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Food Safety and Inspection Service's  
Performance-Based Inspection System

A Statement for the Record by  
John W. Harman, Director,  
Food and Agriculture Issues  
Resources, Community, and Economic Development  
Division

Submitted to the  
Human Resources and Intergovernmental Relations  
Subcommittee,  
Committee on Government Operations  
House of Representatives



Mr. Chairman and Members of the Subcommittee:

We are pleased to submit this statement for your hearing record on the Food Safety and Inspection Service's (FSIS) discretionary inspection plan for meat and poultry processing plants. Under discretionary inspection, FSIS intended to vary the frequency and manner of inspection according to the public health risk posed by a plant. Our statement presents information on the Performance-Based Inspection System, usually referred to as PBIS, which FSIS, an agency of the U.S. Department of Agriculture (USDA), developed to support discretionary inspection at processing plants. PBIS, which can be used whether discretionary inspection is implemented or not, is an automated inspection scheduling and management information system that FSIS uses to direct meat and poultry inspection functions at processing plants. We made the review in response to the Subcommittee's April 17, 1989, request.

As agreed with the Subcommittee, this statement discusses the agency's need for an improved inspection program, the proposed discretionary inspection program's status, PBIS objectives and status, PBIS problems and limitations, agency efforts to correct problems and improve PBIS, the agency's failure to apply management controls over system development, and our recommendations for developing a more efficient and effective inspection scheduling and management information system.

In summary, we found that PBIS has been installed and is operational in all 26 FSIS area offices. The system is generating weekly schedules of inspection tasks for inspectors to perform at all processing plants, inspectors are following the schedules in conducting their inspections, and the system is accumulating inspection results from completed schedules in a data base. FSIS views PBIS as an interim system and plans further development to enhance and expand the system's capabilities.

In reviewing PBIS as it is currently operating, we found various problems involving (1) the reduced capability of the system to achieve its original objectives of producing schedules of randomly selected inspection tasks tied to plant performance and the risk to public health, (2) the uncertainty over the amount of discretion given to inspectors to deviate from their schedules, (3) the lack of documentation and a formal testing plan to validate the system, and (4) limitations in the system's capacity to efficiently process operational data. FSIS efforts to improve PBIS have not yet been fully successful in resolving these problems.

We believe that PBIS' problems are due, in large part, to FSIS' failure to apply management controls, prescribed by USDA, over system development. Implementing these controls, at this point in the system's development, would help ensure that PBIS problems are corrected and that an automated inspection system is developed that more efficiently and effectively supports the agency's inspection program.

We discussed our findings with FSIS management officials, including the Associate Administrator, who is the agency's senior official responsible for managing information resources. While generally agreeing with our assessment of PBIS, the Associate Administrator stated that PBIS is the agency's highest priority, and the agency would make a concerted effort to correct any problems. Agency officials emphasized that PBIS was needed to ensure more uniform application of the inspection regulations, better allocate limited resources, and develop management information on overall industry performance. They also told us that PBIS is a major improvement over the previous manual inspection scheduling system.

Our review included discussions with FSIS and other USDA officials, including those of the Office of Information Resources Management (OIRM), which is responsible at the departmental level for coordinating and monitoring the development and operation of

computer-based systems. We visited three FSIS area offices (Hyattsville, Maryland; Topeka, Kansas; and Jefferson City, Missouri), where we interviewed officials and, at the latter two offices, evaluated PBIS operations in detail. We reviewed the legislation authorizing discretionary inspection; FSIS records, manuals, and other documents relating to meat inspection and PBIS; and USDA administrative regulations and instructions relating to developing and operating computer-based systems. The review was carried out by our Resources, Community, and Economic Development Division and Information Management and Technology Division with assistance from our Kansas City Regional Office.

#### BACKGROUND

Under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.) and the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), FSIS inspects meat and poultry products to ensure that they are safe, wholesome, and accurately labeled. FSIS inspectors, through daily sanitation inspections, laboratory tests, and other means, ensure that plant management meets federal inspection requirements and solves any problems identified.

Through its Meat and Poultry Inspection Operations office, FSIS oversees the domestic field inspection force through a network of 5 regional offices, supported by 26 area offices. According to FSIS, it has the largest inspection force in the federal government, both in absolute numbers and in the ratio of inspectors to regulated facilities. In 1988 about 7,100 federal inspectors, including many veterinarians, carried out the inspection laws in about 6,600 meat and poultry slaughtering and processing plants in the United States. Included in these totals are about 2,100 inspectors assigned to oversee processing operations conducted at about 6,200 plants.

In 1988 FSIS inspected about 150 billion pounds of processed products, such as soup, pizza, sausage, pot pies, and ham. This volume was about a 63-percent increase over the 92 billion pounds inspected in 1978. Over this same period, the number of plants declined by about 4 percent, from 6,452 to 6,202, while the size of FSIS' inspection workforce assigned to processing operations decreased by almost 10 percent. Table 1 contains additional information on FSIS' meat and poultry inspection program.

