually. Although EPA routinely asks FSIS to test for pesticides that the three agencies have together determined to be high health risks, FSIS has, for many years, continued to test for only one type of pesticide, citing its limited resources and the fact that EPA has not established tolerances for many varieties of pesticides.

We acknowledge that FSIS' laboratory testing resources are not unlimited and that the agency must make decisions about what it will and will not test for. However, if EPA, FDA, and FSIS determine that there are additional high risk substances that should be tested, the SAT needs a mechanism for resolving differences and, if necessary, obtaining necessary testing resources. One such mechanism would be to elevate such disagreements to executive-level officials capable of arriving at an appropriate compromise. A 1984 memorandum of understanding to coordinate Federal residue monitoring activities was signed by the FSIS Administrator and other officials at FDA and EPA below the Administrator's level. We believe that residue monitoring is of such importance that the framework of the program should be re-established and approved at the highest levels within the respective Departments.

FSIS, FDA, and EPA Need to Improve Their Methodology for Sampling Hazardous Residues

Once the three agencies involved have determined which substances they will test for, they then decide how they will sample for those substances. We found, however, that different groups have questioned FSIS' sampling methodology, both its sample size and design. For example, FSIS laboratory personnel believe that they should be testing more than 300 samples for some residues, while an outside contractor performing a quality control review recommended that FSIS could test fewer samples "without a significant loss in precision." Members of the SAT and IRCG have also proposed that sampling for some veterinary drugs quarterly instead of monthly would provide equally useful information and could also save laboratory resources.

The SAT is the appropriate forum for discussing issues concerning FSIS' sample design, but at present, the appropriate agency managers and personnel with the relevant qualifications do not always attend SAT meetings, and the agencies have not conducted a thorough review of how they design the sample for these substances. The three agencies should work together to strike a balance between sampling demands, resource limitations, and the relative importance of any given compound. Following appropriate risk analysis principles would provide FSIS with a scientific and structured approach that would also allow the agency to optimize its limited laboratory resources.

FSIS and FDA Need to Determine More Efficient Ways of Approving Newer Methods of Testing for Drug Residues

When testing for the various types of drug residue that the agencies have determined to be high risk, FSIS relies on FDA to approve the testing methods it uses. However, the approved methods are often antiquated and ineffective because they were approved when FDA first approved the drug. "Bridging" testing methods—confirming that a newer and more efficient method will yield acceptable results when compared to the FDA-approved method—is a slow and difficult process, and FDA is not always willing, or able, to undertake the work.

Although FDA and FSIS disagree on how to solve this problem, they agree that until the problem is resolved, FSIS will not be able to test for residues as efficiently as possible. FSIS and FDA should cooperate to improve their efficiency in approving newer methods for FSIS to use in testing for residues, as doing so will enable FSIS to take advantage of advanced technologies, lower its costs, and improve the quality of its analyses.

FSIS, EPA, and FDA Need to Collaborate to Set Tolerances for Additional Residues

If FSIS confirms the presence of residue in a sample of meat, it needs a "tolerance" or a threshold for determining if the concentration of that residue is dangerous for human consumption. For example, FDA has set a tolerance of .05 parts per million for penicillin in beef, so FSIS knows that beef with 10.62 parts per million should be excluded from the food supply. FSIS relies on FDA or EPA to set tolerances for drugs, pesticides, and heavy metals.

We found, however, that tolerances have not been set for many potentially harmful substances, which can impair FSIS' enforcement activities. For example, in 2008, when Mexican authorities rejected a shipment of U.S. beef because it contained copper in excess of Mexico's tolerances, FSIS had no basis to stop distribution of this meat in the United States since FDA has set no tolerance for copper. Though we acknowledge that setting tolerances is an expensive and time-consuming process, FSIS needs a systematic and formal process to request FDA and EPA to set tolerances for residues that are deemed potentially hazardous. FSIS also needs procedures that specify what actions agency personnel are to take regarding the disposition of carcasses that contain potentially hazardous substances when there are no formal tolerances established by EPA or FDA.

Along with the issues of coordination among the three agencies involved in the national residue program, we found that FSIS itself can take action to strengthen the program by requiring slaughter plants to increase their controls when processing dairy cows and bob veal.[5] Plants handling dairy cows and bob veal were, in 2008, responsible for over 90 percent of residue violations found. FSIS allowed such plants to continue treating residue problems as "not reasonably likely to occur"—the determination that would allow plants to justify not implementing additional procedures to control residues. Although FSIS had reviewed these plants' control plans multiple times, agency officials explained that they had not done the analysis to determine that violations were so concentrated among dairy cows and bob veal. As a result, in 2008, individual plants amassed as many as 211 violations—with 21 producers having

[5] Bob veal are calves, usually unwanted male calves born at dairy operations, that are slaughtered within a few days of birth.

multiple violations—and still were able to treat residue as a problem "not reasonably likely to occur."

FSIS has had a longstanding problem of not being able to identify the producers of cattle that have tested positive for residue, as dairy cows often pass through several buyers and sellers before they are presented for slaughter by suppliers. Without this information, FSIS will always be limited in its ability to respond to repeat violators and to prevent such cattle from entering the slaughter plants. In order to resolve this problem, it would be in FSIS' interest to require that plants with a history of residue violations identify the producers of any animals presented for slaughter, so that plants can take proactive measures to prevent or control shipments of cattle at high risk for residues and FSIS can subject the animals to additional testing.[6] However, FSIS officials explained that the Agency does not have the authority to require plants to obtain producer identification for animals arriving for slaughter.[7] As an alternative to obtaining the authority to request producer identification, FSIS should establish procedures that provide incentives for the plants with a history of residue violations to voluntarily request producer's identification for any animal presented for slaughter, such as subjecting every shipment of cattle from unknown producers to additional on-site screening for potential residue testing. Additionally, since FSIS already maintains repeat violator information, it should establish performance measures, such as tracking reductions in the occurrence of repeat residue violations over time.

We also found that FSIS does not recall meat adulterated with harmful residue, even when it is aware that the meat has failed its laboratory tests. Between July 12, 2007, and March 11, 2008, FSIS found that four carcasses were adulterated with violative levels of veterinary drugs[8] and that the plants involved had released the meat into the food supply. Although the drugs involved could result in stomach, nerve, or skin problems for consumers, FSIS requested no recall. Officials explained that when meat enters commerce, the agency must prove that consuming a single serving of the contaminated meat is likely to cause harm. In these cases, FSIS determined that consumers would not likely be "acutely harmed" by consuming a single serving of this meat so it could be difficult to force a plant to implement a voluntary recall. In addition, FSIS faces the task of convincing a U.S. Attorney to file for the product seizure in federal district court if the plant refuses the voluntary recall. According to FSIS officials, seizure of the product is not likely for non-acute health risks, e.g., a small amount of residue adulterated product from a single carcass. However, in the past, FSIS has requested plants initiate voluntary Class II recalls for "low" risk health situations for non-acute causes, such as distribution of product that was produced from animals that had not received a proper ante-mortem inspection.

Finally, we found that FSIS needs to modernize its process for sampling carcasses at slaughter plants and then testing those samples at its laboratories so that the agency can make use of readily available technologies, including barcode scanning, electronic forms for retaining information, and an electronic reservation system for scheduling tests. At present, the agency

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[6] This additional testing was recently required by FSIS publication of Notice 04-09, in January, 2009.

[7] FSIS does have the authority to require producer identification for producers bringing bob veal into slaughter under 9 Code of Federal Regulations 309.16(d)(2), which states that "[t]he identity of the producer of each calf presented for ante-mortem inspection shall be made available by the official establishment to the inspection [inspector] prior to the animal being presented for ante-mortem inspection."

[8] These drugs were Ivermectin, Sulfadimethoxine, Florfenicol, and Sulfamethazine, which are anti-parasitic or anti-bacterial agents.

relies on a system that requires employees to make pen and paper notes on tags that are affixed to carcasses—a system that is slow, cumbersome, and not always very legible. FSIS officials stated that they did not realize their technology was out-of-date and did not know that some plants were already using newer and more innovative techniques for tracking carcasses. Due to this problem, FSIS' public health veterinarians had less time to devote to their primary mission of inspecting and testing animal carcasses for harmful adulterants, and FSIS was testing meat samples for residue less efficiently and reliably than was necessary.

We concluded that FSIS—both alone and in collaboration with FDA and EPA—needs to take a number of important steps to strengthen the national residue program. Those steps should ensure that the program is effectively accomplishing its objectives of ensuring that adulterated meat is not entering the U.S. food supply.

Recommendation Summary

We recommend the following:

- Through discussions with senior management and executive level officials at Health and Human Services (HHS)/FDA and EPA, draft and propose:

  1) a revision to the 1984 memorandum of understanding (MOU) to ensure that it formally establishes the SAT and IRCG and addresses the specific concerns of all three agencies;

  2) a charter for the SAT and IRCG, laying out, at a minimum, the specific mission, goals and agencies' responsibilities and specifying the level of participants, attendees' required qualifications, and the various disciplines to be represented; and

  3) a process for elevating issues and potential recommendations identified in the SAT and IRCG to executive-level officials in order to gain a response and ensure actions are taken for timely resolving the interagency issues or problems discussed at these meetings.

  Formalize the MOU, the charter, and the process for elevating issues and potential recommendations when agreements are reached on the draft proposals.

- Through discussions with the SAT, develop formal plans and reasonable milestones to ensure that the national residue program has the resources it needs to test for all substances identified by the SAT as posing a high risk to public health.

- Through discussions with the SAT, establish policies and procedures with reasonable timeframes to perform structured, periodic review of FSIS' sampling methodology regarding the number and timing of samples taken, using formal risk analysis principles focused on public health outcomes and aimed at improving laboratory efficiency. Revise FSIS' sampling methodology based on the outcome of the review.

- Through discussions with FDA senior management, draft and propose a process to expedite approval of new testing methodologies for FSIS. Include initiating a formal

study to determine the merits of a performance-based, or other new, approaches for regulatory analysis and for testing new drugs in the future. Formalize the proposals and include milestones for completion once agreements are reached, beginning with a formal agreement to bridge[9] the testing method for animal drugs FSIS currently needs.

- Through discussions with EPA and FDA, develop a formal plan with reasonable timeframes to establish policies and procedures for handling hazardous substances with no tolerances, such as heavy metals, animal drugs, and environmental contaminants, including pesticides with cancelled registrations. Formalize the policy and procedures when these agreements are reached. Also, develop and implement detailed FSIS procedures that specify the actions agency personnel are to take regarding the disposition of carcasses that contain potentially hazardous substance(s) when there are no formal tolerances established by EPA or FDA.

- Develop a plan to identify slaughter plants where residue violations have a history of occurring and to set specific timeframes for conducting assessments to evaluate whether those plants have made the proper determination or adequately supported their determination whether residue is a hazard reasonably likely to occur. Require these plants to implement appropriate controls to prevent, detect, and eliminate harmful residues commensurate with the level of risk.

- Develop formal policies and procedures that provide (1) an incentive for plants to voluntarily seek producer identification on animals arriving for slaughter for comparison with plant or FSIS residue violators lists; and (2) a disincentive for plants that continue to purchase from suppliers/producers with repeat residue violations, such as subjecting shipments from suppliers with unidentified producers to additional on-site screening for potential testing if the plant cannot demonstrate that incoming animals are not at high risk for violative levels of residue.

- Provide incentives to prevent plants from releasing potentially adulterated product before residue test results are confirmed and for plants to voluntarily trace and recall meat that is found to have violative levels of residue. Establish a policy to use alternative procedures to recall when violative levels of residue are found in meat that do not result in an acute risk, such as issuing public health alerts.

Within the guidelines of the Capital Planning and Investment Control (CPIC) process,[10] develop detailed plans and formal proposals to adopt and implement (1) an electronic laboratory reservation system for processing residue samples, and (2) an automated system to electronically track detached animal parts, such as barcode scanning, so data can be easily managed in the plant, transferred among FSIS systems, and disseminated to outside agencies.

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[9] "Bridging" is the term used for the process of confirming that a newer, more efficient testing method for a particular drug will consistently yield acceptable results similar in comparison to the testing method FDA originally approved. Currently FDA has an informal agreement to bridge penicillin for FSIS, but the process has taken over 2 years.

[10] The CPIC process is a systematic approach to selecting, managing, and evaluating information technology (IT) investments. CPIC is mandated by the Clinger Cohen Act of 1996, which requires federal agencies to focus more on results achieved through IT investments while streamlining the federal IT procurement process.

Agency Response

FSIS agreed with the report's 14 recommendations. We have incorporated the FSIS response in the Findings and Recommendations section of this report, along with the OIG position. FSIS' response to the official draft is included in its entirety at the end of this report.

OIG Position

Based on FSIS' response, we were able to reach management decision on the report's 14 recommendations.

Background & Objectives

Background

As the public health agency of USDA, FSIS administers the national residue program to ensure that the Nation's food supply is safe from the residues of veterinary drugs, pesticides, and heavy metals that might find their way into meat destined for human consumption.

The effects of these residues on human beings who consume such meat are a growing concern. Not only does overuse of antibiotics help create antibiotic-resistant strains of diseases, but the residues of certain drugs and heavy metals can have potentially adverse health consequences if they are consumed in meat. The following table shows five drugs or substances and the potential side effects or health consequences:

DRUG OR SUBSTANCE	POTENTIAL SIDE EFFECTS
Flunixin	Fecal blood, gastrointestinal erosions and ulcers, and renal necrosis.
Penicillin	Life-threatening allergic reaction (i.e., difficulty breathing, closing of the throat); serious nerve damage; severe inflammation of the colon; swelling of the lips, tongue, or face; bleeding; and diarrhea.
Arsenic	Nonmalignant skin lesions, skin malignancy, internal malignancies, vascular diseases, and hypertension.
Copper	Hemolysis, jaundice, changes in lipid profile, oxidative stress, renal dysfunction, and even death.
Ivermectin	Neurotoxicity (e.g., altering normal activity of the nervous system which can eventually disrupt or even kill neurons, key cells that transmit and process signals from the brain).

