

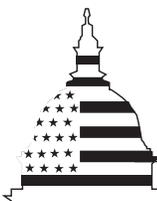
GAO

Report to the Committee on
Agriculture, Nutrition, and Forestry
U.S. Senate

August 2002

MEAT AND POULTRY

Better USDA Oversight and Enforcement of Safety Rules Needed to Reduce Risk of Foodborne Illnesses



G A O

Accountability * Integrity * Reliability

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Abbreviations

FSIS	Food Safety and Inspection Service
GAO	General Accounting Office
HACCP	Hazard Analysis and Critical Control Point
USDA	U.S. Department of Agriculture



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United States General Accounting Office
Washington, DC 20548

August 30, 2002

The Honorable Tom Harkin
Chairman
The Honorable Richard G. Lugar
Ranking Minority Member
Committee on Agriculture, Nutrition, and Forestry
United States Senate

Every year, some meat and poultry products are contaminated with microbial pathogens, such as *Salmonella* and *E. coli*, that cause foodborne illnesses and deaths. To improve the safety of meat and poultry products, and in response to recommendations from GAO and the National Academy of Sciences, the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) implemented additional regulatory requirements for meat and poultry plants. These requirements are intended to ensure that plants operate food safety systems that are prevention-oriented and science-based. These systems, called Hazard Analysis and Critical Control Point (HACCP) systems, were phased in from January 1998 through January 2000 at all meat and poultry slaughter and processing plants. As the foundation of the HACCP system, plants are responsible for developing HACCP plans that, among other things, identify all of the contamination hazards that are reasonably likely to occur in a plant's particular production environment, establish all of the necessary steps to control these hazards, and have valid scientific evidence to support their decisions. As a result of implementing HACCP systems over the past 5 years, plants have accepted significant new responsibilities for producing safe products, and FSIS has made major changes to the roles and responsibilities of its inspection workforce.

FSIS, through its 15 district offices across the country, oversees the activities of about 7,500 federal inspectors who review the operations of about 5,000 plants subject to the HACCP requirements nationwide.¹ About 3,400 inspectors are stationed in plants along slaughter lines to provide traditional carcass-by-carcass inspections using sight, touch, and smell.

¹ According to FSIS, the approximately 5,000 HACCP plants include about 1,200 plants that slaughter and/or process meat, 300 that slaughter and/or process poultry, and 3,500 plants that slaughter and/or process both meat and poultry. FSIS also inspects sanitation at, among others, plants that store or ship meat or poultry products. These plants are not required to have HACCP plans because they do not produce products.

The remaining 4,100 FSIS inspectors oversee HACCP systems in plants. As a part of their oversight, inspectors determine if plants are complying with HACCP requirements, including the requirement that their plans include the following specific components:

- A hazard analysis that identifies all the food safety hazards—biological, chemical, and physical—that are reasonably likely to occur and measures to control them.
- Critical control points in plants’ processes where controls can be applied to prevent, eliminate, or reduce a food safety hazard to an acceptable level.
- Critical limits (maximum or minimum values) at which the hazard is controlled.
- Monitoring requirements to ensure that the measured values are within critical limits.
- Corrective actions to be taken if critical limits are violated.
- Verification procedures to ensure that the plants’ HACCP systems result in safe products.
- Record keeping procedures for documenting HACCP requirements.

To help verify that plants’ HACCP systems are effectively controlling food safety hazards, FSIS inspectors test for the presence of the pathogen *Salmonella* on raw meat and poultry in a series of samples—referred to as a “set.” FSIS established limits for *Salmonella*, known as “performance standards,” which vary depending on the type of product. For example, no more than 1 percent of steer carcasses sampled in a set of tests may contain *Salmonella*. In addition to limits on *Salmonella*, FSIS has established a “zero tolerance” for visible feces on carcasses at slaughter plants and considers the disease-causing pathogen *E. coli* 0157:H7 an adulterant that is not allowed in ground beef. FSIS also considers *Salmonella*, *E. coli* 0157:H7, and *Listeria monocytogenes* adulterants in ready-to-eat products such as hot dogs and luncheon meats.

When FSIS inspectors find a violation of the HACCP requirements, they document the violation on a “noncompliance record” and advise the plant. FSIS writes noncompliance records to document HACCP process violations, such as a plant’s failure to document its monitoring of temperatures for a cooked product, as well as for violations of the rules regarding pathogens. If the plant does not correct the violation, FSIS may take an enforcement action, such as detaining the affected meat or poultry product; slowing one or more production lines; withholding the marks showing that a product has passed USDA inspection; or suspending inspection services for one or more products or the entire plant.

While inspection services are suspended, a plant cannot operate. However, FSIS may place a suspension on hold—referred to as “in abeyance”—to allow the plant to continue operating while it corrects the violation.

In 1999, we reported that weaknesses in FSIS’s training for its inspectors affected its ability to ensure consistent and effective oversight of HACCP.² The following year, a USDA Inspector General report identified shortcomings in plants’ HACCP plans and deficiencies in FSIS’s oversight of HACCP’s implementation.³ To help address these problems, FSIS stepped up its inspector training and initiated two new review mechanisms:

- Food safety systems correlation reviews, which examine a range of inspector practices within FSIS districts to improve the effectiveness of inspections.
- In-depth verification reviews of HACCP plans in plants with serious safety problems to identify weaknesses in the scientific soundness of the plans.

FSIS also introduced consumer safety officers into its workforce with the scientific and technical expertise to, among other things, review the scientific soundness of HACCP plans.

As you requested, this report (1) assesses whether FSIS is ensuring that plants’ HACCP plans meet regulatory requirements, (2) determines whether FSIS is consistently identifying repetitive violations of HACCP requirements, and (3) assesses whether FSIS is ensuring that plants take prompt and effective action to return to compliance after the agency has identified HACCP violations. As part of our review, we analyzed 1,180 noncompliance records from 16 judgmentally selected meat and poultry slaughter and processing plants where FSIS frequently found HACCP-related violations in fiscal year 2001. Our sample included different sizes of plants located in 10 different FSIS districts across the country. We also analyzed files for the 68 HACCP enforcement cases that were active in

² See U.S. General Accounting Office, *Meat and Poultry: Improved Oversight and Training Will Strengthen New Food Safety System*, [GAO/RCED-00-16](#) (Washington, D.C.: Dec. 8, 1999).

³ See U.S. Department of Agriculture, Office of Inspector General, *Food Safety and Inspection Service: Implementation of the Hazard Analysis and Critical Control Point System*, Report No. 24001-3 (Washington, D.C.: June 2000).

fiscal year 2001 in three FSIS districts, including the two districts with the most plants in the country. In addition, we analyzed data from the in-depth verification reviews that FSIS conducted through the end of calendar year 2001 and the food safety systems correlation reviews that it completed by May 2002. Appendix I contains the details of our scope and methodology.

Results in Brief

FSIS is not ensuring that all plants' HACCP plans meet regulatory requirements and, as a result, consumers may be unnecessarily exposed to unsafe foods that can cause foodborne illnesses. In particular, FSIS's inspectors have not consistently identified and documented failures of plants' HACCP plans to comply with requirements. For example, FSIS's food safety systems correlation reviews in three FSIS districts found that, in about 91 percent of the plants sampled, inspectors had failed to document deficiencies in basic requirements such as the requirement that plants have adequate documentation to support the analysis of hazards in their HACCP plans. In addition, although sound science is the cornerstone of an effective HACCP plan, FSIS does not expect its inspectors to determine whether HACCP plans are based on sound science because inspectors lack the expertise to do so. FSIS has made limited progress in reviewing the scientific soundness of plants' HACCP plans. While FSIS's in-depth verification reviews have been useful in identifying numerous scientific weaknesses in HACCP plans, only about 1 percent of plants have undergone these time- and resource-intensive reviews. Similarly, consumer safety officers will improve FSIS's ability to assess the scientific adequacy of plants' HACCP plans. However, only about 6 percent of the officers that FSIS needs are on board, and FSIS managers in two large districts expressed concern that it may take years to assess the plans for all plants in their districts. Finally, we found that inspectors had not documented any HACCP violations in 55 percent of all plants during 2001; yet, when we showed these data to FSIS officials, they were surprised at the large numbers and said the absence of violations was unusual. For example, one field official said that if inspectors are finding no HACCP violations for an entire year, they may not understand their HACCP oversight responsibilities. In August 2002, FSIS told us it has developed, and would soon release, a new directive to clarify inspectors' responsibilities and new guidance for its supervisors to use to verify that inspectors are, among other things, applying appropriate inspection methods. FSIS also told us that it had introduced an interactive computer tool for inspectors and others to use to strengthen their knowledge of HACCP requirements.

FSIS is not consistently identifying repetitive violations, according to our review of 1,180 noncompliance records for fiscal year 2001. This has occurred in part because FSIS has not established specific, uniform, and clearly defined criteria for its inspectors to use in determining when a violation is repetitive. Furthermore, at the district level, FSIS officials' understanding of the criteria to consider in determining if a violation is repetitive varied. Also, in several instances, inspectors have not fully documented the basis for their decisions about repetitive violations on noncompliance records. Identifying repetitive violations, and maintaining accurate documentation on those decisions, is critical in deciding whether a HACCP plan is flawed and/or an enforcement action is needed. Moreover, we found that FSIS's inspection database did not provide summary information on repetitive violations, which could help FSIS's managers oversee inspectors' performance and plants' compliance with HACCP requirements. Summary information should also help FSIS identify common problems that may be better addressed by advising the industry to take corrective actions instead of plant-by-plant enforcement. FSIS officials agreed on the need for consistent criteria for identifying repetitive violations and expect to issue a directive with those criteria by the end of the calendar year. FSIS told us it has begun testing software that will allow its managers to extract summary data from the inspection database to help them better identify repetitive violations.

Finally, FSIS is not ensuring that plants take prompt and effective action to return to compliance after a HACCP violation has been identified. For example, FSIS has not consistently ensured that the actions that plants have taken were effective in eliminating repetitive violations, particularly those relating to "zero tolerance" for visible feces. Although plants are required to take corrective action each time a violation is cited, the number of repetitive violations in various plants—109 in one plant alone—shows that FSIS has not ensured that recurring violations were eliminated. FSIS also has not ensured that plants have taken immediate action, as required under HACCP rules, to meet the *Salmonella* performance standard. At the plants that failed two consecutive sets of tests for *Salmonella*, an average of 20 months elapsed from the date of the failure of the first set until the plants completed and passed a third set. Finally, when FSIS suspended inspections at a plant, it generally placed those suspensions in abeyance—often on the same day. This allowed the plants to operate while they took corrective actions. According to FSIS guidance, suspensions should not be held in abeyance for more than 90 days. However, nearly all the plants that were suspended in the three FSIS districts we examined had their suspensions placed in abeyance and were allowed to remain in abeyance for an average of 10 months, during which

time they continued to operate. Moreover, we were generally unable to verify the time frames in which plants were expected to complete corrective actions or the actual time elapsed before the corrective actions were completed because the enforcement case files did not contain this information. The longer that FSIS allows plants to remain out of compliance with regulatory requirements, the greater the risk that unsafe food will be produced and marketed.

