**To all FSIS employees
who have worked so hard
successfully implementing HACCP**

Preface

This paper presents results from an evaluation of one phase of implementation of the *Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems;* (PR/HACCP) final rule. The Food Safety and Inspection Service (FSIS) took a significant step toward redefining its role as a food safety agency and industry's role as a safe food producer with the publication of this final rule. This clarification of responsibilities resulted in many changes in inspection policies and practices and posed significant challenges to the Agency and the meat and poultry industry. This report integrates the thoughts of many individuals involved in the various activities related to implementing HACCP-based inspection in meat and poultry plants. The purpose of this report is to provide information to the Agency and its employees to facilitate implementation of other phases of the final rule.

The report's format is designed to provide a road map of the needed changes in all major areas to program managers, training developers, field and Headquarters supervisors, compliance officers, as well as front-line Inspectors. Each chapter is written to highlight feedback that was gathered during the data collection effort from many sources. The emphasis is on identifying significant issues of concern and suggestions for modification to facilitate implementation in small and very small plants.

Although this report's purpose is not to praise all of the accomplishments of FSIS and industry personnel, it is befitting to acknowledge the efforts of the dedicated FSIS employees at all levels who have been responsible for ushering in a HACCP-based meat and poultry inspection program. Each Agency employee has had an important role in making HACCP-based inspection a reality and should be commended for their hard work.

It is also important to recognize the accomplishments of the Agency as a whole in facilitating the implementation of the *Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems;* (PR/HACCP) final rule. As the anticipated publication date of the final rule moved closer, FSIS began to reinvent itself and its inspection program. The Agency, in particular Office of Field Operations (OFO), has worked very hard to provide its employees with the necessary training and support to successfully manage the many changes brought about by the publication of the PR/HACCP regulation. To date, the Agency has conducted a number of activities and established support services for its employees and the meat and poultry industry to facilitate implementation that merit acknowledgement.

Office of Field Operations launched a massive training effort in October 1996 to prepare for implementing Sanitation Standard Operating Procedures (SSOPs) in all plants, the first requirement of the final rule. Approximately 4,400 Inspectors, supervisors, and compliance personnel were trained in the new procedures related to SSOP implementation. The following year, a training program was designed and presented to approximately 2,400 inspection and compliance personnel working in over 300 large plants that were required to have operating HACCP plans by January 1998. Planning for each of these training programs was a monumental task especially since policies were being developed during the planning stage. It was an even greater endeavor because the design and preparation of training materials were completed under very tight timelines.

One of the greatest challenges and accomplishments for FSIS was to train employees on the culture change aspect that accompanied the implementation of the PR/HACCP final rule. The generally accepted timeframe for major organizational culture change to occur is three to five

years. In FSIS, as expected, the culture change that began with the publication of the final rule is still in progress. Guiding the inspection workforce into the new approaches, behaviors, and work patterns that must accompany the regulatory changes was, and will continue to be, a formidable task for the Agency during the transition to HACCP-based inspection.

To ease the difficulties of introducing new requirements, policies, and subsequent culture change, the Agency provided a number of support services for its employees and the regulated industry. In particular, the Agency established the Technical Service Center (TSC) in Omaha, Nebraska. The TSC was set up as a central information source for employees and industry with technical questions regarding any aspect of inspection. Established within the TSC was a HACCP Hotline to answer employees' and industry's questions specifically related to HACCP implementation in large plants. Additionally, FSIS's Administrator initiated a series of weekly meetings with industry representatives to resolve issues concerning HACCP implementation. These resources were set up to improve communication and facilitate implementation for all parties.

As part of the Agency's strategy to gather data for well informed decision-making, a series of evaluations are planned for each phase of implementation.   An evaluation was conducted approximately six months after SSOPs were implemented, the initial implementation stage of the final rule. Results from the *SSOP Implementation Follow-up Study* were used by policymakers and trainers to improve the next stage of implementation. This paper presents information from a second evaluation of the implementation of HACCP in large plants, conducted to improve the next stages of implementing HACCP in small and very small plants.

The activities and initiatives described above are an abridged account of the tasks the Agency has accomplished to facilitate implementation since the PR/HACCP final rule was published. All of these activities were conducted at a time when the Agency was facing significant resource constraints as a result of restructuring its resources to maximize support for its front-line employees. Although challenges remain, evaluations such as the *SSOP Follow-up Study* and the one presented in this paper will provide recommendations for modifying future planned activities to strengthen the implementation effort while acknowledging the accomplishments already achieved.