Table 1: Information on FSIS Meat and Poultry Processing Inspection Program for Selected Years

	<u>Fiscal year</u>			
	<u>1978</u>	<u>1983</u>	<u>1988</u>	<u>1989a</u>
Number of plants conducting processing operations	6,452	6,642	6,202	6,130
Inplant inspectors	2,285	2,096	2,067	1,986
Billions of pounds inspected	92.4	112.3	150.4	165.0

<sup>a</sup>Estimated.

Source: Table developed from information provided by FSIS or contained in USDA Budget Explanatory Notes for Committee on Appropriations for fiscal year 1990.

Past Studies Support Need for an Improved Meat and Poultry Inspection Program

Over the last 12 years, our office, USDA's Office of Inspector General, a consulting firm, and a scientific organization have issued reports on studies of FSIS inspection activities. Attachment

I provides a summary of these reports. Generally, the studies have been consistent in identifying the essential principles of an efficient and effective inspection program necessary for protecting public health. These essential principles are (1) the intensity of inspection coverage should be varied in accordance with food safety risks, (2) food processors should have quality-assurance programs that meet regulatory requirements, (3) regulatory agencies should have authority to assess civil penalties for violations of the laws and regulations, and (4) data about plant compliance are needed to manage the inspection program and allocate inspection resources.

In recent years, FSIS has sought to modernize and improve inspection without increasing its cost to the taxpayers. The most significant initiatives have been agency efforts to improve inspection at meat and poultry processing plants by varying the intensity of inspection and developing a risk-based automated inspection scheduling and management information system.

Although this statement discusses problems with these recent FSIS initiatives and their implementation, we believe that the principles upon which the initiatives are based are sound and should continue to be pursued.

#### Status of the Discretionary Inspection Program

On November 10, 1986, the Congress passed Public Law 99-641, the Futures Trading Act of 1986. Title IV of the act, the Processed Products Inspection Improvement Act of 1986, amended the Federal Meat Inspection Act giving USDA the discretion to vary the manner and frequency of inspection for meat processing plants according to the risk posed by the plant, the product, and the process. Up to that time, the Federal Meat Inspection Act had required continuous inspection in processing plants that produce meat products. (Although the Poultry Products Inspection Act does not require continuous inspection in plants processing poultry,

USDA has to date maintained basically comparable inspection requirements for both meat and poultry processing.) In practice, continuous inspection has meant that a plant is visited at least daily by the assigned inspector(s). The amendment gave the Secretary of Agriculture increased authority to determine during a 6-year period ending November 10, 1992, the amount of inspection coverage necessary in meat processing plants.

In 1987 FSIS issued regulations to allow for testing of revised inspection procedures. In three pilot tests, conducted between April 1987 and August 1988, FSIS evaluated elements of a new processing inspection program. Following these tests, FSIS published on November 4, 1988, a proposed regulation in the Federal Register to implement its Improved Processing Inspection (IPI) program. (Previously, FSIS had called the program "Discretionary Inspection.")

The proposed regulation received strong opposition. FSIS received more than 1,800 comments, with most opposed at least in part. Consumers expressed concerns that FSIS would use its new authority simply to reduce inspection and, consequently, reduce the safety and wholesomeness of inspected products. At the same time, the regulated industry expressed concerns that FSIS would place more burdensome requirements on inspected establishments. Also, on April 11, 1989, your Subcommittee held hearings on the proposed inspection program. Witnesses testifying at that hearing were also opposed to FSIS' proposed inspection program.

Because of the opposition, on May 19, 1989, FSIS withdrew the proposed regulation to reconsider how to improve its processing inspection procedures. FSIS plans to gather additional information regarding a processing inspection system and thereafter determine if a new proposal needs to be published.

Although FSIS withdrew its IPI proposal, it continued to develop and install PBIS in its area offices. According to agency officials, PBIS was still needed to ensure more uniform application of the inspection regulations, achieve a better allocation of limited resources, and develop management information on overall industry performance.

#### PBIS OBJECTIVES AND STATUS

PBIS' basic objective was to serve as the inspection scheduling and management information system to support the implementation of IPI. More specifically, the inspection tasks scheduled and their frequency were to be based on plant performance and the risk to public health inherent in the product, process, or operation. To help ensure that the system produced objective information, the schedules were to randomize the tasks, inspectors, and days of plant visits. Management information was to be obtained from a data base documenting inspection findings. PBIS components designed to meet PBIS objectives include the following:

- A plant profile containing various information on plant operations, such as hours of operation, size of plant, and volume and type of product processed.
- A monitoring plan for each processing plant containing applicable inspection tasks.
- "Switching rules" that determine the level of inspection coverage based on plant performance. Switching rules are the standards and criteria within the automated system that use the results of past inspections to determine how frequently to inspect each plant or process in the future. As designed, plants with excellent histories of meeting inspection requirements would receive a reduced level of



inspection while those with poor histories would receive more intensive inspection.

- An inspection scheduling component that generates weekly inspection schedules by randomly selecting specific tasks, inspectors, and days of plant visits according to various criteria, such as the time to perform each task, the number of times a task should be performed annually, and the risk to public health associated with each task.
- A data base of inspection findings collected from completed schedules.
- Management reports summarizing inspection findings from the data base.