We are making several recommendations to the Secretary of Agriculture to ensure that (1) FSIS inspectors better ensure that plants' HACCP plans fully meet regulatory requirements, (2) FSIS inspectors and district officials have consistent criteria for identifying repetitive violations, and (3) plants act promptly and effectively to correct violations. In commenting on a draft of this report, USDA agreed with our recommendations but believes the report does not fully acknowledge FSIS's progress and efforts to ensure that all plants meet regulatory requirements. USDA described a number of actions that FSIS has recently taken or is planning to take that are consistent with our recommendations. We believe that our report reflects the status of FSIS's ongoing and planned actions. If fully carried out and given diligent management attention, these actions could go a long way toward addressing the problems we found in FSIS's oversight and enforcement of HACCP in U.S. meat and poultry plants and reducing consumers' risk of foodborne illnesses.

Background

According to the Centers for Disease Control and Prevention, contaminated foods cause an estimated 76 million illnesses in the United States each year, including 325,000 hospitalizations and 5,000 deaths. Illnesses stemming from contaminated meat and poultry are responsible for an unknown portion of these illnesses and deaths. The Federal Meat Inspection Act and the Poultry Products Inspection Act give USDA responsibility for ensuring the safety and wholesomeness of meat and poultry products that enter interstate commerce.⁴ There are about 5,000 meat and poultry slaughter and processing plants nationwide. According to the American Meat Institute, total meat and poultry production in 2000 exceeded 80 billion pounds and sales were estimated at more than \$100 billion.

⁴ See 21 U.S.C. 601 *et seq.* for meat and 21 U.S.C. 451 *et seq.* for poultry.

In January 1998, FSIS began phasing in HACCP regulatory requirements for meat and poultry slaughter and processing plants. Large plants—those with 500 or more employees—were required to have HACCP systems in place by January 1998; small plants—those with 10 to 499 employees—by January 1999; and very small plants—those with fewer than 10 employees or annual sales of less than \$2.5 million—by January 2000.

As part of its oversight efforts to verify that plants effectively control food safety hazards, FSIS established standards for *Salmonella* in raw meat and poultry products and for visible feces on carcasses in slaughter plants.⁵ For *Salmonella*, FSIS established separate standards for the carcasses of cows/bulls, steers/heifers, market hogs, and broiler chickens, as well as for ground beef, ground chicken, and ground turkey. When a *Salmonella* test is scheduled, the FSIS inspector should take one sample each day the plant produces the product until a set is complete, according to FSIS guidance. The number of samples in the set depends on the product and ranges from a low of 51 samples for broiler chickens to a high of 82 samples for steers and heifers. On July 25, 2002, FSIS issued new, more-detailed guidance on actions the agency and plants will take after *Salmonella* set failures. When a plant fails a first set of *Salmonella* tests, FSIS will, among other things, notify the plant in writing of the failure and assess the plant's HACCP procedures. After a second consecutive *Salmonella* set failure, FSIS will notify the plant that it must reassess its HACCP plan to determine if changes are needed. After the plant completes its reassessment, FSIS will conduct an in-depth verification review, among other things.

With regard to the zero tolerance standard for visible feces, the FSIS inspector checks a prescribed number of carcasses on each production shift to verify that the plant has successfully eliminated visible fecal contamination.⁶ FSIS also requires plants to test meat and poultry carcasses for generic *E. coli*—bacteria that occur naturally in animals' intestinal tracts—to help ensure that the plants are minimizing the risk that harmful bacteria may be on the carcasses.

⁵ According to FSIS, the agency selected *Salmonella* for testing because, among other reasons, it is the most common bacterial cause of foodborne illness and intervention strategies to reduce the presence of *Salmonella* on raw products should be effective against other pathogens.

⁶ The zero tolerance standard also applies to contamination from the contents of the animal's digestive system and its mammary glands (milk).

In December 1999, we reported that FSIS inspectors were confused about their authority to request changes to HACCP plans and recommended that FSIS clarify and provide FSIS inspectors with additional training on their roles, responsibilities, and authorities for reviewing and verifying HACCP plans. We also recommended that FSIS review all plants' HACCP plans to verify that plants identify and control, through their HACCP plans, all food safety hazards that are reasonably likely to occur. In June 2000 USDA's Office of Inspector General reviewed 57 HACCP plans from 15 plants nationwide and reported that 14 of the plants had at least one incomplete HACCP plan.⁷ The report made recommendations to ensure that hazard analyses were complete and all critical control points identified.

In response to these reports, FSIS implemented the following additional oversight mechanisms:

- Food safety systems correlation reviews to improve the effectiveness of FSIS inspection activities. The reviews examine a range of FSIS plant inspection practices using a randomly selected sample of 10 percent or a minimum of 40 plants (whichever is greater) in an FSIS district. From April 2001 to May 30, 2002, FSIS had completed reviews in 7 of its 15 districts. Subsequent to each review, FSIS provides targeted training to inspectors on the basis of the review's findings.
- In-depth verification reviews to examine plants' compliance with HACCP plan design and implementation requirements. The reviews examine elements of plants' HACCP plans, such as hazard analysis, critical control points, and critical limits, and their implementation of these plans. From February 2000 to June 30, 2002, FSIS had completed reviews in 57 plants.
- Consumer safety officers have been trained by FSIS in microbiological hazards, HACCP plan design, epidemiology, and statistics to, among other things, review the scientific basis of HACCP plans. FSIS had 32 consumer safety officers in its district offices as of May 30, 2002.

FSIS plant inspectors have front-line responsibility for reviewing HACCP plans to ensure that they meet basic regulatory requirements. They use a "noncompliance record" to document violations of HACCP requirements

⁷ Plants that operate more than one production process, such as animal slaughter and the preparation of a cooked product, must establish a HACCP plan for each process. As a result, some plants have multiple HACCP plans.

and actions taken by plants to correct the violations. These records include the following information:

- A unique record number.
- The date of the violation.
- The oversight procedure that the inspector was performing (e.g., assessing the process for grinding meat) when the violation was discovered.
- The element of the HACCP system—monitoring, corrective action, record keeping, or plant verification—where the violation occurred.
- A written description of the violation.
- The plant management’s written response stating both the immediate action to correct the violation and any subsequent action to prevent its recurrence.

If actions taken by a plant to correct a problem fail to prevent the violation from recurring, the plant is said to have a “repetitive violation”—a recurring inability to maintain compliance with HACCP requirements. According to HACCP regulations, repetitive violations indicate that a plant’s HACCP system is inadequate and that an enforcement action may be warranted. An enforcement action can also be taken for a single serious violation. FSIS may take the following types of enforcement actions:

- A regulatory control action, which includes the retention of product, rejection of equipment or facilities, slowing or stopping of production lines, or refusal to allow the processing of specifically identified product. This action is considered the least burdensome type of enforcement action and can be initiated by an FSIS inspector to quickly respond to violations that can be easily remedied.
- A withholding action is the inspector’s or district officials’ refusal to allow the USDA marks of inspection to be applied to the product. This action is used for more serious HACCP violations, such as repeated failure to maintain HACCP records adequate for inspectors to determine whether or not a product was adulterated. This action may affect all products in the plant or only those products produced by a particular process. When only a particular process is involved, the plant may continue with its other operations, but it may not distribute the affected product.
- A suspension is an interruption in the assignment of FSIS inspectors and, hence, production, in all or part of a plant. An FSIS district manager may suspend inspections when the violation cannot be resolved through a withholding action or there is an immediate threat to public health. The district manager may put a suspension on hold—“in abeyance”—to give the plant time to execute a plan to correct the violation and prevent its

future recurrence. FSIS guidance recommends that suspension not be held in abeyance for more than 90 days.

- A withdrawal of the grant of inspection is the removal of FSIS from the plant. Under this rarely used action, taken only by the FSIS Administrator, a plant's products cannot enter interstate or foreign commerce.

According to the June 2000 Inspector General's report, while some plants had received numerous noncompliance records for the same deficiency, FSIS's inspectors had no understanding of what number, frequency, or nature of deficiencies would constitute a breakdown in the system requiring an enforcement action. The report further found that FSIS inspectors were unsure when to declare a plant's corrective actions unworkable—a critical step in taking further enforcement action.

FSIS Is Not Ensuring that Plants' HACCP Plans Meet Regulatory Requirements

According to FSIS's food safety systems correlation reviews, inspectors are not consistently identifying and documenting failures of plants' HACCP plans to meet regulatory requirements. Furthermore, FSIS does not expect its inspectors to determine whether HACCP plans are based on sound science—the cornerstone of an effective plan. While in-depth verification reviews examine the scientific aspects of HACCP plans, they have been conducted in very few plants, and consumer safety officers hired to review the scientific soundness of HACCP plans may take several years to assess the plans at all plants. Moreover, inspectors in 55 percent of the 5,000 plants nationwide did not document any HACCP violations during fiscal year 2001. When we brought this information to the attention of FSIS officials, they were surprised that so many plants had no HACCP violations for an entire year.

Food Safety Systems Correlation Reviews Show That FSIS Inspectors Did Not Identify Violations in Plants' HACCP Plans

FSIS's food safety systems correlation reviews show that plants have deficiencies in their HACCP plans that FSIS's in-plant inspectors did not identify and document in noncompliance records.⁸ Through May 2002, FSIS conducted food safety systems correlation reviews for seven districts and completed reports for six of those districts; it plans to complete reviews in the remaining districts by the end of fiscal year 2003. These reviews, which examine a random sample of plants in a district, compare

⁸ We did not talk to inspectors to find out if they identified violations but did not document them in noncompliance records. But because they are required to do so, we assumed that they documented all violations they found.

inspection practices within a district to, among other things, better target inspector training.

While examining the findings of the six completed district review reports, we found that a significant number of plants had deficiencies in their HACCP plans that FSIS inspectors had not identified and documented. For example, in about 91 percent of the plants sampled in three districts, inspectors had failed to issue noncompliance records for deficiencies in basic requirements such as the requirement that plants have adequate documentation to support the analysis of hazards in their HACCP plans.

- In 26 of 27 plants in one of the three districts, inspectors had not issued noncompliance records for HACCP plans that failed to include supporting documentation on the food safety hazards that were likely to occur. Inspectors also had not issued noncompliance records for 15 plants with plans that failed to address the three categories of hazards (biological, chemical, and physical) at each step of their production processes.
- In 10 of 14 plants in another district, inspectors had not issued noncompliance records for HACCP plans that had either not sufficiently documented decisions, not included all likely hazards, or not addressed specific pathogens.
- In the third district, inspectors had not issued noncompliance records for any of the 15 plants with HACCP plans that did not sufficiently document their hazard analyses.