We wish to express our appreciation to all the individuals who took time to be interviewed and hope that their thoughts are adequately reflected in this document.

Summary

On January 26, 1998, the Food Safety and Inspection Service implemented the first phase of the Hazard Analysis and Critical Control Point (HACCP) component of the *Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems;* (PR/HACCP) final rule. On that date, Phase One of HACCP Implementation commenced in all *large* plants that slaughter and/or process meat and poultry. These plants were required to have in place written and operating HACCP plans. Following implementation, this study was conducted to evaluate HACCP implementation activities in large plants and to identify modifications to facilitate the next phases of implementation.

Information was collected on many aspects of implementation – inspection, enforcement, training, technical support, and communications. Study results and recommendations are related to these aspects of implementation. A road map for categorizing this wealth of data is presented in the last chapter. The Four-Steps to successful continued implementation are also noted below.

Step One: Clarify Policy and Terms
    The following topics were mentioned most frequently as needing further clarity:
- HACCP systems concept and system inadequacy
- Trend indicators
- HACCP Procedures 01 and 02
- Pre-shipment review
- Zero tolerance

Step Two: Promote Basic Understanding of Key Concepts and their Practical Application
    Respondents emphasized the need to understand how their daily activities relate to new policies and procedures. This request presents, perhaps, the greatest challenge for the Agency – to translate the cultural change concepts to practical inspection and compliance activities. Hands-on training and the use of experience-based examples during training were identified as needed. The following types of training are essential:
- Introductory training
- Follow-up training
- Supervisory training

Step Three: Improve Communications Among FSIS Employees
    Respondents voiced complaints about the lack of current information being exchanged at all levels of the organization. The following communication mechanisms were mentioned as immediate priorities:
- Computer access for all HACCP-trained inspection personnel
- Work unit meetings for follow-up training and information exchange
- "buddy system" – include the Inspector-In-Charge (IIC) whenever a Compliance Officer meets with plant management

Step Four: Reinforce Essential Inspection Activities
    Four activities were mentioned by respondents as crucial to their success on the job:
- planning time and understanding of conducting plant awareness meetings
- understanding and successful implementation of using one Procedure Schedule
- GS-7 training
- Mechanism for tracking Noncompliance Records (NRs)

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Chapter I
INTRODUCTION

It is a bad plan that admits no modification.[1]

Purpose

In July 1996, FSIS published the *Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems;* (PR/HACCP) final rule[2]. Implementation of the final rule began on January 27, 1997. On that date, all inspected establishments were required to have in place written Sanitation Standard Operating Procedures (SSOPs). On January 26, 1998, Phase one of HACCP implementation commenced in all *large* plants that slaughter and/or process meat and poultry. On this date, these plants were required to have both written HACCP plans and operating HACCP systems.

This paper presents results from an evaluation of the first phase of HACCP implementation.[3] The purpose of this evaluation was to evaluate HACCP implementation activities in large plants and to identify modifications to facilitate implementation of HACCP in small and very small plants. The *Evaluation of Inspection Activities During Phase One of HACCP Implementation* addresses the following general questions:

- How are inspection personnel implementing the new inspection procedures?
- How is the enforcement program operating?
- How is PBIS working?
- How is training being applied in the field?
- How is industry's implementation of HACCP affecting inspection activities?
- How are supervisors carrying out their responsibilities?
- To what extent is the cultural change occurring with respect to inspection personnel and supervisors?
- How are the following staffs supporting HACCP implementation – the Technical Service Center, District Office, Headquarters?
- How are all parties communicating?

This evaluation follows a study conducted during the summer of 1997 that determined the extent SSOPs were implemented in all plants, the initial requirement of the final rule. Although the *SSOP Implementation Follow-up Study*[4] focused on inspection activities specifically related to the SSOP requirement of the final rule, general study questions were similar to those addressed

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[1] Publius Syrus, First Century B.C.

[2] 61FR 38806-38989; Thursday, July 25, 1996.

[3] The first phase of implementation required all large establishments (those with 500 or more employees) to have operating HACCP plans. The second implementation phase beginning January 25, 1999, requires small establishments (those with 10 or more employees but fewer than 500) to have operating HACCP plans. The third and final phase beginning January 25, 2000, requires very small establishments (those with fewer than 10 employees or annual sales of less than $2.5 million) to have operating HACCP plans.