Residues of drugs, pesticides, and heavy metals differ from microbiological pathogens like *E. coli*,[11] *Salmonella*, and *Listeria Monocytogenes*, which the public more readily associates with food safety. While cooking meat properly can destroy these pathogens before they are consumed, no amount of cooking will destroy residues. In some cases, heat may actually break residues down into components that are more harmful to consumers. Since consumers have no easy way of protecting themselves against the residues of harmful substances in their food, it is important that the national residue program's controls be as robust as possible to prevent meat contaminated with harmful substances from reaching the kitchen table.

[11] For purposes of this report, we refer to *Escherichia coli* O157:H7 simply as *E. coli*.

Residues are introduced into meat intended for human consumption for a variety of reasons. Some producers provide antibiotics to dairy cows in order to eliminate an infection after a calf is born. If the producer perceives that the cow is not improving, he may sell the animal to a slaughter facility so that he can recoup some of his investment in the animal before it dies.[12] If the producer does not wait long enough for the antibiotic to clear the animal's system, some of this residue will be retained in the meat that is sold to consumers.

Meat from bob veal calves also frequently contains residue which may enter their system through medicated feed or from waste milk from cows that are going through a drug withdrawal period. Farmers are prohibited from selling milk for human consumption from cows that have been medicated with antibiotics (as well as other drugs) until the withdrawal period is over; so instead of just disposing of this tainted milk, producers feed it to their calves. When the calves are slaughtered, the drug residue from the feed or milk remains in their meat, which is then sold to consumers.

FSIS administers the national residue program in collaboration with the EPA and the FDA. FDA is primarily responsible for approving drugs used by food-producing animals and establishing tolerances for residues of animal drugs in edible tissues.[13] EPA is primarily responsible for establishing tolerances for residues of pesticides in food and has the authority to monitor the effectiveness of surveillance and enforcement.[14] Essentially, FSIS collects, gathers, and tests for residue tissue samples from beef[15] carcasses and organs but follows FDA and EPA guidance on tolerance levels for different substances.

FSIS samples carcasses according to the national residue program's domestic sampling plan, which is comprised of two component sampling plans—the scheduled sampling plan and the inspector-generated sampling plan. Under the scheduled sampling plan, FSIS inspectors collect random samples of healthy-appearing carcasses that have been passed for consumption to determine the prevalence of residues in the national food supply.[16] Under the inspector-generated sampling plan, inspectors judgmentally select a carcass for sampling based on several factors, including: (a) signs or symptoms observed in the live animal; (b) pathological conditions or abnormalities of the carcass or its associated viscera;[17] (c) previous known residue violations by the animal's owner; (d) the animal's herd history; or (e) the fact that an animal is identified as a "high risk" type, such as bob veal.

Each year, FSIS publishes the "National Residue Program Scheduled Sampling Plans" (the Blue Book) and "National Residue Program Data" (the Red Book) as a means of reporting the results

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[12] Such animals are known as "cull cows" or "cull cattle."

[13] FDA is charged with the enforcement of the Federal Food, Drug, and Cosmetic Act, under 21 U.S.C.

[14] EPA is charged with administering and enforcing the Federal Insecticide, Fungicide, and Rodenticide Act, under 7 U.S.C. Under the Toxic Substances Control Act, 15 U.S.C., EPA also regulates other chemical substances that can adulterate food.

[15] FSIS collects residue samples on many different species of animals, such as cattle, hogs, turkeys and chickens; however, our current audit looked strictly at FSIS' residue sampling operations for cattle.

[16] FSIS determines the number of samples to collect for each substance of interest by employing statistical analysis techniques. Statistically, applying sampling rates of 300 per compound assures a 95 percent probability of detecting residue violations if the violation rate in the population is equal to or greater than 1 percent.

[17] Viscera are the organs found in the abdominal cavity. For purposes of this report, viscera are the contents of the abdominal cavity of a bovine animal.

of its national residue program tests. The Blue Book provides detailed discussions describing the principles and methods used to plan and design the national residue program sampling plans. It also summarizes the planned scheduled domestic and import sampling plans for the upcoming calendar year and includes a summary of adjustments to the previous year's national residue program. The Red Book presents details on the testing results of the various national residue program sampling plans conducted throughout the prior calendar year.

FSIS, EPA, and FDA realized years ago that they would need to work together to control residues in the meat supply. In 1984, these agencies signed a memorandum of understanding requiring FSIS to keep FDA and EPA informed of all sampling and testing programs for residues of drugs, pesticides, and environmental contaminants in meat products, and to consult periodically with FDA and EPA. To coordinate residue sampling operations, the agencies formed the SAT. This interagency committee meets once a year and identifies the priority public health residues of concern. FSIS then develops specific sampling plans, which guide the allocation of FSIS' laboratory and inspection resources. In addition to the SAT, there is an IRCG that meets once a month to discuss all pertinent residue testing issues. IRCG meetings are also attended by individuals from FSIS, FDA, and EPA.

FSIS has acknowledged that the national residue program has weaknesses, some of which were first identified in a 1985 National Academy of Sciences' report. More recently, in August 2005, a contractor performing a quality control report noted concerns, including: (1) the need for closer cooperation with FDA and EPA; (2) the need to develop analytical methodologies capable of rapidly detecting pesticide residues in meat; (3) EPA's dissatisfaction with the national residue program's analytical methods for pesticides; and (4) the need to identify and adapt new technologies and methodologies. In this audit, we determined that these issues remain.

During our prior audit, "Evaluation of FSIS' Management Controls over Pre-Slaughter Activities," (Audit 24601-7-KC issued November 2008), we made three recommendations related to residue issues. For this audit, we examined whether FSIS addressed the recommendations. In response to our recommendation that FSIS develop guidance for its in-plant personnel to follow regarding the use of herd history, FSIS issued Notice 04-09[18] which required additional testing of livestock from repeat violators and later provided links to a "same source supplier" listing on their website. FSIS also issued Notice 39-09 as guidance for the implementation and analysis of eSample that addressed our recommendation to develop a process for more oversight of the inspector-generated residue sampling. Lastly, we recommended that FSIS clarify and strengthen requirements for sample collection and safeguards. FSIS subsequently issued Notice 60-09 to address these concerns. The findings in this report address our concerns with the specific corrective actions taken to date.

Objectives

This audit was conducted to evaluate the effectiveness of the national residue program. We evaluated whether the national residue program's objectives for cattle were being met and assessed the program's accomplishments. We evaluated whether FSIS had sufficient management controls to effectively administer and monitor the agency's residue program. We

[18] On January 12, 2010, FSIS reissued Notice 04-09 as Notice 03-10.

further assessed the purpose and effectiveness of the coordination among FSIS, FDA, and the EPA in regards to achieving the program's objectives. Additionally, we reviewed the implementation status of FSIS corrective actions to recommendations made in Audit-24601-7-KC, which were applicable to the scope of this review.

Section 1: FSIS, FDA, and EPA Need to Reestablish the National Residue Program

Finding 1: FSIS and the Other Responsible Agencies Need to Reestablish the National Residue Program so that it Can Accomplish its Mission of Safeguarding the U.S. Food Supply

The three agencies responsible for the national residue program—FSIS, FDA, and EPA—have not effectively coordinated their various roles so that they can ensure that harmful residue is not entering the U.S. food supply. Officials we spoke with at all three agencies stated that they were aware that coordination was a challenge, and that consequently they relied on the SAT and the IRCG as forums for the three agencies to communicate and coordinate. However, we found a wide range of problems with relying on this process: not all agencies were equally committed to the SAT and IRCG; essential participants were not required to attend; and no one agency had authority to ensure that necessary actions were taken to deal with disagreements. Given these types of problems, the SAT and IRCG served as discussion groups, but there was no mechanism for resolving the broader policy issues. Due to these coordination issues, FSIS is unable to determine if meat has unacceptable levels of such potentially hazardous substances as copper and arsenic, does not test for pesticides EPA has determined to be of high risk, and does not employ the most efficient use of its limited laboratory resources or the most efficient ways of testing for harmful residues.

Since 1981, FSIS has administered the national residue program to collect data on residues in meat to ensure that the Nation's food supply is safe from harmful substances. In order to accomplish this mission, three different agencies were given separate responsibilities for different types of residue. FSIS is responsible for ensuring the wholesomeness of meat that consumers eat, and to accomplish this task, it collects samples of meat and tests those samples for residue of veterinary drugs, pesticides, and environmental contaminants.[19] Since some of the residue that FSIS is supposed to prevent from entering the food supply comes from pesticides, FSIS relies on EPA to set tolerances for acceptable levels of pesticides.[20] Similarly, FSIS relies on FDA to set tolerances for veterinary drugs and heavy metals that may find their way into beef.[21] Coordinating these three agencies' work is a challenge. However, when Federal agencies are given the task of completing an objective, they are expected to structure their program so that they will be likely to accomplish their desired objectives.[22]

We found that there were several significant problems with how these three agencies cooperated to achieve the national residue program's mission. These coordination problems concerned all phases of detecting residue in the food supply, such as determining: (a) what residues to test; (b) how FSIS will sample for those substances; (c) what constitutes an acceptable tolerance level for hazardous residues; and (d) how the agencies involved should use the test results. These coordination problems have remained unresolved for over 25 years due to the informality of the

[19] Federal Meat Inspection Act of 1906, as amended, 21 U.S.C. and FSIS Red Book.

[20] Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C.

[21] Federal Food, Drug, and Cosmetic Act, 21 U.S.C.

[22] Office of Management and Budget (OMB) Circular A-123.

SAT and the monthly IRCG meetings where the agencies discuss details of how they will cooperate.[23] Specifically, the SAT lacks a charter specifying its mission, goals, agency responsibilities, or who will attend the meetings.

One of the most significant problems with the SAT is that the agencies involved do not send agency decision-makers to the meetings to effect change in their specific organizations and, thereby, improve the effectiveness of the national residue program. When the memorandum of understanding describing interagency cooperation between FSIS, FDA, and EPA was signed in 1984, the agencies agreed to appoint appropriate senior executives to oversee the team. Yet we found that high-level officials from the agencies involved do not currently attend these meetings, and that there is no mechanism for elevating issues, making recommendations, and ensuring that appropriate actions are taken to solve identified problems. Without such a mechanism, many problems requiring interagency coordination have not been dealt with despite the agencies' awareness of the problems.[24]

FSIS, EPA, and FDA Need to Expand the Substances They Test For

Each year, the SAT brings together representatives from FSIS, EPA, and FDA to decide which residues they will test for, based on their own prioritized lists. FSIS is responsible for actually performing the tests, so it makes the final decisions on how to use its available resources to test the substances that the agencies determine pose the greatest public health risk. In the Blue Book, FSIS details its process for evaluating the relative risks of various drugs. Annually, FSIS publishes its ranking to test for approximately 120 substances in numerous classes of animals.

We found, however, that FSIS' available resources for testing substances of considerable risk were limited, and that the agency could not test for several residues that were regarded as dangerous. Each year, for instance, EPA asks FSIS to test for 23 pesticide types that the three agencies have together determined to be high health risks, but EPA officials complain that FSIS tests for few of these pesticides. According to FSIS, EPA has not, in all cases, provided FSIS with tolerances for how much of these substances in meat would be unsafe for human consumption. Without this information, the tests would be of limited usefulness. EPA generally sets tolerances for pesticides in soil and water, but those tolerances do not necessarily apply to beef or other sorts of meat. We found that in 2008, FSIS ranked 23 types of pesticides in the Blue Book but only tested one type. FSIS did not test for 2 other types of pesticides that were ranked as high and were considered as dangerous as the one that was tested.[25]

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[23] Throughout the report, we include IRCG when we refer to the SAT. SAT meetings occur only once a year, so much of the day-to-day business concerning the details of interagency cooperation is dealt with during IRCG meetings.

[24] In the 1986 FSIS Future Agenda report, FSIS identified the need for "[i]mproved interagency coordination and cooperation in order to strengthen the link between testing (detection) and prevention."

[25] The 2008 Blue Book ranked 23 pesticide compound/compound classes yet the only compound class tested was the chlorinated hydrocarbons and chlorinated organophosphates. Two of the compound/compound classes that were not tested ranked the same in every category of concern (including regulatory concern, the ability for the pesticide to bio-concentrate in fat tissue, and toxicity), as the compound/compound class that FSIS tested. The two untested compound/compound classes consisted of Imazalil and the remainder of the chlorinated organophosphates and organophosphates not tested in FSIS' multi-residue method.

EPA officials expressed frustration with this process. They routinely attended the SAT and indicated that more of these pesticides should be tested for, but FSIS continued testing only for the one type of pesticide that it had been testing for many years. FSIS officials, however, responded that their laboratory resources are limited, and that there are competing demands for detecting a wide range of other adulterants. According to FSIS officials, if the agency tests for additional pesticides, then it must take fewer samples to test for *E. coli* or *Salmonella*.

OIG acknowledges that FSIS' laboratory testing resources are not unlimited, and that the agency must make decisions about what it will and will not test for. However, when there are additional substances that the three agencies determine to be of high risk, then the SAT needs to seek executive-level involvement from all three agencies to resolve differences, and, if necessary, to determine the best method for obtaining the needed testing resources to ensure that the highest priority substances are tested.

FSIS, FDA, and EPA Need to Improve Their Methodology for Sampling Hazardous Residues

Once the three agencies involved have determined which substances they will test for, they then decide how they will sample for those substances. Usually, FSIS tests 300 samples for each substance on its list because it determined that this number would help it arrive at statistically valid conclusions regarding the prevalence of residue in the food supply.