The food safety system correlation reports did not elaborate on the reasons for the lack of documented violations in noncompliance records. However, all the reports included the general observation that “a number of inspection personnel” were unclear about some of the basic requirements of the HACCP program.

The Few In-Depth Verification Reviews Completed to Date Have Found Potentially Serious Problems

FSIS conducted in-depth verification reviews during calendar years 2000 and 2001 at 47 plants that it considered as having potentially serious food safety risks.⁹ The 47 plants included 31 that had failed to meet the *Salmonella* performance standard in two consecutive sets of tests; 8 that tested positive for *Listeria monocytogenes* on ready-to-eat meat or poultry products; 4 that tested positive for *E. coli* 0157:H7 on ground beef; and 4 for other concerns.¹⁰

We found that at 44 of these 47 plants, FSIS identified significant violations of regulatory requirements in HACCP plans. In 42 of these 44 plants, the HACCP plans did not include a complete hazard analysis to identify the biological, chemical, or physical food safety hazards that were reasonably likely to occur.

- One plant did not have the required documentation to substantiate the hazards that were identified in the hazard analysis. Instead, according to the FSIS review team, the hazard analysis was based on the personal experience and general knowledge of plant personnel.
- Another plant’s hazard analysis addressed some but not all parts of its production process where hazards could be introduced. Areas not addressed included returned products, packaging materials, and nonmeat ingredients.
- A third plant’s hazard analysis failed to identify a biological hazard as reasonably likely to occur for one product even though plant personnel were checking the product for pathogenic bacteria. Because the hazard was not identified in the plan and a critical control point was not designated for the hazard, no HACCP documentation was generated and

⁹ From January 1, 2002 to June 30, 2002, FSIS conducted an additional 10 in-depth verification reviews. These reviews fell outside of the time period we used for analysis.

¹⁰ Following the in-depth verification review, one plant had the second set *Salmonella* failure overturned on appeal. In another instance, FSIS conducted an in-depth verification review at a plant that failed three of its past four sets of *Salmonella* tests; the failure that triggered the review was the first set of a new series of tests.

no control measures were implemented to control the biological hazard throughout the process.

In 35 of the 44 plants, the HACCP plans did not adequately identify critical control points in their processes where controls could be applied to prevent, eliminate, or reduce a food safety hazard to an acceptable level.

- One plant's hazard analysis identified several biological and chemical hazards as reasonably likely to occur at various steps in the production process but did not establish critical control points to address those hazards.
- Another plant's HACCP plan for its slaughter activities identified a biological hazard at the animal-receiving step. The plant did not establish a critical control point to address that risk. Instead, it identified USDA inspection activities as the control measure. FSIS regulations require the plant itself to have control measures for all hazards that it identifies as reasonably likely to occur.

The in-depth verification reviews also showed that some plants may have a fundamental misunderstanding of what constitutes a hazard that is reasonably likely to occur. For example, when a plant fails a second set of *Salmonella* tests or a single test for *Listeria monocytogenes* or *E. coli 0157:H7*, it must reassess its HACCP plan to determine whether any changes are needed to prevent the problem from reoccurring. However, 15 of the 47 plants had not identified the pathogen that prompted the in-depth verification review as a hazard that was reasonably likely to occur. For example, the hazard analysis at one plant that had failed two consecutive *Salmonella* sets did not identify *Salmonella* as a hazard that was reasonably likely to occur—an “egregious” omission, according to FSIS's report on the review for that plant.

The in-depth verification reviews are useful in identifying deficiencies in the scientific aspects of plants' HACCP plans. However, according to FSIS officials, they are too time- and resource-intensive to be implemented on a broader scale. As of June 30, 2002, FSIS had conducted reviews at 57 plants—or about 1 percent of the more than 5,000 plants nationwide.

Consumer Safety Officers Improve FSIS's Ability to Assess the Scientific Adequacy of HACCP Plans, but Reviews of All Plans May Take Years to Complete

FSIS has recognized since HACCP's inception that its inspection workforce did not collectively possess the skills needed to evaluate the scientific validity of HACCP plans. As a result, FSIS does not expect its inspectors to evaluate the scientific soundness of HACCP plans. In October 2001, FSIS introduced consumer safety officers with the scientific and technical skills to, among other things, assess the scientific soundness of plants' HACCP plans. Initially, according to district office officials, the consumer safety officers were reviewing HACCP plans at plants where there was an indication of problems and were finding significant violations of HACCP regulatory requirements. In response to those findings, FSIS is taking enforcement actions to address potential food safety risks. For example, in one district, as of June 2002, consumer safety officers reviewed HACCP plans at 59 plants. As a result of these reviews, FSIS suspended 3 plants, sent letters to 17 plants indicating its intention to take enforcement action if changes were not made, and sent letters to 24 plants advising them to reassess their HACCP plans within 30 days to correct deficiencies.

FSIS plans to have 352 consumer safety officers by September 2005: 32 consumer safety officers on-board as of May 30, 2002; 50 more in 2002, plus 25 veterinary medical officers who will perform consumer safety officer duties on a part-time basis; 105 new consumer safety officers in fiscal year 2003; and 140 in fiscal year 2004. An FSIS official estimated, however, that FSIS might need a total of 500 consumer safety officers, including cross-trained veterinary medical officers, to carry out HACCP oversight responsibilities. Initially, FSIS had planned to bring consumer safety officers on board more quickly and in greater numbers. According to FSIS officials, Congress did not approve FSIS's fiscal year 2000 budget request to hire consumer safety officers and FSIS's efforts to retrain existing staff to fill these positions have taken longer than FSIS anticipated.

Officials in the two largest district offices (Alameda, Calif. and Albany, N.Y.) told us that it could take several years to ensure that all HACCP plans at all of the nation's meat and poultry plants have a sound scientific basis if FSIS cannot bring consumer safety officers on board as quickly as expected. If this were to occur, an Alameda District official told us it would take at least 4 years for the two consumer safety officers it has now to review the more than 500 plants in the district. Similarly, an Albany District official estimated that its five consumer safety officers will need from 2 to 5 more years to review HACCP plans at the district's more than 800 plants.

FSIS's Inspection Data Raise Further Concerns About Whether FSIS's Inspectors Are Ensuring That All Plants Meet HACCP Regulatory Requirements

FSIS's headquarters and district officials told us that finding plants with zero HACCP-related noncompliance records for an entire year would be unusual. HACCP requirements are numerous, and FSIS inspects plants on a daily basis, which creates many opportunities to identify and document HACCP violations. And as one district official told us, there are no perfect plants. That notwithstanding, our analysis of information in FSIS's inspection database showed that 55 percent of all plants had no documented HACCP-related violations during fiscal year 2001. (See table 1.) FSIS officials were surprised at the large percentage without violations. FSIS had not analyzed these data for an entire year. An FSIS field official told us that if inspectors are finding no HACCP violations for an entire year at so many plants, they may not understand their HACCP oversight responsibilities.

Table 1: Percentage of Plants with No Documented HACCP Violations during Fiscal Year 2001

FSIS district	Number of HACCP plants	Number of plants with no violations	Percentage of plants with no violations
Lawrence, Kans.	218	144	66
Philadelphia, Pa.	390	249	64
Beltsville, Md.	166	105	63
Pickerington, Ohio	248	154	62
Madison, Wis.	277	168	61
Des Moines, Iowa	195	116	59
Boulder, Colo.	216	127	59
Salem, Oreg.	267	150	56
Atlanta, Ga.	379	211	56
Dallas, Tex.	243	132	54
Jackson, Miss.	221	115	52
Chicago, Ill.	330	170	52
Raleigh, N.C.	165	85	52
Albany, N.Y.	838	425	51
Alameda, Calif.	530	268	51
Springdale, Ark.	183	84	46
Minneapolis, Minn.	191	73	38
Total	5,057	2,776	55

Note: In May 2002, an organizational realignment consolidated FSIS's 17 district offices into 15. In the realignment, the Pickerington, Ohio, office became a satellite office in the Chicago District, and the Salem, Oregon, office became a satellite in the Boulder, Colorado, District.

Source: GAO's analysis of FSIS's data.

As table 1 shows, the percentage of plants, by district, where no HACCP violations were documented on noncompliance records ranged from 38 to 66 percent. Officials in several districts acknowledged that they had reviewed reports that showed that some plants in their districts had no documented HACCP violations. According to FSIS officials, they had not analyzed the data for an entire year and were not aware of the extent to which no violations had been documented. Two officials told us that they had asked their circuit supervisors—who oversee FSIS’s in-plant inspectors—to investigate plants with no documented violations but that they had not asked the supervisors to report back to them with the results.

In fact, at 10 of the 43 plants in which FSIS’s in-depth verification reviews found serious HACCP implementation problems, FSIS inspectors had not documented any HACCP violations on noncompliance records during the 12 months preceding the review. For example, at one of those plants, the in-depth verification review found that (1) corrective actions taken by the plant were not documented, (2) monitoring records did not show the time that product temperatures were checked, and (3) the required annual reassessment of the HACCP plan had not been done. Inspectors had not documented any of these violations.

Although FSIS has implemented a variety of inspector training activities in response to our earlier report recommendations, it is clear that some FSIS inspectors remain uncertain about their roles, responsibilities, and authorities for reviewing and verifying plants’ compliance with HACCP requirements. Following a meeting we had with FSIS officials in June 2002 to alert them of our preliminary findings, FSIS informed us, in a letter dated August 2, 2002, that it was taking a number of actions aimed at addressing the problems we identified. With regard to inspector activities, FSIS stated that it is developing a directive explaining the responsibilities of inspectors under HACCP and has introduced an interactive computer tool for inspectors and others to use to strengthen HACCP problem solving using fictional scenarios.

In its August 2, 2002 letter, FSIS also told us that the agency had developed supervisory guidelines that will be a reference for managers to use to verify that FSIS inspectors are carrying out their responsibilities, including “applying appropriate inspection methods; using effective regulatory decision-making; documenting findings appropriately; and when warranted, implementing enforcement actions properly.” The agency expects to train all field supervisors and implement the new guidelines by October 1, 2002, and believes it will then be better able to hold supervisors accountable for overseeing inspectors’ performance. The letter also stated

that FSIS field offices are evaluating the results of the food safety system correlation reviews to determine how FSIS can improve the reviews and how it can use the reviews to strengthen inspectors' effectiveness.