PBIS was first installed in five of FSIS' larger area offices in September 1988. By April 11, 1989, 16 area offices had PBIS computers. By the middle of May 1989, PBIS was installed and operational nationwide in all 26 FSIS area offices. FSIS considers the current PBIS as an interim system. In a document prepared in February 1989, The Performance Based Inspection System: Progress and Plans, FSIS discusses its plans through 1996 to add minicomputers to a central computing facility, integrate PBIS with other agency data bases, and make other enhancements to the system.

PBIS' microcomputers and printers are generating weekly schedules of inspection tasks to be performed at the approximately 6,200 plants that conduct processing operations. The schedules are printed 1 to 2 weeks ahead of time and then mailed to the inspectors, who use them to conduct inspection tasks at assigned plants. If the inspectors identify a deficiency, they determine whether it is minor, major, or critical and mark the schedule accordingly. If the inspectors cannot perform a task, they mark the task with a code designating the reason why the task was not done.

To the extent time and resources allow, data from completed schedules returned by inspectors are being entered into the system and a data base is being built.

FSIS has not established any formal project control mechanism to track system progress and account for costs incurred. However, information obtained from various documents, although incomplete and not directly comparable, shows milestone slippages and system cost increases. Information that FSIS developed at our request shows that, as of May 23, 1989, about \$2.3 million had been spent on PBIS, excluding salary costs of agency personnel developing and operating the system. This cost compares with initial estimates, made in the summer of 1987 for the agency's long-range information resources plan, that showed a total cost of \$2.1 million for a system that was scheduled to be completed in March 1989. Estimates made the following year showed that the total cost had increased to \$9.1 million, and the completion date for the system's development had slipped to September 1992. The most current estimates, for what FSIS' February 1989 document called the "ultimate" system, show a 10-year life-cycle cost of about \$13 million, including development through September 1992 and operation through 1996. The \$13 million, however, excludes the cost of PBIS minicomputers anticipated for the agency's central computing facility and the salaries of agency personnel in area offices who will manage and operate PBIS.

#### PBIS PROBLEMS AND LIMITATIONS

During our review and detailed evaluation of PBIS operations at two area offices, we observed many problems and limitations with PBIS. We discussed our concerns with FSIS officials, who agreed that problems exist with PBIS. According to the officials, PBIS is the agency's highest priority and FSIS needs it to gain better control over inspection activities; therefore, they are committed to making the system work.

The problems and limitations we observed with PBIS are as follows.

#### System Objectives Not Fully Achieved

As a result of FSIS' decision to withdraw its IPI proposal, work rules in force with the inspectors union, and additional work remaining on the system, certain components and capabilities designed into PBIS are not being fully used. Therefore, PBIS is not fully achieving its objectives. These components and capabilities include the following:

- The switching rules are not being used to reduce the frequency of inspection to less than daily because FSIS has not been able to implement IPI. Inspectors continue to visit each processing plant daily. Also, the switching rules are not being used to increase intensity because FSIS is reexamining the rules and trying to accumulate sufficient data to verify them. FSIS has not set a deadline for completing its reexamination. In the meantime, decisions to increase inspection intensity at individual plants are being made by supervisory personnel familiar with plant conditions, not by PBIS. (FSIS has always had the authority to increase inspection intensity at plants not meeting its processing requirements.)
- The days on which individual plants would be visited were to be selected on a random basis for those plants eligible for less-than-daily inspection. But, again, because the IPI proposal has been withdrawn, every processing plant is visited daily.
- On the basis of its contract with the inspectors union, FSIS continues to give inspectors fixed assignments to specific plants for certain periods of time. For example,

in urban areas inspectors are assigned to specific plants for 6 months. Consequently, PBIS is not randomly assigning inspectors to plants.

Limitations with the inspection schedules that PBIS generated also kept PBIS from fully achieving its objectives. FSIS has not systematically evaluated inspection schedules generated by PBIS to determine whether the inspection tasks randomly selected by the system are reasonable and adequate in terms of protecting public health. The following limitations were identified during our review:

- Some scheduled inspection tasks were not performed at the two area offices where we evaluated PBIS operations in detail. For various reasons, 29 percent and 32 percent of the scheduled tasks at the two offices were not performed during the week we selected for review. For example, if a process that PBIS schedules for inspection is not being carried out at a plant that day, the inspector cannot perform the inspection. Also, the system does not consider unperformed tasks when selecting tasks for subsequent schedules.
- The system assumes that each plant operates Monday through Friday and, therefore, it schedules tasks each weekday even if the plant is not operating.
- In some cases, the type and frequency of tasks scheduled were not commensurate with risk levels. For example, we brought to FSIS' attention an inspector's weekly schedule for June that repeatedly scheduled relatively low-risk inspection tasks. FSIS reviewed the schedule and identified the cause of the problem as an error in the system's programming, which it said it immediately corrected. We also noted that a relatively high-risk

inspection task--checking plant and equipment sanitation prior to starting processing operations, referred to as preoperational sanitation--appeared infrequently on schedules provided us by representatives of the inspectors union. An FSIS official had also received feedback raising questions about the frequency at which PBIS schedules this task. He said that FSIS was looking into the matter.

