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FOOD SAFETY

Weaknesses in Meat and Poultry Inspection Pilot Should Be Addressed Before Implementation

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Contents

Tables

Figures

Abbreviations

CCP	Critical Control Point
CDC	Centers for Disease Control and Prevention
FSIS	Food Safety and Inspection Service
HACCP	Hazard Analysis and Critical Control Point
HIMP	HACCP-Based Inspection Models Project
RTI	Research Triangle Institute
USDA	U.S. Department of Agriculture

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United States General Accounting Office
Washington, DC 20548

December 17, 2001

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

While the food supply in the United States is generally safe, foodborne bacteria, viruses, and other pathogens can cause a significant number of illnesses, a small fraction of which are life-threatening. According to estimates from the Centers for Disease Control and Prevention (CDC), foodborne diseases cause 76 million illnesses in the United States each year, including 325,000 hospitalizations and 5,000 deaths. Meat and poultry products contaminated with bacteria such as *Salmonella*, *Campylobacter*, *Escherichia coli (E. coli)*, and *Listeria* cause most foodborne illnesses and deaths. To control the spread of foodborne illnesses through meat and poultry products, approximately 3,400 U.S. Department of Agriculture (USDA) inspectors at 1,300 slaughter plants are stationed along slaughter lines to provide continuous inspection and conduct organoleptic examinations—using sight, touch, and smell—of each and every carcass.

In 1997, USDA announced the need to modify its meat and poultry slaughter inspection program to make industry more responsible for identifying carcass defects. This approach is consistent with the agency's previous adoption of the Pathogen Reduction: Hazard Analysis and Critical Control Point (HACCP) regulations. The HACCP approach is risk-based and makes industry, rather than federal inspectors, responsible for identifying steps in food production where food safety hazards are most likely to occur and for establishing controls that prevent or reduce it. USDA had not extended the HACCP principles to slaughter inspections because the agency has traditionally provided continuous inspection of each and every carcass. However, USDA believes that changing its traditional inspection system would also reduce inspectors' reliance on organoleptic inspections, allow for a shift to prevention-oriented inspection systems based on risk, and permit redeployment of its resources to better protect the public from foodborne diseases.

Before making a permanent change to its slaughter inspections system, USDA developed a model to test whether such a change would continue to ensure the safety of meat and poultry products. This model is being tested

at several volunteer chicken and hog plants. At plants participating in the project, plant personnel, instead of USDA inspectors, examine each carcass to make an initial determination whether it is unacceptable and should be removed from the slaughter line. At the participating plants, USDA first measures the performance of traditional inspection systems and then compares it with the performance of modified inspections. USDA will propose regulations to modify its inspection system nationwide if the project shows that the modified inspection system performs as well as or better than traditional inspections. A reduced number of USDA inspectors are still at each plant to verify that safety and quality standards are met. In addition, at least one USDA inspector is positioned near the end of each slaughter line in order to comply with a federal court ruling that USDA cannot delegate the inspection of carcasses to plant employees. As of July 2001, the federal cost associated with this project was approximately $5.7 million, and USDA estimates that it will spend another $1.2 million. Australia and Canada have tested similar modified inspection programs for meat and poultry and approved their use on a nationwide basis.

Concerned about the design, methodology, and reliability of the pilot project, you asked us to (1) describe the objectives, design, and scope of the project; (2) identify limitations, if any, in the project's design and methodology; and (3) any design and methodology limitations notwithstanding, determine if the data generated by the project will allow USDA to reach valid conclusions on the relative effectiveness of modified and traditional inspection methods in ensuring food safety and quality. In addressing these objectives, you also asked us to obtain information from similar projects in Australia and Canada.

In response to your request, we reviewed USDA's pilot project as implemented at chicken and hog plants. However, we were able only to analyze data from chicken plants because complete data from hog plants were not yet available. We also visited Australia and Canada to learn about similar pilot projects. Appendix I describes our methodology in detail.

Results in Brief

USDA's original objective in implementing the pilot project was to test whether a prevention-oriented inspection system that uses plant personnel to examine each carcass for safety and quality and USDA inspectors to verify that safety and quality standards are met can provide a level of product safety and quality equal to or better than traditional inspections. At 11 chicken and 3 hog plants that are voluntarily participating in the before and after phases of the project, plant personnel, instead of USDA inspectors, initially determine which carcasses and parts are unacceptable

and should be removed from the slaughter line because they are diseased or unwholesome. USDA is, therefore, able to use fewer inspection personnel at these plants. Using safety and quality performance standards developed for the project, an independent contractor measured how well pilot plants' inspection systems performed against these standards. The contractor measured how well USDA inspectors identified carcass defects under traditional inspections and then conducted similar measurements once plant personnel assumed those duties. Also, as a part of the pilot project, USDA inspectors at the project plants have examined carcasses to evaluate how well plant employees detect carcass defects. USDA will analyze these data to determine if at least the same level of safety and quality is maintained under the modified inspections. USDA has announced that preliminary results from the chicken pilot project show that plants' inspection systems perform better under the modified inspections, and that it expects to propose regulations to modify its slaughter inspection system for all chicken plants early in 2002. Both Australia and Canada have recently tested and adopted modified inspection programs that resemble USDA's pilot project in that they include the replacement of some government inspectors with plant personnel.

USDA's pilot project for chickens has several design and methodology limitations that compromise the overall validity and reliability of its results. Hence, it is questionable whether the data generated by the project are indicative of how all of the chicken plants' inspection systems would perform if modified inspections were adopted nationwide. First, the chicken pilot that USDA designed lacks a control group—a critical design flaw that precludes a comparison between the performance of the inspection systems at those plants that volunteered to participate in the pilot and that of plants that did not participate. Without a control group, USDA cannot determine whether changes in inspections systems are due to personnel changes or other possible explanations, such as the addition of chlorine rinses. Second, the chicken plants that volunteered to participate in the baseline measurement phase of the pilot were not randomly selected, and they did not include plants from all chicken-producing areas or plants of all sizes. Thus, the results cannot be generalized to the entire population of chicken slaughter plants in the United States. Third, the pilot project's methodology did not take into account variables such as seasonal changes and plant modifications that could affect project results. For example, after the project began, many plants added antimicrobial rinses and washers, which usually reduce the levels of microbial contamination. USDA acknowledges some of the project's limitations but maintains that the design is consistent with that of

other USDA studies and that it is difficult to conduct this type of experiment without relying on volunteer participants. Finally, USDA's pilot project did not include features of the modified inspection systems in Australia and Canada that would be important considerations in ensuring the successful implementation of a modified inspection system nationwide. For example, during the pilot project, USDA did not require the training of plant employees. Such training would be important in ensuring that plant personnel are as competent as federal inspectors in identifying carcass defects that can affect product safety and quality. Similarly, the pilot project did not require the use of statistical process controls as required in Australia and Canada. Statistical process controls provide a means to determine whether the plant's production processes are performing within established performance standards. This technique would enable USDA and the plants to better measure and control their performance daily and over time to ensure continuous improvement. Additionally, USDA allowed plants with repeated noncompliance records to continue participating in the pilot project. If USDA decides to permanently modify its inspection system, a phased-in approach such as Canada's would help to ensure that plants continually improve their ability to ensure product safety and quality and that those that have difficulty return to traditional inspections.

Notwithstanding the project's design problems, which we believe make the results unreliable, we found that, so far, the data themselves do not conclusively demonstrate that modified inspections are at least equal to traditional inspections. Part of the difficulty is that the two data sets collected for this pilot show somewhat different results. These data show whether the pilot plants met the seven organoleptic performance standards—two food safety standards and five other consumer protection (quality) standards—that USDA developed to compare, first the inspection systems' performance at plants under traditional inspections and then under modified inspections. The modified inspection systems at plants in the pilot project were expected to perform at least as well as they did under traditional inspections. However, the contractor's data show that while the majority of the chicken plants' inspection systems met or exceeded four or more of the seven organoleptic standards adopted by USDA, none met all seven. Specifically, the contractor's data show that most of the inspection systems at these plants did not meet the safety standard for the presence of fecal material, which could contain harmful bacteria such as *E. coli*. However, the traditional inspection system at these plants was also unable to meet this standard. Most inspection systems also did not meet quality standards for defects such as feathers and oil glands, but USDA officials pointed out that such defects are of a

lesser concern because they are not associated with foodborne illness and they can generally be removed from the carcass after it leaves the slaughter line and moves to the processing area. USDA's contractor also measured whether the modified inspection systems at these plants met two other standards that existed before the pilot project—the pathogen reduction performance standard for *Salmonella* and generic *E. coli*. The data show that 9 of the 11 inspection systems met the *Salmonella* standard and that 80 percent of the samples collected for generic *E. coli* were within the acceptable ranges. On the other hand, the data collected by USDA inspectors at these chicken plants show better results than those shown by the contractor's data. According to USDA's data, 7 of 10 plants' inspection systems met 6 of the 7 standards. While the data generated by the pilot project yielded inconclusive results, the pilot project's inspectors and veterinarians that we surveyed for the most part believe that a modified inspection system results in safer products. More than half of those surveyed said that modified inspections are equal to or somewhat better than traditional inspections in ensuring product safety and quality. Modified inspections allow for additional time to inspect slaughter line operations more thoroughly because inspectors, except for the carcass inspector, are no longer tied to a fixed location.

This report reiterates our previous recommendation for legislative revisions aimed at reducing the potential for further legal challenges by providing USDA with clear authority to modify its inspection system. In addition, this report makes several recommendations to the Secretary of Agriculture aimed at ensuring that, if USDA decides to implement a modified inspection system, such a system will effectively ensure product safety and quality. In commenting on a draft of this report, USDA said that the report's recommendations for executive action are appropriate and that the issues noted in the report can be satisfactorily addressed. USDA also provided technical comments which we incorporated as appropriate.

Background

The Federal Meat Inspection Act and the Poultry Products Inspection Act, 21 U.S.C. sections 604 and 455, respectively, give USDA overall responsibility for ensuring the safety and wholesomeness of meat and poultry products that enter interstate commerce. Acting under these legislative authorities, USDA has engaged in continuous government inspection of each and every carcass at slaughter plants throughout the United States. Within USDA, the Food Safety and Inspection Service (FSIS) is responsible for inspections at all meat and poultry slaughter and processing plants and for ensuring plants' compliance with regulatory requirements.

At slaughter plants, FSIS inspectors are located at fixed stations and examine carcasses to identify and remove defects that impair product safety and quality. Defects that are likely to present a public health risk, such as the presence of potentially pathogenic fecal material, are considered food safety hazards. Product quality defects, such as feathers or bruises on the carcasses, are aesthetic flaws that rarely present a direct safety risk.

Inspectors perform different tasks, depending on the animal species being slaughtered. For example, in chicken plants, the inspectors are located at fixed stations immediately after the place on the slaughter line where carcasses are opened and the organs removed. From these positions, the inspectors examine the exterior, interior cavity, and organs of each carcass. The inspectors then determine which carcasses must be condemned, which have conditions that may be trimmed, and which may proceed to the next stage in the slaughter line. Carcasses are then trimmed, rinsed, and, as the final step of the slaughter line, placed into a chiller. From here, carcasses move to the processing area of the plant, where they are cut up and packaged. In contrast, in hog plants, the inspectors are located at three fixed stations on the slaughter line. At the head station, the inspectors excise and evaluate the head lymph nodes; at the viscera station, they evaluate most organs; and at the final carcass station, they examine each carcass for possible contamination, disease conditions, and other adulterants before it goes into the chiller or cooler.

For a variety of reasons, including responding to recommendations from the National Academy of Sciences and GAO that FSIS shift its resources to a prevention-oriented, risk-based inspection system, in 1996 USDA embarked on regulatory reform efforts to reduce foodborne hazards in meat and poultry products. The agency adopted a new science-based process control system, the Pathogen Reduction: Hazard Analysis and Critical Control Point system. HACCP is a risk-based approach that makes industry, not federal inspectors, responsible for identifying steps in food production where contamination is most likely to occur and for establishing controls that prevent or reduce contamination.

USDA anticipated that the HACCP framework would also require changes in the roles and responsibilities of its inspection workforce, as industry, not government, becomes increasingly responsible for the safety of its products. For slaughter line operations, however, making industry more directly responsible for the safety and quality of their products was problematic because of a legal requirement for continuous carcass-by-carcass inspection. USDA believed that, to more fully integrate the HACCP

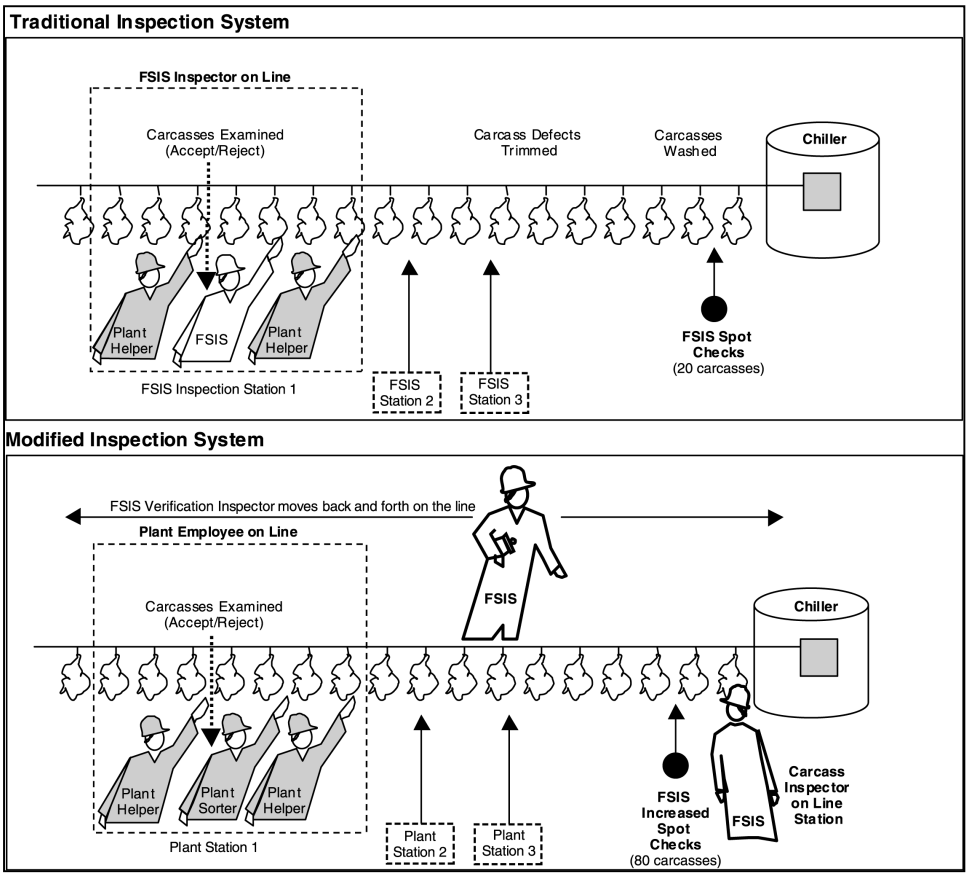
concept into meat and poultry slaughter operations, its traditional inspection system would have to be modified to transfer some of the carcass defect detection responsibilities to industry personnel. Before implementing such an approach, FSIS decided to conduct a pilot to test and evaluate whether product safety and quality could be maintained at a comparable level if plant employees perform the carcass defect detection duties and a reduced number of federal inspectors remain to verify product safety and quality through increased testing and observation.

The pilot project is known as the HACCP-Based Inspection Models Project (HIMP) and its original design was intended to measure the effect of completely removing FSIS inspectors from their fixed locations on the slaughter line while maintaining one oversight and one verification inspector. In April 1998, the inspectors' union filed suit in the United States District Court for the District of Columbia to enjoin the USDA from proceeding with the pilot project, on the grounds that it violated the Federal Meat Inspection Act, 21 U.S.C. section 604, and the Poultry Products Inspection Act, 21 U.S.C. section 455, by not requiring federal government officials to perform carcass-by-carcass postmortem inspections. In June 2000, the United States Court of Appeals for the District of Columbia Circuit ruled that delegating the task of inspecting carcasses to plant employees violated the acts because both statutes require that federal inspectors, rather than private employees, determine whether a product is adulterated. As a result of this ruling, in September 2000, FSIS redesigned the pilot project for chickens and hogs and placed at least one FSIS inspector back at a fixed location on each slaughter line to inspect each carcass.

Following a district court determination in January 2001 that the redesigned pilot project does not violate the acts, the inspectors' union appealed in February 2001. That appeal is still pending. A detailed description of the litigation surrounding the pilot project is contained in appendix II.

Figure 1 depicts inspection responsibilities under FSIS' traditional and modified inspections on a chicken slaughter line.

Figure 1: Traditional and Modified Inspection Systems on a Chicken Slaughter Line



Note: Under the traditional inspection system, the slaughter line's speed at most chicken plants is 91 birds per minute. Each inspector is responsible for about 35 birds per minute. Therefore, three FSIS inspectors are required to inspect carcasses on a slaughter line that runs at a speed of 91 birds per minute. The figure above shows only one FSIS inspector's station in detail. Under the pilot project, a plant employee (sorter) replaces the FSIS inspector who examined the carcasses to determine their condition.

As figure 1 shows, under traditional inspection systems, three FSIS inspectors are present at fixed locations on the slaughter line. In contrast, at chicken plants that participate in the pilot project, one FSIS inspector is present at a fixed location on each slaughter line, while a verification inspector monitors the entire line. The verification inspector is free to move along the slaughter line to continuously observe and evaluate the plant's implementation of its HACCP system and process controls. This inspector is also responsible for randomly selecting and examining 80 carcasses per line per shift to verify that the plant is complying with the performance standards for food safety and quality. A slaughter line

averaging 91 chickens per minute would process over 43,000 chicken carcasses during each shift. The carcass inspector is located at the end of the slaughter line, immediately before carcasses enter the chiller. This inspector visually examines each carcass to comply with a court mandate that each carcass should receive FSIS inspection. At participating hog plants, carcass inspectors are positioned at the head, viscera, and final carcass inspection stations. Most of the inspectors and some veterinarians at the pilot project plants received promotions.

Pilot Project Makes Industry More Responsible and Accountable for Product Safety and Quality, While Continuing Government Monitoring With Fewer Resources

The pilot project's hypothesis was that a prevention-oriented inspection system that uses plant personnel to examine each carcass can provide a level of product safety and quality equal to or better than traditional inspections. At selected chicken and hog plants that voluntarily agreed to participate in the project, plant personnel, instead of FSIS inspectors, initially determine which carcasses and parts are unacceptable and should be removed from the slaughter line. Under this project, FSIS is able to use fewer inspection personnel at each plant. FSIS used an independent contractor to collect and analyze organoleptic and microbial data under the traditional inspection system first and then under the modified inspection system. FSIS developed organoleptic performance standards to measure how well the inspection system at participating plants performed after shifting from traditional to modified inspections. In addition, as part of their duties, FSIS inspectors continued to collect organoleptic performance data at these plants. Recently, both Australia and Canada tested and adopted modified inspection programs that resemble USDA's pilot project.