FSIS's Lack of Consistent Identification and Documentation of Repetitive HACCP Violations Weakens Enforcement

According to our review of 1,180 noncompliance records from 16 plants for fiscal year 2001, plant inspectors have not consistently identified and documented repetitive violations of HACCP requirements. The lack of consistency occurs, in part, because FSIS has not established specific, uniform criteria for identifying repetitive violations. Moreover, even at the district level, officials' understanding of the factors that should be considered in determining repetitive violations varied. Furthermore, we found that FSIS's recently revised inspection data system lacks important summary information that managers need to oversee inspectors' identification of repetitive violations and enforcement decisions. If FSIS does not consistently identify and document repetitive violations, it cannot properly and equitably enforce HACCP requirements.

The Factors That Inspectors Used to Identify Repetitive Violations Differ

FSIS has not established specific criteria for its inspectors to use for determining when violations are repetitive. According to the noncompliance records we analyzed, inspectors did not use the same factors to identify repetitive violations of HACCP requirements. Table 2 shows the plant size and the number of noncompliance records and repetitive violations for the 16 plants we examined.

Table 2: Plant Size, Number of Noncompliance Records, and Number of Repetitive Violations in 16 Plants during Fiscal Year 2001

Plant	Plant size	Number of noncompliance records	Number of repetitive violations
Plant 1	Very small	9	2
Plant 2	Very small	12	3
Plant 3	Very small	15	8
Plant 4	Small	15	4
Plant 5	Small	23	0
Plant 6	Small	26	16
Plant 7	Small	60	34
Plant 8	Small	100	69
Plant 9	Small	112	74
Plant 10	Small	145	44
Plant 11	Large	12	10
Plant 12	Large	70	9
Plant 13	Large	109	85
Plant 14	Large	132	69
Plant 15	Large	167	113
Plant 16	Large	173	19
Total		1,180	559

Source: GAO's analysis of FSIS's documents.

We found the following variations:

- Inspectors differed in determining when a violation was repetitive, which led to inconsistent action on similar violations. For example, in one plant, two inspectors issued noncompliance records documenting three violations over a 15-day period that had the same inspection procedure (slaughter), element of the HACCP system (monitoring), and violation (fecal contamination). One inspector issued the first and second records 5 days apart; the other inspector issued the third record 10 days later. The first inspector did not link the first and second records and determine that the second record was repetitive. However, the inspector who wrote the third record linked it to the two earlier records, and determined that it was repetitive.
- Noncompliance records that contained the same information were not always identified as repetitive, which led to inconsistent action on the same violations and understating the potential seriousness of the problem. For example, on 23 occasions, an inspector in one plant wrote a noncompliance record followed within 2 days by another record containing the same information. However, the inspector linked the

first record to the second and determined that the second was repetitive on only one occasion.

- Inspectors used different time limits in which violations could be linked as repetitive, which may misstate the seriousness of the problem. For example, inspectors at one plant used a calendar month. Violations occurring within the same month could be linked to one another as repetitive, but violations in a subsequent month could not be linked back to incidences in the previous months. Inspectors at another plant used a period of 4 years. At this plant, noncompliance records for some violations were linked as repetitive to as many as 225 other violations. FSIS has not given guidance on an appropriate length of time for linking violations, but for training purposes, it uses a rolling 90-day period as the time limit for linking violations as repetitive, meaning that an inspector would look back 90 days from the date of a violation.

We also found that when inspectors identified violations as repetitive, they did not consistently document the basis for their decision—the record identification numbers of the previous violations. For example, at one plant, inspectors did not record the identification numbers for 75 percent of the previous repetitive violations, while at another plant, 46 percent of repetitive violations did not have this information. When documentation is lacking, FSIS cannot determine with any confidence the number of times a violation has been repeated and whether it warrants further enforcement action.

At the district level, we found that officials in the 10 districts where we sampled noncompliance records used varying factors, such as the type of violation (e.g., fecal contamination) or element (e.g., record keeping), that they said should be considered important in determining whether violations were repetitive. District officials also disagreed on the time period in which violations could be considered repetitive; only one stated that they usually used the rolling 90-day period.

FSIS's Inspection Database Provides FSIS Officials with Limited Information on Repetitive Violations

FSIS's Performance Based Inspection System, a database that captures the results of inspection activities, generates reports on the total number of HACCP inspections conducted and the percentage that resulted in violations. This information is reported by the type of inspection procedure (e.g., slaughter or processing) and the element of the HACCP system where the violation occurred (e.g., monitoring or record keeping). For example, the reports can identify the number and percentage of various HACCP inspection procedures at a plant that resulted in violations related to monitoring. FSIS's managers told us they considered these reports adequate to identify the potential for a repetitive problem and

trigger the need to explore individual noncompliance records to determine if a repetitive problem exists. Consistently and accurately linking repetitive violations is important because FSIS uses repetitive violations as a factor in assessing whether a plant has an effective HACCP system, whether an enforcement action is warranted, and whether the meat or poultry products from that plant are safe for consumers.

However, the inspection database does not capture summary information on the number of repetitive noncompliance records an inspector issues to a plant, the nature of the repetitive deficiencies, or plant managers' success or failure in taking effective preventive action. This type of summary information could assist managers in both overseeing inspectors' performance and plants' compliance with HACCP requirements. In addition, it could serve as one indicator for considering further enforcement action or for advising industry on the need to address a common problem. For example, managers could oversee inspectors' performance by comparing inspectors' rates of identifying repeat violations. If an inspector identified high rates, then a manager could investigate to determine if the inspector proposed or took further enforcement action. If the inspector identified low rates of repetitive violations, but the data showed high numbers of a particular type of violation, then managers could investigate to determine why these inspectors did not identify these as repetitive.

Managers have some information on repetitive violations, but not in summary format. Inspectors enter information into the database on an electronic version of the noncompliance record. Once entered, FSIS inspectors, supervisors, and managers from almost any location nationwide can review these individual noncompliance records. However, to assess the extent of repetitive violations that a particular inspector identified, a manager or supervisor would need to view every noncompliance record—a cumbersome process. FSIS officials maintain that the individual inspector is responsible for assessing the extent of repetitive violations, making a professional judgment on the need for further enforcement action, and bringing this matter to the attention of managers. However, access by managers to summary information on the repetitive violations that inspectors already identified would facilitate management's oversight of HACCP implementation.

Although FSIS headquarters and district officials told us throughout our work that they had sufficient data on repetitive violations, in its August 2, 2002 letter, FSIS stated that it now recognizes that it needs to improve and strengthen its data systems to support management decision making on

repetitive violations. The letter stated that FSIS has implemented several systems over the past 6 months in an effort to address its need for better inspection information from its data systems and is testing software that will enable district officials and managers to extract information and summary reports to help identify problem areas. The letter also stated that FSIS is pilot testing an early warning system for district officials that draws on data from various FSIS databases.

FSIS Is Not Ensuring That Plants Take Prompt and Effective Corrective Action to Return to Compliance with HACCP Requirements after Violations Have Been Identified

FSIS is not ensuring that all plants take prompt and effective corrective action to return to compliance with regulatory requirements after violations have been identified in three areas. First, FSIS does not consistently ensure that plants quickly take effective action to eliminate repetitive violations, particularly those of the zero tolerance standard for visible fecal contamination. Second, FSIS does not ensure that plants take prompt action to meet the *Salmonella* performance standard after a second consecutive failure. Finally, when FSIS suspends inspection services at a plant because of serious violations, it generally places those suspensions in abeyance, allowing the plants to continue operating. However, it rarely identifies a time frame for the plant to take corrective actions, and it does not track the actual time the plant takes to make the correction. The longer that FSIS allows plants to remain out of compliance with regulatory requirements, the greater the risk that unsafe food will be produced and enter the marketplace.

FSIS Does Not Consistently Ensure That Plants Quickly Take Effective Action to Eliminate Repetitive Violations

According to FSIS regulations, enforcement action is warranted when plants fail to demonstrate that their HACCP systems adequately prevent multiple or recurring violations. However, FSIS inspectors do not consistently initiate enforcement actions in such cases. For example, in the 1,180 noncompliance records we examined at 16 plants, the violation of FSIS's zero tolerance standard for fecal contamination was the most common type of repetitive violation. Each time an inspector documents this violation, FSIS regulations require the plant to take corrective action to remove the contamination. However, FSIS did not take withholding or suspension enforcement actions at any of the 11 plants where repetitive fecal contamination was identified. For example, FSIS issued 96 noncompliance records to one plant for these violations and although 88 percent of these records were linked as repetitive, FSIS did not initiate a withholding or suspension enforcement action. District officials stated that FSIS did not initiate an enforcement action because the plant had "done a good job" of addressing violations that were brought to its attention previously and the number of noncompliance records issued to the plant for fecal contamination was "not out of line" for a large plant. In addition, the officials said that violations of the fecal standard are bound to occur and most of the fecal contamination was minuscule—about one-eighth to one-quarter of an inch in diameter.

In another case, inspectors issued 154 noncompliance records to a plant for fecal contamination during the fiscal year, and they identified 109 of the deficiencies (71 percent) as repetitive, yet took no withholding or suspension enforcement action. For this plant, an FSIS official told us that the inspector did not recommend enforcement action because, in the inspector's professional opinion, the findings did not warrant it. However, because fecal matter can harbor serious contaminants, including *E. coli* 0157: H7, any fecal matter is a potentially serious health risk. FSIS's zero tolerance standard for visible feces recognizes this risk.

At plants where FSIS conducted an in-depth verification review, the noncompliance records also indicate that FSIS is not ensuring that plants quickly take effective action to eliminate repetitive violations. For example, at one slaughter plant, over 9-months, FSIS inspectors documented 27 instances of animals presented for slaughter that had levels of antibiotic drug residues that exceeded the amounts allowed by FSIS. On the earliest noncompliance record we reviewed, dated August 2000, the FSIS inspector wrote that the finding of excessive drug residue indicates, "that there may be an inadequacy in [the plant's] HACCP plan to control food safety hazards identified in [its] hazard analysis." However, it

was not until April 2001, 8 months later, that the plant implemented a program designed to prevent drug residues from entering its products.

FSIS has not established consistent criteria for inspectors to consider when assessing whether repetitive violations warrant a withholding or suspension enforcement action. According to FSIS officials, the decision to pursue an enforcement action is left to the professional judgment of each plant inspector. However, some district officials and inspectors we interviewed indicated that they would benefit from having FSIS identify a uniform set of factors for them to assess when considering whether an enforcement action is warranted. These officials suggested, for example,

- the length of time between repetitive violations,
- the number of repetitive noncompliance records issued,
- the nature of the violations, and
- the plant's efforts and/or success in implementing preventive actions.

FSIS officials told us they recognize the need to establish criteria for assessing whether repetitive violations warrant enforcement action and are in the process of updating a policy directive to include such criteria. FSIS expects to implement this directive in early 2003.