- FSIS guidance to inspectors and supervisors on use of schedules needed to be clarified. Agency management and some inspectors view the schedules more as a guide than as an "order" that must be carried out. However, other inspectors maintain that the schedules are orders and complain that PBIS limits their discretion to decide what should be done. An apparent cause of this problem is that PBIS schedules inspectors for as close to a full 8-hour workday as possible, leaving inspectors with little or no discretionary time to pursue possible problem areas, such as deterioration in plant sanitation, based on their experience and first-hand knowledge of plant conditions.

In addition, FSIS has recognized that entering data from completed schedules is a time-consuming task. We confirmed this at one area office, where personnel had been able to enter only about 81 percent of the completed schedules, even though PBIS has been scheduling inspections since the beginning of this year and an additional person had been assisting with data entry. Until all inspection results can be entered into the PBIS data base, any management reports will be of limited use.

In regard to generating management reports, according to area office supervisors and headquarters officials, PBIS is not yet generating management reports for use in managing inspection activities. At the two area offices we visited, management reports were not generated on a routine basis. Office managers were not

using reports and had not received formal training on how to use such reports to improve area operations.

Management reports on the performance of inspectors and plants constitute an important part of the information that PBIS was to produce. At present, FSIS is collecting information in a data base, but it does not have a clear plan for using this information in management reports. Issues of what data are needed and how they will be used are an essential step in system design. Traditionally, FSIS managers have had to conduct special studies to obtain information to assist their operations.

PBIS represents an effort to give managers better factual information by distributing performance reports on a regular basis. The fact that historical data on how inspectors and plants perform are being collected but are not being used by managers limit PBIS' effectiveness as an instrument for setting priorities.

#### No Formal Testing Plan

FSIS did not prepare a formal testing plan for PBIS that includes measurable objectives, criteria, and required performance data. An important element of sound systems development is the testing of system software. Such formal testing should include thorough documentation of testing procedures, data to be collected, criteria for how performance will be evaluated, and actual test results. Although PBIS was included in two of FSIS' pilot tests of IPI, these tests were primarily tests of the effect of the Improved Processing Inspection program on plant compliance, rather than an evaluation of whether the PBIS software functioned correctly and efficiently. The pilot tests evaluated PBIS on the basis of observations and feedback by inspectors, supervisors, and other staff, rather than on predefined test procedures and criteria. Despite the complexity of the system design, an evaluation against measurable objectives was not made either before or after decisions

were made to extend the "prototype" nationwide. Without a formal testing effort, FSIS has no basis for determining whether PBIS is efficiently and effectively meeting agency requirements.

#### Inspection Frequency and Risk Not Documented

As we have noted, an important principle of an efficient and effective inspection program is that the intensity of inspection coverage should be varied in accordance with food safety risks. In a report prepared for FSIS in 1985, Meat and Poultry Inspection-- The Scientific Basis of the Nation's Program, the National Academy of Sciences recommended that, to improve its program, FSIS assess food safety risks by preparing formal, quantitative risk assessments.

Inspection tasks scheduled by PBIS have been assigned weights and risk priorities designed to reflect the relative food safety risk inherent in each particular task. For example, relatively important inspection tasks, such as checking that product-handling equipment is cleaned and free of all residue and foreign material, are given higher weights and higher risk priorities than other relatively less important inspection tasks, such as checking that shipping vehicles are clean and free of odors. Within the context of its randomization process and over a period of time, PBIS is designed to schedule the more important inspection tasks more frequently than the less important tasks.

FSIS has not used formal, quantitative risk assessments in developing PBIS. Instead, PBIS weights and risk priorities were developed by FSIS management and staff experts using an informal process that relied on their experience, professional judgment, and past agency practices. FSIS could not provide documentation explaining the basis for the weights and risk priorities established for the inspection tasks being scheduled by PBIS. FSIS officials told us that formal, quantitative risk assessments may be prepared

in the future when PBIS provides the necessary data and as FSIS continues to modernize its inspection program.

We believe that, for such an important element of an inspection program, documentation should be available to support agency decisions regarding the weights and risk priorities established for particular inspection tasks.

### Capacity Limitations

At the two area offices, we noted that the system, as currently configured, had equipment and software limitations. These limitations relate to the system's overall capacity to efficiently conduct all processing operations (that is, entering inspection results from completed schedules, building and transferring schedule files, updating summary history files, printing schedules, and producing management reports) every work week, especially at the larger area offices. While our observations are based on our visits to two offices, FSIS officials concurred in the problems we identified.

Specifically, we identified limitations regarding the adequacy of original equipment sizing, problems with data entry, and a printing logjam.

FSIS did not conduct an analysis to determine the size and speed of computers needed for PBIS. Instead, agency officials told us that they decided to purchase the fastest and most powerful microcomputer on the market at that time. The agency originally planned for PBIS to use one microcomputer in each of the 26 area offices. However, this was recognized as inadequate and a second microcomputer was added. While the second microcomputer was intended to support other information systems in the area office, we found that it was being devoted to supporting PBIS. We observed that the two computers were configured in a "master-slave network,"



which functioned solely to transfer data files from the first microcomputer ("master") to the second ("slave") unit, for the purpose of printing schedules and reports. During this transfer, both computer systems were in use and could not be used for any additional purpose. This is a highly inefficient configuration and reflects the limited system planning and requirements specification.