Under Pilot, Industry Is More Responsible and Accountable for Product Safety and Quality, While FSIS Provides Inspection Using Fewer Government Resources

To initiate the pilot project, FSIS invited meat and poultry plants that slaughter young, healthy animals—market hogs, fed cattle, and young poultry (including young turkeys)—to volunteer to participate in the project.[1] Sixteen chicken, 5 hog, and 5 turkey plants initially volunteered to participate.[2] No cattle plants volunteered. In general, plant managers that volunteered to participate in the pilot said that they elected to do so because they believe they can enhance product safety and quality if they have better control of slaughter line operations and, at the same time, increase productivity.

FSIS contracted with the Research Triangle Institute[3] (RTI) to collect and analyze organoleptic and microbial data at plants that volunteered to participate in the pilot project. The purpose of this data collection is to evaluate whether the inspection systems at plants operating under modified inspections perform at least as well as the traditional inspection systems. In August 2000, RTI completed its collection of organoleptic and microbial data at 16 chicken, 5 hog, and 5 turkey plants under the traditional inspection. These baseline data documented the accomplishments of the traditional inspections system, and FSIS decided to adopt the results as performance standards for measuring the accomplishments of the same plants' inspection systems after they shifted to modified inspections. After a transition period during which plant personnel practiced their new roles, RTI again collected organoleptic and microbial data under the modified inspection system to provide a before-and-after comparison.[4]

After RTI collected data on the performance of the traditional inspection system at the volunteer plants (baseline data), 5 of the 16 chicken plants

[1]FSIS designed the pilot project for meat and poultry plants that slaughter young animals because this group comprises approximately 90 percent of the animals slaughtered and those carcasses do not have complex pathology or other problems associated with older animals.

[2]Originally, 17 chicken plants volunteered to participate, but 1 of the chicken plants elected to drop out of the project shortly thereafter.

[3]The Research Triangle Institute is an independent nonprofit organization that conducts multidisciplinary research on issues including health and pharmaceuticals, environment, and education and training. RTI's contract with USDA for this pilot project contains modifications for increased future work.

[4]After FSIS placed at least one carcass inspector back on the slaughter line, RTI had to return to collect a new set of food safety and quality data.

and 2 of the 5 hog plants dropped out of the project.[5] As a result, RTI has collected modified inspections data at 11 chicken and 3 hog plants. These data were collected over a 5- to 6-week period. Some managers from plants that dropped out cited uncertainty about the future of the pilot project because of the court's action, which resulted in modifications to the pilot's original design.

Ten additional chicken plants have since volunteered to participate in the pilot, bringing the total number of participating plants to 21, but RTI will collect data at only 5 of the additional 10 plants. According to FSIS, no traditional inspection performance data (baseline data) will be collected at these additional plants. Table 1 shows the number of slaughter plants that participated both in the baseline data collection phase (traditional inspections) and in data collection after they switched to modified inspections.

Table 1: Number and Types of Pilot Plants That Participated in Traditional and Modified Inspections

Species	Plants that completed baseline data collection under traditional inspections	Plants that completed data collection under modified inspections
Chickens	16	11 (10) [a]
Hogs	5	3
Turkeys	5	0

[a]One plant dropped out after it completed data collection under the modified inspection system.

Source: USDA, FSIS.

Because turkey plants have not participated in modified inspections and because data from hog plants under modified inspections are not yet available, this report discusses pilot project results from chicken plants only. (See app. III for information on the development of performance standards for hogs.)

At the pilot project plants, FSIS has been able to use fewer inspection resources than would otherwise be used under traditional inspection systems, resulting in an overall 22 percent reduction (from 259 to 202 inspectors) in the number of FSIS inspectors on the slaughter floor. At most of the 14 chicken and hog plants, the reduction of inspectors ranged

[5]All five turkey plants dropped out after the baseline data were collected.

from 1 and 10 inspectors, depending on the number of slaughter lines and the speed of those lines. Under traditional inspections, there were three inspectors per line on average, compared with two inspectors per line under modified inspections. At three of the pilot project plants, the change in the number of inspectors was not entirely due to the modified inspection system.

The Pilot's Scope Included the Development of Safety and Quality Standards to Measure Performance of Traditional Inspections as Compared With Modified Inspections

To collect and analyze organoleptic data on the defects that the FSIS inspectors had overlooked under traditional inspections at chicken plants, RTI veterinarians at each volunteer plant examined approximately 2,000 randomly selected carcasses that had passed FSIS' slaughter inspection. RTI veterinarians examined carcasses to record the same type of defects that FSIS inspectors identify when they examine each carcass. These included safety defects, such as visible fecal material and evidence of septicemia and/or toxemia, and other consumer protection defects (quality defects) such as feathers, hairs, or bruises. FSIS grouped this information into two food safety and five other consumer protection (quality) categories:

- Food Safety 1: Infectious conditions such as septicemia and/or toxemia.
- Food Safety 2: Contamination with fecal material.
- Other Consumer Protection 1: Animal diseases such as airsaculitis.
- Other Consumer Protection 2: Defects such as bruises and sores.
- Other Consumer Protection 3: Contamination with digestive tract contents (ingesta).
- Other Consumer Protection 4: Dressing defects such as feathers and oil glands.
- Other Consumer Protection 5: Dressing defects of the digestive tract tissue such as bursa and cloaca.

FSIS then developed performance standards for each of these seven categories. The quality performance standards were set at position 12 (out of 16) on the basis of measurement of the traditional inspection system at the 16 chicken plants. That is, 25 percent of the plants' inspection systems (4 different plants) would have to improve on their baseline results in each of the 7 performance categories. FSIS officials explained that they decided to adopt the 12th position of the baseline results as the standard to ensure that most participants would be able to meet them. The officials stated that this represents a reasonable tightening of the traditional system's accomplishments.

To better protect consumers from defects that may be harmful, FSIS set the two food safety standards at zero rather than adopting the results of the 12th position. Thus, a performance standard of zero for fecal contamination means that FSIS expects all carcasses slaughtered during a shift to be free of fecal material. Conversely, an 80-percent performance standard for dressing defects such as feathers and oil glands means that if 80 of 100 carcasses have these defects, the performance standard is met. The performance standards represent the percentage of carcasses per shift with each defect that FSIS considers acceptable. Table 2 shows the traditional inspection system's baseline results for the 16 chicken plants.

Table 2: Traditional Inspection System's Results (Baseline Data) From 16 Chicken Pilot Plants: Defects per Shift in Percents

Best performance ↓ Worst performance

Rank	FS1	FS2	OCP1	OCP2	OCP3	OCP4	OCP5
1	0.00	0.00	0.10	5.50	0.30	25.40	1.30
2	0.00	0.00	0.10	7.75	2.34	37.38	2.00
3	0.00	0.05	0.34	15.65	2.55	50.10	2.40
4	0.00	0.10	0.35	16.60	3.45	51.15	3.05
5	0.00	0.10	0.35	18.20	3.85	56.90	4.85
6	0.00	0.10	0.41	19.15	4.54	60.15	8.55
7	0.00	0.10	0.55	19.65	6.40	67.00	10.30
8	0.00	0.20	0.60	24.90	6.75	75.17	10.77
9	0.00	0.60	0.70	34.18	10.43	76.90	12.76
10	0.00	0.60	0.95	42.22	15.50	77.02	16.55
11	0.05	0.90	1.25	49.75	15.87	77.10	19.85
12	0.05	1.50	1.69	52.54	18.55	79.95	20.80
13	0.05	2.30	2.20	65.80	20.25	80.66	26.85
14	0.05	2.39	2.25	74.10	22.63	89.90	29.30
15	0.41	3.15	2.45	75.77	26.55	91.68	32.45
16	1.55	3.25	6.44	86.89	54.55	98.80	52.84

Performance standard

Note: Ranking numbers represent different plants for different food safety and OCP standards. Although the 12th position's performance was 0.05 percent for Food Safety 1 and 1.5 percent for Food Safety 2, FSIS adopted a zero tolerance policy for these two standards. For Food Safety 2, the zero tolerance standard was used because it is already a regulatory requirement.

Source: RTI.

RTI also measured the prevalence of generic *E. coli* and *Salmonella* under traditional inspections and modified inspections at the 11 chicken plants to determine if changes in the inspection system would have an effect on the microbial profile of carcasses. RTI collected and analyzed 300 samples

for both microorganisms over a 6-week period. RTI analyzed the *Salmonella* samples to determine if they met FSIS' already existing regulatory standard for *Salmonella* and the generic *E. coli* samples to determine if the results were in the acceptable, marginal, and unacceptable ranges established by FSIS.

FSIS is also collecting data on product safety and quality defects at chicken plants in the pilot project and is analyzing these data to compare how well traditional inspection systems perform versus modified inspection systems. FSIS inspectors collect the data as they conduct scheduled and unscheduled verification tests at each chicken plant. These tests evaluate, among other things, how well plant employees detect carcass defects. When the pilot project is concluded, FSIS plans to analyze these data to determine if at least the same level of safety and quality is maintained under the pilot program. FSIS has announced that preliminary results from the chicken pilot project show that inspection systems perform better after the plants shifted to modified inspections, and that it expects to propose regulations to modify its traditional slaughter inspection system for all chicken plants in 2002.

Pilot Projects in Australia and Canada Used a Similar Strategy

The Australian Quarantine and Inspection Service and the Canadian Food Inspection Agency have tested and adopted alternative inspection systems similar to that tested in the FSIS pilot project. (See apps. V and VI for additional details.)

Australia has tested and adopted a modified inspection system for all meat plants that produce products for domestic consumption. In addition, Australia is now in the process of implementing the Meat Safety Enhancement Program at plants that export meat. Under the program, plants are responsible for plant process controls, including sanitation, the microbial monitoring of pathogens, and detecting product defects. The program incorporates the use of government-licensed company employees, acting under the supervision and oversight of government veterinarians, to replace government inspectors. In order to be licensed by the government, the company's employees are required to undertake about 600 hours of training and pass an examination. The Australian Quarantine and Inspection Service sets public health product standards and audits plant operations to ensure that food safety standards are met. A key feature of the program is the mandatory use of statistical process controls to track plants' performance over time.

Canada has adopted a new poultry inspection system, known as the Modernized Poultry Inspection Program that allows plant personnel to assume defect detection duties and remove defective carcasses from the slaughter line under the supervision of government inspectors. The program is being implemented in a phased approach. Performance standards for Canadian poultry plants participating in this program are similar but not identical to FSIS' standards for chicken plants in the U.S. pilot project. Like the Australian program, the Canadian program has stringent training requirements for industry personnel replacing inspectors. Industry personnel are required to demonstrate competency through testing and certification.

Design and Methodology Limitations Compromise Overall Validity and Reliability of Pilot Project Results

The pilot project has several design and methodology limitations that compromise the overall validity and reliability of its results. For example, the lack of a control group prevents valid comparisons between the inspection system of participating plants and that of nonparticipating plants. In addition, the participating plants were not randomly selected; therefore, results from these plants cannot be generalized to the entire population. Finally, the pilot project does not appropriately explain how variables, such as seasonal changes and plant modifications, could affect the project's results. In addition, the pilot project does not include important features of similar programs in Australia and Canada.

Pilot Project Lacks a Control Group

FSIS officials characterized the design of the pilot project as a classic before-and-after experiment that is typical of other FSIS experiments. A classic before-and-after experiment involves both a control and an experimental group and thus provides a basis for comparing the results of the two groups. Ideally, the groups are as similar as possible, except for the variable that the experiment is attempting to measure. However, because this level of rigor is rarely achievable in applied settings, quasi-experimental designs are often used in which comparison groups are established to compare the impact of a new program with the status quo. According to our discussion with FSIS officials, the volunteer plants were not separated into a control group and an experimental group because the agency felt that it would have been unfair to exclude volunteer plants from taking part in the modified inspection aspect of the experiment. Nevertheless, under a quasi-experimental design, FSIS could have used as a control group the five chicken plants that decided to discontinue participation in the pilot project after their baseline performance under the traditional system was measured. The agency could have then compared the results from these plants with the results obtained from the

plants that participated in the modified inspections. Lacking such a comparison, it is difficult to determine how the inspection systems at the plants that did not participate in the pilot project would have performed under the performance standards established for the pilot project.

The managers of two large chicken plants that dropped out of the pilot said that they proposed another approach to FSIS. Namely, these managers wanted to conduct what could have been a controlled experiment within their own plant. Both of these plants have multiple slaughter lines, and the managers wanted to operate half of their slaughter lines under traditional inspections and the other half under modified inspections. However, FSIS would not authorize such an arrangement because the agency wanted the entire plant to be under one inspection system. Officials said that it would have been too difficult to maintain two separate inspection systems in the same plant. As a result, both of these plants withdrew from the pilot project.

The Australian pilot project compared three plants that volunteered to participate in the pilot project with three plants operating under traditional inspections, so the pilot had both an experimental group and a control group. The plants in the experimental group removed the government inspectors from the slaughter line and replaced them with plant personnel, while the control group plants made no changes to their inspection system. The pilot project measured both microbial and organoleptic data at plants in both groups to determine how well they complied with standards. The results were then compared in order to determine how the modified inspections affected food safety and quality. The Canadian Food Inspection Agency did not use a control group.

Plants Participating Are Not Randomly Selected and Do Not Represent the Population

Because the volunteer chicken plants were not randomly selected, the results cannot be generalized to the population of plants that slaughter young chickens. FSIS is not authorized to compel plants to participate in any pilot project; therefore, it had to rely on volunteer plants instead of randomly selecting participants. However, FSIS did have the option to randomly select a subgroup to serve as a control group from the volunteer plants, but decided not to pursue that option. Australia and Canada also did not select plants on a random basis.

FSIS officials acknowledge that the number of plants in the pilot was not statistically derived. The officials believe, however, that the 16 chicken plants that originally volunteered constitute a sufficient number to estimate results for the population. However, only 11 chicken plants have

participated in all phases of the pilot project. These plants represent about 6 percent of the population of young chicken plants nationwide, or 11 of 186 plants in 1999. We estimate that 125 randomly selected plants would need to participate in the project in order for FSIS to obtain results that can be generalized to the population of chicken plants.[6]

As a result of the pilot project's reliance on volunteer plants, the results of the pilot do not provide sufficient geographic representation. That is, the 11 chicken plants that have participated in all phases of the pilot project are located in 7 of 35 states that produce young chickens, or about 20 percent of the chicken-producing states. These plants are concentrated in the southern region of the United States and account for about 57 percent of U.S. young chicken production. (See fig. 2.) Unlike FSIS, the Canadian Food Inspection Agency designed its pilot to include chicken plants from the western, eastern, and central provinces. As a result, the Canadian pilot project has better geographic representation.

[6]This sample size is calculated to provide for results of plus or minus 5 percent at the 95-percent confidence interval.

Figure 2: Location of Chicken Pilot Plants

Note: Numbers indicate how many chicken plants participated in the baseline data collection phase of the pilot project.

Source: USDA, FSIS.

In addition, there are eight large plants, three small plants, and no very small plants in the pilot project. According to FSIS, there are 112 large, 61 small, and 13 very small plants that slaughter young chickens in the United States. We discussed with officials at all participating plants in the pilot project whether the plants represent the population of chicken plants in the United States. Most of them said that, in their opinion, the plants are representative of the industry nationwide. FSIS officials are also of the opinion that all plants that volunteered to participate are similar to nonparticipants in all respects except for the fact that they volunteered. However, since only volunteer plants participated in the pilot, potential selection bias is introduced because such plants may be predisposed to better performance.

Pilot Project's Methodology Does Not Take Into Account Variables That Could Affect Results

The pilot project does not adequately control for the effect that seasonal variations and plant modifications can have on the its results. Because seasonal changes can cause animals to develop diseases and/or poor health, two poultry science experts that we consulted said that it is imperative to collect samples over sufficiently long periods of time to cover all seasons. Seasonal variations significantly affect microbial results, especially in the case of bacteria such as *Salmonella*, which was measured in the pilot project. However, the pilot project's design called for 6 consecutive weeks of microbial data collection. Accordingly, the experts we consulted believe that microbial data collected during the pilot project are of limited value because the data cover less than 2 months at each plant.

The pilot project's results may also be affected by another set of variables. Most of the plant managers at pilot project plants told us that they introduced changes to their slaughter lines to improve product safety and quality after the baseline performance of the traditional system was measured. These changes included the addition of new brushes and scrubbers, plain water washes, and antimicrobial washes. Some managers also modified their evisceration equipment and developed computerized systems to track carcass safety and quality defects. All the inspectors and veterinarians at pilot project plants that we surveyed indicated that at least one change had been made after modified inspections were implemented at the plant. In effect, it is not possible to discern whether the before-and-after results measured by the two food safety and five quality standards are to be solely attributed to the shift from traditional to modified inspections at these plants.

According to FSIS officials, the pilot project was designed to measure the accomplishments of the traditional inspection system and the accomplishments of the models inspection system allowing for measuring multiple process changes—not isolated comparisons between FSIS inspector performance and plant employee performance. If this is the case, then the pilot project should have included the measurement of all the process changes introduced, not just the only change introduced by the agency; namely, the transfer of carcass defect detection from FSIS inspectors to plant personnel. We understand that, at their initiative, plants decided to make changes to their process during this pilot. However, FSIS did not collect data on what changes were made or on what the effect of those changes may be on the overall pilot project results.

USDA officials disagree that the pilot project does not take into account variables that could affect its results. They stated that, if the results from

all plants are viewed collectively, their sample extended over a sufficient period of time to consider the effect of seasonal variations, evisceration line effects, and other non-quantifiable variables. Even if all plants are considered collectively, FSIS is still missing microbial data for the entire year. According to officials, from January through April, no data were collected at any of the pilot plants. Moreover, according to the experts we consulted, FSIS should have a year's worth of microbial data from each plant in the pilot to be able to account for seasonal variations.

In discussing these limitations with USDA officials, they explained that the focus of the project is studying an entire system, including all changes made by the plants, and not simply comparing the work of company employees with that of government inspectors. However, we note that the project's stated objective was to determine whether a modified inspection system is at least as good as the traditional system. In order for such a comparison to be valid, USDA would have to determine that other variables introduced into the slaughter line, such as the addition of rinses or brushes, are not the cause of changes noted after the shift in inspection systems took place.