In addition, for repetitive violations, FSIS does not require inspectors to document whether they had considered and recommended or decided against an enforcement action. Such documentation would assist other inspectors at the same plant in determining whether enforcement actions are warranted when they issue additional noncompliance records for similar violations. This documentation could also assist supervisors and district office officials in overseeing plants' implementation of HACCP requirements.

FSIS Does Not Ensure That Plants Take Prompt Actions to Meet the *Salmonella* Performance Standard after a Second Consecutive Failure

FSIS does not ensure that plants take prompt corrective actions after they fail to meet the *Salmonella* performance standard. The HACCP regulations require that plants take immediate action to meet this standard if they have failed a set, but they do not explain what is meant by “immediate action.” However, our analysis of elapsed time shows that plants are not taking prompt corrective actions in these instances.

After a plant fails a second consecutive set of *Salmonella* tests, FSIS requires the plant to reassess its HACCP plan to determine if it should make any changes. In addition, FSIS has conducted in-depth verification reviews to evaluate the design and implementation of HACCP plans at plants that failed a second set of *Salmonella* tests. In 2000 and 2001, FSIS conducted in-depth verification reviews at 31 of these plants. In one case, FSIS conducted an in-depth verification review at one plant that had failed three of the past four sets of tests. However, the failure that triggered the review was the first set in a new series. Following the in-depth verification review, 14 plants passed a third set of tests and 5 failed. As of April 2002, for the remaining plants, sampling was in process or FSIS was waiting to begin the third set of tests.¹¹

As shown in table 3, our analysis of time frames for each step in the process, from first-set failure to passing a third set of *Salmonella* tests, shows that considerable time elapsed. These time frames are not consistent with ensuring that plants immediately meet the performance standard after a failure, as the regulations require.

¹¹ As of April 4, 2002, of the five plants that failed a third consecutive set of tests, one had failed a fourth set, two had passed, one had sampling in progress, and one had not yet begun further sampling.

Table 3: Elapsed Time—From Failure of First Set to Passing Third Set—at Plants with Second-Set Failures of the *Salmonella* Performance Standard and In-Depth Verification Reviews

Event	Average number of days elapsed	Range of days elapsed	Number of plants
First- to second-set <i>Salmonella</i> failure	198	113 to 337	30 ^a
Second-set failure to in-depth verification review	96	21 to 322	26 ^b
In-depth verification review to reassessment letter	76	11 to 284	28 ^c
FSIS's reassessment letter to plant's written response	37	12 to 82	26 ^d
In-depth verification review to third-set result	320	155 to 543	16 ^e
First-set <i>Salmonella</i> failure to third-set pass	608	340 to 929	14 ^f

^aSubsequent to the in-depth verification review, one of the 31 plants had its second-set *Salmonella* failure overturned on appeal. Consequently, it was not included in this calculation.

^bFSIS conducted an in-depth verification review at one plant that had failed three of the past four sets of tests. However, the failure that triggered the review was the first set in a new series. Therefore, the time from second-set failure to the review could not be calculated. Also, in three cases FSIS began the third set of tests prior to the in-depth verification review. Therefore, these plants are not included in this calculation.

^cFSIS did not send reassessment letters to 2 of the 30 plants because the in-depth verification reviews were conducted before the agency required reassessment letters in these situations.

^dTwo plants did not receive reassessment letters and so did not send a response to FSIS. One plant's response to the reassessment letter was not dated, and FSIS did not provide us with the plant's response letter in one case.

^eAs of April 4, 2002, FSIS had completed the third set of *Salmonella* tests at 19 plants. However, in three cases the third set of tests was begun prior to the in-depth verification review. Therefore, the time from the review to third-set result could not be calculated for these plants.

^fOf the 19 plants for which a third set of *Salmonella* tests were completed as of April 4, 2002, 14 passed and 5 failed.

Source: GAO's analysis of FSIS's data.

Our analysis showed that, on average, it took FSIS about 3 months from the date of the second-set failure to begin an in-depth verification review. Once the in-depth verification review was complete, an average of 2½ months elapsed before FSIS sent its “reassessment” letter to the plant listing all of the deficiencies in the design and implementation of the HACCP plan found during the review. In one case, the period from review to FSIS letter was 284 days—or more than 9 months. The reassessment letter instructs the plant to respond to FSIS in writing within 30 days

stating the changes that will be made to meet the *Salmonella* performance standard.

We found that plants came close to meeting this time frame—replying within 37 days on average. On the other hand, FSIS does not consistently require that plants quickly take steps to correct the deficiencies identified by the in-depth verification reviews. As shown in table 3, FSIS has allowed plants to take an average of 608 days—or over 1½ years—from their first-set *Salmonella* failure until the successful completion of a third set of tests. Over half that time, or about 11 months, elapsed from the date of the in-depth verification review until the successful completion of the third set of tests. For example, at one plant in the Dallas district, 18 months elapsed from the date of the in-depth verification review until the completion of the third set of tests. (See table 4.)

Table 4: Time Line of Events between In-Depth Verification Review and Third Set of *Salmonella* Tests at One Plant

Date	Action
Oct. 30 to Nov. 2, 2000	FSIS team conducts the in-depth verification review.
Apr. 3, 2001	FSIS sends the reassessment letter to the plant.
Apr. 25, 2001	The plant responds to FSIS about what changes it will make to its operations.
May 21, 2001	The plant asks for a delay in conducting the third set of tests.
Aug. 23, 2001	FSIS writes the plant that the agency has not yet received written notification of the completion dates for the plant's improvement projects.
Oct. 31, 2001	The plant writes to FSIS that the improvements would be completed by mid-November and asks that the third set of tests not begin until after December 1, 2001.
Dec. 3, 2001	Sampling for the third set of tests begins.
Apr. 26, 2002	The third set is completed and the plant passes.

Source: GAO's analysis of FSIS's documents.

Officials in the Dallas District Office told us that 5 months elapsed between the date of the in-depth verification review and FSIS's reassessment letter largely because of the amount of time needed to incorporate all of the in-depth verification review team's comments and complete the report of the review's findings. About 8 months elapsed from the date of the plant's response to the reassessment letter until the third set of *Salmonella* tests began because, according to the district officials, the district did not closely monitor the progress of the changes the plant was making and because the plant requested and received FSIS's permission to delay the third set until those changes were made.

Because plants may continue to produce products that could pose a *Salmonella* risk from the first-set failure until they pass, it is important that the second- and third-set tests be scheduled and completed as soon as possible. An FSIS headquarters official acknowledged that, in some cases, the time between the second and third set of *Salmonella* tests has been too long. However, the official stated that plants sometimes make significant changes to their operations after an in-depth verification review and the time needed to reassess, modify and validate HACCP plans can be considerable. Nonetheless, in the Dallas district case described above, at least a portion of the delays were due to inattentive oversight by FSIS. In its August 2, 2002, letter to us, FSIS said it has designed and is ready to test a tracking system for the in-depth verification reviews to assist the agency in keeping those reviews timely and to allow for trend analysis of review results over time.

FSIS further stated in that letter that USDA's Under Secretary for Food Safety, in consultation with the Secretary of Agriculture, established a new office—the Office of Program Evaluation, Enforcement and Review—to ensure that its programs and policies are implemented and monitored correctly. The new office, which began operating on July 15, 2002, will conduct in-depth examinations of FSIS policies to determine if the policies are adequate or if additional actions are needed. The new office began by looking at the *Salmonella* testing program to determine whether it is accomplishing all it should to protect human health. It expects to report its findings by mid-September 2002. In addition, FSIS noted, “using [the GAO preliminary findings] as a guide, [the new office] has begun to assess the adequacy of the field staff's implementation of HACCP.” This preliminary report is also due in mid-September.

FSIS Does Not Always Ensure That Plants Whose Suspensions Have Been Placed on Hold Take Prompt Action to Return to Compliance

FSIS is also not ensuring that plants take prompt corrective actions when it places plants' suspensions in abeyance. When a suspension is in abeyance, FSIS inspection services resume, and the plant continues operating while it makes corrections. In analyzing 60 HACCP administrative enforcement case files for 2001 for plants in the Albany, Alameda, and Madison districts, at which FSIS had suspended inspection services, we found that 57 of the 60 suspensions were placed in abeyance. In half of the suspensions that were in abeyance (28 of the 57 cases), FSIS placed the suspension in abeyance on the same day the suspension was issued. Because there was either no or very limited interruption in inspection services at the plant, the effect on the plant, in terms of economic loss or disruption, was negligible.

On January 24, 2001, FSIS published policy guidance stating that no plant's suspension should remain in abeyance for more than 90 days without a specific "operational reason," such as a violation that involved a process that the plant operates intermittently. Limiting the time that suspensions can remain in abeyance was also FSIS's practice prior to the January 2001 policy notice establishing a specific time frame. Our sample of the 57 enforcement cases included 30 plants that had suspensions in abeyance that were closed after the 90-day policy went into effect in January 2001. Of these 30 enforcement cases, only 1 was closed within 90 days. The average number of days from suspension in abeyance to case closure was 316 days, or over 10 months. According to FSIS officials in charge of enforcement in the three district offices where we reviewed enforcement cases, the 90-day time frame for holding suspensions in abeyance was not met because (1) the district office did not require inspection personnel to report to them on whether the plants had completed their corrective and preventive actions within the 90-day period, (2) it often took longer than 90 days for inspection personnel to inform the district office that plants had completed their corrective and preventive actions and the cases could be closed, and (3) closing these cases was a low priority for the district office.

Further, none of FSIS's "Notice of Suspension of Inspection" documents or other correspondence in the enforcement files for the 30 cases we examined specified a date by which corrective actions were expected to be implemented and their effectiveness verified. As long as FSIS does not establish specific deadlines for plants with suspensions in abeyance to correct their problems, plants have little incentive to quickly implement and verify the effectiveness of their corrective actions.

In addition, we were generally unable to verify that violations were corrected before FSIS issued the letter ending the suspension in abeyance and closing the case. The enforcement case files frequently did not contain evidence showing how and when the district offices determined that the plants had completed corrective and preventive actions. However, in the Albany District Office, 6 of the 21 closed enforcement files contained correspondence from inspection personnel to the district office documenting how and when the plant had corrected the violation and recommending closing the case. An FSIS headquarters official responsible for enforcement activities told us that he would expect to see documentation showing how decisions were reached in all case files.

Moreover, in the Alameda district office, two of the four plants we reviewed continued to have violations of the same requirements for which

the plant was suspended, according to the inspectors' documentation. Nevertheless, the suspension remained in abeyance, and FSIS did not take any further enforcement action. For example, one suspension that was placed in abeyance on the day it was issued in October 2000 was the result of the plant's repeated failure to keep adequate HACCP records to verify that critical control points were being properly monitored to ensure food safety. In March 2001, inspectors documented three more instances of the plant's failure to keep the same type of HACCP records and two more instances in the following months until the case was closed in September 2001.