In observing current software performance at the two area offices, we noted slow response times despite the purchase of "state-of-the-art" hardware. Although this problem may be easily solvable, we found that FSIS did not initially evaluate alternative software for writing PBIS programs. For example, if FSIS had tested or evaluated software alternatives, it might have selected another software package for the PBIS system. We found some indications, reported in a recently published test of seven database software products, including the one used in PBIS, that the software FSIS chose is slower than four of the other six database management software products when measured by an extensive set of benchmark tests using hardware similar to that in use at FSIS.

We found additional inefficiencies in the design of the data entry task. Each inspector may generate data on a hundred or more observed performance areas each week for the plants visited. These manually prepared data are then transferred by data entry clerks into the data base on individual plant performance. The current configuration permits only one of the two microcomputers to be used to enter data. As a result of these conditions, data entry for PBIS is time consuming. For example, in one area office, we found that data entry takes up to 27 hours each week.

Printing functions are also inefficient and reflect poor system planning and design. The weekly printing of schedules at the two area offices takes about 16 hours. The printing programs do not take advantage of features that allow for simultaneous activity.

Instead, the programs alternately process data and print short sections, until the report or schedule is finished. This condition cuts the printing speed to half of what it could be. In addition, the printers' paper bins are not large enough to hold most schedules or other voluminous documents in their entirety. As a result, these documents cannot be printed overnight, because office staff must be present to periodically unload the bins.

#### AGENCY EFFORTS TO CORRECT PROBLEMS AND IMPROVE PBIS

Since May 1988, FSIS has been working to correct problems with PBIS. Its basic approach has been to tackle one component at a time. For example, until May 1989, FSIS concentrated on the scheduling component and the related software. Now that it believes that the scheduling component is performing adequately, FSIS has turned to the data entry component. When that is working to its satisfaction, FSIS intends to deal with the management reporting component.

At the close of our review, FSIS had various initiatives or plans underway to improve PBIS. These initiatives included (1) developing a more flexible system for inspectors to exercise their independent judgment, (2) devising a method for reporting positive as well as negative inspection findings, (3) reexamining the switching rules, (4) evaluating what types of reports would be useful to agency managers and supervisors, (5) evaluating the method used to classify inspection deficiencies to determine if changes are needed, (6) designing a larger printer paper bin, and (7) exploring methods to speed up system processing. In addition to implementing these initiatives, FSIS plans further development through 1992 to enhance and expand the system's capabilities, including acquiring minicomputers for the agency's central computing facility.

## MANAGEMENT CONTROLS NOT APPLIED

Through its administrative regulations, USDA has established a series of management controls over the development of automated information systems, such as PBIS. (These controls are generally part of an overall approach to managing information resources, called information resources management, or IRM.) These controls are intended to ensure that proposed automated information systems are successfully developed so that they efficiently and effectively meet agency needs. USDA's Office of Information Resources Management is the designated USDA staff office responsible for developing policies and regulations and overseeing IRM activities of USDA agencies and offices.

USDA's management controls include the following:

- Agency preparation of annual long-range IRM plans and their approval by OIRM, including an evaluation for technical feasibility and consistency with departmental IRM policy and direction. An agency IRM plan is a 5-year strategic plan for the agency as a whole focusing on significant IRM objectives within the agency.
- An OIRM technical review and approval process for agency IRM acquisitions above certain dollar thresholds.
- Agency self-reviews of all its important IRM systems and resources over a 3-year period.
- Selective reviews performed jointly by OIRM and an agency to assess the agency's automated system, project, or IRM management.

- Agency IRM Review Boards of top agency management responsible for reviewing and approving IRM development projects.
  
- The use of a life-cycle management approach and related documentation, such as a functional requirements study, benefit-cost analysis, and system test plan, for planning, developing, and acquiring major IRM systems.

None of these management controls were applied during the development of PBIS for various reasons, as follows:

- Although FSIS' long-range IRM plans for the last 3 years were approved by OIRM, OIRM did not evaluate the proposed PBIS project because it was never identified as a "new" agency objective. Because of limited resources, OIRM has focused its evaluation of agency long-range IRM plans on "new" objectives.
  
- FSIS did not ask OIRM for technical approval for PBIS acquisitions because the agency did not believe that dollar thresholds were exceeded. At the close of our work, FSIS was planning to prepare a formal request to OIRM for technical approval based on the agency's latest plans and cost estimates for PBIS.
  
- FSIS' agency self-review for fiscal year 1988, which would have likely included PBIS, was deferred for 1 year because of FSIS' heavy workload.
  
- PBIS has not been the subject of a selective review. At our suggestion, FSIS and OIRM have agreed to a selective review of PBIS, which was expected to start the end of July or early August 1989.

- FSIS' IRM Review Board did not consider review of PBIS' progress during its development necessary because Review Board members were actively involved in helping to develop PBIS.
  