Pilot Project Lacks Key Elements

The pilot project did not address three important features of similar programs in Australia and Canada. Those features would help to ensure that plant personnel are able to discharge their carcass defect detection duties as well as federal inspectors and that plants are capable of continuing to ensure the safety and quality of their products under a modified inspection system. First, the pilot project did not require that, prior to assuming their new duties, plant personnel receive any training and pass competency tests. Second, the pilot project did not require the use of statistical process controls as a means to ensure that plants continually improve their processes under the modified inspection system. Third, the plants continued in the pilot project irrespective of repetitive noncompliance with regulatory requirements.

Project Does Not Require Formal Employee Training and Certification

FSIS did not require that plant employees complete training before assuming the carcass defect detection duties that FSIS inspectors' performed. Furthermore, FSIS did not establish a way to measure plant employee's knowledge and competence. FSIS officials told us that training for plant personnel will not be required if the system is adopted nationwide. Plant personnel and FSIS inspectors at each pilot project plant did participate, however, in a transition phase during which they practiced their new roles. FSIS officials told us that the transition phase was also

used to explain how and when data were to be collected during the project.

If FSIS implements modified inspections nationwide, plant personnel will be assuming carcass defect detection duties previously performed by FSIS inspectors who have received formal training on how to identify carcass defects and determine whether they are suitable for human consumption. However, unless FSIS institutes training requirements, plant personnel will not have received comparable training. We asked plant managers participating in the pilot project about the training that they have provided for plant employees. They replied that they provided various levels of training. Individual plants have sole discretion for determining the type of training provided for their employees as FSIS does not approve or monitor plants' training programs. According to plant officials, FSIS is supportive but does not endorse a training program that the International HACCP Alliance developed for plant personnel participating in this pilot project.[7] In some instances, the Alliance, not FSIS, has accredited plants' training programs but it does not certify trainees who complete these courses.

Seven of the 14 pilot project managers whom we interviewed support a training program for plant personnel. About two-thirds of the managers also were in favor of developing a joint training program between industry and FSIS. At nine pilot project plants, plant employees were required to pass a test before being assigned to their new jobs, and seven plants adopted some kind of continuous on-the-job training. The managers told us that classroom training for plant employees ranged from 4 to 80 hours. The duration of on-the-job training ranged from 8 to 160 hours.

In contrast, the Australian modified inspection program requires plant personnel to complete about 600 hours of classroom training as a prerequisite to participation in the modified inspection program. Plant personnel must also pass a competency test and be certified. Upon completion of the on-the-job training, state authorities license the plant personnel. The Australian government's veterinarian-in-charge at each plant is authorized to withdraw or deny license renewal of plant personnel on the basis of performance.

[7]The International HACCP Alliance membership includes over 120 members from nine countries representing industry associations, professional associations, educational foundations, universities, third party/private companies, and government cooperators. Their mission is to promote international public health and safety by facilitating uniform development and implementation of HACCP programs from farm to table.

Similarly, under Canada's modified inspection program, government inspectors train plant personnel. The required training includes standardized classroom training, in-plant training, a final examination, and a demonstration of competency on verification tests and finished product standards. At the completion of the training, the Canadian Food Inspection Agency accredits plant employees. Plant employees must be reaccredited every 6 months, and the agency's inspectors reserve the right to conduct additional reaccreditation of plant employees at any time.

Sixty-seven percent of the FSIS inspectors and veterinarians whom we surveyed believe FSIS should develop a training program that includes mandatory testing and certification of plant employees.

Project Does Not Require Use of Statistical Process Controls

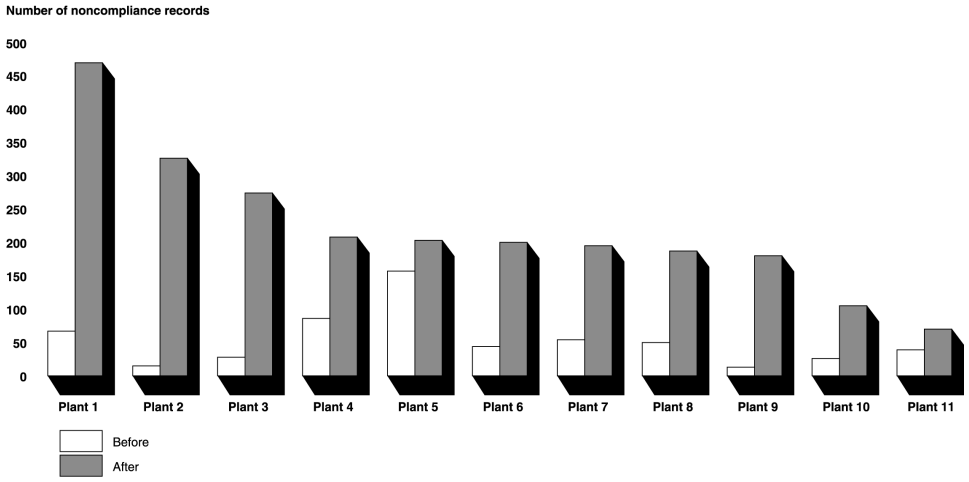
Although FSIS has encouraged plants in the pilot project to use statistical process controls, it is not a requirement of the pilot. However, three-quarters of the inspectors and veterinarians responding to our survey indicated that their plants use statistical process controls. About a third of these respondents believe that the use of statistical process controls have the effect of making food safety and quality better, while a quarter of them believe that it does not make a difference. At the pilot project plants, FSIS inspectors do not review or analyze plant data using statistical process controls. However, by applying process controls, FSIS could obtain a more comprehensive assessment of the effectiveness of the modified inspection system because it could review the performance of an individual plant's data to determine whether the plant's systems are continually improving over time.

In contrast, the Australian and Canadian food inspection agencies use statistical process control methods to audit a plant's performance over time. This method entails verification by the plant's management that its production process is stable, that it is capable of producing products that meet performance standards, that it takes appropriate actions if changes occur in the process before it results in unacceptable products, and that it takes actions to continuously improve its process.

Project Does Not Fully Take Into Account Plants' Repeated Instances of Noncompliance With Regulatory Requirements

FSIS allowed all plants to continue participating in the pilot project even though several had multiple instances of noncompliance with regulatory requirements for fecal contamination.[8] Our analysis of noncompliance records issued by FSIS inspectors at 11 chicken pilot plants showed an increased number of such records after the plants shifted to modified inspections for fecal noncompliance. In two instances, however, FSIS took additional action and notified plants of problems with repeated noncompliance. FSIS officials told us that they are now considering how many repeated instances of noncompliance will result in further regulatory action.

Figure 3: Fecal Noncompliance Records Under Traditional and Modified Inspections



Note: Data are provided for a 12-month period before and after the pilot project's implementation. However, at some plants, data reported after the implementation of the pilot project covered periods of less than 12 months, data for plant 7 cover 8 months, data for plants 1 and 10 cover 10 months, and data for plant 9 cover 11 months. It is likely that a full twelve months of data for these plants would result in an even higher number of noncompliance records.

Source: USDA, FSIS.

As figure 3 shows, the number of noncompliance records resulting from fecal material increased significantly at several plants after they shifted from traditional inspections to modified inspections. At one plant, FSIS

[8]FSIS inspectors document each instance of noncompliance with regulatory requirements in a noncompliance record that plant managers must address immediately. If this is done, the plant continues to operate without interruption. When deficiencies occur repeatedly, FSIS may take further action to withhold products or to suspend inspections. If FSIS suspends inspections, the plant cannot operate.

inspectors issued 469 fecal material noncompliance records during a 10-month period after the plant shifted to modified inspections. Many noncompliance records reflect multiple violations recorded within the same record. At one plant, FSIS inspectors reported that over 90 percent of the fecal material noncompliance records reflected repetitive failures.

FSIS officials acknowledge the rise in the number of noncompliance records and attribute it to the fact that at pilot project plants, FSIS inspectors have more time to verify compliance with regulatory requirements and to document instances of noncompliance when they occur. The officials also point out that, as part of the their verification duties, FSIS inspectors now examine 80 carcasses per line per shift compared with 20 carcasses under the traditional inspection system.[9] In addition, unscheduled verification tests of additional carcasses are conducted under each inspection system. Officials also told us that staffing shortages existed under traditional inspections and that in some instances, it was not possible to complete verification activities on 20 carcasses for each line. Even accounting for the fourfold increase in the number of verification checks taking place under the modified inspections system, one plant experienced a more than twentyfold increase in the number of noncompliance records for fecal contamination. At other plants, however, the number of noncompliance records did not even double.

Another factor may also account for the increases in noncompliance records issued for fecal failures. Although inspectors and veterinarians working at pilot project plants who responded to our survey were not comparing line speeds to those of the traditional inspection system, about 60 percent of them think that line speeds are too fast under modified inspections to ensure product safety. For example, one inspector stated that fast line speeds cause inexperienced employees to miss carcasses with visible fecal contamination. FSIS does not regulate line speeds under this pilot. However, under traditional inspections, each inspector is responsible for about 35 carcasses per inspector per minute. Canadian inspectors told us that line speeds need to be regulated under modified inspection systems.

[9]Each carcass is inspected under both traditional and modified inspections. In addition, under both systems, inspectors also select a sample of carcasses at the end of each line to verify that the inspection system is working as intended.

In contrast to FSIS, the Canadian Food Inspection Agency decided to proceed with a phased approach to nationwide implementation of Canada's modified inspection program, the Modernized Poultry Inspection Program. Under this approach, poultry plants must pass a preliminary assessment before being accepted into the program and are required to pass additional audits as they move from one phase of the program to the next. Producers that choose not to participate in or do not qualify for a partially modified or fully modified inspection system are inspected under the traditional system.

Pilot Project Results Are Inconclusive, but FSIS Inspection Personnel Generally Support Modified Inspections

Notwithstanding the design and methodology limitations, we found that data from the chicken pilot that RTI and FSIS inspectors collected show somewhat different results and do not provide a conclusive basis for FSIS to make a decision regarding the merits of one inspection system compared with another. However, 71 percent of the FSIS inspectors and veterinarians that we surveyed believe that product safety is equal to or somewhat better under modified inspections. Some of them commented that under the modified system, they are able to oversee the entire slaughter line and have more time to collect carcass samples for detailed examination. However, they also raised concerns about the modified inspection system.

Contractor's Data Do Not Conclusively Show That Modified Inspection Systems at Chicken Pilot Plants Performed "As Well As or Better Than" Traditional Inspection Systems

RTI's data do not conclusively show that inspection systems at chicken plants perform as well as or better than they did after they switched to modified inspections. Under modified inspections, none of the inspection system at these plants met all of the performance standards that FSIS developed to measure their performance. Table 3 shows the performance standards that the inspection systems at these plants were expected to meet after shifting to modified inspections.[10]

[10]These standards, set by data gathered at the 16 plants under the traditional inspection system, reflect the performance level of the 12th position. (See p. 13.)

Table 3: Performance Standards for Inspection Systems at Chicken Plants in the Pilot Project

Categories	Performance standards (percentage of defects allowed per shift)
Food Safety (FS) 1: Infectious condition such as septicemia and toxemia	0
FS2: Digestive content contamination (visible fecal material)	0
Other Consumer Protection (OCP) 1: Animal diseases such as airsaculitis	1.7
OCP2: Miscellaneous such as bruises, sores, etc.	52.5
OCP3: Digestive content contamination (ingesta)	18.6
OCP4: Dressing defects such as feathers and oil glands	80.0
OCP5: Dressing defects of digestive tract such as bursa and cloaca	20.8

Source: USDA, FSIS.

Data from the inspection systems at the 11 chicken plants whose performance RTI measured under both inspection systems show that, while the majority of the systems met four or more of the performance standards for food safety and quality under modified inspections, none met all seven of the standards.[11] The data show that 10 of the 11 plants' inspection systems met the food safety standard for septicemia and/or toxemia, but only 1 of the 11 systems met the zero-tolerance food safety standard for visible fecal material, which could contain harmful bacteria such as *E. coli*. Most plants' inspection systems, however, were also unable to meet the fecal material standard under the traditional inspection system. All 11 systems at these plants met the quality standard for bruises and sores (OCP2), but only 3 met the quality standard relating to the presence of feathers (OCP4). According to FSIS officials, carcasses with product quality defects are of a lesser concern than those with food safety defects because they are not associated with foodborne illness and quality defects can generally be removed from the carcass after it leaves the slaughter line and moves to the cut-up and processing area.

[11]We analyzed the statistical significance of inspection system changes at each plant using the 95-percent confidence level.

Three of the 11 plants' inspection systems met six of the seven standards, 3 plants met five of the standards, 4 plants met four standards, and 1 plant met two standards. Table 4 shows which systems met the performance standards that FSIS set for the pilot project.

Table 4: Eleven Chicken Plants' Inspection Systems Compliance With Performance Standards (RTI's Data)

	Food safety standards		Food quality standards (in percent)				
Plant	FS1: septicemia and/or toxemia (zero allowed)	FS2: visible fecal material (zero allowed)	OCP1: animal disease, e.g., airsaculitis (1.7 allowed)	OCP2: bruises, sores, etc. (52.5 allowed)	OCP3: ingesta (18.6 allowed)	OCP4: feathers, oil glands, etc. (80.0 allowed)	OCP5: bursa, cloaca, etc. (20.8 allowed)
1	Yes	No	Yes	Yes	Yes	No	Yes
2	Yes	No	Yes	Yes	Yes	No	No
3	Yes	No	Yes	Yes	Yes	No	No
4	Yes	No	Yes	Yes	Yes	Yes	Yes
5	Yes	No	Yes	Yes	Yes	Yes	Yes
6	Yes	No	Yes	Yes	Yes	No	No
7	Yes	No	Yes	Yes	Yes	No	No
8	Yes	Yes	Yes	Yes	Yes	No	Yes
9	No	No	Yes	Yes	No	No	No
10	Yes	No	Yes	Yes	Yes	No	Yes
11	Yes	No	Yes	Yes	No	Yes	Yes
Plants that met standard	**10**	**1**	**11**	**11**	**9**	**3**	**6**

Source: RTI.

As discussed earlier, under its contract with FSIS, RTI collected microbial data as well. Specifically, it analyzed samples for the presence of *Salmonella* and generic *E. coli*. The results show that 9 of the 11 chicken plants' inspection systems met the performance standard for *Salmonella*. Also, about 80 percent of the samples collected at the11 plants were within the acceptable ranges that FSIS specifies for generic *E. coli*.

Irrespective of whether plants' inspection systems met the performance standards, we analyzed these data to determine if, under modified inspections, the systems performed at least as well as they did under traditional inspections. Table 5 summarizes the results of this analysis.

Table 5: Eleven Chicken Plants' Inspection Systems Performance After Shifting to Modified Inspections (RTI's Data)

	Microbial standards		Food safety standards		Food quality standards				
Performance Changes	**Generic *E. coli***	***Salmonella***	**FS1: septicemia and/or toxemia**	**FS2: visible fecal material**	**OCP1: animal disease, e.g. airsaculitis**	**OCP2: bruises, sores, etc.**	**OCP3: ingesta**	**OCP4: feathers, oil glands, etc.**	**OCP5: bursa, cloaca , etc.**
Better	2	2	1	4	5	5	4	3	4
Same	9	4	10	7	5	3	1	1	1
Worse	0	5	0	0	1	3	6	7	6
Total	**11**	**11**	**11**	**11**	**11**	**11**	**11**	**11**	**11**

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

The data show that some of the plants' inspection systems improved or remained unchanged in certain categories such as the food safety standard for septicemia and/or toxemia. On the other hand, the systems' ability to meet the quality performance standards deteriorated over time. In general, most measures of performance showed deterioration in one or more plants. In fact, every inspection system showed deterioration for at least one of the nine standards measured. At 5 of the 11 plants, results for *Salmonella* were worse under modified inspections than they were under the traditional inspection system—only 2 improved their performance in this category. FSIS has stated that any new inspection system should perform at least as well as the current system of inspections.

FSIS' Data Do Not Conclusively Show That Plants' Inspection Systems Perform "As Well As or Better" Under Modified Inspections

FSIS' data for 10 chicken plants in the pilot project also show that none of their inspection systems met all seven standards.[12] In contrast to the RTI data, however, the FSIS data show that 7 of the 10 systems met six of seven standards, and the remaining 3 plants met five of the seven standards. FSIS officials stated that the differences in results might be caused, at least in part, by differences in data collection. As part of FSIS inspectors' verification duties at the chicken plants participating in the pilot project, the inspectors sample and analyze carcasses to determine whether they meet performance standards. Inspectors are not required to collect and analyze microbial samples, as RTI was required to do for the pilot project. The data collected cover a longer period than RTI's and include much larger samples per plant. The FSIS officials acknowledge,

[12]We analyzed FSIS data from 10 of the 11 plants at which RTI collected data for both traditional and modified inspections because one plant dropped out of the pilot shortly after RTI completed data collection.

however, that disparities in the FSIS and RTI data for some performance standards, such as dressing defects (e.g., feathers and oil glands), suggest a need for further investigation.

The FSIS data show that 7 of the 10 chicken plants' inspection systems met six of the seven performance standards, but none of the plants met the zero-tolerance standard for fecal material over time. It should be noted, however, that the actual performance of the 12th position for this standard was 1.5 percent, not zero as required by FSIS' performance standard. So noncompliance with this standard may not provide a basis for comparing performance of the modified with traditional inspection systems. After shifting to modified inspections, each of the 10 plants' systems had reached a performance that was better than 1.5 percent for this standard. We analyzed data on individual inspection systems' performance from the time that each plant implemented modified inspections through June of 2001. Table 6 shows a summary of the inspection systems' performance at individual plants.

Table 6: Ten Chicken Plants' Inspection Systems Compliance With Performance Standards (FSIS' Data)

	Food safety standards			Food quality standards			
Plant	**FS1: septicemia and/or toxemia**	**FS2: visible fecal material**	**OCP1: animal disease, e.g., airsaculitis)**	**OCP2: bruises, sores, etc.**	**OCP3: ingesta**	**OCP4: feathers, oil glands, etc.**	**OCP5: bursa, cloaca, etc.**
1	Yes	No	Yes	Yes	Yes	Yes	Yes
2	Yes	No	Yes	Yes	No	Yes	Yes
3	Yes	No	Yes	Yes	Yes	Yes	Yes
4	Yes	No	Yes	Yes	Yes	Yes	Yes
5	Yes	No	Yes	Yes	Yes	Yes	Yes
6	No	No	Yes	Yes	Yes	Yes	Yes
7	Yes	No	Yes	Yes	Yes	Yes	Yes
8	Yes	No	No	Yes	Yes	Yes	Yes
9	Yes	No	Yes	Yes	Yes	Yes	Yes
10	Yes	No	Yes	Yes	Yes	Yes	Yes
Plants that met standard	**9**	**0**	**9**	**10**	**9**	**10**	**10**

Note: FSIS inspectors do not collect and analyze generic *E. coli* and *Salmonella* as part of their verification duties in this pilot project.

Source: FSIS inspectors' verification data from November 2000 through June 2001.

