EXHIBIT 49

U.S. Department of Agriculture

Office of Inspector General

FSIS National Residue Program for Cattle

Audit Report 24601-08-KC
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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