- FSIS did not develop PBIS using the USDA-prescribed systems life-cycle management approach; rather, it followed a "prototype" approach with limited documentation in order to develop PBIS quickly. According to agency officials, a prototype approach was necessary because PBIS and IPI were entirely new approaches to processing inspection, and many policy issues needed to be addressed whose outcome would affect how PBIS would function. A prototype approach was viewed as providing the flexibility to adjust to this evolving policy. Agency officials also told us that it was their understanding that life-cycle management requirements did not apply to a prototype project. However, according to OIRM staff, the life-cycle management approach should be applied to all software development projects, including prototypes. They explained that for smaller projects and prototypes, the level of detail would not have to be as great as for larger projects.

As these items indicate, FSIS had reasons for not applying individual management controls to PBIS development. Our concern, however, is that the overall lack of these controls resulted in the absence of any objective, independent oversight or evaluation of how well PBIS development was progressing. We believe that better management control over the system could have helped avoid the existing problems and limitations.

## CONCLUSIONS

As shown in attachment I, the need for changes in the current inspection system at processing plants, directed at identifying

high-risk areas and processes for intensified inspection while developing reliable quality-control systems, is well documented by our office and other organizations. This approach has been further supported by the Processed Products Inspection Improvement Act of 1986. But for such an approach to be credible and to gain the confidence of both consumers and the processors being inspected requires the development and use of a management information system that can be relied on to provide accurate information for making management decisions. In fact, such a system is needed under the current approach to inspecting processing plants.

Developing a major automated management information system requires that certain controls be followed. USDA's OIRM has established a series of analytical and oversight requirements for agencies to follow to help ensure the successful development of information systems. Proper justification and analyses along with management oversight are required to reduce the risk of delays and failure to meet user needs. In its haste to develop PBIS, FSIS did not apply certain of these controls. As a result, PBIS cannot currently be relied on to give the type of quality information needed as a basis for making decisions.

FSIS has made a substantial investment of time, money, and staff resources in implementing this system and continues to invest resources in trying to correct problems and achieve system objectives. It also has plans to add minicomputers at agency headquarters, integrate PBIS with other data bases, and otherwise enhance the system. Yet FSIS is following this course without having an adequate framework of planning, documentation, and oversight in place to ensure an efficient and effective system.

Before FSIS invests additional resources in equipment and nonmaintenance-type software for PBIS, it should halt further enhancements and prepare a plan for how it will begin to implement management controls over PBIS. In addition, FSIS should take this

opportunity to document the scientific basis for the risk factors and frequencies used to schedule inspection tasks, evaluate whether the system is scheduling appropriate tasks for protecting public health, and clarify the amount of discretion available to inspectors.

#### RECOMMENDATIONS TO THE SECRETARY OF AGRICULTURE

We recommend that the Secretary direct the FSIS Administrator to

- operate PBIS as is and suspend additional investment in equipment and nonmaintenance-type software for PBIS until a plan is developed to apply system development life-cycle principles and other management controls to the current and any future system;
- document the basis, including the rationale and scientific support, for the risk factors and frequencies used by PBIS to schedule inspection tasks;
- periodically evaluate the reasonableness and adequacy of PBIS-generated inspection tasks to ensure that they protect public health; and
- issue a directive to inspection staff clarifying use of schedules, including the degree of discretion available to inspectors to use their experience and judgment in deciding on the inspection tasks to perform.

Rather than PBIS completely scheduling each inspector's workday, the Administrator may also want to consider setting aside a certain amount of time periodically for inspectors to apply their experience and knowledge in deciding what inspection tasks to perform.

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This statement completes our work in response to your April 17, 1989, request. We will be glad to further discuss meat and poultry inspection issues with you or your staff.



SUMMARY OF GAO AND OTHER REPORTS ON FSIS INSPECTION PROGRAMGAO REPORTSA Better Way for the Department of Agriculture to Inspect Meat and Poultry Processing Plants (CED-78-11, Dec. 9, 1977)

GAO reported that most processing plants are inspected daily, even though an inspector may spend only a few hours each day at a plant. According to GAO, the Food Safety and Inspection Service's (FSIS) inspection resources could be used more efficiently and effectively if inspection frequency at processing plants was tailored to the inspection needs of individual plants. Periodic unannounced inspections would allow FSIS to inspect more plants or inspect plants needing upgrading more frequently. Upgrading certain plants would provide greater assurance that consumers are getting wholesome, unadulterated, and properly branded products. Any system of periodic unannounced inspections should require an in-plant quality-control system. The authority to require plant managements to develop and carry out adequate, reliable quality-control systems should be coupled with authority to apply strong penalties or sanctions when plant managements fail to carry out their responsibilities under these systems.

GAO recommended that the Congress amend the Federal Meat Inspection Act and the Poultry Products Inspection Act to authorize the Secretary of Agriculture to make periodic unannounced inspections of meat and poultry processing plants; require meat and poultry processing plants to develop and implement quality-control systems; and withdraw inspection or impose civil penalties of up to \$100,000 for a processing plant failing to take appropriate action when the quality-control system identifies a deficiency or when

plants fail to comply with inspection requirements. GAO also recommended that, if the Congress amends the acts, the Secretary develop criteria for deciding the optimal inspection frequency for individual processing plants and for assessing penalties within the provisions of the acts. In addition, GAO recommended that the Secretary, in cooperation with industry, develop criteria for determining the quality-control systems needed at various types and sizes of processing plants.