[4] *Results of the SSOP Implementation Follow-up Study*, U.S. Department of Agriculture, Food Safety and Inspection Service, December 1997.

in this study. In addition to addressing the questions listed above, this study tracks changes that occurred since the SSOP study.

Evaluation is a major component of the Agency's strategy for implementing the PR/HACCP final rule. Four formative evaluations will be conducted, one after each major implementation stage of the final rule.[5] As stated above, an evaluation of the SSOP component is complete. This paper presents results from the second evaluation – *Evaluation of Inspection Activities During Phase One of HACCP Implementation*. Two other evaluations are planned following Phases Two and Three of HACCP Implementation. Results and recommendations from each formative evaluation will be used to improve planning, training, and implementation for each consecutive stage. Finally, once implementation of the final rule is complete, a summative evaluation[6] will be conducted by an independent contractor to evaluate the impact of the final rule on foodborne illness, industry, inspection, farm-to-table food safety and consumer confidence. This strategy comports fully with the recent General Accounting Office Study[7] that states:

> *Agency decision-makers need evaluative information about whether federal programs are working well or poorly, both to manage programs effectively and to help decide how to allocate limited federal resources.*

Background

To further the goal of reducing the risk of foodborne illness from meat and poultry products, FSIS issued the *Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems;* (PR/HACCP) final rule in July 1996. The PR/HACCP final rule provided a framework for a new approach to inspection. In contrast to the traditional command-and-control inspection approach for ensuring food product safety, HACCP-based inspection is a proactive strategy that anticipates food safety hazards[8] in a process or practice and identifies the critical control points at which these hazards can be managed. With the implementation of this rule, FSIS requires establishments to take preventive and corrective measures at each stage of the food production process where food safety hazards are reasonably likely to occur.

The HACCP system is a process control system designed to identify, prevent, or control microbial and other hazards in food production. It includes steps designed to prevent problems before they occur and to correct deviations as soon as they are detected. Establishments are required to develop HACCP plans based on the seven principles articulated by the National Advisory Committee on Microbiological Criteria for Foods

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[5] Formative evaluation provides evaluation results and recommendations to policymakers during program implementation to improve the program in its early stages before it is fully implemented.

[6] Summative evaluation summarizes evaluation results after program implementation is complete. It is designed to assess the impact of the program, usually for accountability to external audiences such as Congress, industry, or the public.

[7] *Program Evaluation: Agencies Challenged by New Demand for Information on Program Results*, General Accounting Office, April 1998.

[8] Food safety hazards include biological, including microbial, chemical, and physical hazards.

(NACMCF)[9]. The seven HACCP principles recommended by NACMCF in 1992 provide the framework for the PR/HACCP final rule. While the seven principles are not explicitly listed as such in the regulation they are embodied in the regulatory requirements of 9CFR Part 417. The seven principles, as revised by NACMCF on August 14, 1997[10], appear below:

1. Conduct a hazard analysis.
2. Determine the critical control points.[11]
3. Establish critical limits.[12]
4. Establish monitoring procedures.
5. Establish corrective actions.
6. Establish verification procedures.
7. Establish record keeping and documentation procedures.

Each meat or poultry product produced in large plants must be covered by a HACCP plan. Each HACCP plan must be validated by the establishment to determine that it effectively prevents hazards in the production process.

In addition to requiring the development of HACCP plans, the final rule included a number of requirements focusing on pathogen reduction in meat and poultry products. All establishments that slaughter animals or ship raw ground product are required to meet pathogen reduction performance standards for *Salmonella*. The purpose of the *Salmonella* performance standards is to provide incentives for producers of raw meat and poultry products to reduce the prevalence of *Salmonella* on their products, and to provide an objective basis for judging the effectiveness of establishments' HACCP plans by both FSIS and establishments. All slaughter establishments are further required to implement generic *E. coli* testing programs. This microbial testing by slaughter establishments is useful to verify the adequacy of the establishment's process controls for the prevention and removal of fecal contamination and associated bacteria.