We found, however, that different groups—within FSIS and outside—have questioned this sample size, and have reached different conclusions. For example, FSIS laboratory personnel believe that they should be testing more than 300 samples for some residues because they present a greater risk to the public and the agency needs greater confidence concerning the residue's prevalence. However, an outside contractor performing a quality control review recommended that FSIS could perform fewer samples "without a significant loss in precision." The contractor suggested that by testing fewer samples per substance, FSIS could test for more substances, given its limited resources. Additionally, officials from FSIS and FDA agreed that FSIS could likely improve its laboratory efficiency by testing some, regularly used, substances quarterly instead of monthly.

According to FSIS lab officials, the decision to collect 300 samples may have initially been an appropriate statistical target, but the number needs to be reviewed using a structured process that includes formal risk analysis principles. For example, some chemicals tested for are used consistently throughout the year rather than seasonally so FSIS could compress the 300 samples into one quarter without skewing the annual results. Compressing its samples in this way would allow the agency to re-tool its laboratory, and then use its resources to test other compounds. The FSIS official in charge of assessing risk for FSIS' national residue program stated that changing the sample size or timing could be useful, but that residues would have to be evaluated on a case-by-case basis.

We concluded that the SAT is the appropriate forum for discussing issues concerning sample design, but at present, the relevant personnel with appropriate qualifications and expertise do not always attend the SAT meetings and the agencies have not conducted a thorough review of how they design the sample for these residues. FSIS officials stated that the SAT should include experts in risk assessment, statistics, toxicology, and laboratory testing from all three agencies.

These experts would help identify and rank hazards and evaluate test methods, and their opinions would be provided to senior management at FDA, EPA, and FSIS as management finalized the national residue program's annual sampling method. We believe that the agencies should work together to strike a balance between sampling demands and the relative risk of a given compound. Following risk analysis principles, such as hazard identification, risk assessment, or risk ranking would provide FSIS with a scientific and structured approach. We further believe that assessments of sampling design need to be periodically reassessed to adjust to changes in environmental substances and veterinary drug prevalence. This would also allow the agency to optimize its limited laboratory resources.

FSIS and FDA Need to Determine More Efficient Ways of Approving Newer Methods of Testing for Residues

When testing for the various types of residue that the agencies have determined to be high risk, FSIS is unduly restricted in the test methods it can use to detect each type of residue and is prohibited from using more efficient and more effective alternatives. When FDA approves drugs, it only approves one method of testing for that drug's presence. Drug companies submit the testing method as part of FDA's approval process. Once approved, that method becomes the only official way that FSIS can confirm the residue's presence in meat. This test, however, is not always the most efficient way of confirming the presence of residue, because it may have been developed years ago, or used techniques and equipment that are now obsolete. FSIS cannot simply use a new method, even though the new method is quicker, more efficient, or even more accurate. Realizing that new and improved methods would allow FSIS to achieve significant savings in terms of its laboratory resources, agency officials have enlisted FDA's assistance in demonstrating scientifically that the new methods would yield equivalent results compared to the old method. This process is known as "bridging."[26]

We found that, although FDA had stated its willingness to help bridge antibiotic tests for FSIS, there is no formal agreement establishing timeframes and FDA has been slow in making progress, taking more than 2 years to bridge the first substance. For example, to confirm the presence of penicillin, FSIS is, at present, forced to use an antiquated test. It has requested that FDA help it bridge to a new and more efficient test, but in order to do so, FDA has spent months trying to obtain the old machines and then training staff on how to perform the tests on the old equipment. To date, FDA has not completed bridging to this new test method, yet this "bridge" is only the first of several test methods that FSIS officials currently want to see completed. FSIS has requested that FDA bridge "ceftiofur"[27] next, but FDA has declined, stating that bridging this substance would be extremely difficult. One FSIS official stated that FDA's decision not to bridge this substance "demonstrates the difficulty for FSIS in approaching and updating its existing [testing] methods."

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[26] "Bridging" is a process whereby FSIS can scientifically demonstrate that the results of a new testing method correlate with the results from previously used FDA-approved New Animal Drug Application (NADA) testing methods. "Bridging" assures that accurate comparisons can be made between the testing results obtained by various testing methods. "Bridging" data is obtained from analyzing real samples from the field and comparing the testing results of the NADA/enforcement method to a newly-developed FDA testing method. FSIS has determined that "bridging" is necessary for drugs/species/tissues where FDA has established tolerances where there is an NADA method and where quantification is necessary.

[27] Ceftiofur is an antibiotic.

FSIS officials also explained that bridging penicillin is the first step in bringing new equipment online, which will ultimately enable FSIS to test for drugs much more efficiently. Over the long-term, however, bridging is not an optimal solution because test methods will continue to change, and today's method will have to be bridged to tomorrow's. We found that FDA and FSIS do not agree on the best long-term solution to this problem. Some FSIS officials stated that they should be moving to a performance-based approach like those used in the European Union.[28] Moving from the FDA's method to a performance-based approach would allow for new technology to be implemented immediately without the need for any bridging work. Transitioning to a performance-based approach would also parallel EPA's approach since EPA considers performance specifications to be acceptable. As a result, there is no bridging work required with EPA-regulated contaminants.

FDA, however, has reservations about performance-based testing, and has instead proposed to encourage drug companies to: (1) use the most practical methods available when the drugs are approved; (2) consult with FSIS on the chosen methods; and (3) keep their tests up-to-date. Both agencies agree that until this problem is solved, FSIS will be unable to test for residues as efficiently as possible.

We concluded that FSIS and FDA should cooperate to develop a plan for improving their efficiency in approving newer methods for FSIS to use in testing for residues. The status quo is not acceptable because it impairs FSIS' efficiency in testing for residues. Using more efficient methods would allow FSIS to take advantage of advanced technologies as they become available.

FSIS, EPA, and FDA Need to Collaborate to Set Tolerances for Additional Residues

If FSIS confirms the presence of residue in a sample of meat, it needs a "tolerance" or a threshold for determining if the concentration of that residue is dangerous for human consumption. For example, FDA has set a tolerance of .05 parts per million for penicillin in beef, so FSIS knows that beef with 10.62[29] parts per million should be excluded from the food supply. FSIS relies on FDA to set tolerances for drugs and heavy metals and EPA to set tolerances for pesticides and environmental contaminants.

Although many veterinary drugs have established tolerances, we found that tolerances have not been set for many potentially harmful pesticides and heavy metals, or for substances that were once legal but have since been made illegal. Without tolerances, FSIS often lacks justification for acting to prevent the meat from entering the food supply. For example:

- Unlike other countries, FDA has not set a tolerance for copper. As a result, in 2008, when Mexican authorities rejected a shipment of U.S. beef because it contained copper in

[28] According to FSIS officials, "[m]odern scientific thought process is to follow a performance-based approach where a method is compared to an expected performance characteristic such as a detection level or recovery. This approach allows for different regulatory authorities from different countries to use different analytical methods while achieving the same human health protection level."

[29] The cited example is a confirmed 2009 penicillin residue violation, which was detected in the muscle of a cow from a dairy farm in Idaho.

excess of Mexico's tolerances, FSIS had no basis to stop distribution of this meat in the United States.[30]

- Unlike other countries, FDA has not set a tolerance for arsenic. In 2008, a producer self-reported that arsenic had been mistakenly ingested by his cattle, and voluntarily withheld contaminated animals from the food supply after they were slaughtered and tested positive for arsenic poisoning. If the producer had not acted voluntarily, FSIS would not have had a basis to stop distribution of this meat once it was in commerce.

Both heavy metals and pesticides need tolerances established so that FSIS can take appropriate regulatory action when it finds unacceptable traces of these substances in meat. While some heavy metals like copper and arsenic exist in nature, others are by-products of industry and veterinary drugs formulations, and accumulate in the water, agricultural soil, and residential soil. Apart from the tolerance for arsenic in poultry, there are no established tolerances for heavy metals, such as lead, cadmium, copper, or arsenic in meat. Since other countries have established tolerances for heavy metals in meat, the lack of tolerances in the U.S. could potentially have a detrimental effect on U.S. beef exports, because other countries may question the willingness of our meat industry to control hazardous residues.

The need for tolerances has been a longstanding issue for the national residue program, as the National Academy of Sciences recommended that tolerances should be established for "all 'important substances' or chemicals" in 1985.[31] When we spoke to officials at the FDA and FSIS about these problems, FSIS officials stated that they felt they needed these tolerances. However, FDA officials explained that setting tolerances is a time-consuming, resource-intensive process and since they had not been asked to set thresholds for many of these substances, they have not done so.

In addition, there are no established action levels for persistent organic pollutants, such as dioxin, polybrominated diphenylethers (fire retardants), and pesticides with cancelled registrations. EPA recently cancelled the use of all pesticide products containing the pesticide lindane,[32] which means that the agency will also revoke the current lindane tolerance. One FSIS official stated that without a tolerance or a zero tolerance if FSIS finds lindane as a residue, it will have no basis for acting to protect the U.S. food supply from unacceptable levels of this pesticide. Another FSIS official disagreed and noted that in the absence of a tolerance (e.g., for lindane) any residue of a pesticide would be illegal and would adulterate the food – making it unnecessary to create a zero tolerance. Regardless of their position, both officials agreed that the agency needed to clarify its procedures regarding the actions agency personnel are to take concerning the disposition of carcasses that contain a potentially hazardous substance where no official

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[30] The documentation provided to OIG by FSIS did not indicate the number of pounds of product that were involved or where it was distributed.

[31] Taken from "Meat and Poultry Inspection: The Scientific Basis of the Nation's Program, Prepared by the Committee on the Scientific Basis of the Nation's Meat and Poultry Inspection Program, Food and Nutrition Board Commission on Life Sciences National Research Council," National Academy Press, Washington, D.C. 1985, and FSIS Future Agenda, Response to the National Academy of Sciences Recommendations, June 1986

[32] Since 1998, pesticide companies have voluntarily cancelled a large number of lindane uses, including direct treatment of livestock, fallow areas, forestry areas, and alfalfa and soybean fields. By 2002, all lindane uses were voluntarily cancelled, except seed treatments; those uses have since been cancelled. Lindane side effects include neurotoxic effects and liver and kidney toxicity. Infants and children may be more susceptible to the potential adverse effects of lindane than adults.

tolerance has been established by FDA or EPA. These officials also informed us that FSIS is currently developing guidance to address this situation.

OIG maintains that FSIS, working with EPA and FDA, needs to develop a formal plan with reasonable timeframes to establish policies and procedures for handling hazardous substances with no tolerances, such as heavy metals, animal drugs, and environmental contaminants, including pesticides with cancelled registrations. FSIS also needs to develop and implement detailed procedures that specify the actions agency personnel are to take regarding the disposition of carcasses that contain potentially hazardous substance(s), when there are no formal tolerances established by EPA or FDA.

FSIS Needs to Share the Results of its Tests More Rapidly

When FSIS concludes its annual testing, it publishes the results in its Red Book; however, the book is not published for up to 12 months after the test period ends.

Officials from EPA and FSIS complained about the timeliness of this publication, noting that the test results were old by the time they were published. FSIS officials noted that publishing the red book takes considerable time because a small staff of scientists must manually analyze the testing data, edit the document, and at the same time perform their normal duties. One FSIS official stated that he believes its agency scientists should not be spending their time editing the Red Book.

EPA and FDA officials told us that their research capabilities would be enhanced if they had direct electronic access to FSIS' raw test results. FDA officials also stated that they would like access to both positive and negative FSIS sample test results instead of just violations, so that they can perform trend analyses on the rate of violations compared to the total number of samples tested, among other analyses. FSIS officials responded that they were unaware of FDA's and EPA's data needs, but would be willing to work with these agencies to provide the necessary data in the future.

FSIS, EPA, and FDA Should Involve Non-Governmental Advisors in the Selection of Residues to Test

We also noted that the three agencies could improve how they administer the national residue program by encouraging those outside government—such as industry leaders, farmers, and veterinarians—to provide insight from their field of expertise. These individuals could provide useful information concerning which drugs are currently being given to cattle and therefore might enter the food supply. In general, the agency officials we spoke to were receptive to this idea. In the United Kingdom, non-governmental advisors participate in the British equivalent of the SAT; they generally have more current knowledge about the drugs veterinarians are administering. Since the outside contractor who performed a quality control review of the SAT noted that the team lacked up-to-date knowledge concerning what drugs and pesticides are "in vogue," following the British model and involving non-governmental advisors might help to improve this knowledge base.

FSIS officials agreed that private sector participation would reflect up-to-date scientific advances and provide valuable information for the national residue program, such as current marketing

data for veterinary drugs and pesticides, new technology, and methodology to assess dietary exposure. Current marketing data for the production and sale of veterinary drugs and pesticides would indicate which products are being sold in large quantities, and thus are being used often. According to FSIS, a viable option would be to hold annual meetings with the drug industry and private practitioners to seek their input. Findings from these meetings could then be used at the government-only the SAT meeting.

We concluded that FSIS needs to take a number of steps to strengthen coordination with EPA and FDA relating to the national residue program, beginning with improving the SAT. In coordination with EPA and FDA, FSIS also needs to take steps related to expanding the substances they test for, setting tolerances for additional residues, improving their methodology for sampling hazardous residues, and determining more efficient ways of approving newer methods of testing for drug residues.

Recommendation 1

Through discussions with senior management and executive level officials at the HHS/FDA and EPA, draft and propose:

1) a revision to the 1984 MOU to ensure that it formally establishes the SAT and IRCG and addresses the specific concerns of all three agencies;

2) a charter for the SAT and IRCG, laying out, at a minimum, the specific mission, goals, and agencies' responsibilities and specifying the level of participants, attendees' required qualifications, and the various disciplines to be represented; and

3) a process for elevating issues and potential recommendations identified in the SAT and IRCG to executive-level officials in order to gain a response and ensure actions are taken for timely resolving the interagency issues or problems discussed at these meetings.