FSIS also allows plants to have multiple suspensions in abeyance in effect simultaneously, each for a separate production process, or to have sequential suspensions in abeyance that last for extended periods of time. As a result, a plant can continually struggle to meet requirements and require special regulatory oversight for an extended period of time and yet remain in business. For example, the plant in the Alameda District mentioned above had sequential suspensions placed in abeyance. In October 2001, just 1 month after the earlier suspension was lifted, the district office sent the plant a letter indicating FSIS's intention to take enforcement action because of the plant's failure to collect product samples for *E. coli* testing, as required by the HACCP regulations. On the basis of the plant's response to the letter, the district office deferred any enforcement action for 90 days. Recognizing that this was a problem plant, in November 2001, the district had a consumer safety officer conduct a comprehensive review of the plant's HACCP system. Owing to the HACCP design and implementation problems discovered by the consumer safety officer, such as deficiencies in the hazard analysis and record keeping, inspection was again suspended in early December 2001 and the suspension was placed in abeyance 2 days later. In January 2002, because of the plant's failure to adhere to its October 2001 plan to improve its *E. coli* sampling procedures, inspection was again suspended and then placed in abeyance 1 day later. Alameda district officials told us they recommended to FSIS headquarters that FSIS withdraw this plant's grant of inspection and were told that there was insufficient cause to take this action.

In its August 2, 2002, letter to us, FSIS stated that an administrative enforcement data system, which it implemented in January 2002, "for distributing copies, tracking status, and querying for information on administrative actions" provides, among other things, "status reports [that] show suspensions in abeyance to assist District Managers in assuring proper follow up at these establishments." It further stated that it sets

“very specific timelines for the plant to meet with respect to corrective or preventive measures” and that its “in-plant personnel conduct verification activities to ensure they are meeting the conditions outlined in the timeline. If [plants] do not follow through on the timeline/plan, the suspension is reinstated.” FSIS’s letter went on to note that “[t]he average time for the closure of suspension actions placed in abeyance in [fiscal year] 2002 has been 105 days.” However, unlike our analysis, this average time is based on FSIS enforcement cases for violations of sanitation standards as well as HACCP enforcement cases and, as the letter points out, does not include an unspecified number of cases that remain open.

Conclusions

Meat and poultry plants have many incentives to operate safely and certainly many appear to be doing so under HACCP. Nevertheless, FSIS’s oversight and enforcement needs to be improved to ensure that it is achieving its intended food safety objectives. FSIS inspectors are currently not consistently identifying and documenting violations of HACCP regulatory requirements, and FSIS has not assessed the scientific soundness of all HACCP plans in a timely manner. Moreover, some FSIS inspectors still do not have a clear understanding of their roles, and FSIS managers have not been diligent in overseeing inspectors’ activities. Finally, until consumer safety officers complete their assessments, some plants may be operating with unsound HACCP plans. These weaknesses limit the effectiveness of the HACCP system in reducing the risks posed by pathogens and contaminants on meat and poultry.

With regard to identifying repetitive violations—signs that a plant may be struggling to fully meet HACCP requirements—FSIS’s inspectors and managers are confused about the factors that should be considered. Until FSIS establishes clear, consistent criteria for determining and documenting repetitive violations—and ensures that its inspectors and managers understand these criteria—serious problems may go unrecognized. The extraction of summary information on repetitive violations from FSIS’s inspection database would help determine, among other things, when repetitive violations might indicate problems common to an industry sector or an FSIS district.

Finally, the longer that FSIS allows plants to remain out of compliance with HACCP requirements, the greater the risk that unsafe food will be produced. When plants do not take actions that promptly and successfully prevent repetitive violations—such as multiple recurring violations of the zero tolerance standard for visible fecal contamination—FSIS managers and officials must take enforcement actions to compel plants to revise

their HACCP plans to address these problems. The system that FSIS has in place to address plants that fail *Salmonella* performance standards—allowing plants to operate while increased food safety risks persist for months and months—needs to be reexamined. Similarly, FSIS’s practice of placing a plant in suspension but then immediately putting the suspension in abeyance for protracted periods of time negates an important incentive for plants to quickly correct problems. While some corrective actions could take a significant period of time to implement—and placing a suspension in abeyance might be warranted when FSIS is sure that interim actions will provide for food safety—the circumstances should be clearly established and progress closely monitored and documented to ensure that plants are returning to compliance as soon as possible.

Recommendations for Executive Action

To ensure that all HACCP plans fully meet regulatory requirements, we recommend that the Secretary of Agriculture direct FSIS to

- provide inspectors with additional training on their roles and responsibilities under the HACCP system and use data, such as the results from the food safety system correlation reviews, to help target training to address specific weaknesses;
- develop procedures for its field supervisors and district managers to use to monitor inspector activities, including, among other things, ensuring that FSIS inspectors are consistently applying HACCP requirements;
- develop a risk-based strategy and time frames for consumer safety officers to complete their reviews of HACCP plans at all plants; and
- develop a strategy for its supervisors, managers, and officials to systematically use data, including annual data on noncompliance records by districts, to help oversee plants’ compliance with HACCP requirements.

To ensure that FSIS inspectors and district officials use consistent criteria for identifying repetitive violations of HACCP regulatory requirements, we recommend that the Secretary of Agriculture direct FSIS to

- establish specific, uniform criteria for identifying repetitive violations;
- ensure that inspectors consistently document repetitive violations;
- modify data management systems to capture the extent to which inspectors are identifying repetitive violations at plants; and
- develop a strategy for its supervisors, managers, and officials to systemically use available data, including summary information, to help identify repetitive violations.

To ensure that plants take prompt actions to correct violations, we recommend that the Secretary of Agriculture direct FSIS to

- establish clear, consistent criteria for inspectors to use when considering whether to recommend suspension because of repetitive violations;
- require its inspectors to document the basis for their decision on whether or not to recommend further enforcement action based upon documented repetitive violations;
- develop guidance with specific time frames for actions to be taken at plants that fail a second set of *Salmonella* tests, including time frames for FSIS to initiate an in-depth verification review, report the results of the review, and initiate a third set of tests;
- establish, and document in enforcement case files, time frames for plants with suspensions in abeyance to implement and verify the necessary corrective actions; and
- document in the enforcement case file how and when the district office determined that the plant had completed its corrective actions and, if the suspension is allowed to remain in abeyance for more than 90 days, the reason for the extension.

Agency Comments and Our Response

We provided USDA with a draft of this report for review and comment. USDA concurred with our recommendations but believes the report does not fully acknowledge FSIS's progress and continuous efforts to ensure that all plants meet regulatory requirements. Noting that FSIS has placed significant resources into the processes and systems that provided the data for our study, USDA states that FSIS has efforts ongoing to evaluate the same data and has been open about addressing these and other similar concerns and the need for associated program improvements. USDA describes a number of actions that FSIS has recently taken or is planning to take that are consistent with our recommendations. We believe that our report accurately reflects the status of FSIS's ongoing and planned actions. If fully carried out and given diligent management attention, these actions could go a long way toward addressing the problems we found in FSIS's oversight and enforcement of HACCP in U.S. meat and poultry plants and helping to reduce the risk of foodborne illness for American consumers. USDA's comments are presented in appendix II. USDA also provided technical suggestions, which we incorporated into the report as appropriate.

We conducted our review from August 2001 through August 2002 in accordance with generally accepted government auditing standards.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the date of this letter. At that time, we will send copies of this report to the congressional committees with jurisdiction over food safety issues; the Secretary of Agriculture; the Administrator, Food Safety and Inspection Service; the Director, Office of Management and Budget; and other interested parties. We also will make copies available to others upon request. In addition, the report will be available at no charge on the GAO Web site at <http://www.gao.gov>

If you have any questions about this report, please contact me or Erin Lansburgh at (202) 512-3841. Key contributors to this report are listed in appendix III.



Lawrence J. Dyckman
Director, Natural Resources
and Environment

Appendix I: Scope and Methodology

Our review of the Food Safety and Inspection Service's (FSIS) enforcement of the Hazard Analysis and Critical Control Point (HACCP) requirements focused exclusively on domestic meat and poultry slaughter and processing plants subject to federal oversight. To assess whether FSIS is ensuring that plants' HACCP plans meet regulatory requirements, we analyzed data from several sources. These sources included the following:

- The findings on the adequacy of HACCP plans from the food safety systems correlation team review reports in six districts.
- The findings concerning HACCP plans from FSIS's reports for the 47 in-depth verification reviews of plants' HACCP systems completed in calendar years 2000 and 2001.
- The approximately 700 HACCP-related noncompliance records written at plants where FSIS conducted an in-depth verification review to determine the type of deficiencies inspectors identified in the year prior to the review.
- FSIS's Performance Based Inspection System database to identify the number of plants in each district where no HACCP-related violations were documented during fiscal year 2001.

We also visited 17 plants in California to view their HACCP systems in operation and observe FSIS's oversight. We visited plants in each of FSIS's three size categories—large (500 or more employees), small (10 to 499 employees), and very small (fewer than 10 employees or annual sales of less than \$2.5 million). The plants we visited were engaged in the slaughter and/or processing of chickens, turkeys, hogs, and cattle. We reviewed HACCP-related documents and discussed the plant's HACCP system with FSIS officials at each of the plants we visited. In addition, we obtained information from headquarters and district office officials on the goals, training, and responsibilities of consumer safety officers. We also reviewed the HACCP regulations, FSIS directives and other policy documents, and interviewed FSIS officials from headquarters and the Technical Service Center regarding the agency's approach to reviewing HACCP plans.

To determine whether FSIS is consistently identifying repetitive violations of HACCP requirements, we judgmentally selected 16 plants located in 10 FSIS districts. We selected these plants from among those where FSIS frequently found violations in fiscal year 2001. Specifically, we selected our sample from among those plants where 8 percent or more of the time, when FSIS conducted a HACCP inspection, it found a violation. Only about 4 percent of the total plants subject to HACCP inspection met this criterion. We excluded from our sample any plants that are participating in

FSIS's HACCP-Based Inspection Models Project or those that had been subject to an enforcement action.¹ Of the 16 plants we selected, FSIS considers 6 to be large, 7 small, and 3 very small. Ten of the plants we selected were poultry plants and 6 were beef plants. We analyzed all of the HACCP-related noncompliance records provided by FSIS for fiscal year 2001 at these 16 plants—in total 1,180 records—to determine the extent to which inspectors had identified repetitive violations. We interviewed district officials from the 10 district offices to determine the factors they consider important in determining whether violations were repetitive. The district officials we spoke to included district managers; assistant district managers for enforcement; HACCP inspection coordinators; managers of inspection staff at a group of plants in a district, known as “circuit supervisors;” and veterinarians and an inspector at plants. We also interviewed FSIS headquarters officials and district officials to discuss issues raised from our review of the noncompliance records. We reviewed FSIS's policy documents and training materials related to determining repetitive violations.