Table 6 shows which plants' inspection systems did not meet specific performance standards. That is, plant 6 did not meet the food safety standard for infectious conditions (e.g., septicemia and/or toxemia); plant 8 did not meet the food quality standard for animal diseases such as airsaculitis; and plant 2 did not meet the food quality standard for digestive content contamination (ingesta). At the pilot plants, FSIS inspectors are issuing noncompliance records when plants do not meet the performance standards; however, FSIS officials have not yet decided how many instances of noncompliance will be tolerated before the agency can decide to take further action to ensure regulatory compliance.

We reviewed data collected by FSIS inspectors after the plants shifted to modified inspections during two different time periods. In comparing these two periods, we found that in several categories, the inspection system's performance at each plant deteriorated over time. Table 7 summarizes the changes for these 10 plants.

Table 7: Changes in Chicken Plants' Inspection Systems Performance Over Two Time Periods After Shifting to Modified Inspections (FSIS' Data)

	Food safety standards		Food quality standards				
Performance	FS1: septicemia and/or toxemia	FS2: visible fecal material	OCP1: animal disease, e.g., airsaculitis	OCP2: bruises, sores, etc.	OCP3: ingesta	OCP4: feathers, oil glands, etc.	OCP5: bursa, cloaca, etc.
Better	0	1	1	5	2	0	5
Same	10	9	9	0	2	1	2
Worse	0	0	0	5	6	9	3
Total	10	**10**	**10**	**10**	**10**	**10**	**10**

Note: During the first period, the plants were implementing the original pilot project design in which there were no FSIS inspectors stationed at fixed positions on the slaughter lines. During the second, period, a carcass inspector was reinstated at each slaughter line to comply with a court ruling. The first period starts just after each plant shifted from traditional to modified inspections and ends on October 31, 2000. The second period starts November 1, 2000, and ends on June 30, 2001.

Source: GAO's analysis of FSIS inspectors' verification data from implementation of modified inspections until June 2001. We used a difference of plus or minus 0.5 percent to analyze the changes for the seven categories described in the table. We estimated that, on average, 43,000 chickens are processed per line, per shift.

On the basis of this information, in addition to providing plant managers with feedback on a daily basis, FSIS inspectors could identify plants whose inspection systems need to improve. In addition, FSIS could aggregate data from these plants and use this type of analysis to evaluate whether a specific performance standard needs to be revised. For example, we made two observations by analyzing the data as follows:

- As shown in table 7, 9 of the 10 plants' performance under the OCP4 standard deteriorated over time. While this standard permits 80 percent of carcasses per shift to have this defect and still meet the standard, this trend may suggest the need for FSIS to investigate why the inspection system's performance at an individual plant is deteriorating.

- As shown in table 7, 9 of the 10 plants maintained their performance and one improved under the FS2 standard.

Australian officials told us that under their modified inspection system, the Australian Quarantine and Inspection Service requires plants to use process controls to demonstrate continuous improvement in plant sanitation, microbial pathogen reduction, and quality defect reduction. The agency uses these data to monitor plant performance and enforce compliance with standards.

Most FSIS Inspectors and Veterinarians Believe That Modified Inspections Are Equal to or Better Than Traditional Inspections for Ensuring Product Safety

About 70 percent of the respondents to our survey of FSIS inspectors and veterinarians believe that modified inspections are equal to or somewhat better than traditional inspections for product safety while more than half believe that modified inspections are the same as or better than traditional inspections for product quality. Table 8 summarizes inspectors' and veterinarians' responses to major topics covered by our survey. (See app. IV for further detail on the survey responses.)

Table 8: Summary of Responses to GAO's Survey of USDA Inspectors and Veterinarians

Topic	Responses in percentages
Product safety	71: same as or better under modified inspections versus traditional inspections 24: better under traditional inspections 5: unsure
Product quality	57: same as or better under modified inspections versus traditional inspections 39: better under traditional inspections 5: unsure
Effect of plants' adding anti-microbial rinses and washes[a]	62: food safety the same as or better than without rinses and washes 3: food safety worse than without rinses and washes 10: don't know its effect on food safety
Line speeds: Concerning product safety	59: line speed is too fast 39: line speed is about right 0: line speed is too slow 2: unable to determine

Topic	Responses in percentages
Concerning product quality	64: line speed is too fast 33: line speed is about right 0: line speed is too slow 2: unable to determine
Original modified inspection system versus modified system after court order:	
Concerning product safety	57: modified system after court order is better 27: original modified system is better 8: they are about the same 8: no opinion on which is better
Concerning product quality	45: modified system after court order is better 25: original modified system is better 19: they are about the same 11: no opinion on which is better.
Noncompliance records	76: increased under the modified inspections versus traditional inspections[b] 11: decreased under the modified inspections versus traditional inspections 10: the same under the modified inspections and traditional inspections 3: don't know
Training of plant personnel:	
Concerning adequacy of plant sorter training	15: plant's training helped to a great extent 51: plant's training helped to some extent 28: plant's training helped to little or no extent 6: unable to determine
Concerning USDA's development of standardized training curriculum for plant personnel	67: FSIS should develop curriculum 17: FSIS should not develop curriculum 15: neutral 2: unable to determine
Concerning USDA's development of a testing and certification program for plant personnel	64: FSIS should develop this program 18: FSIS should not develop this program 16: neutral 1: unable to determine.
FSIS training for pilot project inspectors	40: helped to a great extent 51: helped to some extent 8: helped to little or no extent 1: have not received training for the pilot project 0: unable to determine.

[a]This change was experienced by 75 percent of respondents at their plants after modified inspections were implemented.

[b]Some inspectors cited more time and freedom to find defects and write noncompliance records and more carcasses are sampled under modified inspections.

Note: Because of rounding, numbers may not add up to 100 percent.

Nearly all of the inspectors and veterinarians provided additional written comments on several issues of concern and made suggestions for improvement. The inspectors commented that under the modified system, they are able to oversee the entire slaughter line and have more time to collect carcass samples for detailed examination. In addition, 27 of the 210 inspectors and veterinarians commented that they were concerned about regulatory noncompliance and enforcement issues. Particularly noteworthy are comments that indicate that stronger measures should be in place to reduce repetitive instances of fecal material noncompliance and that inspectors should have more authority to hold a plant accountable for multiple and/or repetitive problems. In addition, four inspectors would like each failure of the zero-tolerance standard for fecal material to be documented in separate noncompliance records rather than recording multiple instances in a single record, which may obscure the frequency of the problem. Thirty-nine inspectors and veterinarians also raised concerns regarding product quality. In addition, seven inspectors stated that the quality performance standards need to be tightened so that fewer defects are overlooked.

In addition, 30 inspectors and veterinarians commented that they are concerned that the zero-tolerance standard for fecal material is not adequately enforced, especially since the carcass inspector examines only the back of the carcass and does not look inside the cavity. Seven suggested that FSIS place a mirror or provide some other mechanism to facilitate observation by the carcass inspector.

Finally, 62 inspectors commented that working conditions under the modified inspection system are better because the inspectors no longer need to make repetitive motions, as they did when they continuously examined each carcass on the slaughter line by touch. Sixteen inspectors also said that they like the ability to physically move from their location at least once every hour. Twenty-five of them mentioned, however, that the carcass inspectors' location might expose them to agents, such as chlorine or trisodium phosphate that could adversely affect their health.

Conclusions

We believe that a risk-based inspection system—such as the one that USDA is pilot-testing at chicken plants and is starting at hog plants—has merit in concept and is consistent with the existing risk-based framework for HACCP. However, while we support this approach, we believe that the design of this pilot will not permit USDA to reach conclusions about whether the new system of modified inspections performs as well as the traditional system.

If, as planned, USDA undertakes to modify its current inspection system for chicken plants, it will need to consider several factors that we discuss in this report and that are also key features of the Australian and Canadian modified inspection systems. First, if USDA issues regulations that require all chicken plants to modify their inspection systems concurrently without first determining whether individual plants are able to meet standards, it may risk including those plants with repeated records of noncompliance. Such plants may have difficulty meeting their new responsibilities. Continued participation in a modified inspection system should depend on the plants' ability to maintain good performance. Second, adding a requirement that plants use statistical process control systems to identify variations in performance will allow the plants to better manage and control their production processes and will also allow USDA to appropriately monitor and verify inspection systems' performance at each plant over time. Third, without requiring that plant personnel receive adequate training to undertake carcass defect detection responsibilities, USDA may jeopardize product safety and quality. At the very least, USDA should ensure that personnel conducting carcass defect detection duties have knowledge and training comparable to that of USDA inspectors who were previously responsible for these duties. Last, inspectors and veterinarians responding to our survey provided several useful comments on how to enhance a modified inspection system. For example, they believe that USDA needs to address multiple instances of plant noncompliance with regulatory requirements. As discussed in this report, many plants had repeated instances of noncompliance with a critical food safety performance standard.

In addition to the current legal challenges, USDA faces future potential legal challenges unless its statutory inspection authorities are revised. These challenges will likely hinder the Department's objective of modifying its inspection system at meat and poultry slaughter plants. We continue to believe that, as we have recommended before, the Congress should consider revising the Meat and Poultry Acts, 21 U.S.C. sections 604 and 455, to provide FSIS with the flexibility and discretion to target its inspection resources for the most serious food safety risks. Such revisions would eliminate the requirements that USDA has traditionally implemented through continuous carcass-by-carcass government inspection and replace them with a risk-based inspection system that includes government oversight and verification.

Recommendations for Executive Action

If USDA decides to implement modifications to its inspection system, we recommend that the Secretary of Agriculture direct FSIS to

- phase in the implementation of modified inspections so that only plants with a good history of regulatory compliance are eligible to participate and continue in the program;
- require plants to adopt statistical process control systems to manage and control their production and require FSIS personnel to monitor and verify these systems;
- in conjunction with industry, develop a training and certification program for personnel involved in tasks previously performed by federal inspectors and require that only trained and certified plant personnel perform these duties; and
- consider the merits of adopting suggestions from inspectors and veterinarians at pilot project plants contained in this report, such as how to address repetitive instances of noncompliance with regulatory requirements.

We further recommend that, if in addition to the current pilot project for chickens, USDA decides to conduct similar pilots for other species—hogs, turkeys, or cattle—the Department take steps to ensure that the pilot's design and methodology are sufficiently rigorous to allow more valid conclusions than those in this chicken pilot.

Agency Comments and Our Evaluation

We provided USDA with a draft of this report for review and comment. In written comments, USDA said that the report's recommendations were appropriate and that the agency will address them when it seeks public comment prior to making any regulatory changes. USDA provided technical comments, which we incorporated in the report as appropriate. USDA's comments and our responses are contained in appendix VII.

We performed our review from December 2000 through October 2001, in accordance with generally accepted government auditing standards.

As agreed with your offices, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of this letter. At that time, we will send copies to congressional committees with jurisdiction over food safety issues; the embassies of

Australia and Canada; the Secretary of Agriculture; the Director, Office of Management and Budget; and other interested parties. We will make copies available to others on request.

If you have any questions about this report, please contact me at (202) 512-3841. Major contributors to this report are listed in appendix VIII.

Lawrence J. Dyckman
Director, Natural Resources
and Environment

Appendix I: Scope and Methodology

To describe the objectives, design, and scope of the pilot project, we interviewed cognizant government and industry officials. Specifically, we interviewed officials and/or reviewed documents from the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS); Office of Policy, Program Development, International Programs, and Field Operations; and Foreign Agriculture Service. We also consulted with the National Joint Council of Food Inspection Locals, Research Triangle Institute (RTI), Center for Science in the Public Interest, Government Accountability Project, European Union Commission, Consumer Federation of America, National Chicken Council, National Turkey Federation, National Veterinarian Association, and American Meat Institute. We obtained information as well from *Federal Register* notices and court filings. Additionally, we visited and interviewed plant managers, USDA inspectors, and veterinarians at five chicken plants and one hog plant participating in the pilot project. To provide information on similar projects in Australia and Canada, we visited and toured their meat and poultry plants. We also interviewed Australian and Canadian government officials, inspectors, and veterinarians, consumer groups, and plant managers to obtain their perspectives on their country's modified inspection systems. We did not evaluate the validity of the Australian and Canadian projects' design and methodology.

To identify limitations, if any, in the project's design and methodology, we reviewed USDA's contract with RTI and discussed data collection and data analysis methods with statisticians from USDA, the Australian Quarantine and Inspection Service, and the Canadian Food Inspection Agency. We obtained input on the pilot project's design from consumer groups, industry associations, poultry science experts, and our design methodologists. We also reviewed the sample sizes selected by USDA and determined whether the results generated from the volunteer plants can be generalized to entire population. We interviewed managers of pilot project plants to identify the length of industry training provided for plant personnel who replaced USDA inspectors on the slaughter line and any modifications made to the slaughter line before and during the pilot project that could affect the project's results. Moreover, we participated in FSIS' three-day training course covering pilot project inspections.

Additionally, we analyzed noncompliance records issued by USDA inspectors for failures to meet the zero-tolerance standard for fecal material at chicken plants. We asked USDA to provide a complete set of noncompliance records for each of the 11 chicken plants that participated in the baseline and modified inspection phases of the pilot project. That is, we asked for noncompliance records 1 year before and 1 year after

implementation of the modified inspections at each plant. To the best of our knowledge, we received complete data from all the plants. However, for some plants, we did not receive 12 months' worth of data reflecting the modified inspections because the plants had been operating under modified inspections for less than a year.

We began our analysis by removing duplicate noncompliance records and noncompliance records resulting from sanitation and other nonfecal problems. We then counted the number of noncompliance records resulting from fecal material violations by month for each plant to determine whether the total number of noncompliance records was increasing or decreasing after implementation of the modified inspections. Since each noncompliance record can document multiple violations, we also analyzed, on a monthly basis, whether the total number of carcasses contaminated with fecal material for each plant was increasing or decreasing under the modified versus traditional inspections. Furthermore, we counted and compared the number of noncompliance records generated from the same type of system failure (repetitive failures) before and after implementation of the modified inspections. For some months, we did not have any noncompliance records documenting problems with fecal material.

To evaluate whether the data generated by the pilot project will allow USDA to reach valid conclusions on the relative effectiveness of the modified inspection system tested in the pilot project, we reviewed, compared, and contrasted pilot project data gathered by USDA inspectors and RTI. We requested and received pilot project data gathered by RTI at the 11 chicken plants that participated in both the baseline and modified inspection phases of the pilot project. We compared the individual plants' results with the two food safety and five food quality performance standards to determine if each plant was able to meet the standards. We also determined whether plants improved their performance over time under modified inspections by comparing individual plants' results under modified inspections with their results under traditional inspections. We also requested USDA inspectors' verification data from the same 11 chicken plants. Because one plant dropped out of the pilot project in early 2001, we did not evaluate the data from this plant. USDA averaged the verification results from all of the plants together to determine if the plants collectively met the performance standards. We chose to average each plant's results individually to determine its ability to meet or exceed the performance standards over time.

In addition, we surveyed all pilot project inspectors and veterinarians who the USDA identified as working at pilot project plants to obtain their views and concerns regarding the modified inspection system. USDA officials provided the survey respondents with 1 hour of compensatory time for completing our survey. In designing our survey, we interviewed pilot project program officials, inspectors, and veterinarians to determine what issues should be included in the survey. During the pretesting phase of our survey, it became evident that respondents considered the survey questions to be highly sensitive. To address these concerns, we used procedures to guarantee the anonymity of all survey responses. However, the use of a separate return postcard for follow-up purposes allowed us to track which respondents did and did not mail back survey responses. After developing an initial draft of the survey questionnaire, we visited and pretested the questionnaire with 10 respondents at two chicken plants and one hog plant to obtain comments from pilot project inspectors and veterinarians and to ensure that the survey was appropriate for both species of animals. We revised the questionnaire in accordance with their comments. Then we incorporated input from union officials and USDA officials before sending out the questionnaires. We distributed them by mail according to a list provided by USDA officials. However, we sent additional questionnaires to those pilot project inspectors and veterinarians who were missing from the initial list and who called us to say they did not receive one. We also sent three follow-up reminders in the weeks following the initial distribution of the questionnaire. We reviewed each survey response to identify internal data inconsistencies. We sent out questionnaires to 225 persons and received 210 responses, for a 93-percent-response rate.

We performed our review from December 2000 through October 2001, in accordance with generally accepted government auditing standards.

Appendix II: Chronology of Pilot Project Litigation

6/10/97	USDA's Food Safety and Inspection Service sought public comment on the development of new inspection models for the slaughter and processing of meat and poultry in connection with the implementation of its previously promulgated HACCP rule.[1] FSIS stated that the inspection models would not include fixed FSIS inspection stations on slaughter lines, as under existing procedures. Instead, FSIS inspectors would provide oversight at the slaughter lines and verification that plants were properly implementing HACCP, among other things. FSIS further stated that, upon completion of the models project, it will initiate rulemaking, as appropriate, to change existing inspection procedures.
4/8/98	American Federation of Government Employees (AFGE) filed a complaint in the U.S. District Court for the District of Columbia seeking to enjoin the USDA from proceeding with the pilot project, on the grounds that it violated the Federal Meat Inspection Act, 21 U.S.C. section 604, and the Poultry Products Inspection Act, 21 U.S.C. section 455, by not requiring federal government officials to perform carcass-by-carcass postmortem inspection.
9/23/99	U.S. District Court (Lamberth, R.) granted USDA's motion for summary judgment, holding that neither the Federal Meat Inspection Act nor the Poultry Products Inspection Act was violated by the HACCP-Based Inspection Models Project. *American Federation of Government Employees v. Glickman*, No. 98-0893 (D. D.C. Sept. 23, 1999). The court reasoned that even though the statutes require postmortem inspections by USDA inspectors, the word "inspection" in these statutes does not necessarily mandate direct, physical "organoleptic"—involving sight, touch, and smell—examination by USDA inspectors.
6/30/00	AFGE appealed the district court's ruling to the U.S. Court of Appeals for the District of Columbia Circuit, which reversed the district court's decision. The court of appeals held that delegating the task of inspecting carcasses to plant employees violated the Federal Meat Inspection Act and the Poultry Products Inspection Act because both statutes require that federal inspectors, rather than private employees, determine whether a product is adulterated. *American Federation of Government Employees v. Glickman*, 215 F.3d 7, 9 (2000). The court of appeals remanded the case to the district court for further proceedings consistent with its opinion.

[1]"HACCP-Based Meat and Poultry Inspection Concepts," 62 *Fed. Reg*. 31553 (June 10, 1997).