Formalize the MOU, the charter, and the process for elevating issues and potential recommendations when agreements are reached on the draft proposals.

Agency Response

FSIS will schedule meetings with senior management and executive level officials at the HHS/FDA and EPA to attempt to establish guidelines for the context of a revised MOU between the three agencies. FSIS will review the 1984 MOU and revise and update, as applicable, FSIS commitments regarding FSIS responsibilities to the national residue program and FDA and EPA. After an internal clearance process, FSIS will share these revisions with FDA and EPA for their comment. The revised document will include language on collaborative periodic reviews.

FSIS will attempt to solicit input from FDA and EPA to draft a charter for both the SAT and the IRCG. Both the SAT and IRCG were established by the 1984 MOU but little detail is provided as to their structure. The draft charters will include statements on mission, goals,

and clearly stated responsibilities of each agency to the mission and goals of the groups as well as to the other agencies.

Because formalizing the MOU will require agreement by both FDA and EPA, FSIS will provide the draft charters for the SAT and IRCG, as well as a draft Standard Operating Procedure (SOP) that outlines the process of elevating issues and recommendations discussed within the SAT or IRCG to executive level officials for closure of the recommendation.

FSIS intends to complete these draft documents by March 2011.

OIG Position

We accept FSIS' management decision.

Recommendation 2

Through discussions with the SAT, develop formal plans and reasonable milestones to ensure that the national residue program has the resources it needs to test for all substances identified by the SAT as posing a high risk to public health.

Agency Response

FSIS will assess the chemical residue program to identify high risk chemicals that could potentially contaminate the food supply. Using the Surveillance Advisory Team model and under the leadership of the Office of Public Health Science Risk Assessment Division's Chemical Residue Risk Branch, FSIS and the other members of the SAT will identify and rank high-risk chemicals. FSIS will evaluate and, if needed, redesign its residue sampling program to ensure that sampling for high-risk residues is prioritized in view of available resources. FSIS intends to complete this assessment by March 2011.

OIG Position

We accept FSIS' management decision.

Recommendation 3

Through discussions with the SAT, establish policies and procedures with reasonable timeframes to perform a structured, periodic review of FSIS' sampling methodology regarding the number and timing of samples taken, using formal risk analysis principles focused on public health outcome and aimed at improving laboratory efficiency. Revise FSIS' sampling methodology based on the outcome of the review.

Agency Response

FSIS will work with FDA and EPA to develop a SOP for managing the national residue program including timelines for structured, periodic review of the national residue program design. On an annual basis and prior to the convening of the SAT, FSIS will analyze the violative tissue results of both the scheduled sampling program and the inspector-generated program to inform the annual scheduled sampling program. When possible, a risk-based approach will be used to determine priority in scheduling that takes into account public

health and laboratory efficiency. A final report documenting the decision making process, including decisions made using expert elicitation, will be generated and made available to members of the SAT. FSIS will develop and clear internally a draft SOP outlining the process for designing and reviewing the annual program. FSIS intends to complete the draft SOP by March 2011.

OIG Position

We accept FSIS' management decision.

Recommendation 4

Through discussions with FDA senior management, draft and propose a process to expedite approval of new testing methodologies for FSIS. Include initiating a formal study to determine the merits of a performance-based, or other new, approach for regulatory analysis and for testing new drugs in the future. Formalize the proposals and include milestones for completion once agreements are reached, beginning with a formal agreement to bridge the testing method for animal drugs FSIS currently needs.

Agency Response

FSIS is actively pursuing discussions with the leadership at the FDA's Center for Veterinary Medicine and other FDA offices to develop a process to expedite the development of new methods that FSIS can use for chemical residue testing programs. The initial meeting took place in Shepherdstown, WV, on February 18, 2010. FSIS is also planning a "Residue Summit" in the Spring of 2010 where key Agency representatives from all relevant FSIS programs will be able to identify and discuss residue related issues, and then develop plans to address identified needs. One of the outcomes of these discussions will be a proposal from FSIS to the FDA that will outline and propose (1) a smooth process to approve performance-based multi-residue methods, and (2) a system and process to compare these new performance-based methods with the FDAs approved (NADA) methods, which may include the use and availability of incurred tissue. FSIS intends to complete the proposal by March 2011.

OIG Position

We accept FSIS' management decision.

Recommendation 5

Through discussions with EPA and FDA, develop a formal plan with reasonable timeframes to establish policies and procedures for handling hazardous substances with no tolerances, such as heavy metals, animal drugs, and environmental contaminants, including pesticides with cancelled registrations. Formalize the policy and procedures when these agreements are reached. Also, develop and implement detailed FSIS procedures that specify the actions agency personnel are to take regarding the disposition of carcasses that contain potentially hazardous substance(s), when there are no formal tolerances established by EPA or FDA.

Agency Response

FSIS will include this issue in the draft MOU and SOP discussed in the response to Recommendation Number 1. FSIS will issue a Notice or other policy document regarding actions it will take in regard to carcasses that contain hazardous substances for which there are no formal tolerances. FSIS intends to complete the draft MOU and SOP and to issue the FSIS policy document by March 2011.

OIG Position

We accept FSIS' management decision.

Recommendation 6

Through discussions with the SAT, develop a formal plan with reasonable timeframes to facilitate the exchange of residue testing data between FSIS, EPA, and FDA to enhance the opportunities for expanded research and identification of trends in violations.

Agency Response

FSIS will include this plan in the draft MOU and SOP discussed in the response to Recommendation Number 1. FSIS intends to complete the draft MOU and SOP by March 2011.

OIG Position

We accept FSIS' management decision.

Recommendation 7

Develop a formal plan with reasonable timeframes (include EPA and FDA to the extent practical) that requires FSIS personnel to, at least annually, canvass the drug industry, private practitioners, and other non-governmental experts to obtain information, such as current marketing data for veterinary drugs and pesticides, new technologies, and methodologies to assess dietary exposure for use at the SAT meetings in determining compounds to test.

Agency Response

FSIS will use information systems similar to the *National Animal Health Monitoring System* (NAHMS) maintained by the Animal and Plant Health Inspection Service to better inform the SAT during the process of developing the annual national residue program. Specifically, FSIS will review NAHMS reports detailing the most current drug usage data and compare to most recent list of compounds tested under national residue program. FSIS will document the consideration and decision to include or not include compounds indicated by NAHMS reports but not tested under the national residue program. FSIS will produce a final report after the SAT meetings as a record of the rationale supporting decisions made. FSIS intends to complete this final report after the SAT meetings by March 2011.

OIG Position

We accept FSIS' management decision.

Section 2: FSIS Needs to Strengthen Oversight at Plants and Upgrade the National Residue Program's Technology

Finding 2: FSIS Needs to Strengthen Oversight of the National Residue Program, Especially at Plants Slaughtering Dairy Cows and Bob Veal

FSIS has not required that slaughter plants processing dairy cows and bob veal implement adequate controls to ensure that residue is not entering the food supply, even though these plants are at much higher risk than plants processing beef cattle. This has occurred because Hazard Analysis and Critical Control Point (HACCP) principles allow slaughter plants themselves to make the determination as to whether residue problems were "reasonably likely to occur"—the threshold for implementing additional controls—and the primary function of the FSIS plant-level personnel is not to challenge the hazardous risk assessment but to verify or monitor the plant's application of the existing controls. FSIS did not exercise additional oversight despite the fact that plants handling dairy cows and bob veal were responsible for over 90 percent of residue violations in 2008.[33] Agency officials had not performed the analysis necessary to determine that violations were concentrated within dairy cows and bob veal, and they regard residue as a lower priority than other sorts of adulterants, such as *E. coli* and *Salmonella*. As a result, in 2008, one plant amassed as many as 211 violations—another had 21 producers with multiple violations—and other plants treated residue as a problem "not reasonably likely to occur" (see Table 1, below). Furthermore, we verified that at least four beef carcasses were adulterated with violative levels of residue, entered commerce, and were not recalled by the slaughter plant or FSIS.[34]

The following table summarizes the number of residue violations at 7 selected cattle slaughter establishments during the 2008 calendar year. The violation data was taken from the Residue Violation Information System (RVIS).[35] This information includes OIG's assigned plant identification number (1 – 7), the number of residue violations at each plant, the number of repeat offenders that delivered cattle to the plant, the number of residue violations that occurred at the plant from repeat offenders, and the overall percentage of residue violations at the plant that came from repeat offenders.

[33] The 2008 data from the RVIS database was the most recent full calendar year information available at the time of our field work.

[34] Since FSIS did not request a voluntary recall by the establishments, the plants did not collect the production data necessary for FSIS to determine the number of pounds of product from the four carcasses with the violative amounts of Ivermectin, Sulfadimethoxine, Florfenicol, and Sulfamethazine.

[35] During the course of our audit, we did not verify information in the RVIS, and make no representation of the adequacy of the system or the information generated from it.

PLANT	VIOLATIONS	REPEAT OFFENDERS	VIOLATIONS FROM REPEAT OFFENDERS	PERCENT OF VIOLATIONS FROM REPEAT OFFENDERS
1	211	12	24	11 percent
2	196	21	57	29 percent
3	102	6	14	14 percent
4	90	9	22	24 percent
5	58	1	2	3 percent
6	50	3	6	12 percent
7	42	7	17	40 percent

FSIS' mission is to ensure that the Nation's supply of meat is wholesome. The agency accomplishes this mission, not by directly inspecting every meat product, but by working with slaughter plants to ensure that the plants have instituted controls necessary to ensure that meat is wholesome. In general, plants are expected to establish controls when they determine that a hazard is "reasonably likely to occur." Once plants have determined that a hazard is reasonably likely to occur, they have increased responsibilities for implementing controls to prevent, reduce, or eliminate risk from that hazard.

Improving HACCP Oversight of Residue

When the HACCP process was originally implemented, FSIS debated how best to implement controls for residue, but that debate was never concluded. For HACCP purposes, 9 of the 13 plants we visited concluded that residue was not "reasonably likely to occur,"[36] which meant that they did not need to establish critical control points to detect and eliminate residue once it had entered the plants. Some plants felt that they had adequate preventive measures to stop contaminated cattle from entering plants; other plants felt that residue was being detected at their plant at a rate no higher than the national average, and so no additional controls were necessary. As a result, FSIS was left to institute its own controls for sampling and detecting residue, and the plants simply reacted to any positive findings FSIS identified.

OIG concluded that this status quo is not acceptable because we found that residue is a hazard "reasonably likely to occur" in the absence of preventive controls within two production classes of the animals sent to slaughter in the United States—dairy cows and bob veal. Unlike cattle raised for meat, dairy cows are usually slaughtered when they are near the end of their

[36] We visited 13 plants which had a combined total of 571 violations. The 9 plants that determined residue was not reasonably likely to occur had 329 of the 571 violations.

productive usefulness. They frequently have been medicated to increase their productive longevity, and so they can reach the slaughterhouse with a variety of antibiotics and animal drugs in their system. Similarly, some bob veal are fed medicated feed/milk replacer to increase their longevity or they are fed milk from cows that have been medicated sometime during the course of their lactation cycle, making the cow's milk unmarketable for human consumption and requiring a mandatory withdrawal period. Instead of disposing of the milk, farmers feed this waste milk to their calves. As a result, these drugs can find their way into meat being sold to U.S. consumers. According to our analysis of FSIS' RVIS data, over 90 percent of the violations for residue were found in dairy cows and bob veal. This strongly indicates that residue is a problem localized within slaughter plants that handle these classes of animals.

Within these plants, residue is much more likely to occur than in plants handling only cattle raised for beef. In 2007, the national average for residue violations at all slaughter plants was 2 violations per plant, but we found instances in which plants handling dairy cows or bob veal had as many as 211 violations. OIG visited 5 of the 7 plants with the most residue violations in 2008, and found that 4 of the 5 plants had determined that chemical residue hazards were "not reasonably likely to occur." Yet, these 4 plants had a combined total of 284 violations for an average of 71 violations per plant in one year.[37] Since the rate of residue violations for dairy cows and bob veal (over 90 percent) exceeds the rate of residue violations for beef cattle (4 percent) by a factor of 23, we concluded that meat from dairy cows and bob veal is much more likely to be adulterated with harmful residue.[38]

Moreover, a small subset of producers account for a significant portion of this problem—repeat violators. Of the cattle with harmful residue brought to the slaughterhouse by repeat violators, 94 percent were dairy cows or bob veal. These repeat violators included individuals who have a history of picking up dairy cows with drugs in their system and dropping them off at the plant. At the plant that had 196 violations in a single year, 21 producers were repeat violators, including 8 who had 3 to 6 violations each. Another plant had 42 violations, with 7 producers having repeat violations that accounted for over 40 percent of the violations at that plant.[39] FSIS has recognized that much of the residue problem occurs because certain establishments repeatedly purchase animals from the same sources, and those sources have a history of presenting animals with drugs in their system.

Based on this information, OIG concluded that FSIS could take steps to control the residue problem by focusing on plants that handle a high volume of dairy cows, and taking special precautions when dealing with repeat violators. Since some plants involved have already assessed themselves and have incorrectly determined that residue is not likely to occur at their establishment, FSIS must better enforce how plants arrive at their HACCP assessments, require plants with violations to improve their controls, and increase its own oversight of such plants. As part of that oversight, it should perform more thorough assessments to evaluate whether

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[37] The 5 plants that OIG visited had a total of 495 residue violations (41 percent of all the violations in 2008).