To assess whether FSIS is ensuring that plants take prompt and effective action to return to compliance after the agency has identified HACCP violations, we analyzed data from three different sources. First, we analyzed the type and rate of repetitive violations identified by inspectors in our sample of 16 plants and spoke to FSIS officials in district offices to discuss why no further action was taken. Second, we analyzed FSIS's data on the 31 plants that failed a second set of *Salmonella* tests and, at which FSIS conducted an in-depth verification review, to identify the time that elapsed between the first, second, and third sets of *Salmonella* tests. Third, we analyzed the case files for 68 HACCP administrative enforcement cases that were active in fiscal year 2001 from three FSIS districts (Albany, Alameda, Madison). We selected these three districts because they represented large, medium and small enforcement caseloads and were located in three different regions of the country. Albany and Alameda are the districts with the largest number of plants. We interviewed the assistant district managers for enforcement in each of the three districts regarding the actions taken on these cases. We also spoke to FSIS headquarters officials about enforcement issues and reviewed FSIS's policy documents related to HACCP enforcement.

¹ At plants participating in this project, plant personnel, instead of FSIS inspectors, examine each carcass to make an initial determination whether it is unacceptable and should be removed from the slaughter line. A reduced number of FSIS inspectors are still at each plant to ensure that safety and quality standards are met.

We conducted our review from August 2001 through August 2002 in accordance with generally accepted government auditing standards.

Appendix II: Comments from the U.S. Department of Agriculture

Note: GAO's comments supplementing those in the report's text appear at the end of this appendix.



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

AUG 26 2002

Lawrence J. Dyckman
Director, Natural Resources and Environment
Food and Agriculture Issues
U.S. General Accounting Office
441 G Street, N.W. Room 2T23
Washington, DC 20548

Dear Mr. Dyckman:

Thank you for the opportunity to review and provide comments on the U.S. General Accounting Office (GAO) Draft Report, Meat and Poultry – Better USDA Oversight and Enforcement of Safety Rules Needed to Reduce Risk of Foodborne Illnesses, No. GAO-02-902. Although we agree with the GAO recommendations, we believe that the report does not fully acknowledge our progress and continuous efforts to fully ensure that all plants meet regulatory requirements. Further, it should be recognized that FSIS has placed significant resources into the processes and systems that generate the data and information used by GAO to evaluate our program. FSIS has ongoing efforts to routinely evaluate the same type of data. FSIS has been open about addressing these and other similar concerns and the need for associated program enhancements.

Our comments will highlight a number of actions that we have taken to ensure that regulatory requirements are met. Many of these actions have been implemented over the last few months and are reflected in Agency Directives, Notices and other guidelines. FSIS has used much of the same data as GAO in conducting its internal assessments that have led to many actual and planned improvements of our internal policies, procedures and guidance. Further, we believe that the GAO report validates, through its recommendations, the course of action that the Agency is taking to enhance the implementation of the Hazard Analysis and Critical Control Point (HACCP) program and continue to ensure that plants are meeting our regulatory requirements.

GENERAL COMMENTS

1. We believe that the title of the report is a bit misleading. We suggest a different title such as "Continued USDA Oversight and Enforcement of Safety Rules Needed to Reduce Risk of Foodborne Illnesses".
2. The GAO report noted what appears to be inconsistent implementation of HACCP. Similar observations made earlier by FSIS officials resulted in several directives and notices being prepared to provide supplemental guidance and clarification of existing policies and requirements.

See comment 1.

See comment 2.

Appendix II: Comments from the U.S.
Department of Agriculture

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See comment 3.

- a. In response to decision by the United States Court of Appeals for the Fifth Circuit, No. 00-11008, *USDA v. Supreme Beef Processors, Inc.*, the Agriculture Secretary Ann M. Veneman announced several initiatives that FSIS would undertake to address issues related to implementation and enforcement of the *Salmonella* performance standards. These initiatives include the development of procedures to ensure that inspection activities continue to adequately verify an establishment's total food safety program and revisions in the Agency's response to *Salmonella* sample set failures.
- b. FSIS has developed FSIS Notice 28-02, Action To BE Taken In Establishments Subject to Salmonella Testing, dated July 25, 2002. This notice provides program personnel with verification activities that they are to carry out in slaughter operations subject to the *Salmonella* performance standards and grinding operations that are subject to *Salmonella* testing. Carrying out these activities is a way to ensure the proper performance of verification activities with respect to an establishment's total food safety program. This notice also provides new steps the Agency will take should an establishment fail to meet the standards.

See comment 4.

- c. FSIS also issued FSIS Notice 36-01, Rules of Practice, dated September 5, 2001. The directive was issued to ensure that all inspection program personnel are knowledgeable about the enforcement actions that the Agency may take (generally) in inspected establishments, the circumstances under which the various types of enforcement actions are appropriate and can be taken, and the procedures that the Agency will follow in doing so. The rules of practice provide a key link between inspection and enforcement activities.

See comment 5.

- d. On August 9, 2002, we issued FSIS Notice 29-02, HACCP Verification Procedures and the 30-day Reassessment Letter, which clarifies how inspection program personnel should respond when they find evidence of a deviation from a critical limit or a HACCP noncompliance while performing an 01 and 02 HACCP verification procedure. This notice also clarifies issues regarding when inspection program personnel should issue 30-day reassessment letters.

See comment 6.

- e. The Under Secretary for Food Safety, Dr. Elsa A. Murano, in consultation with Secretary Veneman, established within FSIS an office that is designed to ensure our programs and policies are implemented and monitored correctly. This new office, Office of Program Evaluation, Enforcement and Review (PEER), will be headed by two veterans of FSIS – one with vast Headquarters experience and the other with extensive field experience. PEER, was established to provide focus to internal review of FSIS programs, as well as an additional set of eyes for the Administrator in assessing effectiveness of regulatory activities. PEER began functioning as a unit on Monday, July 15, 2002, will conduct in-depth examinations of policies established by FSIS to determine if those policies are adequate or if additional steps are necessary. For example, as its first review, the PEER staff began on Monday, July 15, a review of the FSIS Salmonella testing program to determine if that program is accomplishing all that

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it should in protecting public health. Recent reports by consumer activists are being studied to highlight areas of concern to be examined.

Review of the implementation of policies by Field staff is also a function of the PEER office. The PEER staff has also begun to assess the adequacy of the field staff's implementation of HACCP. This initial review will include an assessment of Food Safety System Correlation (FSSC) reports, conversations with District Managers and other officials. This staff, which includes investigators located in the field, will also be able to conduct quick investigations when problems arise in the field, although compliance officers are also on site for such investigations.

See comment 7.

f. We are also updating FSIS Directive 5000.1, Enforcement of Regulatory Requirements in Establishments Subject to the HACCP System Regulations (including regulations on Sanitation Standard Operating Procedures (SSOP's), E. coli Testing and Criteria, and Salmonella Performance Standards). This directive provides instructions to supervisory personnel, consumer safety officers, circuit supervisors, and inspection program personnel for reviewing an establishment's HACCP plan and otherwise enforcing the HACCP system regulations (9 CFR part 417). It also updates previous instructions to inspection program personnel regarding the regulations on sanitation performance standards (SPS) and SSOP's (9 CFR part 416). This directive fully explains to our inspectors their responsibilities under SPS, SSOP, and HACCP and provides them questions to consider in performing their responsibilities.

3. The GAO report recognized our FSSC reviews for identifying trends/weaknesses in our verification and enforcement activities under HACCP. The FSSC's also identify areas in which the industry needs to improve in terms of the quality of industry HACCP plans. The FSIS is continuing these reviews and the correlation/training sessions it holds for its inspection force and for industry following completion of the reviews in each District. Correlation in all the district offices will be completed by the end of FY 2003. FSIS is evaluating the FSSC's on an ongoing basis to determine what additional improvements can be made and how the trends identified can be used to strengthen the knowledge and effectiveness of the inspection force and industry.

See comment 8.

4. FSIS is improving its systems for ensuring frontline accountability by putting in place a formal process and tools that will be mandatory for frontline supervisors to use to ensure that inspection program personnel carry out their assigned job responsibilities as required under the Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) regulations.

FSIS Directive 4430.3, In-Plant Performance System (IPPS) Reviews, dated June 17, 2002, and comprehensive Supervisory Guidelines have been distributed through the Agency directives system. These documents provide specific instructions and guidance on how to assess the performance of *non-supervisory* inspection program personnel in PR/HACCP system environment. The Supervisory Guidelines are a reference for verifying that inspection program personnel are carrying out their responsibilities. These include applying appropriate inspection methods; using effective regulatory decision-making;

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documenting findings appropriately; and when warranted, implementing enforcement actions properly.

The IPPS directive requires that each field supervisor conduct as many as three formal, on-site reviews of each non-supervisory, in-plant employee focusing on specific aspects of the individual's job requirements. The supervisor will be required to document the results of each review by indicating the specific job requirements that were reviewed, and by documenting any deficiencies in knowledge or execution identified. The supervisor must also document the follow-up activities taken to address the deficiencies. This tool not only targets accountability of non-supervisory personnel but also targets the accountability of the field supervisors who are responsible for monitoring the activities of inspection personnel and ensuring consistent and effective verification of regulatory requirements by those personnel.

All field supervisors will receive training in the IPPS system by October 1, 2002, when the system will be fully implemented. FSIS will also audit the training and the implementation of the system, once in place, to ensure that it is being carried out as intended.

See comment 9.

5. In a continuing effort to enhance and improve the scientific basis of our inspection activities, FSIS has implemented a new service to facilitate greater sharing of knowledge and information with and among FSIS field personnel. This new service is identified as the "Interactive Knowledge Exchange (IKE)," and is described below.

The IKE is a new tool available to all field employees. It helps keep employees current, and provides correlation, on regulatory requirements, directives, notices, HACCP, SSOP, and/or agency sampling programs. Through the use of scenarios IKE allows, an employee to review FSIS requirements and hopefully to correlate with his or her work-group and supervisor regarding the application of those requirements

A scenario pertaining to an inspection related subject is sent out electronically on a bi-weekly basis to all field employees. Each scenario includes a "what would you do?" or "what is the correct action to take?" section, with suggested solutions to problems or issues raised in the scenario.

Any employee may ask questions regarding these scenarios. It is believed, however, that the greatest benefit may be gained from discussions of the scenarios and questions within individual work groups and with supervisors. The scenarios, and any subsequent questions and answers, are intended to aid FSIS employees through increased understanding and correlation of regulations, policies, and standards for the inspection of meat, poultry, and egg products. If questions pertaining to any of the scenarios or answers given on IKE are not resolved through discussions within the work-group or with the supervisor, they can be submitted via electronically for further review and resolution to the Technical Service Center.