Improving Sanitation and Federal Inspection at Slaughter Plants:  
How to Get Better Results for the Inspection Dollar (CED-81-118,  
July 30, 1981)

GAO identified, among other matters, weaknesses in the collection of management data at meat and poultry slaughter plants. GAO said that inspection program supervisors, at times, did not adequately document the results of their monthly reviews. Lack of documentation, GAO concluded, weakened FSIS monitoring of plant compliance with inspection program requirements. Documentation should provide a record of compliance trends and deficiencies in need of follow-up. GAO recommended that the Secretary of Agriculture direct the Administrator, FSIS, to instruct plant inspectors on the need to document all deficiencies found during sanitation inspection and emphasize to supervisors that deficiency records need to be kept.

Monitoring and Enforcing Food Safety--An Overview of Past Studies,  
(GAO/RCED-83-153, Sept. 9, 1983)

This study provided an overview of (1) studies on federal food safety regulation done by groups outside GAO between 1976 and 1981 and on the status of recommended statutory and organizational changes, (2) GAO food safety-related reports done between 1972 and 1981 and the status of federal actions on GAO recommendations, and (3) issues that remained to be addressed.

GAO stated that an important part of any regulatory program is recordkeeping. Records must be kept about producers, inspection results, and violations and their frequency so that agencies can concentrate limited resources on firms, processes, and products most likely to present significant problems.

In addition, GAO stated that regulating food safety is a complex, technical, and labor-intensive undertaking. To make the best use of increasingly limited resources, agencies need to make effective use of personnel to assure maximum productivity, plan adequately for staff requirements to meet workloads, and ensure that employees are adequately trained and are performing well.

Finally, GAO stated that agencies responsible for regulating food need information about firms and products that are included within the scope of their regulatory activity. Management data about product volume, product problems, and problem firms are needed to help the agencies determine which problems require attention first.

Compendium of GAO's Views on the Cost Saving Proposals of the Grace Commission, Vol. II--Individual Issue Analyses (GAO/OCG-85-1, Feb. 19, 1985)

This report contains GAO's analyses of 581 individual issues and associated recommendations made by the President's Private Sector Survey on Cost Control--commonly known as the Grace Commission. Addressing the issue of meat and poultry inspection, the Grace Commission said that

"By giving the Secretary of Agriculture discretion . . . [to determine] the intensity of inspection of meat [and poultry and egg products] processing operations, a saving of . . . \$27.7 million [could be realized over] . . . three years."

GAO stated that it believed that, overall, this issue had merit. Also, GAO agreed with the specific Grace Commission recommendation that the U.S. Department of Agriculture (USDA) inspection resources could be used more efficiently and effectively if the inspection frequency at processing plants were tailored to the inspection needs of individual plants. (This is the same position GAO took in its 1977 report--CED-78-11--summarized above.)

Inspection Activities of the Food Safety and Inspection Service (GAO/T-GGD-87-15, May 15, 1987)

In May 1987 testimony before the Subcommittee on Oversight of Government Management, Senate Committee on Governmental Affairs, GAO said that FSIS may need to improve its data on measures of plant quality and the quality of inspector performance. GAO testified that indications were that FSIS did not have objective,

systematic measures of quality on a plant-by-plant basis that would permit a quantitative assessment of quality among various plants, or an assessment of a plant's quality over time. GAO also noted that FSIS did not appear to have the objective information to assure the quality of an inspector's performance or to assess how well inspectors were following procedures. GAO emphasized that it was particularly important for FSIS to have a means to measure (1) the quality of the plants being inspected at key points during slaughtering and processing operations and (2) the quality of the work performed by inspectors.

Internal Controls: Program to Address Problem Meat and Poultry Plants Needs Improvement (GAO/RCED-89-55, Mar. 31, 1989)

GAO reviewed FSIS' Intensified Regulatory Enforcement (IRE) program for problem meat and poultry plants that chronically violate requirements for health, safety, and product standards. GAO reported that FSIS could not ensure that all problem plants were being identified and considered for IRE because it did not have an adequate method to identify the universe of potential IRE candidates. GAO also noted that FSIS did not have a systematic method of analyzing plant conditions to determine if they had worsened when plants were removed from the IRE program. GAO recommended that the Secretary of Agriculture direct the FSIS Administrator to develop and implement criteria for placing plants in the IRE program and a data information system based on these criteria that profiles all plants inspected.

USDA OFFICE OF INSPECTOR GENERAL REPORTFood Safety and Inspection Service Meat and Poultry Inspection Program, Audit Report No. 38607-1-At, Sept. 26, 1986

The USDA Office of Inspector General (OIG) evaluated FSIS management of the meat and poultry inspection program. During the audit, OIG staff visited 132 federally inspected meat and poultry plants. The OIG found that, generally, FSIS had been effective in fulfilling its mission of ensuring that the nation's meat and poultry supply was wholesome and unadulterated. However, the OIG identified areas of concern that it said needed attention by FSIS management, including two areas to be addressed through legislative changes. The OIG reported that it believed that FSIS needed additional authority to impose appropriate and meaningful "middle-ground" sanctions in instances where educational efforts failed to bring about voluntary compliance but violations were not severe enough to justify criminal prosecution or judicial seizure. Additionally, the OIG stated that the legislative requirement for continuous inspection in all federally inspected meat and poultry plants, regardless of the degree of risk present, had limited FSIS' ability to maximize the effectiveness of inspection efforts.