[38] From our analysis of the RVIS data for 2008, we determined the following violation rates: dairy cows, 67 percent; bob veal, 24 percent; beef cattle, 4 percent; heavy calves, steers, heifers, bulls, calves, cows, formula fed calves, and non-formula fed calves each had a 1 percent or less violation rate.

[39] This particular plant said that residue was not reasonably likely to occur because it used a notification system to inform producers when they had a violation.

plants have adequately supported their determination that residue is a hazard reasonably likely to occur or not, and should ensure that plants have implemented appropriate controls to address the risk.

In order for FSIS and the plants to focus on repeat violators, however, they must be able to identify the producers of the cattle being slaughtered at their plants. Since 1986, FSIS has been aware that identifying the producers of contaminated cattle is a problem because dairy cows often pass through several hands (buyers) before they are slaughtered, and it can be difficult to trace a residue violation to the responsible party. During the course of our audit, FSIS posted a list on its public website that began identifying the source suppliers of cattle for slaughter that have received one or more residue violations since January 2009 (referred to as the "same source supplier list"). The list is available to plant owners so they can turn away or refuse to purchase animals from these same source suppliers. While OIG recognizes that this is a positive step, this list is only effective if the plant owners or FSIS veterinarians can identify the responsible producers of animals purchased, so that these persons can be matched up against the list of repeat violators on the same source supplier list. Unfortunately, however, plants cannot always identify source producers of animals purchased through livestock auctions or sales facilities and traders may not provide a complete listing of animal owners when they present their livestock for slaughter.

Fundamentally, this problem will never be solved until plants require those bringing their animals to slaughter to identify the animal's producer so that any residue-related problems can be traced back to that owner's farming practices. FSIS officials commented that their authority over plants does not allow them to make producer identification prior to slaughter a requirement. However, unlike information for mature cattle, FSIS already has the regulatory authority it needs to require this information for bob veal, though we noted that, in at least one case, FSIS was not enforcing these regulations.[40] At one bob veal plant we visited, we learned that between July 14, 2008, and June 18, 2009, one source supplier had 20 violations, yet the inventory sheet he provided the plant only showed the number of calves he picked up from dairy farmers and not the names of the individuals who produced the cattle. Without this information, FSIS could not identify repeat offenders, only the individual who dropped the cattle off.

In our view, FSIS should obtain the necessary regulatory authority, similar to that for bob veal, to require plants to identify possible residue violators during ante-mortem inspection for potentially additional post mortem residue testing. Also, FSIS should establish procedures that provide incentives for the plants with a history of residue violations to voluntarily request producer identification for any animal presented for slaughter. When plants receive the producer identification prior to slaughter, FSIS then has the ability to subject the animals to additional testing, as prescribed in FSIS Notice 04-09, "How to Proceed in Establishments that have Multiple FSIS Laboratory Confirmed Residue Violations from the Same Source Supplier." This notice requires that four subsequent shipments be subject to additional testing before a violator can be ruled as residue-free. An FSIS official agreed that without any preliminary producer identification from such institutions as livestock sales, the only producers that Notice 04-09 would realistically affect would be those producers who sold their animals directly to the plant.

[40] 9 Code of Federal Regulations 309.16(d)(2) states that "[t]he identity of the producer of each calf presented for ante-mortem inspection shall be made available by the official establishment to the inspection [inspector] prior to the animal being presented for ante-mortem inspection."

If a plant does not maintain the names of the animals' producers, OIG believes that FSIS should subject every shipment of cattle to that plant from unknown producers to additional on-site screening for potential residue testing.

Although FSIS maintains repeat violator information in the form of the same source supplier list, FSIS does not have a formal process to track whether the number of repeat residue violators is increasing or decreasing from year to year. However, USDA does measure how effective industry has been in reducing the public's overall exposure to pathogens like *Salmonella, Listeria Monocytogenes,* and *E. coli,* which are also contaminants found in beef products. These three measures are included under Strategic Goal 4, Enhanced Protection and Safety of the Nation's Agriculture Food Supply in the USDA's Annual Performance and Accountability Report. With both pathogens and residues USDA monitors establishments' compliance with science-based food safety systems, which are the foundation for preventing and controlling contamination of the food supply, during slaughter and processing. The responsibility is on the slaughter facility to implement systems for monitoring and controlling these types of contamination. However, USDA has established performance measures only for pathogens but not potentially harmful residues. Therefore, we believe that FSIS should establish additional performance measures for residues and consider including them in Strategic Goal 4, along with tracking changes in the rate of repeat residue violations over time.

We also noted that, although the problems discussed in this finding pertain only to cattle, especially dairy cows and bob veal, similar problems might exist for some of the other production classes FSIS monitors—from bison to geese to rabbits. FSIS should periodically review data relating to residue violations involving not only cattle, but also these other production classes so that it can take steps to vigorously enforce specific residue standards for these animals as well.

FSIS Does Not Recall Meat Contaminated with Harmful Residue

It is especially important that FSIS take steps to strengthen its preventive controls over contaminated animals entering the slaughter plants because we found significant weaknesses in how the agency recalls beef that is adulterated with residue and yet has been released into the food supply. Although the agency can request that plants voluntarily recall this meat, it has not done so since 1979 according to an agency official. FSIS officials explained that recalls of meat contaminated with residue are difficult to enforce, because they cannot show that eating a single serving of the product is likely to result in immediate sickness or death, as would consuming a serving of beef adulterated with *E. coli* or *Salmonella.* Instead, the effects of residue are generally chronic as opposed to acute, which means that they will occur over time, as an individual consumes small traces of the residue. In addition, FSIS must request that a U.S. Attorney file for the product seizure in federal district court if the plant refuses the voluntary recall.[41] According to FSIS officials, seizure of the product is not likely where only a small amount of residue-adulterated product is concerned, e.g., product from a single carcass. However, FSIS documentation describes that the "inappropriate use of antibiotics is undesirable for two main reasons. Residues may produce toxic or allergic reactions in susceptible

[41] According to FSIS officials, the seizure would be pursuant to 21 USC 673.

individuals who eat meat or poultry that contains antibiotic residues; and microorganisms may develop resistance to frequently used antibiotics."[42] Based on this documentation and FSIS' vigilant actions to prevent mad cow disease—a food-borne hazard with a low probability of occurring[43]—OIG believes the agency should take aggressive steps to prevent the harmful effects of residue, whether chronic or acute.[44]

When FSIS takes scheduled samples, plants sometimes do not hold the sampled carcass until the test results are returned. Between July 12, 2007, and March 10, 2008, FSIS took scheduled samples and found that four carcasses were adulterated with violative levels of veterinary drugs, such as Ivermectin, Sulfadimethoxine, Florfenicol, and Sulfamethazine.[45] The plants involved had released the meat from these carcasses into the food supply. Consuming these drugs could result in stomach, nerve, or skin problems, but FSIS ordered no recall. Officials stated that when meat enters commerce and FSIS orders a recall, the decision to actually recall the meat is voluntary on the plant's part. If the plant refuses to recall the product then the agency must take legal action and prove that the product is unfit for consumption. To do this, it must prove that consuming a single serving of the adulterated meat is likely to cause harm. In this example, FSIS determined that consumers were not likely to be acutely harmed by this meat. We noted there have been other situations when product has entered commerce with potentially "low" adverse health risks (e.g., the product was produced from animals that had not received a proper ante-mortem inspection), and FSIS has still requested that the establishment initiate a Class II recall and the plants actually did issue a recall (e.g., Hallmark).

We concluded that FSIS needs to provide incentives to prevent plants from releasing potentially adulterated product before residue tests are confirmed, and strengthen its recall process so that when residues are found, plants voluntarily trace and recall meat that is found to have violative levels of residue. FSIS needs to establish a policy to use alternative procedures to recall (such as issuing public health alerts) when violative levels of residue are found in meat that do not result in an acute risk.

Recommendation 8

Develop a plan to identify slaughter plants where residue violations have a history of occurring and to set specific timeframes for conducting assessments to evaluate whether those plants have made the proper determination or adequately supported their determination whether residue is a hazard reasonably likely to occur. Require these plants to implement

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[42] FSIS, OPHS MLG34.02 Title: Bioassay for the Detection, Identification and Quantitation of Antimicrobial Residues in Meat and Poultry Tissue, effective May 02, 2007.

[43] FSIS officials explained that consuming certain portions of an animal affected with mad cow disease (bovine spongiform encephalopathy) could introduce the prions that cause new variant Creutzfeldt–Jakob disease. Although a very small number of cases of mad cow disease have occurred in the United States in comparison to cows adulterated with chemical and drug residues, FSIS officials view the possibility of mad cow disease as an acute problem warranting recalls, as opposed to the chronic problem related to residue exposure

[44] Penicillin residues could cause potentially life-threatening allergic reactions in individuals susceptible to penicillin.

[45] These four substances are anti-parasitic or anti-bacterial agents. Our analysis of the FSIS residue violation database identified a total of seven carcasses that were adulterated with violative levels of residues that entered commerce and were never recalled by the establishment. Three of the carcasses were found to be violative before FSIS issued Directive 10,800.1, July 12, 2007. Prior to the issuance of this directive, FSIS personnel were not required to inform plant management that scheduled samples were being collected or that plant management should consider holding the tested carcass. The new directive, however, stated that "FSIS inspection program personnel should inform the establishment that the Agency recommends that industry hold these scheduled sample carcasses until FSIS reports the results to prevent a recall if the laboratory detects a residue as a violative level." The plant, however, may or may not choose to hold the carcass.

appropriate controls to prevent, detect, and eliminate harmful residues commensurate with the level of risk, e.g., number of violations being identified at the plants.

Agency Response

FSIS staff at Office of Field Operations Headquarters, in partnership with the Office of the Chief Information Officer, has already started generating residue violation history by District, by month. FSIS will expand this program to break this data down further for cattle slaughter plants in each District. This information will be made available monthly to the District Veterinary Medical Specialist in each District for their follow-up action via the in-plant Public Health Veterinarian, so the latter may discuss these findings monthly with the plant management.

Plants where residue violations occur repeatedly, are required to address in their HACCP program the prevention, detection, and elimination of these hazards from the product they market for human consumption using the guidelines published in the Federal Register Notice 70 FR 70809, November 28, 2000, entitled "*Residue Control in a HACCP Environment.*" Also, FSIS enforces the guidelines published in FSIS Notice 03-10 dated January, 12, 2010: "*How to Proceed in Establishments that have Multiple FSIS Laboratory Confirmed Residue Violations from the Same Source Supplier.*" FSIS intends to complete the expansion of residue violation history by March 2011.

OIG Position

We accept FSIS' management decision.

Recommendation 9

Obtain the necessary regulatory authority, similar to that for bob veal, to require slaughter plants where residue violations have a history of occurring to identify the producers of all animals presented for slaughter and compare those to the same source supplier list for the required additional testing. Establish formal procedures to enforce the new identification requirement at plants with repeat violations and for bob veal.

Agency Response

Although establishments are required to maintain records showing the person from whom they purchased animals, in many cull cow establishments, that person often is not the producer. Without knowing the name of the producer, purchasers cannot consult the FSIS "Same Source Supplier - Residue Violator List" to determine whether the animal is being supplied by a producer with a history of residue violations, and thus assess the risk in buying the animal. FSIS will take two steps to address the issues presented in Recommendations 9 and 10. First, it will prepare a compliance guide to make sure that establishments understand why it is in their interest to inquire of anyone who is offering to sell them animals, such as an auction barn or an itinerant seller of animals, about the name of the producer. Second, in addition to the compliance guide, FSIS is creating the following incentives and disincentives to encourage establishments to only buy from a source that can and will identify the producer:

(1) Incentives: Plants must make every effort to ensure animals purchased for food production are free from violative levels of residues. Plants that demonstrate a history of compliance are tested at a frequency less than those with a poor history of compliance.

(2) Disincentive: For plants that continue to purchase animals from a source supplier with repeated residue violations, FSIS will follow the guidelines under FSIS Notice 03-10. This will include:

   a. Testing of two or more animals each time the establishment receives animals from the same or any unknown source, up to 100% of animals presented.

   b. Continue this level of testing until four consecutive shipments from a known supplier are negative.

   c. For additional violations after issuing a Memorandum of Interview, the Public Health Veterinarian will

      I) Issue a Noncompliance Record citing 9 Code of Federal Regulations 318.20 to document the establishment's failure to prevent slaughter of residue violative animals.

      II) At weekly meetings, discuss findings to point out establishment's failure to prevent this hazard.

      III) Link the findings to Noncompliance Records, as appropriate.

      IV) Assess whether the HACCP system is adequate under 9 Code of Federal Regulations 417.6 and Rules of Practice.

FSIS intends to complete the compliance guide by March 2011.

OIG Position

We accept FSIS' management decision.

Recommendation 10

Until regulatory authority is obtained, develop formal policies and procedures that provide (1) an incentive for plants to voluntarily seek producer identification on animals arriving for slaughter for comparison with plant or FSIS residue violators lists; and (2) a disincentive for plants that continue to purchase from suppliers/producers with repeat residue violations, such as subjecting shipments from unidentified producers to additional on-site screening for potential testing if the plant cannot demonstrate that incoming animals are not at high risk for violative levels of residue.

Agency Response

In response to the official draft, FSIS provided the same response to Recommendation 10 as Recommendation 9 above. As noted above, FSIS expects to complete corrective actions regarding these recommendations by March 2011.

OIG Position

We accept FSIS' management decision.

Recommendation 11

Develop a process for periodically reviewing residue violation data relating to all production classes and taking necessary steps to enforce food safety standards if violations show a significant increase. Include within the process performance measures as a standard for evaluating the agency's progress in reducing the amount of residue in meat products, such as reducing the number of repeat residue violators over time.