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See comment 10.

6. GAO's report recognizes that FSIS knew it needed a more scientifically trained and capable workforce to ensure that it could identify problems with the design of HACCP plans. GAO accurately relays FSIS' plan to add several hundred Consumer Safety Officers (CSO) to its workforce. However, budget constraints have meant that hiring and training CSOs can happen only incrementally over a period of years. FSIS plans to hire up to 50 CSO per year. In addition to hiring and training CSOs for each district, FSIS has trained its District Veterinary Medical Specialists and will be training additional members of its workforce in the CSO methodology to increase the cadre of employees capable of assessing the design and scientific aspects of establishments' HACCP plans.

See comment 11.

7. GAO also concludes that FSIS' inspection related data systems provide FSIS managers with limited information on repetitive noncompliance. FSIS has implemented several systems over the past 6 months in an effort to address this need which we have also recognized as an issue. Following is a brief description of each system:

- **PBIS 5.0** – GAO's report outlines the capabilities of PBIS 5.0 but also points out that trend analysis and summaries are not generated by an automated system to help managers identify problem areas. FSIS is testing software that will enable field managers to use PBIS 5.0 to extract needed information and summary reports for this purpose.
- **District Early Warning System** – This system is being pilot tested. This system will extract and compile data from various FSIS databases relating to inspection, sampling, and enforcement and generates an "early warning" for District Managers when the combination of certain events or findings reach pre-determined thresholds.
- **Administrative Enforcement Data System** – This electronic system for distributing copies, tracking status, and querying for information on administrative actions was implemented in January 2002. Among other things, status reports show suspensions in abeyance to assist District Managers in assuring proper follow up at these establishments.
- **FSIS Directive 5000.1** – This directive will set out factors to consider in deciding whether there has been repetitive noncompliances.

See comment 7.

See comment 12.

8. FSIS Notice 5-01, District Managers Responsibilities in assessing an Establishment's Response to a Notice of Intended Enforcement (NOIE), dated January 24, 2001, establishes deferral and abeyance processes after a NOIE is issued. Under this notice, a District Manager (DM) can defer action on a NOIE or hold a suspension action in abeyance if the establishment, in response to the NOIE, submits corrective actions that the District Manager has substantial reason to believe are adequate. The District Manager is expected to make a decision on the adequacy of the action as soon as sufficient information becomes available. The notice indicates deferrals and abeyance should be for no more than 90 days without

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cause. This allows us to put plants on notice and then allow the plant to implement the plan and demonstrate the plan is effective.

FSIS does not believe that plants are given too much time to comply with regulatory requirements. For example, when a suspension is put in abeyance, the plant establishes specific timelines for corrective or preventive measures, and our in-plant personnel conduct verification activities to ensure they are meeting the conditions outlined in the timeline. If they do not follow through on the timeline/plan, the suspension is reinstated. As of July 10, there have been 13 reinstatements of suspension in FY 2002 compared to 11 in FY 2001.

FSIS policy provides for a 90-day timeframe for monitoring and verifying effective plant implementation of corrective and preventive actions proposed in response to an enforcement action. Timeframes may be shortened in appropriate cases.

The Agency implemented enhanced electronic and management systems for tracking the status of administrative enforcement actions in order to ensure effective oversight and follow-up actions by Districts to close or initiate enforcement action. When FSIS verification shows plant implementation has been effective and resulted in compliance with regulatory requirements, the enforcement action is closed. If FSIS verification shows continued noncompliance or failure of the plant to implement its proposed corrective actions, the agency takes enforcement action, such as the suspension of operations. When plants are unable to restore sanitary conditions and assure future compliance with food safety requirements, the agency proceeds with additional action, which may include formal legal action to continue the suspension or withdraw the grant of inspection.

See comment 13.

9. An analysis of current enforcement data shows substantial improvement in the enforcement arena. The average time for the closure of suspension actions placed in abeyance in FY 2002 has been 105 days. This average is based upon violations of HACCP and SSOPs. This data has been provided to GAO auditors. Other cases remain open for reasons such as voluntary suspensions, ongoing criminal or other investigations, voluntary cessation of operations, or for other reasons.

See comment 14.

The GAO report also sites a concern regarding multiple suspensions in a single plant. Many federal establishments conduct both slaughter and processing operations or may have processing operations under various production categories. Enforcement actions may be initiated based on problems in different segments of plant operations. Thus, multiple actions may be appropriate in some cases.

10. The GAO concluded that the time between a Salmonella set failure and an In-Depth Verification (IDV), time between the on-site IDV work, the final report and 30-day reassessment letter are too long. We agree that improvements in the timeliness of the IDV process are needed. The timeliness between IDV and reporting of results has steadily improved. However, we realize further improvement is needed. The FSIS Technical Service Center (TSC) is revamping the IDV process, to require the report of findings be issued immediately after the conclusion of the review. An IDV tracking system is being

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developed to ensure timeliness and to allow for trend analysis of IDV results over time. The system is designed and ready for testing.

11. FSIS announced recently that it would notify all suppliers of ground beef grinders of positive *E. coli* O157:H7 results at the time a positive sample result is obtained on ground beef. Notification will be both orally and in writing, and will state that although FSIS is unsure which supplier may have provided the product in question, FSIS encourages all of these suppliers to conduct their own investigations and testing until such time as the cause of the positive is determined. This will serve to decrease response time on suspect positives.
12. Lastly, the Agency has moved to establish "End Dates" for the completion of third Salmonella sets. It is clear that too much time elapse not only between sample sets but in some cases, within a sample set. PEER is specifically looking at this issue as part of its review of the Salmonella testing program and will make recommendations quickly. Additionally, a trend analysis data center is being established at the FSIS TSC in Omaha, NE. The function of this office will be to review test results and other data concerning the effectiveness and safety of a plants operations and provide an early warning system of problems.

Enclosed you will find additional technical and editorial comments. If you have any questions, please contact Ronald F. Hicks, Assistant Administrator for Program Evaluation, Enforcement and Review.

Sincerely,



William J. Hudnall
Acting Administrator

Enclosure

The following are GAO's comments on the August 26, 2002, letter from the U.S. Department of Agriculture.

GAO's Comments

1. USDA believes the report does not fully acknowledge FSIS's progress and continuous efforts to ensure that all plants meet regulatory requirements. It noted that FSIS has placed significant resources into the processes and systems that provided the data for our study and that FSIS has efforts ongoing to evaluate the same data. Our draft report acknowledges that in response to reports from GAO and USDA's Office of Inspector General, FSIS initiated the food safety systems correlation reviews and in-depth verification reviews and recognizes that these reviews have been useful in identifying problems with HACCP implementation. USDA describes a number of actions that FSIS has recently taken or is planning to take that are consistent with our recommendations. Many of these actions, if fully carried out, may go a long way toward addressing the problems we found in FSIS's oversight and enforcement of HACCP. However, diligent management attention will be needed to ensure this.
2. USDA believes that the title of the report is misleading. We disagree. We believe the title accurately reflects the concerns detailed throughout the body of the report.
3. The July 25, 2002, FSIS notice 28-02—Action to Be Taken in Establishments Subject to *Salmonella* Testing—does not establish specific time frames for actions to be taken at plants that fail a second set of *Salmonella* tests as we recommend.
4. While the September 5, 2001, notice 36-01—Rules of Practice—identifies FSIS's various enforcement tools and general circumstances in which each type would be appropriate, it does not establish clear, consistent criteria for inspectors to use when considering whether to recommend a suspension as an enforcement action in response to repetitive violations. We are recommending that FSIS do so.
5. FSIS's August 9, 2002, notice 29-02—HACCP Verification Procedures and the 30-day Reassessment Letter—addresses our recommendation for the need for additional training for inspectors on their roles and responsibilities. However, FSIS's efforts to provide training for inspectors on their roles and responsibilities, in response to our previous report recommendation, were not fully effective. We are

keeping this recommendation because it is too early to tell whether this effort will be effective.

6. Our draft report acknowledged that FSIS had established a new office to ensure that its programs and policies are implemented and monitored correctly. While the review of the *Salmonella* testing program does not directly address any of our recommendations, it may help FSIS to provide inspector training and procedures for field supervisors and district managers to oversee inspector activities—which we do recommend—with respect to *Salmonella* requirements.
7. FSIS directive 5000.1—Enforcement of Regulatory Requirements in Establishments Subject to HACCP System Regulations (including regulations on Sanitation Standard Operating Procedures, *E. coli* Testing and Criteria, and *Salmonella* Performance Standards)—should help FSIS address several of our recommendations, including those related to ensuring that all HACCP plans fully meet regulatory requirements and ensuring that plants take prompt actions to correct violations.
8. FSIS directive 4430.3—In-Plant Performance System (IPPS) Reviews—should respond to our recommendation regarding procedures to monitor inspector activities. FSIS is planning to implement the new directive and begin training supervisors in October 2002. We are keeping this recommendation to ensure the directive is implemented as planned.
9. This new interactive computer tool that inspectors, supervisors, and managers can use to strengthen HACCP problem solving using fictional scenarios. It should help FSIS address our recommendations regarding inspector training and supervisor oversight of inspector activities.
10. The draft report acknowledged the budget constraints regarding the hiring of consumer safety officers.
11. FSIS is still testing the PBIS 5.0 and district early warning systems, which should provide useful data for FSIS managers to carry out their HACCP responsibilities.
12. FSIS does not believe that plants are given too much time to comply with regulatory requirements. We disagree. Our review of enforcement case files found that, on average, these cases were closed in 10 months

rather than the 3 months (90 days) recommended by FSIS. In addition, while it may be FSIS's policy to establish specific time frames for plants to make corrective actions, none of the 30 enforcement case files we examined for plants with suspensions in abeyance that were closed after the 90-day policy went into effect contained this information.

13. We were not able to determine whether there has been improvement in the average amount of time it takes FSIS to close HACCP-related suspensions in abeyance because the data FSIS provided us with included suspensions for both sanitation violations as well as those for HACCP violations. In addition, when they are closed, it is not known how the unspecified number of cases that currently remain open will affect the average closure time.
14. We did not question the appropriateness of plants having multiple suspensions. Rather, we questioned the appropriateness of placing suspensions in abeyance at plants that have had repeated problems or multiple problems. The examples cited in our report involved (1) a plant suspension that remained in abeyance even though the plant continued to violate the same requirements for which it had been originally suspended and (2) a plant that had multiple sequential suspensions placed in abeyance.

Appendix III: GAO Contacts and Staff Acknowledgments

GAO Contacts

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Acknowledgments

In addition to those named above, Leo G. Acosta, Judy K. Hoovler, James L. Ohl, and Stephen D. Secrist made key contributions to this report.

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