8/25/00	AFGE moved the district court to enter an order declaring that the pilot project violated the Federal Meat Inspection Act and the Poultry Products Inspection Act and permanently enjoining USDA from delegating its statutory duty to inspect each meat and poultry carcass and its parts to anyone other than federal inspectors.
9/15/00	USDA responded to AFGE's motion, stating that to comply with the court of appeals' decision, FSIS was modifying the pilot project so that an FSIS inspector would directly inspect every carcass. Specifically, USDA stated that in the 11 chicken plants in the pilot project, one FSIS inspector would be stationed toward the end of the slaughter line, between the final wash and the chiller. This inspector would be responsible for examining each carcass and determining whether it is adulterated. In the three hog plants, FSIS inspectors would be placed at up to three fixed locations on the slaughter line and would be responsible for examining the carcass, head, and viscera, and determining whether they were adulterated.
11/6/00	All pilot project plants had implemented the redesigned inspection model.[2]
1/17/01	U.S. District Court for the District of Columbia ruled that the redesigned pilot project does not violate the court of appeals ruling in *American Federation of Government Employees v. Glickman*, 215 F.3d 7 (2000) and does not violate the Federal Meat Inspection Act and the Poultry Products Inspection Act. *American Federation of Government Employees v. Glickman*, No. 98-893 (Jan. 17, 2001). According to the district court, the redesigned pilot project is consistent with the court of appeals decision because the thrust of that opinion was that to satisfy its inspection duties, FSIS must do more than merely observe others performing inspections, and in the redesigned project, federal inspectors will make the critical determination as to whether a product is adulterated. Furthermore, the redesigned pilot project satisfied the requirements of the federal meat and poultry inspection statutes, according to the district court, because it reflects a reasonable interpretation of the meaning of the term "inspection" within those statutes.

[2]See FSIS Briefing Paper: The History of the HACCP-Based Inspection Models Project (Jan. 19, 2001).

2/5/01	AFGE filed a notice of appeal to the U.S. Court of Appeals for the District of Columbia Circuit. The appeal is still pending.

Appendix III: Performance Standards for Hog Plants

For hog plants, FSIS developed three food safety and three food quality standards from traditional inspections data (baseline data) gathered at five plants. (See table 9.) These standards were set slightly below the performance of the fourth (out of five) plants.[1] At the time of our review, FSIS did not have complete pilot project data available for the hog plants.

Table 9: Performance Standards for Inspection Systems at Hog Plants in the Pilot Project

Categories	Performance standards (percentage of defects allowed per shift)
Food Safety 1: Infectious conditions such as septicemia and toxemia	0
Food Safety 2: Digestive content such as fecal material, ingesta, milk	0
Food Safety 3: Antemortem symptoms such as neurologic conditions	0
Other Consumer Protection 1: Carcass pathology such as arthritis, emaciation, etc.	4.1
Other Consumer Protection 2: Visceral pathology such as enteritis/gastritis, fecal contamination of viscera, etc.	7.2
Other Consumer Protection 3: Miscellaneous such as anemia, bile, bruises, scabs, etc.	20.5

Source: USDA, FSIS.

USDA is using the safety and quality performance standards developed for this project to determine, among other things, if the plants can perform at least as well as they did under traditional inspections.

[1]USDA developed the hog performance standards from the following formula: (0.25 * 3rd plant's performance) + (0.75 * 4th plant's performance). These standards are comparable to the 25th percentile established for the chicken pilot.

Appendix IV: Survey Results

United States General Accounting Office

GAO

Natural Resources and Environment

Survey of USDA Inspectors and Veterinarians: HIMP Inspection System

To Ensure Your Anonymity

To maintain your **anonymity** in responding to this survey, please remove the postcard below from this booklet and mail it back separately at the same time as you return your survey booklet. This postcard is coded so that we will know only which employees responded to our survey. No other identification of you is included in the survey materials. In order to protect your anonymity, the postcard is returned to San Francisco, California, while the survey booklet is returned to Washington, D.C.

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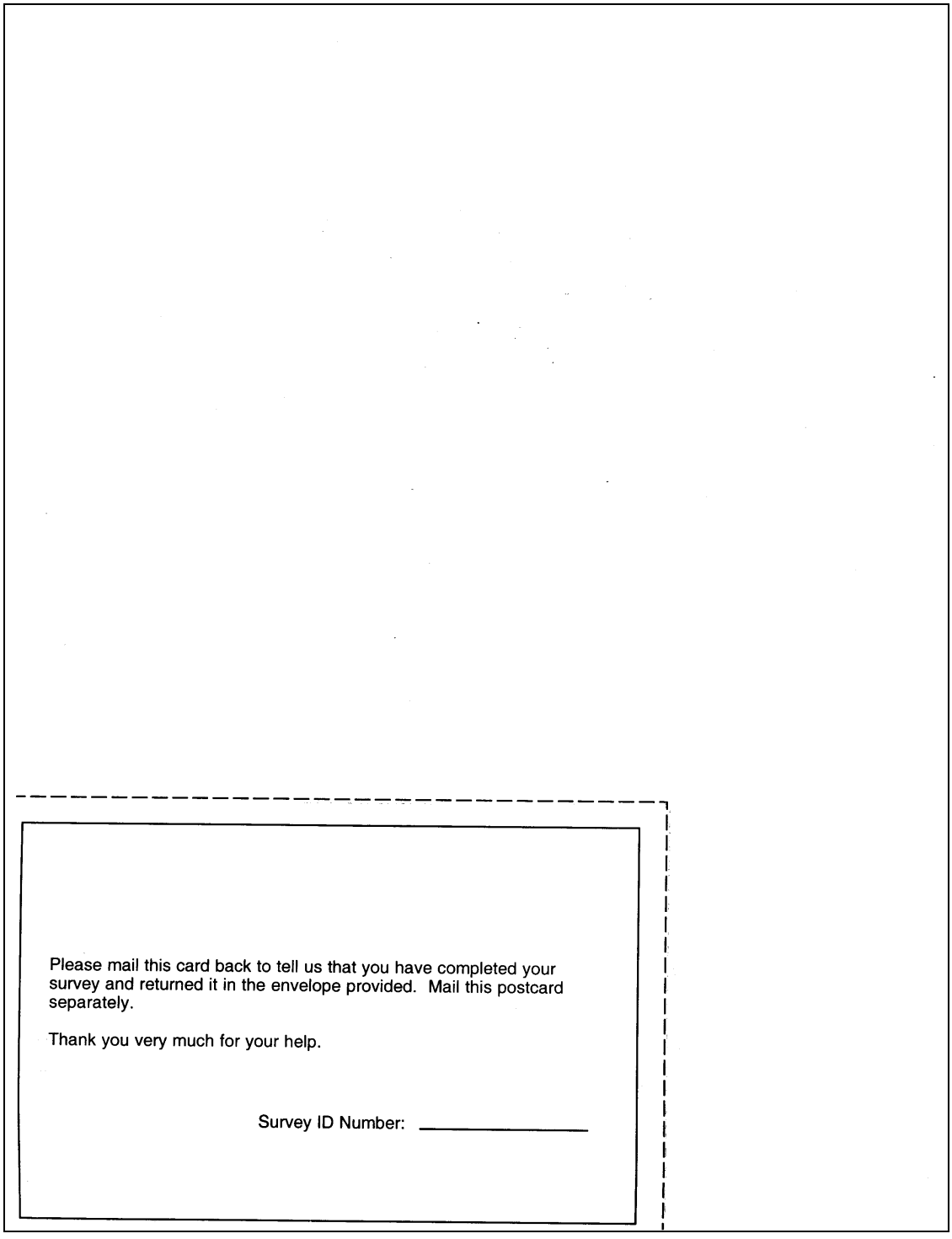

Please mail this card back to tell us that you have completed your survey and returned it in the envelope provided. Mail this postcard separately.

Thank you very much for your help.

Survey ID Number: _____

United States General Accounting Office

GAO
Accountability * Integrity * Reliability

Survey of USDA Inspectors and Veterinarians: HIMP Inspection System

Introduction

The U.S. General Accounting Office (GAO) is an agency of the legislative branch that reviews federal programs for the U.S. Congress. As part of a review of the HIMP (HACCP-based Inspection Models Project) pilot program, we are currently surveying USDA inspectors and veterinarians at HIMP plants about their experiences and opinions.

This survey is completely anonymous. There is no identification of you or your plant on the survey. Please return the attached postcard separately after completing the survey. The number on the postcard will allow us to track our participation rates. There is no information that can link the postcard with your survey.

Your participation in this survey is vital so that we can tell the Congress what works well for HIMP inspections and what could be improved. It takes about 30 minutes to complete the survey, depending on your experiences. We made every effort to minimize the amount of information requested. Your prompt response will help us avoid costly follow-up mailings.

If you have any questions about our review or this survey, please contact Cris Gobin via our toll-free number at 1-888-868-0344 or via e-mail at gobinm@gao.gov, or contact John Nicholson at 202-512-9858 or via e-mail at nicholsonj@gao.gov.

If the envelope is missing, please return your survey to

Ms. Cris Gobin
U.S. General Accounting Office
441 G Street NW, Mail Stop 2T23
Washington, DC 20548

Thank you very much for taking time to contribute to this study.

Your Inspection Experience

1. Have you ever worked at a plant that uses the HIMP inspection system?

   1. Yes **210 (100.0%)**
   2. No **0**
   N=210

2. Have you ever worked at a plant that uses the traditional (not HIMP) inspection system, either now or in the past?
   1. Yes **210 (100.0%)**
   2. No **0**
   N=210

Food Safety and Quality Under HIMP Inspection

3. In your opinion, how does the *overall safety of the food products* under the HIMP inspection system compare with the safety of the food products under the traditional inspection system? *(Check one.)*
   1. Much safer under HIMP **50 (23.8%)**
   2. Somewhat safer under HIMP **78 (37.1%)**
   3. No difference in safety **21 (10.0%)**
   4. Somewhat safer under traditional **33 (15.7%)**
   5. Much safer under traditional **17 (8.1%)**
   6. Unsure **11 (5.2%)**
   N=210

4. In your opinion, how does the *overall quality of the food products* under the HIMP inspection system compare with the quality of the food products under the traditional inspection system? *(Check one.)*
   1 Much higher quality under HIMP. **30 (14.3%)**
   2. Somewhat higher quality under HIMP **55 (26.2%)**
   3. No difference in quality **34 (16.2%)**
   4. Somewhat higher quality under traditional **51 (24.3%)**
   5. Much higher quality under traditional **30 (14.3%)**
   6. Unsure **10 (4.8%)**
   N=210

Changes That Could Affect Food Safety and Quality Under HIMP

Questions 5 through 26 ask about innovations or things that *may have* changed at some HIMP plants, as compared to plants still under the traditional inspection system. For each item, if that kind of change has occurred at HIMP plants where you have worked, please indicate your opinion of how the change has affected food safety or food quality.

If the change has not happened where you have worked, mark the box next to choice (1) that begins with "Does not apply."

5. In your opinion, what is the effect on **food safety** of *redesigning the slaughter line? (Check one.)*
   1. Does not apply – plant did not redesign the slaughter line **56 (26.7%)**
   2. Made food safety better **77 (36.7%)**
   3. Made no difference to food safety **32 (15.2%)**
   4. Made food safety worse **25 (11.9%)**
   5. Don't know/No way to tell effect on food safety **20 (9.5%)**
   N=210

6. In your opinion, what is the effect on **food quality** of *redesigning the slaughter line? (Check one.)*
   1. Does not apply – plant did not redesign the slaughter line **56 (26.7%)**
   2. Made food quality better **58 (27.6%)**
   3. Made no difference to food quality **43 (20.5%)**
   4. Made food quality worse **43 (20.5%)**
   5. Don't know/No way to tell effect on food quality **10 (4.8%)**
   N=210

7. In your opinion, what is the effect on **food safety** of *the addition of new or more scrubbers/brushes? (Check one.)*
   1. Does not apply – plant did not add any scrubbers/brushes **87 (41.4%)**
   2 Made food safety better . **80 (38.1%)**
   3. Made no difference to food safety **22 (10.5%)**
   4. Made food safety worse **3 (1.4%)**
   5. Don't know/No way to tell effect on food safety **18 (8.6%)**
   N=210

8. In your opinion, what is the effect on **food quality** of *the addition of new or more scrubbers/brushes? (Check one.)*
   1. Does not apply – plant did not add any scrubbers/brushes **87 (41.4%)**
   2. Made food quality better **50 (23.8%)**
   3. Made no difference to food quality **53 (25.2%)**
   4. Made food quality worse **4 (1.9%)**
   5. Don't know/No way to tell effect on food quality **16 (7.6%)**
   N=210

9. In your opinion, what is the effect on **food safety** of *new or modified evisceration equipment? (Check one.)*
   1. Does not apply – plant did not change the evisceration equipment **119 (56.7%)**
   2. Made food safety better **51 (24.3%)**
   3. Made no difference to food safety **24 (11.4%)**
   4. Made food safety worse **10 (4.8%)**
   5. Don't know/No way to tell effect on food safety **6 (2.9%)**

   N=210

10. In your opinion, what is the effect on **food quality** of *new or modified evisceration equipment? (Check one.)*

    1. Does not apply – plant did not change the evisceration equipment **119 (56.7%)**
    2. Made food quality better **35 (16.7%)**
    3. Made no difference to food quality **39 (18.6%)**
    4. Made food quality worse **10 (4.8%)**
    5. Don't know/No way to tell effect on food quality **7 (3.3%)**

    N=210

11. In your opinion, what is the effect on **food safety** of *adding a computer on the line for recording reasons for condemning carcasses? (Check one.)*

    1. Does not apply – plant did not add a computer on the line for recording reasons for condemning carcasses **101 (48.1%)**
    2. Made food safety better **24 (11.4%)**
    3. Made no difference to food safety **60 (28.6%)**
    4. Made food safety worse **4 (1.9%)**
    5. Don't know/No way to tell effect on food safety **21 (10.0%)**

    N=210

12. In your opinion, what is the effect on **food quality** of *adding a computer on the line for recording reasons for condemning carcasses? (Check one.)*

    1. Does not apply – plant did not add a computer on the line for recording reasons for condemning carcasses **101 (48.1%)**
    2. Made food quality better **26 (12.4%)**
    3. Made no difference to food quality **57 (27.1%)**
    4. Made food quality worse **5 (2.4%)**
    5. Don't know/No way to tell effect on food quality **21 (10.0%)**

    N=210

13. In your opinion, what is the effect on **food safety** of *adding radios for communication between inspectors? (Check one.)*

    1. Does not apply – plant did not add radios for communication between inspectors **2 (1.0%)**
    2. Made food safety better **142 (67.6%)**
    3. Made no difference to food safety **51 (24.3%)**
    4. Made food safety worse **0**
    5. Don't know/No way to tell effect on food safety **15 (7.1%)**

    N=210

14. In your opinion, what is the effect on **food quality** of *adding radios for communication between inspectors? (Check one.)*

    1. Does not apply – plant did not add radios for communication between inspectors **2 (1.0%)**
    2. Made food quality better **124 (59.0%)**
    3. Made no difference to food quality **69 (32.9%)**
    4. Made food quality worse **0**
    5. Don't know/No way to tell effect on food quality **15 (7.1%)**

    N=210

3

15. In your opinion, what is the effect on **food safety** of *the plant using Statistical Process Controls (SPC)? (Check one.)*

1. Does not apply – plant does not use Statistical Process Controls (SPC) **47 (23.0%)**

2. Made food safety better **70 (34.3%)**
3. Made no difference to food safety **51 (25.0%)**
4. Made food safety worse **10 (4.9%)**

5. Don't know/No way to tell effect on food safety **26 (12.7%)**

N=204

16. In your opinion, what is the effect on **food quality** of *the plant using Statistical Process Controls (SPC)? (Check one.)*

1. Does not apply – plant does not use Statistical Process Controls (SPC) **47 (23.0%)**

2. Made food quality better **67 (32.8%)**
3. Made no difference to food quality **51 (25.0%)**
4. Made food quality worse **15 (7.4%)**
5. Don't know/No way to tell effect on food quality **24 (11.8%)**

N=204

17. In your opinion, what is the effect on **food safety** of *increased verification sampling? (Check one.)*

1. Does not apply – we did not increase our verification sampling **4 (1.9%)**

2. Made food safety better **156 (75.4%)**
3. Made no difference to food safety **34 (16.4%)**
4. Made food safety worse **3 (1.4%)**

5. Don't know/No way to tell effect on food safety **10 (4.8%)**

N=207

18. In your opinion, what is the effect on **food quality** of *increased verification sampling? (Check one.)*

1. Does not apply – we did not increase our verification sampling **4 (1.9%)**

2. Made food quality better **122 (58.9%)**
3. Made no difference to food quality **66 (31.9%)**
4. Made food quality worse **7 (3.4%)**

5. Don't know/No way to tell effect on food quality **8 (3.9%)**

N=207

19. In your opinion, what is the effect on **food safety** of *having a system to match each sorter to the product they have checked (for example, coloring coding or numbering)? (Check one.)*

1. Does not apply – there is no system to match each sorter to the product they have checked **123 (59.4%)**

2. Made food safety better **39 (18.8%)**
3. Made no difference to food safety **30 (14.5%)**
4. Made food safety worse **2 (1.0%)**

5. Don't know/No way to tell effect on food safety **13 (6.3%)**

N=207

20. In your opinion, what is the effect on **food quality** of *having a system to match each sorter to the product they have checked (for example, coloring coding or numbering)? (Check one.)*

1. Does not apply – there is no system to match each sorter to the product they have checked **123 (59.4%)**

2. Made food quality better **38 (18.4%)**
3. Made no difference to food quality **31 (15.0%)**
4. Made food quality worse **2 (1.0%)**
5. Don't know/No way to tell effect on food quality **13 (6.3%)**

N=207

21. In your opinion, what is the effect on **food safety** of *replacing USDA inspectors with plant sorters*? (*Check one.*)

    1. Does not apply – plant did not replace USDA inspectors with plant sorters **3 (1.5%)**

    2. Made food safety better **53 (25.9%)**
    3. Made no difference to food safety **63 (30.7%)**
    4. Made food safety worse **69 (33.7%)**

    5. Don't know/No way to tell effect on food safety **17 (8.3%)**

    N=205

22. In your opinion, what is the effect on **food quality** of *replacing USDA inspectors with plant sorters*? *(Check one.)*

    1. Does not apply – plant did not replace USDA inspectors with plant sorters **3 (1.5%)**

    2. Made food quality better **44 (21.5%)**
    3. Made no difference to food quality **54 (26.3%)**
    4. Made food quality worse **89 (43.4%)**

    5. Don't know/No way to tell effect on food quality **15 (7.3%)**

    N=205

23. In your opinion, what is the effect on **food safety** of *the addition of new or more anti-microbial rinses/washers*? (*Check one.*)

    1. Does not apply – plant did not add any anti-microbial rinses/washers **51 (24.6%)**

    2. Made food safety better **116 (56.0%)**
    3. Made no difference to food safety**13 (6.3%)**
    4. Made food safety worse **7 (3.4%)**

    5. Don't know/No way to tell effect on food safety **20 (9.7%)**

    N=207

24. *(Answer if you work at a **poultry** plant:)* In your opinion, what is the effect on **food safety** of *having only the carcass and not the viscera at the carcass inspection station?* (*Check one.*)

    1. Does not apply – both carcass and viscera are at the carcass inspection station **21 (10.8%)**

    2. Made food safety better **16 (8.2%)**
    3. Made no difference to food safety **45 (23.1%)**
    4. Made food safety worse **86 (44.1%)**
    5. Don't know/No way to tell effect on food safety **17 (8.7%)**
    6. Do not work at poultry plant **10 (5.1%)**

    N=195

25. In your opinion, what is the effect on **food safety** of *any other FSIS or plant changes under the HIMP system? (Please write in change and then check one box):*

    119 (56.7%) of questionnaires included a response

    1. Does not apply – FSIS and plant did not make any other changes **80 (39.8%)**
    2. Made food safety better **64 (31.8%)**
    3. Made no difference to food safety **3 (1.5%)**
    4. Made food safety worse **49 (24.4%)**
    5. Don't know/No way to tell effect on food safety **5 (2.5%)**

    N=201

26. In your opinion, what is the effect on **food quality** of *any other FSIS or plant changes under the HIMP system* that you specified in Question 25? *(Check one.)*

    1. Does not apply – FSIS and plant did not make any other changes **80 (39.8%)**
    2. Made food quality better **56 (27.9%)**
    3. Made no difference to food quality **14 (7.0%)**
    4. Made food quality worse **46 (22.9%)**
    5. Don't know/No way to tell effect on food quality **5 (2.5%)**

    N=201

5

Line Operations and Line Speed

In the following questions, IIC refers to the Inspector in Charge.