Agency Response

A process for periodically reviewing residue violation data relating to all production classes has already been established. Monthly updates will be provided to the FSIS inspection personnel via the District Veterinary Medical Specialist in each District. Necessary steps mentioned above in Recommendations 8 and 10, would be used to enforce food safety standards if violations show a significant increase. While the industry will be held responsible for reducing violative residue levels, FSIS-Office of Field Operations will enforce FSIS Notice 03-10 to ensure appropriate action is taken to reduce the likelihood of same source residue violations. FSIS intends to provide the monthly updates by October 2010.

OIG Position

We accept FSIS' management decision.

Recommendation 12

Provide incentives to prevent plants from releasing potentially adulterated product before residue test results are confirmed and for plants to voluntarily trace and recall meat that is found to have violative levels of residue. Establish a policy to use alternative procedures to recall when violative levels of residue are found in meat that do not result in an acute risk, such as issuing public health alerts.

Agency Response

FSIS intends to announce a tentative policy determination that no product that has been tested for an adulterant will receive the mark of inspection until the test results are back, and the product has been found to be negative for the adulterant. This action, more than providing an incentive, will prevent potentially adulterated product from entering commerce. While FSIS is considering make some exceptions to this policy, for example for poultry, which has virtually no history of violative residues, this action should fully address OIG's concern. FSIS intends to announce this policy determination by March 2011.

OIG Position

We accept FSIS' management decision.

Finding 3: FSIS Needs to Use Available Technology to Improve Efficiency within Slaughter Plants and at FSIS Laboratories

FSIS' process for sampling carcasses at slaughter plants and then testing those samples at its laboratories does not make use of readily available technology, such as barcode scanning, electronic forms for retaining information, and an electronic reservation system for scheduling tests. Instead, the agency relies on a manual and labor-intensive system that requires employees to make pen and paper notes on tags that are affixed to carcasses—a system that is slow, cumbersome, and not always legible. FSIS officials stated that they had not considered their current technology as out-of-date and did not realize that some plants were already using newer and more innovative techniques, nor did they deem it necessary to request additional funding for any improvements. Due to FSIS' way of handling this work process, public health veterinarians had less time to devote to their primary mission of inspecting and testing animal carcasses for harmful adulterants, and FSIS was testing meat samples for residue less efficiently and reliably than it could have.

OMB states that agencies should take advantage of opportunities to update their information technologies in order to improve the efficiency and effectiveness of their work processes.[46] For FSIS' national residue program, one of the agency's most fundamental work processes is how it samples meat at slaughter facilities and then tests those samples for residue contamination in its laboratories.

We found that FSIS could realize significant improvements in the efficiency with which it processes samples by modernizing its sampling process, beginning with how it gathers meat samples from carcasses at the slaughter plants and concluding with how it tests those samples at its laboratories.

Improving Efficiency at the Slaughter Plants

When FSIS decides to test an animal carcass for residue, regulations require that the agency maintain "the identity of every such retained *carcass, detached organ, or other part* ... until the final inspection has been completed."[47] To accomplish this, these parts are tagged and stored until FSIS completes its testing.

We found that FSIS' current system for tagging these animal parts is archaic, and not adequate to tag every part. "U.S. Retained" tags are issued in groups of four (see photo No.1, on the next page), yet FSIS personnel often need additional tags to adequately identify at least six pieces from each carcass, including the two carcass sides, head, viscera, pluck,[48] and samples. In one case, we observed plant personnel taking yellow strips of paper, writing down the last two digits from a tag, and placing these improvised strips with the pluck (see photo No.2, on the next page). We concluded that this was not a reliable and efficient way of tagging all the animal parts that were tested.

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[46] OMB Circular A-130, 7.a.

[47] 9 Code of Federal Regulations 310.3.

[48] Pluck is the animal's heart and lungs.

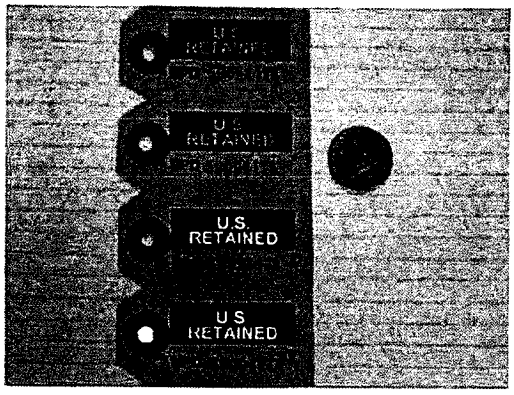

Photo No.1

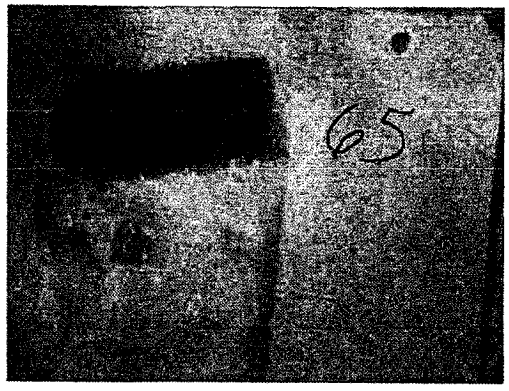

Photo No.2

We also noted that public health veterinarians use these tags to take notes during their diagnosis regarding the reason for the disposition. They often make their notes on the sides of the tags, which are about the size of a movie ticket, so as to properly identify the correct animal with the correct diagnosis. Taking notes in this fashion is awkward, especially if the tag gets wet after being attached to a carcass or organ (see photos No.3 and 4, below).

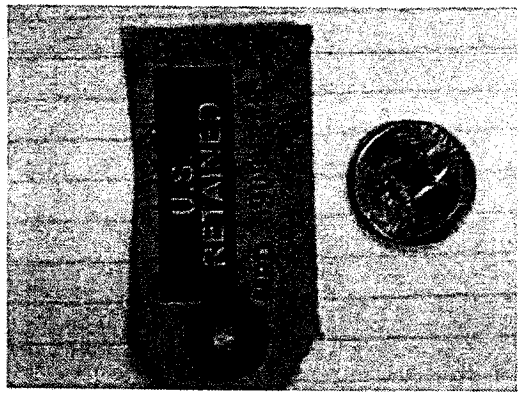

Photo No.3

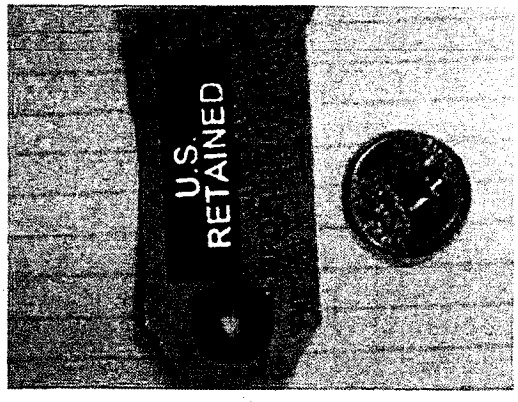

Photo No.4

We concluded that FSIS can improve how it takes samples at slaughter plants by adopting barcode scanning technology similar to the technology used by package delivery companies. Several of the plants we observed have already adopted this technology. FSIS personnel at these plants order tags and, upon arrival, the plants order and pay for their own version of the tags using the same tag numbers FSIS received, but these tags also have a barcode (see photo No.5, on the next page). Plant personnel then use a hand-held scanner to track the carcasses that FSIS selects for further inspection.

Photo No.5

FSIS could build upon this barcode scanning system by integrating drop-down menus to allow public health veterinarians to enter brief notes. At the end of the shift, the information collected through the day could be transferred to electronic versions of FSIS documentation. By developing electronic versions of forms, such as daily disposition reports, lab submission forms, and other related documentation, public health veterinarians could quickly and efficiently move data into usable formats that would allow for state-of the-art food safety management. When we spoke to FSIS personnel regarding the potential benefits of improved tags, they agreed that such a system would be both feasible and advantageous. They added that an IT investment like this, however, would involve going through the CPIC process, which is a systematic approach to selecting, managing, and evaluating IT investments. CPIC is mandated by the Clinger Cohen Act of 1996, which requires federal agencies to focus more on results achieved through IT investments while streamlining the federal IT procurement process.

Such a system would also benefit other agencies that use this data. For example, the Agricultural Marketing Service (AMS) relies on FSIS to collect samples for an EPA pesticide program. AMS informed us that FSIS submits manual information to their labs where their personnel must reenter the information into its electronic format. If FSIS were to adopt barcode scanning technology, it could then distribute information to other agencies electronically, which would eliminate the need to re-enter data from handwritten forms.

Improving Efficiency at the Laboratories

We also found that FSIS could improve efficiency at its laboratories by moving towards an electronic reservation system that would help laboratory managers prepare for the samples they are going to receive. FSIS laboratories receive two types of samples: (1) inspector-generated samples, which are taken from animals that public health veterinarians believe may be contaminated with residue; and (2) scheduled samples, which are randomly collected samples from slaughtered animals that do not appear contaminated.

At present, FSIS laboratories learn what samples are arriving only when the delivery truck has arrived and unloaded. Not only do they not know how many inspector-generated samples and how many scheduled samples are pending until the truck is opened, they also do not know what sorts of tests they will be running. This information is important because a test for one substance can vary considerably from another test for another substance, both in terms of time and resources needed.

If FSIS implemented an electronic reservation system, the agency's laboratories could improve their efficiency in three ways:

- Laboratories could be alerted when veterinarians take an inspector-generated sample, and they could plan appropriately;

- Laboratories could schedule the rate at which random samples would arrive, which would allow the laboratories to test samples in batches and, thereby, optimize resources; and

- Laboratories could reduce the time it takes to process tests, which would mean that plants would not have to hold carcasses for as many days.

When we spoke to FSIS officials about the possibility of using an electronic reservation system of this type, they stated that FSIS expects to complete an information systems project that will allow it to implement a lab reservation system by late 2010. Officials stated that they expect the completed system will improve laboratory efficiency and reduce sample testing turnaround times by about 10 to 20 percent.

OIG believes that implementing scanning technology at the slaughter plants and an electronic reservation system at the laboratories will contribute greatly to FSIS' ongoing efforts to modernize its testing process. Recently the agency has begun the process of upgrading its equipment by purchasing a state-of-the art machine for detecting chemical residues—a fast-liquid chromatography-tandem mass spectrometry machine. This device is noteworthy because it will allow FSIS to quantify and confirm residues simultaneously, which would improve efficiency at the laboratories. However, FSIS laboratory officials noted several concerns which may prevent them from fully utilizing their new testing machine:

- FSIS' and the Agricultural Research Services' (ARS) preliminary studies have shown that the new machine will identify contaminants at a lower threshold, increasing the number of positive test results and requiring an increase in staff resources to confirm preliminary results;

- FSIS will need to train its laboratory staff extensively and certify their training before the new testing equipment can be used fully, taking time away from critical duties involving testing national residue program scheduled and inspector-generated samples; and

- ARS may be able to develop and validate only a small portion of dozens of testing protocols which the machine is capable of performing, including the capability for quantifying and confirming residues simultaneously.

Although ARS first predicted that it would transfer the machine and train FSIS staff beginning December 2009, the expected transfer date has moved to September 2010, and FSIS has not developed a formal plan for overcoming these obstacles or set specific timeframes for the necessary training.

FSIS should develop an overall plan for modernizing how it samples and processes tests, from slaughter plant to laboratory, including a plan for bringing this new machine online and using its capabilities fully.

Recommendation 13

Consistent with CPIC requirements, propose a detailed plan with reasonable timeframes for modernizing FSIS' residue testing process to (1) adopt and implement an electronic laboratory reservation system for processing residue samples, and (2) train and certify laboratory staff on the fast-liquid chromatography-tandem mass spectrometry machine and using the machine's full capabilities over time.

Agency Response

FSIS is actively pursuing modernization of the national residue program testing process. As outlined here FSIS is in the process of developing the Public Health Information System (PHIS). PHIS will replace most of the existing electronic systems and applications within FSIS. Expected deployment of PHIS (phase 1) is targeted for Fall 2010. The districts will be phased in incrementally. The Domestic Inspection module will provide field collectors a 'home page' with a task calendar. Various tasks assigned to an establishment will be managed via this calendar and allow the inspection personnel to 'schedule' their various tasks via the calendar.

Within PHIS a module is being developed for Sampling Management which will include a Laboratory Capacity/Reservation function. This module/functionality is expected to be deployed in the Fall of 2011 once all the districts have been phased into PHIS. The Sampling Management modules will be used to establish the various sampling programs/projects within FSIS to provide a mechanism to define the project, identify the sampling algorithm to be used for scheduling, how often to run the algorithm, and other rules that may apply for the project.

To address the second part of this recommendation, FSIS has an MOU with the USDA ARS to train and certify laboratory analysts on up-to-date testing methods. Over the past two years, the Midwestern Laboratory (ML) has purchased two ultra high-performance liquid chromatographic systems (UHPLC/MS/MS). These units have been purchased in anticipation of the transfer of methods and technology that will enable a more rapid antibiotics/veterinary drug screening/quantification/confirmation process and/or other advancements of methodology. As part of the solicitation processes, the ML procured vendor training which was completed at the ML and resulted in the training of 8 chemists on the instrumentation.

Presently, the ARS plans to transfer two methods based on the UHPLC/MS/MS system. The first method is for the screening, determination, and confirmation of aminoglycosides. ARS

has presented their analytical findings to FSIS Midwestern Laboratory and Laboratory Quality Assurance Division (LQAD) for review. LQAD has provided ARS with the results of their data review and will meet with ARS to discuss any feedback. After this is completed, the ML will begin the process of verifying the method as transferred from ARS. ARS is continuing to perform method validation work for the screening/quantification/confirmation of additional antibiotics and veterinary drugs (again analyte/matrix dependent). Upon completion, ARS will share the data for FSIS review. The data will be reviewed with feedback and discussion between ARS/FSIS. Again, upon completion of this process, the ML will verify this method. The goal of the implementation of these two methods is to improve the overall efficiency and specificity in relation to current FSIS residue testing methodologies. FSIS expects to begin implementation of these methods by September 2010.