The OIG reported that FSIS did not have the flexibility to use its resources in ways that maximize the effectiveness of inspection efforts. Existing legislation required FSIS to provide continuous inspection in all federally inspected meat and poultry plants, regardless of FSIS' assessment of the degree of risk associated with the establishment or its operations. As a result, the agency could not effectively use advanced technologies or other innovative approaches that could streamline the inspection process while continuing to provide assurance that the nation's meat and poultry

supply was wholesome and safe. The OIG stated that, with a risk-based, statistical approach to the inspection process, FSIS could maintain or increase the current level of consumer protection and be in a better position to effectively respond to potential budget reductions.

The OIG's report noted that 18 small processing plants included in its review, with individual production of less than 14 million pounds annually, had simple operations--operations limited to the cutting, grinding, and repackaging of previously federally inspected products and the assembly of these products into meals, pizzas, or other consumer items not requiring the addition of restricted substances, such as sodium nitrate.

The report concluded that implementation of risk-based intermittent inspection in plants of this type would have little impact on the degree of health risk associated with processed meat and poultry products. The handling of these products is generally the same as in retail grocery stores and butcher shops. Most retail operations are exempt from the provisions of the Federal Meat Inspection Act and Poultry Products Inspection Act. The report noted that although small plants like these with simple operations were responsible for the production of only about 4 billion pounds, or 4.7 percent, of the 1984 national production of processed meat and poultry products, they required about 615 staff years, or almost 30 percent, of total processing inspector time.

STUDIES BY A CONSULTING FIRM AND A SCIENTIFIC ORGANIZATION

Study of the Federal Meat and Poultry Inspection System, Booz, Allen, and Hamilton, Inc., June 1977

This study's purpose was to identify alternative inspection systems that would improve cost-effectiveness, eliminate unnecessary interference in commerce, and still ensure that meat and poultry for human consumption was unadulterated and not misbranded.

The report concluded that several areas of the meat and poultry inspection operations and management, including inspection at processing plants, offered opportunities to improve cost-effectiveness. A monitoring approach to inspection at processing plants in which an inspector uses a firm's quality-control records, accompanied by frequent verification samples, was considered the best alternative to improve cost-effectiveness and consumer protection at processing plants.

The report recommended a mandatory system of quality control for processing plants, which would place the responsibility for compliance with inspection requirements squarely on industry's shoulders. The report envisioned a quality-control system that would embrace all areas of product flow, including incoming products, processing of products, and outgoing products.

According to the report, FSIS, industry, and consumers would all benefit from a system of inspectors monitoring in-plant quality control. FSIS would have greater staffing flexibility and would be able to cover more plants with the same number of inspectors. Industry and consumers would benefit, according to the study,



because quality-control programs would result in a more consistent product entering food channels and less throwaway at the plant.

The report concluded that an in-plant quality-control system must be accompanied by new enforcement tools. Economic deterrents were considered the most effective means to ensure compliance. The report recommended that FSIS devise a plant rating system tied to a progressive enforcement system that includes economic penalties, such as charging for extra inspection time spent in problem plants.

Meat and Poultry Inspection--The Scientific Basis of the Nation's Program, National Research Council, National Academy of Sciences, 1985

In 1983 FSIS asked the Food and Nutrition Board of the National Research Council to evaluate the scientific basis of the existing system for inspecting meat, poultry, and meat and poultry products. The Council concluded that FSIS had made progress in reducing risks to public health from conditions that can be observed during antemortem and postmortem inspection and that can be evaluated during processing. However, the Council also concluded that substantial challenges continued to confront the agency. It said that some aspects of the inspection system were poorly defined in terms of objectives relevant to public health, and it suggested that a risk-based allocation of resources, supported by modern technology and a systematic evaluation of the program, would be valuable.

According to the Council, it could not make an overall assessment of risks and benefits associated with new processing inspection procedures because it could find no comprehensive statement of criteria, no systematic accumulation of data, and no

complete technical analysis of the hazards or benefits to human health in the traditional inspection program or as a consequence of the adoption of the new techniques.

Overall, the report recommended that the precepts of risk assessment (identification of the problem, exposure assessment, hazard assessment, and quantitative health risk assessment) be systematically embodied in the planning and evaluation of all phases of meat and poultry inspection, and that risk-assessment criteria be used regularly to assess consequences to public health of any modifications in the inspection process.

The report identified the characteristics of an optimal meat and poultry inspection program. One component of this optimal program is an inspection system with different levels of intensity, reflecting the degree of public health risk at various stages in the process, the reliability of the monitoring system, the compliance history of the slaughterhouse or processing plant, and the special needs of the intended consumer (for example, military personnel and school children).

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