27. According to how things worked the last time you were inspecting under the traditional inspection system, who could **stop** the line for a **food safety** issue? (*Check one.*)

    1. The inspector only **0**
    2. The IIC only **5 (2.4%)**
    3. Either the inspector or the IIC **200 (95.2%)**
    4. Neither the inspector nor the IIC **3 (1.4%)**
    5. Don't remember **2 (1.0%)**
    N=210

28. According to how things worked the last time you were inspecting under the traditional inspection system, who could **stop** the line for a **food quality** issue? (*Check one.*)

    1. The inspector only **0**
    2. The IIC only **23 (11.0%)**
    3. Either the inspector or the IIC **169 (80.5%)**
    4. Neither the inspector nor the IIC **11 (5.2%)**
    5. Don't remember **7 (3.3%)**
    N=210

29. According to how things worked the last time you were inspecting under the traditional inspection system, who could **slow** the line down for a **food safety** issue? (*Check one.*)

    1. The inspector only **0**
    2. The IIC only **148 (70.5%)**
    3. Either the inspector or the IIC **59 (28.1%)**
    4. Neither the inspector nor the IIC **2 (1.0%)**
    5. Don't remember **1 (0.5%)**
    N=210

30. According to how things worked the last time you were inspecting under the traditional inspection system, who could **slow** the line down for a **food quality** issue? (*Check one.*)

    1. The inspector only **0**
    2. The IIC only **152 (72.4%)**
    3. Either the inspector or the IIC **43 (20.5%)**
    4. Neither the inspector nor the IIC **7 (3.3%)**
    5. Don't remember **8 (3.8%)**
    N=210

31. According to how things currently work under the HIMP system, who can **stop** the line for a **food safety** issue? (*Check one.*)

    1. The inspector only **2 (1.0%)**
    2. The IIC only **7 (3.3%)**
    3. Either the inspector or the IIC **191 (91.4%)**
    4. Neither the inspector nor the IIC **8 (3.8%)**
    5. Don't know **1 (0.5%)**
    N=209

32. According to how things currently work under the HIMP system, who can **stop** the line for a **food quality** issue? (*Check one.*)

    1. The inspector only **0**
    2. The IIC only **37 (17.7%)**
    3. Either the inspector or the IIC **81 (38.8%)**
    4. Neither the inspector nor the IIC **83 (39.7%)**
    5. Don't know **8 (3.8%)**
    N=209

33. According to how things currently work under the HIMP system, who can **slow** the line down for a **food safety** issue? (*Check one.*)

    1. The inspector only **0**
    2. The IIC only **85 (40.7%)**
    3. Either the inspector or the IIC **19 (9.1%)**
    4. Neither the inspector nor the IIC **95 (45.5%)**
    5. Don't know **10 (4.8%)**
    N=209

34. According to how things currently work under the HIMP system, who can **slow** the line down for a **food quality** issue? (*Check one.*)

    1. The inspector only **0**
    2. The IIC only **60 (28.7%)**
    3. Either the inspector or the IIC **13 (6.2%)**
    4. Neither the inspector nor the IIC **123 (58.9%)**
    5. Don't know **13 (6.2%)**
    N=209

35. What is your opinion of the current line speed generally used at the HIMP plant(s) where you work, in terms of ensuring **safety** of products? (*Check one.*)

    1. Much too slow **0**
    2. Somewhat too slow **0**
    3. About right **82 (39.0%)**
    4. Somewhat too fast **68 (32.4%)**
    5. Much too fast **55 (26.2%)**
    6. Unable to determine **5 (2.4%)**
    N=210

36. What is your opinion of the current line speed generally used at the HIMP plant(s) where you work, in terms of ensuring **quality** of products? (*Check one.*)

    1. Much too slow **0**
    2. Somewhat too slow **0**
    3. About right **70 (33.3%)**
    4. Somewhat too fast **72 (34.3%)**
    5. Much too fast **63 (30.0%)**
    6. Unable to determine **5 (2.4%)**
    N=210

Original and Modified HIMP

37. In your opinion, which is better for **food safety** – original HIMP (oversight and verification inspectors) or modified HIMP (carcass and verification inspectors)? (*Check one.*)

    1. Original HIMP was much better **35 (17.0%)**
    2. Original HIMP was somewhat better **21 (10.2%)**
    3. They are about the same **16 (7.8%)**
    4. Modified HIMP is somewhat better **52 (25.2%)**
    5. Modified HIMP is much better **65 (31.6%)**
    6. No opinion on which is better **17 (8.3%)**
    N=206

38. In your opinion, which is better for **food quality** – original HIMP (oversight and verification inspectors) or modified HIMP (carcass and verification inspectors)? (*Check one.*)

    1. Original HIMP was much better **32 (15.3%)**
    2. Original HIMP was somewhat better **20 (9.6%)**
    3. They are about the same **40 (19.1%)**
    4. Modified HIMP is somewhat better **45 (21.5%)**
    5. Modified HIMP is much better **50 (23.9%)**
    6. No opinion on which is better **22 (10.5%)**
    N=209

Work Environment and Processes

39. In your opinion, has plant employees' sense of responsibility about the safety and quality of the food increased or decreased under HIMP? *(Check one.)*
    1. Greatly increased under HIMP **49 (23.4%)**
    2. Somewhat increased under HIMP **65 (31.1%)**
    3. About the same **45 (21.5%)**
    4. Somewhat decreased under HIMP **19 (9.1%)**
    5. Greatly decreased under HIMP **25 (12.0%)**

    6. Don't know/no opinion **6 (2.9%)**
    N=209

40. Before changing to the HIMP system, to what extent did inspector shortages decrease the plant's volume of production? *(Check one.)*

    1. Little or no extent **138 (66.0%)**
    2. Some extent **40 (19.1%)**
    3. Moderate extent **10 (4.8%)**
    4. Great extent **5 (2.4%)**
    5. Very great extent **5 (2.4%)**

    6. Didn't work here before HIMP **5 (2.4%)**
    7. Don't know/no opinion **6 (2.9%)**
    N=209

41. Since HIMP implementation, to what extent have inspector shortages affected the plant's volume of production? *(Check one.)*

    1. Little or no extent **194 (92.8%)**
    2. Some extent **3 (1.4%)**
    3. Moderate extent **3 (1.4%)**
    4. Great extent **0**
    5. Very great extent **1 (0.5%)**
    6. Don't know/no opinion **8 (3.8%)**
    N=209

42. *(Answer if you work at a **poultry** plant:)* Currently, under the modified HIMP system, there is a requirement to have carcass-by-carcass inspection. What do you think is the best location for the carcass inspector? *(Check one.)*

    1. At the sorting station **10 (5.6%)**
    2. At the trimming station **7 (4.0%)**
    3. Right before the final wash **8 (4.5%)**
    4. At the end of the line, right before the chiller **132 (74.6%)**
    5. Other, please specify: **17 (9.6%)**

    6. Don't know **3 (1.7%)**
    7. Do not work at poultry plant **0**
    N=177

43. *(Answer if you work at a **swine** plant:)* Currently, under the modified HIMP system, there is a requirement to have carcass-by-carcass inspection. What do you think are the two best locations for the carcass inspectors? *(Check **two** boxes.)*
    1. At rail station **15 (62.5%)**
    2. At the viscera table **22 (91.7%)**
    3. At the head station **6 (25.0%)**
    4. Other, please specify: **2 (8.3%)**

    5. Don't know **0**
    6. Do not work at swine plant **0**
    N=24

44. Do you think that it is easier or harder to record **quality defects** (Other Consumer Protections) under the HIMP system than it was to record **quality defects** (Finished Product Standards) under the traditional inspection system? *(Check one.)*

    1. Much easier to record under HIMP **79 (38.3%)**
    2. Somewhat easier to record under HIMP **39 (18.9%)**
    3. About the same **50 (24.3%)**
    4. Somewhat easier to record under traditional **8 (3.9%)**
    5. Much easier to record under traditional **18 (8.7%)**
    6. Don't know/no opinion **12 (5.8%)**
    N=206

8

45. Has the **number** of NRs (Non-compliance Records) written increased, decreased, or stayed about the same under HIMP as compared to the traditional system? *(Check one.)*

1. Greatly increased since HIMP → Please go to Question 46. **102 (49.0%)**
2. Somewhat increased since HIMP → Please go to Question 46. **56 (26.9%)**
3. About the same → Please go to Question 48. **21 (10.1%)**
4. Somewhat decreased since HIMP → Please go to Question 47. **16 (7.7%)**
5. Greatly decreased since HIMP → Please go to Question 47. **7 (3.4%)**
6. Don't know → Please go to Question 48. **6 (2.9%)**

N=208

If you answered "Greatly increased" or "Somewhat increased" to Question 45 above, please answer Question 46 and then go to Question 48.

46. Why do you think the number of NRs has increased? ***(Check all that apply.)***

Does not apply: Did not answer "increased" to Question 45 **49 (23.3%)**

1. More carcasses are sampled under HIMP than previously **76 (48.1%)**
2. Inspectors issue more NRs to exert authority over plant processes. **6 (3.8%)**
3. Plant sorters are not as effective at finding problems as USDA inspectors were under the traditional system. **47 (29.7%)**
4. Inspectors have more time or more freedom to find defects and prepare NRs under the HIMP system. **83 (52.5%)**
5. The location of the carcass inspector makes it easier to find defects. **52 (32.9%)**
6. Other, please specify: **26 (16.5%)**

N=157

Please go to Question 48.

If you answered "Greatly decreased" or "Somewhat decreased" to Question 45 above, please answer Question 47.

47. Why do you think the number of NRs has decreased? ***(Check all that apply.)***

Does not apply: Did not answer "decreased" to Question 45. **180 (85.7%)**

1. There is new or improved equipment on the line. **3 (13.0%)**
2. More employees (plant and USDA) are available to find problems before NRs must be written. **12 (52.2%)**
3. Plant sorters are more effective at finding problems than USDA inspectors were under the traditional system. **3 (13.0%)**
4. Inspectors have less time or less freedom to find defects and prepare NRs under the HIMP system. **3 (13.0%)**
5. The location of the carcass inspector makes it harder to find defects. **0**
6. Other, please specify: **8 (34.8%)**

N=23

Job Satisfaction Under HIMP

48. Please put a check mark (✓) in the box that comes closest to your opinion about your job **under the HIMP system**, as compared with the traditional inspection system. *(Check one box for each row).*

	Much less (1)	Less (2)	Neither more nor less (3)	More (4)	Much more (5)	Not applicable/ No basis to judge (6)
a Under HIMP, my job has variety. ***N=208***	**9 (4.3%)**	**11 (5.3%)**	**29 (13.9%)**	**79 (38.0%)**	**78 (37.5%)**	**2 (1.0%)**
b Under HIMP, my job is enjoyable. ***N=206***	**10 (4.9%)**	**12 (5.8%)**	**26 (12.6%)**	**72 (35.0%)**	**85 (41.3%)**	**1 (0.5%)**
c Under HIMP, my job includes authority to determine product safety. ***N=206***	**23 (11.2%)**	**34 (16.5%)**	**47 (22.8%)**	**65 (31.6%)**	**34 (16.5%)**	**3 (1.5%)**
d Under HIMP, my job includes authority to determine product quality. ***N=207***	**41 (19.8%)**	**54 (26.1%)**	**38 (18.4%)**	**45 (21.7%)**	**27 (13.0%)**	**2 (1.0%)**

49. How concerned are you about your job security under HIMP? *(Check one.)*

1. Not at all concerned **56 (26.9%)**
2. Somewhat concerned **46 (22.1%)**
3. Moderately concerned **31 (14.9%)**
4. Very concerned **29 (13.9%)**
5. Extremely concerned **42 (20.2%)**
6. No opinion/don't know **4 (1.9%)**

N=208

50. In your opinion, how does your work environment under the HIMP system compare to what it was under the traditional inspection system, in terms of your personal health and safety? *(Check one.)*

1. Much better for my health and safety under HIMP **111 (53.4%)**
2. Somewhat better for my health and safety under HIMP **41 (19.7%)**
3. About the same **28 (13.5%)**
4. Somewhat worse for my health and safety under HIMP **19 (9.1%)**
5. Much worse for my health and safety under HIMP **7 (3.4%)**
6. Don't know **2 (1.0%)**

N=208

51. Please describe what, if anything, has made your health and safety **better** under HIMP: (Write "NONE" if not better).

Entered 'None' 37 (17.6%)
Entered something 153 (72.9%)
Left question blank 20 (9.5%)
N=210

52. Please describe what, if anything, has made your health and safety **worse** under HIMP: (Write "NONE" if not worse).

Entered 'None' 109 (51.9%)
Entered something 54 (25.7%)
Left question blank 47 (22.4%)
N=210

Training

53. Considering your current HIMP job duties, to what extent was the HIMP training program adequate to help you do your job? (*Check one.*)
    1. Little or no extent **17 (8.2%)**
    2. Some extent **45 (21.7%)**
    3. Moderate extent **61 (29.5%)**
    4. Great extent **63 (30.4%)**
    5. Very great extent **19 (9.2%)**
    6. Unable to determine/don't remember **0**
    7. Haven't received HIMP training **2 (1.0%)**

    → Please go to Question 55.

    N=207
54. Based on what you learned at HIMP training, to what extent do you feel you received enough information to properly classify quality defects according to the new OCP (Other Consumer Protection) categories? (*Check one.*)
    1. Little or no extent **17 (8.3%)**
    2. Some extent **42 (20.4%)**
    3. Moderate extent **63 (30.6%)**
    4. Great extent **58 (28.2%)**
    5. Very great extent **23 (11.2%)**
    6. Don't remember from training **1 (0.5%)**
    7. Training did not cover classifying OCPs **0**
    8. Haven't received HIMP training **2 (1.0%)**

    N=206
55. Considering your current HIMP job duties, to what extent was the *HACCP* training program adequate to help you do your job? (*Check one.*)
    1. Little or no extent **13 (6.3%)**
    2. Some extent **36 (17.3%)**
    3. Moderate extent **76 (36.5%)**
    4. Great extent **60 (28.8%)**
    5. Very great extent **23 (11.1%)**
    6. Unable to determine/don't remember **0**
    7. Haven't received HACCP training **0**

    N=208
56. In your opinion, to what extent was plant sorters' training adequate to help them do their jobs? (*Check one.*)
    1. Little or no extent **59 (28.4%)**
    2. Some extent **65 (31.3%)**
    3. Moderate extent **41 (19.7%)**
    4. Great extent **24 (11.5%)**
    5. Very great extent **7 (3.4%)**
    6. Unable to determine/no basis to judge **12 (5.8%)**

    N=208
57. Do you think that USDA/FSIS should develop a standardized training curriculum for plant sorters? (*Check one.*)
    1. Definitely should **92 (44.4%)**
    2. Probably should **46 (22.2%)**
    3. Neutral **30 (14.5%)**
    4. Probably should not **12 (5.8%)**
    5. Definitely should not **23 (11.1%)**
    6. Unable to determine/no basis to judge **4 (1.9%)**

    N=207
58. Do you think that USDA/FSIS should develop a testing and certification program for plant sorters after they are trained? (*Check one.*)
    1. Definitely should **91 (43.8%)**
    2. Probably should **42 (20.2%)**
    3. Neutral **34 (16.3%)**
    4. Probably should not **16 (7.7%)**
    5. Definitely should not **22 (10.6%)**
    6. Unable to determine/no basis to judge **3 (1.4%)**

    N=208

Closing

59. What kind of plant do you currently work in? *(Check one.)*
    1. Poultry **180 (85.7%)**
    2. Swine **24 (11.4%)**
    3. Other, please specify: **6 (2.9%)**

    N=210

60. What is your current position? *(Check one.)*
    1. Inspector in Charge or Veterinary Medical Officer (IIC/VMO) **26 (12.6%)**
    2. Inspector (GS-8 or GS-9) **169 (81.6%)**
    3. Relief Inspector **0**
    4. Relief Veterinarian (IIC/VMO) **8 (3.9%)**
    5. Other, please specify: **4 (1.9%)**

    N=207

61. Please indicate any changes you would suggest that could be made to the HIMP system to improve food quality or safety.

    165 (78.6%) entered comments

62. Please provide any additional comments that you have about HIMP or anything else covered in this survey.

    145 (69.0%) entered comments

12

Appendix V: Australia's Meat Safety Enhancement Program

Australia's Meat Safety Enhancement Program (MSEP) is a pilot meat inspection program developed by the Australian Quarantine and Inspection Service (AQIS) for use in meat export plants. MSEP is patterned after the Australian domestic meat inspection system, which is grounded in the theory of Hazard Analysis Critical Control Point procedures and uses a quality systems approach to control for hazards in food processing. Under the Australian inspection approach, slaughter plants are clearly identified as being responsible for plant process control, including sanitation, microbial monitoring, and inspection of the product for quality defects. AQIS sets public health product standards and audits plant operations to ensure that food safety standards are being achieved.

Background and Trends That Led to the Program

Australia's traditional system of meat inspection had an end-product inspection focus and employed government staff to perform inspections. However, Australian authorities were concerned that this system did not adequately address all of the risks to food safety. For example, public health officials, among others, thought that proper emphasis was not being given to microbial contaminants, such as *E. coli* and *Salmonella*, or residues of veterinary and agricultural chemicals and antibiotics, which had emerged as threats to the safety of fresh meat and meat products.