The ML has already used the instrumentation to demonstrate successful analyst training for two current Chemistry Laboratory Guidebook methods (CLG-FLX4 Determination and Confirmation of Flunixin and CLG-PBZ2 Confirmation of Phenylbutazone). In the years to come, we envision this type of enhanced technology will allow FSIS to address requests for a broad range of analytical data needs in an increasing number of drug and/or pesticide analyses. This technology has the potential to improve laboratory efficiency.

FSIS intends to complete these modernization initiatives by March 2011.

OIG Position

We accept FSIS' management decision.

Recommendation 14

Consistent with CPIC requirements, propose a detailed plan and formal proposal to adopt an automated system to electronically track detached animal parts, such as barcode scanning, so data can be easily managed in the plant, transferred among FSIS systems, and disseminated to outside agencies. Include converting the agency's retain tags to allow the use of scanning technology. In the interim, assess whether improving the agency's retain tags to better track all animal parts and related samples, as well as providing additional tags, would be cost-effective in protecting public health.

Agency Response

FSIS will examine this recommendation and produce a proposal for IT investment that will be considered within the Agency's CPIC process. Through the CPIC process, FSIS will determine whether the investment will support the Agency's strategic goals cost effectively and make an investment decision based on that determination. FSIS will propose as part of its CPIC process an IT investment that achieves the goals of the OIG recommendation by March 2011.

OIG Position

We accept FSIS' management decision.

Scope and Methodology

To accomplish our audit objectives, we first looked at the national residue program as a whole, including: (1) how it was established, including the 1984 memorandum of understanding; (2) the structure used to communicate and coordinate among the various responsible agencies, such as the SAT and the IRCG; and (3) the overall coordination among the responsible agencies in accomplishing the program's mission of safeguarding the U.S. food supply from harmful residues.

Between January and October 2009, we performed our audit at FSIS Headquarters in Washington, D.C.; the Eastern Laboratory in Athens, Georgia; the FSIS Policy Development Division in Omaha, Nebraska; and three slaughter establishments in California and Washington State. In addition, we contacted two FSIS district offices via telephone, and spoke with representatives of a meat industry group in Washington, D.C., and various other agencies outside of FSIS.

FSIS Headquarters

At FSIS Headquarters, we determined the responsibilities of the following offices as they relate to residue sampling and testing, and interviewed the appropriate senior-level officials:

- Policy and Program Development provides leadership in the identification of policy needs, and develops policy solutions to address the intent and application of verification and enforcement policy in plant activities. In addition, Policy and Program Development provides direct technical support to FSIS field personnel. We talked with officials at the FSIS national office and visited the Policy Development Division in Omaha, Nebraska.

- Field Operations manages national inspection and enforcement activities. We interviewed FSIS officials at the national office and talked to two field district offices via telephone.

- Program Evaluation, Enforcement and Review assesses FSIS' program functions and operations. At the national office, we talked to officials from the Office of the Chief Information Officer, as well as the Program Evaluation and Improvement Staff. The Office of the Chief Information Officer is responsible for supporting food safety, public health, and food security requirements through development and implementation of information systems. Program Evaluation and Improvement provides leadership and technical expertise in the area of program evaluation.

- Data Integration and Food Protection coordinates all emergency response, food defense, and data analysis activities within FSIS. At the national office, we talked with officials from the Data Analysis and Integration Group. This group is responsible for evaluating individual FSIS data streams, ensuring data analyses are consistent and of high quality, and conducting data analyses to inform agency decisions.

- Office of Public Health Science provides expert scientific analysis, advice, data, and recommendations on all matters involving public health and science that are of concern

to FSIS. We spoke with the appropriate Public Health Science officials at the national office in Washington, D.C. We also spoke with officials at the Regulatory Field Services Laboratory in Athens, Georgia. In order to support FSIS' farm-to-table food safety strategies, three field laboratories conduct scientific tests in the disciplines of chemistry, microbiology, and pathology.

Slaughter Establishments

During the course of the audit, we interviewed appropriate FSIS officials and reviewed files, procedures, and operations related to FSIS' performance of the national residue testing program in two cull cattle slaughter establishments in California and Washington State, and one bob veal establishment in California.[49] We selected these plants based on either (1) the high number of dairy cows and bob veal violations associated with the plant, or (2) the high number of repeat violators at the plant.

Since dairy cows, including bob veal, account for over 90 percent of confirmed residue violations, we concluded that establishments that slaughter dairy cows are at a higher risk for residue violations, mainly because of the condition, age, and health of the animals slaughtered. Therefore, we limited the scope of our fieldwork to establishments that slaughter primarily dairy animals. We also followed up on issues identified during our evaluation of FSIS' management controls over pre-slaughter activities, which was conducted in response to the recall of beef product at the Hallmark-Westland Meat Packing Company in Chino, California, in February 2008.[50] As a part of the review, we evaluated the effectiveness of FSIS' inspector-generated sampling program for residues at 10 cull cow establishments.

We observed the FSIS inspection staff taking residue samples, retaining carcasses, and performing in-plant screening tests. We also interviewed public health veterinarians and plant managers at each establishment we visited.

As part of our record review covering July 2007 through December 2008,[51] we reviewed the weekly same source supplier list (also known as the residue violator list), as well as the monthly repeat violator alert list. We also analyzed information from the performance-based inspection system. We did not test any of the data from these systems for accuracy or validity.

Other Agencies Outside of FSIS

We talked to the following agencies, groups, and entities outside of FSIS about residue detection and control:

- ARS promotes scientific discoveries that help solve problems in crop and livestock production and protection, human nutrition, and the interaction of agriculture and the environment.

[49] FSIS information indicates that there are over 600 cattle slaughter establishments.

[50] The audit report "Evaluation of FSIS' Management Controls over Pre-Slaughter Activities" (Audit No. 24601-7-KC) was issued in November 2008

[51] We also reviewed other documents from calendar year 2009 when we deemed it necessary.

- AMS develops quality grade standards for agricultural commodities; administers marketing regulatory programs, marketing agreements, and orders; and makes food purchases for USDA food assistance programs.

- Grain Inspection, Packers and Stockyards Administration facilitates the marketing of livestock, poultry, meat, cereals, oilseeds, and related agricultural products and promotes fair and competitive trading practices for the overall benefit of consumers and American agriculture.

- FDA is an agency within the U.S. Department of Health and Human Services and protects public health by assuring the safety, efficacy, and security of human and veterinary drugs.

- EPA endeavors to abate and control pollution systematically, by proper integration of a variety of research, monitoring, standard setting, and enforcement activities.

- Office of the General Counsel provides legal advice and services to the Secretary of Agriculture and to all other officials and agencies of the Department with respect to all USDA programs and activities. We interviewed an Office of the General Counsel official at the FSIS national office in Washington, D.C., to clarify our understanding of the legislative and regulatory authorities provided to FSIS in the residue program.

- A meat packing industry trade group headquartered in Washington D.C.

Finally, we also interviewed professors at Kansas State University and Michigan State University to speak to them about residue testing issues currently facing the meat industry.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives. During the course of our audit, we did not verify information in the agency RVIS system, and make no representation of the adequacy of the systems or the information generated from them.[52]

[52] The RVIS system is used by FSIS, FDA, and EPA to track residue violations and information associated with each violation.

Abbreviations

AMS..... Agricultural Marketing Service
APHIS..... Animal and Plant Health Inspection Service
ARS..... Agricultural Research Service
CLG..... Chemistry Laboratory Guidebook
CPIC..... Capital Planning and Investment Control
EPA..... Environmental Protection Agency
FDA..... Food and Drug Administration
FSIS..... Food Safety and Inspection Service
HACCP..... Hazard Analysis and Critical Control Points
HHS..... Health and Human Services
IT..... Information Technology
IRCG..... Interagency Residue Control Group
LQAD..... Laboratory Quality Assurance Division
ML..... Midwestern Laboratory
MOU..... Memorandum of Understanding
NADA..... New Animal Drug Application
NAHMS..... National Animal Health Monitoring System
PHIS..... Public Health Information System
RVIS..... Residue Violation Information System
OIG..... Office of Inspector General
OMB..... Office of Management and Budget
SAT..... Surveillance Advisory Team
SOP..... Standard Operating Procedure
USDA..... United States Department of Agriculture

USDA'S

FOOD SAFETY AND INSPECTION SERVICE

RESPONSE TO AUDIT REPORT

United States Department of Agriculture | Food Safety and Inspection Service | Washington, D.C. 20250

TO: Gil H. Harden
Acting Assistant Inspector General
Office of Inspector General

FROM: Alfred V. Almanza /S/ March 2, 2010
Administrator
Food Safety and Inspection Service

SUBJECT: Office of Inspector General (OIG) Official Draft Audit Report – FSIS National Residue Program for Cattle, Report number 24601-08-KC

We appreciate the opportunity to review and comment on this report. The Food Safety and Inspection Service (FSIS) has reviewed the draft report and has responded to each of the recommendations.

Recommendation 1
Through discussions with senior management and executive level officials at the HHS/FDA and EPA, draft and propose:

1) a revision to the 1984 memorandum of understanding (MOU) to ensure that it formally establishes the SAT and IRCG and addresses the specific concerns of all three agencies;

2) a charter for the SAT and IRCG, laying out, at a minimum, the specific mission, goals, and agencies' responsibilities and specifying the level of participants, attendees' required qualifications, and the various disciplines to be represented; and

3) a process for elevating issues and potential recommendations identified in the SAT and IRCG to executive-level officials in order to gain a response and ensure actions are taken for timely resolving the interagency issues or problems discussed at these meetings.

Formalize the MOU, the charter, and the process for elevating issues and potential recommendations when agreements are reached on the draft proposals.

Agency Response
FSIS will schedule meetings with senior management and executive level officials at the HHS/FDA and EPA to attempt to establish guidelines for the context of a revised memorandum of understanding (MOU) between the three agencies. FSIS will review the 1984 MOU and revise and update, as applicable, FSIS commitments regarding FSIS responsibilities to the National Residue Program and FDA and EPA. After an internal clearance process, FSIS will share these revisions with FDA and EPA for their comment. The revised document will include language on collaborative periodic reviews.

FSIS will attempt to solicit input from FDA and EPA to draft a charter for both the Surveillance Advisory Team (SAT) and the Inter-Agency Residue Control Group (IRCG). Both the SAT and IRCG were established by the 1984 MOU but little detail is provided as to their structure. The draft charters will include statements on mission, goals, and clearly stated responsibilities of each agency to the mission and goals of the groups as well as to the other agencies. To close out this recommendation, FSIS will draft a charter for both groups to provide to FDA and EPA for consideration.

FSIS will make every effort to work with FDA and EPA to draft a Standard Operating Procedure (SOP) that details the steps necessary to reach closure on issues or recommendations that cannot be resolved by the procedural processes identified in the charters of the SAT or IRCG. To close out this recommendation, FSIS will draft and provide an SOP to FDA and EPA for consideration.

Because formalizing the MOU will require agreement by both FDA and EPA, FSIS will provide the draft charters for the SAT and IRCG as well a draft SOP that outlines the process of elevating issues and recommendations discussed within the SAT or IRCG to executive level officials for closure of the recommendation.

Completion Dates: FSIS intends to complete these draft documents by March 2011.

Recommendation 2
Through discussions with SAT, develop formal plans and reasonable milestones to ensure that the national residue program has the resources it needs to test for all substances identified by SAT as posing a high risk to public health.

Agency Response
FSIS will assess the chemical residue program to identify high risk chemicals that could potentially contaminate the food supply. Using the Surveillance Advisory Team model and under the leadership of the OPHS Risk Assessment Division's Chemical Residue Risk Branch, FSIS and the other members of the SAT will identify and rank high-risk chemicals. FSIS will evaluate and, if needed, redesign its residue sampling program to ensure that sampling for high-risk residues is prioritized in view of available resources.

Completion Dates: FSIS intends to complete this assessment by March 2011.

Recommendation 3
Through discussions with the SAT, establish policies and procedures with reasonable timeframes to perform a structured, periodic review of FSIS' sampling methodology regarding the number and timing of samples taken, using formal risk analysis principles focused on public health outcome and aimed at improving laboratory efficiency. Revise FSIS' sampling methodology based on the outcome of the review.

Agency Response
FSIS will work with FDA and EPA to develop a Standard Operating Procedure (SOP) for managing the National Residue Program including timelines for structured, periodic review of the NRP design. On an annual basis and prior to the convening of the SAT, FSIS will analyze the violative tissue results of both the scheduled sampling program and the inspector-generated program to inform the annual scheduled sampling program. When possible, a risk-based approach will be used to determine priority in scheduling that takes into account public health

and laboratory efficiency. A final report documenting the decision making process including decisions made using expert elicitation will be generated and made available to members of the SAT. To close out this recommendation, FSIS will develop and clear internally a draft SOP outlining the process for designing and reviewing the annual program.

Completion Dates: FSIS intends to complete the draft SOP by March 2011.

Recommendation 4
Through discussions with FDA senior management, draft and propose a process to expedite approval of new testing methodologies for FSIS. Include initiating a formal study to determine the merits of a performance-based, or other new, approach for regulatory analysis and for testing new drugs in the future. Formalize the proposals and include milestones for completion once agreements are reached, beginning with a formal agreement to bridge the testing method for animal drugs FSIS currently needs.