Australia first moved in 1991 to address these emerging food safety issues with a comprehensive review of domestic meat inspection. Upon the completion of this review, the review task team outlined changes to existing meat inspection procedures that it thought would result in a more cost-effective system while maintaining adequate safeguards to public health. The recommended changes included strategies for implementing quality assurance programs and HACCP procedures.

Over an 18-month period, commencing in early 1992, three domestic slaughter plants developed quality assurance systems that included replacing regulatory agency inspectors with company employees. AQIS subsequently approved this new inspection approach for trial. In the trial, each plant was paired with a nearby similar plant as a control plant. The control plants continued operations under the traditional meat inspection system. According to AQIS, the trial results showed that all three plants operating under their quality assurance systems and using company-employed meat inspectors were capable of maintaining standards of food safety at least equal to those of the control plants.

These findings were examined and endorsed by a scientific panel composed of officers from AQIS, universities, and meat inspector representatives of the Public Sector Union and the Australian Meat Research Council. All Australian domestic meat establishments in each state subsequently moved to a self-regulated system of meat inspection, whereby companies assumed responsibility for meat safety. MSEP, which was implemented in 1996 for meat export facilities, was an outgrowth of the domestic movement to quality assurance systems using HACCP procedures and company-employed inspectors.

How the MSEP System Works

The MSEP model incorporates the use of routine meat inspection performed by qualified company employees working under a system approved and legislated by the government. The government, acting through AQIS, maintains full-time oversight, verification, and certification of the final product. As a part of Australia's MSEP system, a full-time AQIS veterinary officer, whose salary is reimbursed by the company, is required to be on duty at all times in each participating export plant. At establishments producing products for export to the United States, an AQIS inspector assists the veterinary officer in performing the zero tolerance and end-product inspection. Company management is responsible for on-line inspection using company-paid inspectors that have been trained in accordance with a standardized curriculum and are under the general supervision of the full-time AQIS veterinary officer. The officer provides continuous oversight, verification, and daily audit of plant operations and production control systems. The company-paid inspectors must also be licensed by their respective states before they may act as inspectors. To be eligible for a license, they must complete about 600 hours of formal classroom training and pass examinations. The division of responsibilities between AQIS and companies under MSEP are as shown in table 10.

Table 10: Division of Responsibility Under Australia's Meat Safety Enhancement Program

Function	Company's responsibility	AQIS' responsibility
Antemortem inspection	Sort healthy animals for slaughter and separate animals identified as potential suspects for inspection by AQIS.	Inspect suspect animals and decide on their disposition.
Postmortem inspection	Develop procedures for carcass, head, and offal inspection using all the inspection activities required by AQIS.	Conduct regular oversight and verification checks of post-mortem inspection activity at least daily.
	Set up monitoring checks for all inspection activities conducted by company-employed inspectors.	Conduct independent checks of the inspection procedures during the monthly audit review.

Function	Company's responsibility	AQIS' responsibility
E. coli and *Salmonella* monitoring	Company Quality Assurance officers or inspectors will take samples for testing.	Check the *E. coli* samples to ensure that processing is consistent with good laboratory practice. Supervise each *Salmonella* test. Review microbiological results in the monthly review of the plant.
End-of-line inspection	Take appropriate corrective action if the AQIS veterinary officer detects defects.	Perform regular "check the checker" audits of company inspection and quality assurance personnel.
Monitoring	Monitor all procedures and all aspects of the HACCP program.	Continuously monitor and recheck • antemortem and postmortem inspections and • microbiological testing and the HACCP program.

Source: AQIS.

Prerequisites for Plants to Participate in MSEP

According to AQIS officials, the service has established several prerequisites for companies that wish to participate in MSEP and sell products for export. In addition, plants must demonstrate the following before they can be a part of the program. Specifically, plants must

- have a good operational/coregulatory trade record;
- have demonstrated a commitment to and appreciation of HACCP/Quality Assurance principles, to include an adequate company infrastructure and training competencies;
- accept responsibility for performing the sorting (inspection) function;
- develop and maintain a plant-specific, AQIS-approved Meat Safety Quality Assurance System;
- act as a promotional site for industry/overseas officials; and
- maintain a comprehensive plant quality assurance manual that was developed by and is "owned" by relevant areas of plant operations. The manual must be a working document and receive AQIS' approval. When approved, the HACCP/Quality Manual acts as a legal contract between the plant and AQIS on the specific procedures, controls, and standards at the plant.

Participation in the program is currently voluntary. However, eventually, all plants will be required to move to the new inspection system.

AQIS' Evaluation of Its Program

According to AQIS officials, much empirical evidence on the effectiveness of HACCP quality assurance systems has accumulated since MSEP was implemented in Australia. AQIS officials told us they are fully confident that the MSEP approach to regulatory inspection control achieves guarantees of food safety that are at least equivalent to those of the traditional approach to meat inspection. They said the system incorporates a reengineering of meat inspection practices and results in various changes to the culture or philosophy of food inspection, including changes that

- prevent rather than correct,
- build quality in rather than rely on end-product inspection,
- place more reliance on microscopic verification,
- transfer responsibility from government to industry for performing certain functions and maintaining standards, and
- incorporate government verification and certification.

Appendix VI: Canada's Modernized Poultry Inspection Program

The Canadian Food Inspection Agency (CFIA) recently adopted a new poultry inspection system that allows industry to progressively assume defect detection duties and remove defective carcasses from the slaughter line. The agency began pilot testing this modified inspection system in September 1997. The pilot project is similar in design to USDA's pilot project for poultry. The new system, known as the Modernized Poultry Inspection Program (MPIP), has goals to reduce microbial pathogens in raw poultry products and to enhance the use of science and risk-based management in Canada's poultry inspection system. MPIP builds on a precursor program—the Canadian Poultry Inspection Program (CPIP)—which also allows industry operators to assume some defect-detection duties. The significant difference between the two programs is that under MPIP, industry personnel are also responsible for detecting viscera defects. Under both programs, CFIA inspectors monitor poultry plants' slaughter operations and verify industry's compliance with food safety and quality standards. For poultry plants that choose not to participate in either of the programs, government inspectors continue to perform all carcass defect detection and removal duties.

Background

Before CFIA amended its meat inspection regulations to adopt the MPIP program in May 2001, the agency pilot tested the modified inspection system at four chicken plants that represented about 10 percent of the total chicken production. CFIA officials told us that several factors contributed to their decision to modify the poultry inspection system, including the desire to make inspections more consistent with the HACCP framework. The use of the HACCP system is not yet mandatory at meat and poultry plants in Canada, but it is a prerequisite for participation in MPIP. In addition, CFIA officials noted that the United States was engaging in a similar effort to modify its slaughter inspection system and said that Canada, which was modifying its poultry inspection system, wanted to obtain equivalency status with the United States to facilitate bilateral trade. Finally, CFIA officials noted that the Canadian poultry industry is investing in new evisceration equipment with technical improvements that permit faster line speeds without compromising food safety and quality.

How the MPIP Pilot Works

MPIP was a voluntary pilot project, and now that Canada has issued regulations to implement the program nationwide, participation continues to be voluntary. Prior to being accepted into MPIP, poultry plants must pass a preliminary assessment. Later, they must pass additional audits as they move from one phase of the program to the next. The audits, which

are performed by a CFIA audit team, are an important tool for the agency and plant managers. Clearly stated audit objectives help plant managers to plan for and address potential deficiencies before they occur, allowing the plant to succeed in the program. Plants participating in the program move through three phases.

Phase 1 begins after a CFIA preliminary assessment of a volunteer plant's eligibility to participate in the modified inspection program. All volunteer plants must have been operating under CPIP before participating as an MPIP pilot plant. As with USDA's pilot project, baseline data are collected and analyzed before MPIP implementation. That is, microbial and quality defect-detection data are collected at volunteer plants while they are operating under CPIP. In addition, plant personnel are trained and accredited in their new role as plant defect detectors.

Phase 2 resembles the transition phase in USDA's pilot project. It is the trial phase during which CFIA inspectors back up plant personnel in detecting defects on the slaughter line. Plant personnel are required to pass four weekly practical on-line tests as viscera detectors. In addition, the plant must also pass a national compliance and verification review.

Phase 3 entails operating under MPIP and the collection and analysis of data after MPIP's implementation at the plant. Accredited plant personnel detect carcass, cavity, and viscera defects, while plant preselectors cull carcasses with specific processing and pathology defects, such as contamination from the intestines and septicemia. On average, a Canadian poultry plant runs one evisceration line and will have one veterinarian-in-charge and two CFIA inspectors (one evisceration floor inspector per line working on the slaughter floor and one processing area inspector). If an equivalency agreement with the United States requires federal inspection of each and every carcass, CFIA will place one on-line government inspector on each slaughter line at plants that want to export to the United States.

Prerequisites for Plants to Participate in the MPIP Pilot

CFIA has established several prerequisites that plants must meet before they are accepted to participate in MPIP. CFIA considers, at a minimum, the following criteria for each plant:

- The state of the current plant inspection system, its quality control operations, and the gap between these and MPIP.

- The stage of plant-specific HACCP system development and implementation—at a minimum, the plant must have a functioning HACCP system in place to commence MPIP.
- The implementation of *E. coli* and *Salmonella* testing protocols.
- The types of poultry processing conducted by the plant, as it is desirable to have several classes of poultry slaughtered to improve efficiency in training staff, data collection, and implementing future pilots in the area.
- The geographic location (desire to implement MPIP and collect data from across Canada).
- The compliance history of the plant.
- The range of the health status of flocks and average condemnation rates in the plant selected to pilot MPIP to ensure adequate training and accreditation of plant defect detectors to handle condemnation rates and a range of disease conditions under an HACCP-MPIP system.

Performance Standards

CFIA's MPIP national performance standard categories for poultry are similar but not identical to USDA's pilot project standards for chickens. The poultry standards address the following factors, among others:

- Microbial contamination.
- Processing defects, including all types of contamination—such as fecal and bile—extraneous material, extensive bruising, extensive overscald/mutilation, and inadequate bleeding.[1]
- Pathology defects, including septicemia/toxemia, airsacculitis, ascites, emaciation, cellulitis, dark-colored carcasses, and other diseases.[2]
- Finished product defects, such as bruises, feathers, trachea, oil glands, lungs, intestines, and crop.[3]

To analyze microbial contamination as part of the MPIP project, in 1997 and 1998, CFIA performed a national baseline survey at 36, or 55 percent, of the 65 federally registered chicken plants nationwide over a 1-year period. CFIA's performance standards for microbial contamination are

[1]USDA's food safety performance standard 2 and other consumer protection (food quality) performance standards 2 and 3 for the pilot project include these types of defects.

[2]USDA's food safety performance standard 1 and other consumer protection (food quality) performance standard 1 for the pilot project include these types of defects.

[3]USDA's other consumer protection (food quality) performance standards 4 and 5 for the pilot project include these types of defects.

identical to USDA's Pathogen Reduction: HACCP regulations for generic *E. coli* and *Salmonella*.

To evaluate both processing and pathology defects, in 1997 and 1998, CFIA conducted another national survey to establish the average level of overlooked processing and pathology defects on carcasses passed by CFIA inspectors or by trained and accredited plant detectors under the traditional and CPIP methods of chicken inspection. Performance standards for processing and pathology defects were developed from data gathered at 35, or 54 percent, of the 65 federally registered chicken plants nationwide. The performance standards for processing defects were set at 4.0 percent; however, as part of the MPIP project, CFIA subsequently tightened them to 2.5 percent, meaning that 97.5 percent of the carcasses passed by plant employees must be free of processing defects. The performance standards for pathology defects were set at 0.4 percent, meaning that 99.6 percent of the carcasses passed by plant employees must be free of pathology defects.

CFIA conducted an additional national survey to amend its Finished Product Standards program. This is the same program developed and used by USDA in all chicken plants operating under the traditional carcass-by-carcass inspection systems. CFIA, however, has tightened the Finished Products Standards' pass/fail criteria for plants operating under CPIP's and MPIP's inspection systems. In addition, CFIA continues to enforce a zero-tolerance policy for fecal contamination on ready-to-chill carcasses as part of this program.

MPIP Pilot Success Attributed to Extensive Training of Inspectors and Industry

CFIA developed an extensive training program for government and industry personnel to ensure that everyone participating in MPIP has the necessary skills and knowledge to perform his/her new duties. The training includes classroom training, a final exam, in-plant training, and the demonstration of competency. After successfully completing the training, CFIA trainers accredit the trainees.

The entire MPIP training program was developed by CFIA. CFIA officials believe that no outside organization can replicate in-house expertise. In addition, in order to encourage union cooperation, CFIA inspectors conduct the training. At MPIP plants, every CFIA employee must participate in the training program.

CFIA officials modeled MPIP's industry-training program on the training program they developed for their own staff. The agency adopted a train-the-trainer approach for industry. That is, CFIA inspectors train the plant trainers who in turn train the plant employees (defect detectors). The training is conducted in two phases. Phase 1 covers classroom and on-the-job training and concludes when the defect detector is accredited to perform his/her new duties under MPIP. The plant managers decide which plant employees will become defect detectors and receive MPIP training. The training covers three types of defect detection: (1) preselection before evisceration, (2) internal examination of carcasses, and (3) poultry viscera examination. On-the-job training ensures that defect detectors learn how to identify carcass pathology conditions that are indicative of disease. Once the defect detectors are comfortable with identifying diseases, they are tested on 20 carcasses and the corresponding viscera to see if they can correctly decide whether the carcasses pass or need to be examined by the veterinarian. In addition, the defect detectors have to demonstrate the ability to detect defects on fast-moving lines. The defect detector must pass three 15-minute tests to be accredited.

After the defect detector is certified, he/she enters a 4-week trial period (phase 2) where he/she performs his/her new MPIP duties on the slaughter line. Defect detectors can be trained and accredited in more than one station (cavity, carcass, and/or viscera) and will have weekly evaluations at each of these stations during the trial phase. In addition, the trainer evaluates defect detectors on a periodic basis, as specified in the plant's HACCP plan. Plant defect detectors are reevaluated on an ongoing basis and lose their accreditation if they fail a periodic review test. Ongoing testing ensures continuing competence as line speeds and/or disease patterns change. CFIA reserves the right to conduct additional reaccreditation tests of plant detectors at any time. In addition, CFIA reserves the right to conduct additional tests for missed defective carcasses at any time.

Under MPIP Pilot, CFIA Officials Monitor Plant Performance Trends

According to CFIA officials, MPIP is successful because the data generated from the pilot plants show a downward trend in carcass defects. The plants that participate in the MPIP pilot are performing better than the performance set by the national standards. Part of the program's strength is that CFIA officials periodically review data results with plant managers to discuss the plant's record of performance against the standards. Through discussions with plant managers, CFIA officials learn what types of corrective actions are successful in addressing the plant's system

failures. In turn, CFIA officials share this knowledge with managers of other pilot plants to help them improve their own process controls.

Current Status of MPIP

CFIA modified its meat-inspection regulations to implement MPIP on a nationwide basis on May 23, 2001. The agency will continue to maintain three types of poultry inspection systems (traditional, CPIP, and MPIP). CFIA does not plan to make changes to the MPIP program and will continue to use a phased approach for implementing MPIP at volunteer plants. Plants will still be required to pass a preliminary assessment before being accepted into MPIP. Under MPIP, CFIA officials will continually monitor the plants' performance through informal discussions and formal audits. The agency expects MPIP plants to perform better than the performance set by the national standards for the microbial, food safety, and other consumer protection defects. If a plant fails to meet these standards, the plant will lose its license to operate under MPIP and must be relicensed to operate either under CPIP or traditional inspections. In addition, the agency expects MPIP plants to continually improve their performance over time. Furthermore, CFIA will continue to emphasize the importance of training through its mandatory training program and certification requirements for both CFIA employees and industry personnel.

Since CFIA has formally adopted MPIP, the agency will maintain an oversight inspector and a veterinarian-in-charge at each MPIP plant. Unlike USDA's pilot project, CFIA's MPIP program does not require an on-line carcass inspector performing carcass-by-carcass inspections. However, if the equivalency agreement with the United States requires an on-line carcass inspector, CFIA will comply with this requirement and place a CFIA inspector on the slaughter line at those plants that export to the United States.

Appendix VII: 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

NOV 30 2001

Mr. Lawrence J. Dyckman
Director, RCED Division
Food and Agriculture Issues
U.S. General Accounting Office
441 G Street, NW, Room 2T23
Washington, DC 20548

Dear Mr. Dyckman:

Thank you for the opportunity to provide comments on the Draft Report GAO-02-59, "Food Safety: Weakness in Meat and Poultry Inspection Pilot Should be Addressed Before Implementation." We are pleased the General Accounting Office agrees that our data shows a risk-based inspection system such as the current HACCP-Based Inspection Models Project (HIMP) pilot has merit. Further, we believe the recommendations for executive action, and the issues that you noted, can be satisfactorily addressed.

GENERAL COMMENTS

We consider the report's recommendations appropriate, and FSIS will address them as we seek public comment for any proposed regulatory changes. We believe that GAO's intent in its recommendations is to strengthen our ongoing efforts to enhance public health by innovative, science-based programs and activities. Our general responses to recommendations are as follows:

A. Phase in the implementation of modified inspections so that only plants with a good history of regulatory compliance are eligible to participate and continue in the program.

Response: We intend, as part of a proposed rule on HIMP, to seek public comment on how best to determine which plants should be covered/participate as well as solicit suggestions on a range of program issues and appropriate program criteria.

B. Require plants to adopt statistical process control systems to manage and control their production and require FSIS personnel to monitor and verify these systems;

Response: We believe that statistical process control systems are important tools for plants to use to manage and control their production. This matter will be covered in the rulemaking process.

1

FSIS FORM 2630-9 (6/86) EQUAL OPPORTUNITY IN EMPLOYMENT AND SERVICES

C. In conjunction with industry, develop a training and certification program for personnel involved in tasks previously performed by federal inspectors and require that only trained and certified plant personnel perform these duties.

Response: The Agency's appropriate role in a HACCP environment is to set science-based performance standards, and allow industry the flexibility in how best to meet those standards. FSIS will seek public comment on mandating plant employee training during the rulemaking process.

D. Consider the merits of adopting suggestions from inspectors and veterinarians at pilot project plants contained in this report, such as how to address repetitive instances of noncompliance with regulatory requirements.

Response: FSIS will carefully consider all comments and suggestions from inspectors, veterinarians, industry and the general public related to this project in developing the Agency's rulemaking on HIMP. The suggestions included in this report will also be considered.

E. If in addition to the current pilot project for chickens, USDA decides to conduct similar pilots for other species – hogs, turkeys, or cattle – the Department take steps to ensure that the pilot's design and methodology are sufficiently rigorous to allow more valid conclusions than in this poultry pilot.

Response: FSIS will address the recommendations and issues in this report as they apply in proposing regulatory changes or future pilot projects.

TECHNICAL COMMENTS

We would like to recommend that you consider a new title for the GAO report. A more balanced title would be: "Food Safety: Meat and Poultry Inspection Pilot Needs Enhancement Prior to Implementation." The following comments summarize the basis for FSIS' position that the HIMP study design was reliable and valid, and, with appropriate enhancements, can support proposing future regulatory changes.

See comment 1.

1. The study design for the HIMP pilot was established to measure the accomplishments of the traditional inspection system with the accomplishments of the models inspection system. It is an oversimplification to state that the measurement was intended to test one intervention, such as the removal of FSIS inspectors from sorting activities or the addition of spray nozzles. FSIS is evaluating whether inspection conducted in an environment in which plants have extended their HACCP plans across all aspects of slaughter production and are allowed flexibility in establishing operating procedures, to meet performance standards, will result in a product that is as good or better than that produced under the traditional inspection system.

See comment 2.

2. FSIS' use of volunteer plants is a legitimate and valid practice. In many real-world applications, especially those involving animal experiments, it is impossible or

2

See comment 3.

impractical to use truly random samples. (Daniel WW. Estimation. *Biostatistics: A Foundation for Analysis in the Health Sciences.* NY, NY: John Wiley & Sons, Inc.;1999: 150-203). The HIMP study is a time-series design, a type of quasi-experimental study. Time-series studies are useful for long term experiments that cannot be randomized (Hulley SB. Experiments. *Designing Clinical Research.* Baltimore, MD: Williams & Wilkins: 1988: 110-127). FSIS did conduct a partial randomization of in-plant variables. Because broilers are slaughtered at 6 weeks, the period of 6 weeks for microbiological analyses, and 5 weeks of organoleptic data collection, along with the sample sizes (300 samples/plant for microbiological analyses, and 2000 samples/plant for organoleptic data), accounted for variability in flock effects, worker effects, time of day effects, and other variables. Sample collection was randomized by time, slaughter line, chilling system, and grower.

See comment 4.

3. Although not randomly selected, there is evidence that volunteer plants participating in the study are typical of the industry. The volunteer plants represent diversity in geography, corporate structure, management styles, numbers of evisceration lines, product distribution patterns, inspection systems in use prior to the pilot (New Line Speed Inspection System, Streamlined Inspection System, etc.), and other variables. Plants in the 16-plant baseline originated from states comprising 52% of broiler slaughter plants and 63% of national broiler production. Plants in the 16-plant model phase originated from states comprising 56% of broiler slaughter plants and 74% of national broiler production.

See comment 5.

4. Various portions of the report incorrectly characterize FSIS activities by the use of the term "oversight". As the U.S. Court of Appeals for the District of Columbia circuit clearly concluded, FSIS inspectors conduct an examination to make a critical appraisal on each carcass.

See comment 6.

5. **Page 1, second paragraph**: The term "contamination" should be replaced with regular HACCP terminology i.e., food safety hazard.

See comment 7.

6. **Page 2: Paragraph** one**,** the last two sentences should be changed. The report mischaracterizes the cost of this program. The program was not design as a cost savings initiative, but an effort to further enhance public health benefits through alternative inspection models.

Now on p. 2.
See comment 8.

7. **Page 3**: The report indicates 11 chicken plants. The report should state that there were 11 plants at the time of the audit, since now there are 20 plants in the project.

Now on pp. 2-3.
See comment 9.

8. **Page 3**: FSIS recommends that the first two full sentences be modified to: "At 11 chicken and 3 hog plants that are voluntarily participating in the project, plant personnel, instead of USDA inspectors, **make initial determinations on** which carcasses and parts are unacceptable and should be removed from slaughter line because they are diseased or unwholesome. USDA is, therefore able to use fewer inspection personnel at these plants, **and utilize these resources elsewhere in the farm-to table continuum.**

3

See comment 10.

9. **Page 3:** The report inconsistently states the purpose of the RTI data collection. The following sentence in the middle of the top of the paragraph, page 3, does not accurately reflect the purpose of the data collection "The contractor measured how well USDA inspectors identified carcass defects under the traditional inspections and then conducted similar measurements once plant personnel assumed those duties" The original project protocols from 1998 describe the study design as measuring accomplishments of the traditional system and accomplishments of the models system. Federal inspectors under traditional inspection and plant employees under the models system are but one component of these system measurements. Page 10 of the report accurately describes the purpose of the data collection. Page 12 again misstates the purpose of data collection by referring to measurements of the inspectors' accomplishments.

See comment 11.

10. **Page 5**: Poultry did not come under mandatory inspection until 1957.

See comment 12.

11. **Page 6**: CI at final carcass station in hog plants not only look for contamination before they go into chiller or *cooler*, they also look for disease conditions and other adulterants.

See comment 13.

12. Page 6: In the paragraph beginning with "Inspectors perform different tasks..." Last sentence: the term head **glands** should be changed to **head lymph nodes.**

See comment 14.

13. **Page 10: In** the first paragraph, the cattle model has not been developed but plants have volunteered.

See comment 15.

14. **Page 11**: The number of participating plants 21 should be explained; one plant dropped out and was replaced in the project.

See comment 16.

15. **Page 12:** Paragraph beginning with "FSIS then developed....." The last sentence of the paragraph does not accurately reflect why the performance standard level was selected. The Agency selected the 12th position of the baseline results because it was a reasonable initial tightening of the traditional system accomplishments along with a stricter definition for classifying defects.

See comment 17.

16. **Page 19:** Paragraph beginning with "The pilot project's results may..." The last sentence characterizes the study as unable to discern whether results are solely attributed to the shift from traditional to model inspections. Such a comparison was never intended by the Agency. The original project protocols from 1998 make it clear that the study design measured accomplishments of the traditional inspection system and accomplishments of the models inspection system. The focus on system descriptions, not plant or inspection performance, was intentional and allowed for measuring multiple process changes – not isolated comparisons between FSIS inspector performance and plant sorter performance.

See comment 18.

17. **Page 20:** Regarding the discussion on training, the Agency has not mandated plant employee training for participating in the pilot. The Agency's appropriate role in a

HACCP environment is to set science-based performance standards, and allow industry the flexibility in how best to meet those standards. FSIS will seek public comment on mandating plant employee training during the rulemaking process.

Now on p. 23. See comment 19.

18. **Page 22:** The discussion on repeated instances of noncompliance with regulatory requirements is misleading because it focuses on total numbers of non-compliance rather than the HACCP regulatory requirements in 9 CFR part 417 and the Rules of Practice in 9 CFR Part 500. The Agency has consistently stated, since HACCP implementation began in 1998, that judgements about the adequacy of HACCP systems, not individual non-compliance records, determine the enforcement actions. Under HIMP, the Agency has replaced verification on approximately 20 carcasses per line for fecal contamination under traditional broiler inspection with verification on 80 carcasses per line. In addition to the increased verification sampling, under HIMP, Agency employees inspect 100% of carcasses for fecal contamination at a new location at the end of the slaughter line. Contrary to the report, it is therefore not unexpected that increased fecal findings are documented when 100% inspection began at the HIMP location. Consistent with HACCP compliance with Part 417, the response of the plant to these fecal findings, rather than the number of findings, determines regulatory compliance. Page 27, Table 4, of the report captures the important food safety result that, despite dramatically increased monitoring by the Agency, 10 of the 11 plants improved or maintained their zero tolerance accomplishments.

Now on p. 24. See comment 20.

19. **Page 22:** On the subject of actions taken when there are multiple instances of zero tolerance NR's: The actions taken—or not—are based on the same decision-making criteria in both HIMP and non-HIMP plants.

Now on p. 24. See comment 21.

20. Page 23: The paragraph beginning "Another factor may also account for the increases in noncompliance records issued for fecal failures." The report hypothesizes, without reference, that increased line speeds may account for increased documentation of fecal failures. The Agency is not aware of any study that supports this hypothesis. As noted above, it is far more plausible that the 100% increase in inspection at the end of the line led to an increase in the documentation. Additionally, results from the inspector survey note that they have more time under the HIMP system to collect carcass samples for detailed examination.

Now on p. 26. See comment 22.

21. Page 25: The last sentence that discusses the occurrence of feathers and other quality defects should be changed to: "According to FSIS officials, quality defects are of lesser concern because they are not associated with foodborne illness". FSIS does not have a zero tolerance for non-food safety related defects. The same clarification should be made on page 5, second full sentence.

Now on pp. 27-28. See comment 23.

22. **Page 26:** The presence of generic *E. coli* on carcasses is acknowledged as a useful indicator of process control as *E. coli*, a common finding in the intestinal tract of food animals, is used to assess the effectiveness of sanitary dressing procedures in preventing and removing fecal and associated microbial contamination. The 12%

Now on p. 27.
See comment 24.

Now on p. 28.
See comment 25.

Now on p. 29.
See comment 26.

Now on p. 30.
See comment 27.

Now on p. 34.
See comment 28.

See comment 29.

See comment 30.

increase in acceptable carcasses in the model's phase represents a statistically significant improvement in process control from baseline performance.

23. Page 26: The discussion on Table 3 is should be adjusted to focus on inspection systems rather than plant performance. Table 3 clearly shows that ten of eleven plants met the FS1 standard, all eleven plants met the OCP1 and OCP2 standards, and nine of eleven met the OCP3 standard. The FS2 zero tolerance standard remains a challenge to meet, but the Agency remains committed to this policy goal. To date, these five performance standards (FS1-2 and OCP1-3) have been of most interest to the public. Public expectations on meeting the OCP4 and OCP5 standards will be sought through the rulemaking process.

24. Page 27: Table 4 is incomplete; all columns do not add up to 11 as stated.

25. Page 28: The discussion on Table 5 should be refocused on inspection systems rather than plant performance consistent with the project design. If that is done, the discussion on Table 5 would reflect that, for each performance standard except FS2, 90% to 100% of the plants met the individual performance standard categories. Each food safety finding by inspection personnel was documented on a non-compliance record.

26. Page 29: Table 6 should clearly state what criteria determine performance changes of better, same, or worse. A decline in performance of fractions of one percent may be statistically "worse" but not a meaningfully different for such biological measurements. We concur that continuous improvement is an important goal, although performance may have changed over time. The type of analysis in Table 6 merits further consideration, and the Agency intends to conduct further analysis over seasonal periods that are directly comparable.

27. Page 33: The paragraph beginning with "If, as planned,.." contains four items for consideration. The third item states that, unless the department requires adequate training of plant personnel, then USDA may be jeopardizing product safety and quality. As we indicated earlier, we believe the question of training is one in which FSIS will seek public comment.

28. In the section titled "How the MSEP System Works" line 6 talks about salary reimbursement. AQIS would insert the word "partially" before the word "reimbursement." At the end of that sentence they would insert a new sentence to read "In establishments producing for the USA, the veterinary officer is assisted by an AQIS-employed inspector performing zero-tolerance end product inspection."

29. FSIS completed its evaluation of MSEP in 1999 and on June 1 we issued AQIS a formal letter accepting it as equivalent. No MSEP establishments are currently shipping product to the U.S. and have never done so.

6

We appreciate your consideration of our comments. If you have any questions, please contact Jeanne O. Axtell, Acting Deputy Administrator for Management at (202) 720-4425.

Sincerely,

for Margaret O'K. Glavin
Acting Administrator

7

The following are GAO's comments on the U.S. Department of Agriculture's letter dated November 30, 2001.

GAO's Comments

1. We believe that the report's title describes the overall results of our study. Therefore, we have not modified the title as USDA suggested.

2. We do not agree that our report oversimplifies the goals of the pilot project. The pilot project's objective was to compare the accomplishments—as measured by USDA's safety and quality performance standards—of two inspection systems at volunteer plants. We understand that the plants participating in the pilot project made various other changes at different times during the pilot project. However, the only change that USDA required of plants volunteering to participate in the pilot was the replacement of USDA inspectors with plant personnel. As USDA states, this project was designed as a "before-and-after" experiment. The "before" refers to traditional inspections with USDA inspectors performing the carcass defect detection duties, and the "after" refers to the plant employees' performance of the carcass defect detection duties. As explained in our report, USDA's independent contractor first went to each participating plant to collect carcass defect data under traditional inspections, waited until the plant employees went through a transition period, and then returned to collect the same type of data after plant employees assumed the inspectors' duties. If USDA wants to compare the accomplishments of two different inspection systems that include many variables, it is critical to use a control group. Indeed, the lack of a control group in USDA's study prevents them from knowing the extent to which plants that do not participate in the study (about 175 plants nationwide) made changes in their processing systems that improved safety and quality while continuing to inspect under the traditional system. We continue to believe that the design of the USDA's pilot project does not permit USDA to interpret what changes account for the experiment's outcomes.

3. We agree with the premise that the use of volunteer plants is a legitimate approach and our report acknowledges that, once USDA decided to go forward with this pilot project design, it could not compel plants to participate and, therefore, had to rely on volunteer plants. However, given that USDA decided to proceed with this design, our report points out that USDA had the option of randomly selecting a subgroup from the volunteer plants to serve as a control group. The problem with relying on volunteers for this study is that there are a

small number of plants participating—there are only 11 chicken plants for which before and after data have been collected. Even if the plants had been randomly selected, they would not represent a sufficient number to enable USDA to generalize the results to the entire population of chicken plants. Therefore, USDA cannot assume that the results from these 11 plants would apply to all the plants that in the future may participate in a modified inspection system. Finally, neither USDA nor RTI provided GAO with any evidence that the pilot project was either designed or analyzed as a time-series study.

4. We do not agree with USDA that the plants participating in the study are typical of the industry in that they represent diversity in geography, corporate structure, management styles, numbers of evisceration lines, product distribution, and other variables. As figure 2 of our report shows, the pilot project has before-and-after data for 11 plants that are located in the southern region of the United States. Therefore, particularly with respect to microbial data, the results from these plants may not be indicative of how plants in other areas of the United States may behave. Geographic distribution and seasonal variations are important variables that cannot be ignored in assessing a program. As a recent USDA study points out, *Salmonella* and *E. coli* 0157:H7 rates appear to differ dramatically by season, while geography seems to affect only *Salmonella* results. When, as part of this study, USDA researchers investigated the regional patterns, they found higher positive rates for *Salmonella* in warmer climates. For example, in southern operations, the rates were about 8 percent, whereas the rate was just under 5 percent in northern operations. This study highlights the importance of variables such as seasonal variations and geographic distribution. As discussed in our report, the design of USDA's pilot project did not appropriately consider these variables.

5. Our report accurately describes the duties of FSIS inspectors and plant personnel as they have changed during the course of the litigation outlined in appendix II. However, as noted in comment 9, we have modified our characterization of current plant personnel activities in accordance with USDA comments.

6. We made the technical changes as appropriate.

7. We disagree. Our report does not describe the program as being designed as a cost-saving initiative.

8. We modified our report to state that there are only 11 chicken plants with before-and-after data.

9. We have made the first change suggested. However, USDA has not provided any information to demonstrate that inspection resources are being utilized elsewhere in the farm-to-table continuum other than performing for plant inspections.

10. We disagree. We believe that the report consistently describes the purpose and type of data collected by RTI. See comment 2.

11. We made the technical changes as appropriate.

12. We made the technical changes as appropriate.

13. We made the technical changes as appropriate.

14. We disagree. According to the documentation provided by USDA, there is a model for fed cattle and, as of October 2001, no cattle plants had volunteered to participate.

15. Table 1 and its footnotes describe the number of plants participating in the project.

16. We made the technical changes as appropriate.

17. We made the technical changes as appropriate.

18. We agree with the agency that it should look at this during the rulemaking process.

19. We disagree. Our report acknowledges that inspectors' verification checks increased from 20 to 80 at pilot project plants, a fourfold increase in verification checks. However, the number of noncompliance records issued by inspectors at some of the plants far exceeded the level expected by the increase in verification checks. At one plant, there was a twentyfold increase in noncompliance reports. Our intent is to alert USDA of the fact that, after shifting to modified inspections, some of the plants appear to have problems with fecal contamination. USDA's HACCP Rules of Practice contemplate the Department's taking action for noncompliance by withholding the marks of inspection or by suspending inspections in instances where it decides that it is necessary to do so because of multiple or recurring

regulatory noncompliances evidenced by noncompliance records. We understand from FSIS officials that they are now considering how many repeated instances of noncompliance will result in further regulatory action.

20. We agree that actions taken when there are multiple instances of noncompliance are based on the same decision-making criteria in both project pilot plants and in traditional plants.

21. About 60 percent of our survey respondents said that line speeds are somewhat too fast or much too fast for food safety.

22. We made the technical changes as appropriate.

23. We agree with USDA's comment that, as shown in table 5 of our report, the generic *E. coli* results show improvement after the plants shifted to modified inspections. As the table shows, 2 of the 11 plants improved while 9 remained unchanged.

24. We disagree. As stated in our report, we believe that looking at individual plant inspection systems' performance is relevant and appropriate because each plant is expected to meet the standards. Therefore, in table 4, our report shows how each plant performed, as measured by USDA's performance standards.

25. We made the technical changes as appropriate.

26. We disagree. As stated in our report, we believe that looking at individual plant inspection systems' performance is relevant and appropriate. Therefore, in table 6, our report shows how each plant performed, as measured by USDA's performance standards.

27. We agree. Our original criterion for analyzing changes in the data presented in—table 7 was .01 percent—which we used because it reflects the level of precision in the data that USDA provided to us. However, in response to USDA's comment that declines in performance of fractions of 1 percent may not be meaningfully different, we modified our criterion to 0.5 percent. This means that a plant's change from "same" to "worse" or "better" would now represent 215 chickens per line per shift compared with 4.3 chickens per line per shift in terms of quality and safety. By changing our analysis, we now find that in 16 instances, the plants' performance under modified inspections moved from "better" to "same" and in 8

instances the plants' performance moved from "worse" to "same." In summary, even after changing our criterion, we find that in several instances, the plants are not meeting USDA's goal—that is, that modified inspections should achieve at least the same level of performance as traditional inspections. We modified table 6 to reflect these changes. In table 6, we clearly identify which plants have or have not met each individual performance standard.

28. We agree. As stated in our report, we believe that training of plant personnel is an issue that must be addressed by USDA.

29. We made the technical changes as appropriate.

30. We made the technical changes as appropriate.

Appendix VIII: GAO Contact and Staff Acknowledgments

GAO Contact

Robert C. Summers (404) 679-1839

Acknowledgments

In addition to the name above, Maria Cristina Gobin, John M. Nicholson, Diana P. Cheng, Shana B. Wallace, Fran A. Featherston, Karen K. Keegan, and Cynthia Norris made key contributions to this report.

GAO's Mission

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