Agency Response
FSIS is actively pursuing discussions with the leadership at the FDA's Center for Veterinary Medicine and other FDA offices to develop a process to expedite the development of new methods that FSIS can use for chemical residue testing programs. The initial meeting took place in Shepherdstown, WV on February 18th. FSIS is also planning a "Residue Summit" in the Spring of 2010 where key Agency representatives from all relevant FSIS programs will be able to identify and discuss residue related issues, and then develop plans to address identified needs. One of the outcomes of these discussions will be a proposal from FSIS to the FDA that will outline and propose (1) a smooth process to approve performance-based multi-residue methods and (2) a system and process to compare these new performance-based methods with the FDAs approved (NADA) methods, which may include the use and availability of incurred tissue.

Completion Dates: FSIS intends to complete the proposal by March 2011.

Recommendation 5
Through discussions with EPA and FDA, develop a formal plan with reasonable timeframes to establish policies and procedures for handling hazardous substances with no tolerances such as heavy metals, animal drugs, and environmental contaminants, including pesticides with cancelled registrations. Formalize the policy and procedures when these agreements are reached. Also, develop and implement detailed FSIS procedures that specify the actions agency personnel are to take regarding the disposition of carcasses that contain potentially hazardous substance(s), when there are no formal tolerances established by EPA or FDA.

Agency Response
FSIS will include this issue in the draft MOU and SOP discussed in the response to Recommendation Number 1. FSIS will issue a Notice or other policy document regarding actions it will take in regard to carcasses that contain hazardous substances for which there are no formal tolerances.

Completion Dates: FSIS intends to complete the draft MOU and SOP and to issue the FSIS policy document by March 2011.

Recommendation 6
Through discussions with the SAT, develop a formal plan with reasonable timeframes to facilitate the exchange of residue testing data between FSIS, EPA, and FDA to enhance the opportunities for expanded research and identification of trends in violations.

Agency Response
FSIS will include this plan in the draft MOU and SOP discussed in the response to Recommendation Number 1.

Completion Dates: FSIS intends to complete the draft MOU and SOP by March 2011.

Recommendation 7
Develop a formal plan with reasonable timeframes (include EPA and FDA to the extent practical) that requires FSIS personnel to at least annually, canvass the drug industry, private practitioners, and other non-governmental experts to obtain information such as current marketing data for veterinary drugs and pesticides, new technologies, and methodologies to assess dietary exposure for use at the SAT meetings in determining compounds to test.

Agency Response
FSIS will use information systems similar to the *National Animal Health Monitoring System* (NAHMS) maintained by the Animal and Plant Health Inspection Service (APHIS) to better inform the SAT during the process of developing the annual NRP. Specifically, FSIS will review NAHMS reports detailing the most current drug usage data and compare to most recent list of compounds tested under NRP. FSIS will document the consideration and decision to include or not include compounds indicated by NAHMS reports but not tested under the NRP. FSIS will produce a final report after the SAT meetings as a record of the rational supporting decisions made.

Completion Dates: FSIS intends to complete this final report after the SAT meetings by March 2011.

Recommendation 8
Develop a plan to identify slaughter plants where residue violations have a history of occurring and to set specific timeframes for conducting assessments to evaluate whether those plants have made the proper determination or adequately supported their determination whether residue is a hazard reasonably likely to occur. Require these plants to implement appropriate controls to prevent, detect, and eliminate harmful residues commensurate with the level of risk, e.g., number of violations being identified at the plants.

Agency Response
FSIS staff at OFO Headquarters, in partnership with the OCIO, has already started generating residue violation history by District, by month. FSIS will expand this program to break this data down further for cattle slaughter plants in each District. This information will be made available monthly to the DVMS in each District for their follow-up action via the in-plant PHV, so the latter may discuss these findings monthly with the plant management

Plants where residue violations occur repeatedly are required to address in their HACCP program the prevention, detection, and elimination of these hazards from the product they market for human consumption using the guidelines published in the Federal Register Notice 70 FR 70809, November 28, 2000, entitled "*Residue Control in a HACCP Environment*". Also,

FSIS enforces the guidelines published in FSIS Notice 03-10 dated 1/12/2010: "*How to Proceed in Establishments that have Multiple FSIS Laboratory Confirmed Residue Violations from the Same Source Supplier*".

Completion Dates: FSIS intends to complete the expansion of residue violation history by March 2011.

Recommendation 9
Obtain the necessary regulatory authority, similar to that for bob veal, to require slaughter plants where residue violations have a history of occurring to identify the producers of all animals presented for slaughter and compare those to the same source supplier list for the required additional testing. Establish formal procedures to enforce the new identification requirement at plants with repeat violations and for bob veal.

Agency Response
Although establishments are required to maintain records showing the person from whom they purchased animals, in many cull cow establishments, that person often is not the producer. Without knowing the name of the producer, purchasers cannot consult the FSIS "Same Source Supplier - Residue Violator List" to determine whether the animal is being supplied by a producer with a history of residue violations, and thus assess the risk in buying the animal. FSIS will take two steps to address the issues presented in Recommendations 9 and 10. First, it will prepare a compliance guide to make sure that establishments understand why it is in their interest to inquire of anyone who is offering to sell them animals, such as an auction barn or an itinerant seller of animals, about the name of the producer. Second, in addition to the compliance guide, FSIS is creating the following incentives and disincentives to encourage establishments to only by from a source that can and will identify the producer:

(1) Incentives: Plants must make every effort to ensure animals purchased for food production are free from violative levels of residues. Plants that demonstrate a history of compliance are tested at a frequency less than those with a poor history of compliance.

(2) Disincentive: For plants that continue to purchase animals from source supplier with repeated residue violations, FSIS will follow the guidelines under FSIS Notice 03-10. This will include:

a. Testing of two or more animals each time the establishment receives animals from the same or any unknown source, up to 100% of animals presented.

b. Continue this level of testing until four consecutive shipments from a known supplier are negative.

c. For additional violations after issuing an MOI, the PHV will

I) Issue an NR citing 9 CFR 318.20 to document the establishment's failure to prevent slaughter of residue violative animals.

II) At weekly meetings, discuss findings to point out establishment's failure to prevent this hazard.

III) Link the findings to NRs, as appropriate.

IV) Assess whether the HACCP system is adequate under 9 CFR 417.6 and Rules of Practice.

Completion Dates: FSIS intends to complete the compliance guide by March 2011.

Recommendation 10
Until regulatory authority is obtained, develop formal policies and procedures that provide (1) an incentive for plants to voluntarily seek producer identification on animals arriving for slaughter for comparison with plant or FSIS residue violators lists; and (2) a disincentive for plants that continue to purchase from suppliers/producers with repeat residue violations, such as subjecting shipments from unidentified producers to additional on-site screening for potential testing if the plant cannot demonstrate that incoming animals are not at high risk for violative levels of residue.

Agency Response
Although establishments are required to maintain records showing the person from whom they purchased animals, in many cull cow establishments, that person often is not the producer. Without knowing the name of the producer, purchasers cannot consult the FSIS "Same Source Supplier - Residue Violator List" to determine whether the animal is being supplied by a producer with a history of residue violations, and thus assess the risk in buying the animal. FSIS will take two steps to address the issues presented in Recommendations 9 and 10. First, it will prepare a compliance guide to make sure that establishments understand why it is in their interest to inquire of anyone who is offering to sell them animals, such as an auction barn or an itinerant seller of animals, about the name of the producer. Second, in addition to the compliance guide, FSIS is creating the following incentives and disincentives to encourage establishments to only by from a source that can and will identify the producer:

(1) Incentives: Plants must make every effort to ensure animals purchased for food production are free from violative levels of residues. Plants that demonstrate a history of compliance are tested at a frequency less than those with a poor history of compliance.
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a. Testing of two or more animals each time the establishment receives animals from the same or any unknown source, up to 100% of animals presented.
b. Continue this level of testing until four consecutive shipments from a known supplier are negative.
c. For additional violations after issuing an MOI, the PHV will
I) Issue an NR citing 9 CFR 318.20 to document the establishment's failure to prevent slaughter of residue violative animals.
II) At weekly meetings, discuss findings to point out establishment's failure to prevent this hazard.
III) Link the findings to NRs, as appropriate.
IV) Assess whether the HACCP system is adequate under 9 CFR 417.6 and Rules of Practice.

Completion Dates: FSIS intends to complete the compliance guide by March 2011.

Recommendation 11
Develop a process for periodically reviewing residue violation data relating to all production classes and taking necessary steps to enforce food safety standards if violations show a significant increase. Include within the process performance measures as a standard for evaluating the agency's progress in reducing the amount of residue in meat products, such as reducing the number of repeat residue violators over time.

Agency Response
A process for periodically reviewing residue violation data relating to all production classes has already been established. Monthly updates will be provided to the FSIS inspection personnel via the DVMS in each District. Necessary steps mentioned above in Recommendations #8 and #10, would be used to enforce food safety standards if violations show a significant increase. While the industry will be held responsible for reducing violative residue levels, FSIS-OFO will enforce FSIS Notice 03-10 to ensure appropriate action is taken to reduce the likelihood of same source residue violations.

Completion Dates: FSIS intends to provide the monthly updates by October 2010.

Recommendation 12
Provide incentives to prevent plants from releasing potentially adulterated product before residue test results are confirmed and for plants to voluntarily trace and recall meat that is found to have violative levels of residue. Establish a policy to use alternative procedures to recall when violative levels of residue are found in meat that do not result in an acute risk, such as issuing public health alerts.

Agency Response
FSIS intends to announce a tentative policy determination that no product that has been tested for an adulterant will receive the mark of inspection until the test results are back, and the product has been found to be negative for the adulterant. This action, more than providing an incentive, will prevent potentially adulterated product from entering commerce. While FSIS is considering make some exceptions to this policy, for example for poultry, which has virtually no history of violative residues, this action should fully address OIG's concern.

Completion Dates: FSIS intends to announce this policy determination by March 2011.

Recommendation 13
Consistent with CPIC requirements, propose a detailed plan with reasonable timeframes for modernizing FSIS' residue testing process to (1) adopt and implement an electronic laboratory reservation system for processing residue samples, and (2) train and certify laboratory staff on the fast-liquid chromatography-tandem mass spectrometry machine and using the machine's full capacities over time.

Agency Response
FSIS is actively pursuing modernization of the National Residue program testing process. As outlined here FSIS is in the process of developing the Public Health Information System (PHIS). The Public Health Information System (PHIS) will replace most of the existing electronic systems and applications within FSIS. Expected deployment of PHIS (phase 1) is targeted for Fall 2010. The districts will be phased in incrementally. The Domestic Inspection module will provide field collectors a 'home page' with a task calendar. Various tasks assigned to an establishment will be managed via this calendar and allow the inspection personnel to 'schedule' their various tasks via the calendar.

Within PHIS a module is being developed for Sampling Management which will include a Laboratory Capacity/Reservation function. This module/functionality is expected to be deployed in the Fall of 2011 once all the districts have been phased into PHIS. The Sampling Management modules will be used to establish the various sampling programs/projects within

FSIS to provide a mechanism to define the project, identify the sampling algorithm to be used for scheduling, how often to run the algorithm and other rules that may apply for the project. To address the second part of this recommendation, FSIS has an MOU with the USDA Agriculture Research Service (ARS) to train and certify laboratory analysts on up-to-date testing methods. Over the past two years, the Midwestern Laboratory (ML) has purchased two ultra high-performance liquid chromatographic systems (UHPLC/MS/MS). These units have been purchased in anticipation of the transfer of methods and technology that will enable a more rapid antibiotics/veterinary drug screening/quantification/confirmation process and/or other advancements of methodology. As part of the solicitation processes, the ML procured vendor training which was completed at the ML and resulted in the training of 8 chemists on the instrumentation.

Presently, the Agriculture Research Service (ARS) plans to transfer two methods based on the UHPLC/MS/MS system. The first method is for the screening, determination, and confirmation of aminoglycosides. ARS has presented their analytical findings to FSIS Midwestern Laboratory and Laboratory Quality Assurance Division (LQAD) for review. LQAD has provided ARS with the results of their data review and will meet with ARS to discuss any feedback. After this is completed, the ML will begin the process of verifying the method as transferred from ARS. ARS is continuing to perform method validation work for the screening/quantification/confirmation of additional antibiotics and veterinary drugs (again analyte/matrix dependent). Upon completion, ARS will share the data for FSIS review. The data will be reviewed with feedback and discussion between ARS/FSIS. Again, upon completion of this process, the ML will verify this method. The goal of the implementation of these two methods is to improve the overall efficiency and specificity in relation to current FSIS residue testing methodologies. FSIS expects to begin implementation of these methods by September 2010.

The ML has already used the instrumentation to demonstrate successful analyst training for two current Chemistry Laboratory Guidebook methods (CLG-FLX4 Determination and Confirmation of Flunixin and CLG-PBZ2 Confirmation of Phenylbutazone). In the years to come, we envision this type of enhanced technology will allow FSIS to address requests for a broad range of analytical data needs in an increasing number of drug and/or pesticide analyses. This technology has the potential to improve laboratory efficiency.

Completion Dates: FSIS intends to complete these modernization initiatives by March 2011.

Recommendation 14
Consistent with CPIC requirements, propose a detailed plan and formal proposal to adopt an automated system to electronically track detached animal parts, such as barcode scanning, so data can be easily managed in the plant, transferred among FSIS systems, and disseminated to outside agencies. Include converting the agency's retain tags to allow the use of scanning technology. In the interim, assess whether improving the agency's retain tags to better track all animal parts and related samples, as well as providing additional tags, would be cost-effective in protecting public health.

Agency Response
FSIS will examine this recommendation and produce a proposal for IT investment that will be considered within the Agency's Capital Planning and Investment Control (CPIC) process. Through the CPIC process, FSIS will determine whether the investment will support the Agency's strategic goals cost effectively and make an investment decision based on that determination.

Completion Dates: FSIS will propose as part of its CPIC process an IT investment that achieves the goals of the OIG recommendation by March 2011.