Also under the HACCP regulations, critical control points to eliminate contamination with visible fecal material are essential components of all slaughter establishments' HACCP plans. Initial validation of a HACCP plan requires verifying the documentation in establishment records and demonstrating the effective continuous operation of the plan's controls. These three components -- valid HACCP systems assuring compliance with the food safety standards, such as zero fecal contamination; compliance with *Salmonella* performance standards[13] by establishments that slaughter or ship raw ground product; and generic *E. coli* testing programs

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[9] NACMCF was established in April 1988 as a result of a recommendation by the National Academy of Sciences. NACMCF provides advice and recommendations to the Secretaries of Agriculture and Health and Human Services concerning microbiological and epidemiological aspects of food safety and foodborne diseases and provides specific information to the Departments of Defense and Commerce.

[10] Journal of Food Protection, Vol. 61, No. 6, 1998, Pages 762-775.

[11] A Critical Control Point (CCP) is a step in a manufacturing process where hazards can be introduced and therefore must be monitored to either prevent hazards or take corrective action if hazards occur.

[12] Critical limits must be met at each CCP and be designed to ensure all applicable regulations, targets, or performance standards established by FSIS are met.

[13] Discussion about *Salmonella* testing and generic *E. coli* performance standards is included as background information only. Due to time constraints necessary to complete this study in a timely manner, the report presents feedback on HACCP-based inspection and enforcement activities during HACCP implementation in large plants. The pathogen reduction programs, *Salmonella* performance standards and generic *E. coli* criteria, are not specifically addressed.

conducted by slaughter establishments -- provide an integrated approach to process control and pathogen reduction.

To allow establishments time to adequately prepare for necessary changes to their production processes, requirements of the final rule were implemented in stages. The initial stage was implemented on January 27, 1997. On that date, all establishments were required to have in place written Sanitation Standard Operating Procedures (SSOPs) to ensure they are meeting their responsibility to keep their facilities and equipment clean. Additionally, slaughter establishments were required to perform generic *E. coli* process control testing.

The next three stages scheduled HACCP implementation by plant size. Phase One of HACCP Implementation began on January 26, 1998. On that date, large establishments were required by regulations to have in place written and operative HACCP plans and to begin meeting *Salmonella* pathogen reduction performance standards. During the next two consecutive years, small plants and very small plants, respectively, will be bound to the same requirements.

Implementation of HACCP clarifies the responsibility of industry and FSIS. FSIS's main role is to set appropriate food safety standards and maintain vigorous inspection oversight and verification to help ensure that those standards are met. Industry is required to monitor and verify the performance of the controls in their HACCP plans, and maintain records of this monitoring and verification. Slaughter establishments are responsible for implementing generic *E. coli* testing programs to verify the adequacy of their process controls for the prevention and removal of fecal contamination and associated bacteria.

As a result of this clarification of responsibility, FSIS inspection personnel perform new inspection procedures to verify a HACCP plan's basic compliance with regulatory requirements, the effectiveness of an establishment's HACCP plan(s), and whether the establishment meets pathogen reduction standards. An Inspector verifies a HACCP plan by determining through review and observation and review of records whether the establishment has properly implemented its HACCP plan and met other regulatory requirements. If regulatory requirements are not met or an establishment fails to maintain its control systems properly, the noncompliance is documented and, as needed, appropriate regulatory action is taken. Additionally, inspection personnel conduct *Salmonella* sampling in establishments that slaughter animals or ship raw ground product. These samples detect whether an establishment is meeting pathogen reduction performance standards and determine whether corrective action by the plant or regulatory action by FSIS is warranted to help ensure those standards are met.

The introduction of new inspection regulatory requirements and procedures summarized above posed significant challenges to the inspection workforce. FSIS initiated several activities to help overcome those challenges. To prepare inspection personnel to regulate HACCP in large plants, FSIS provided an Introductory HACCP Technical Training Program for Inspectors, compliance personnel, District Office personnel, and field supervisors and managers. This training was delivered by trained facilitators who presented a video-based program instructing participants about the new procedures required for inspecting establishments operating HACCP systems. Training sessions were conducted from November 1997 through January 1998.

Another activity that was undertaken by the Agency to prepare for Phase One implementation was to update the Performance Based Inspection System (PBIS)[14] to reflect changes in inspection procedures (see Appendix A). The first step was to develop an Inspection Systems Procedures (ISP) guide.[15] The ISP Guide provides the in-plant procedures that the Agency currently views as appropriate in enforcing HACCP-based regulatory requirements and administering inspection mandates. Second, the automated system of PBIS was redesigned to reflect changes in the ISP and generate schedules for in-plant procedures and to create reports based on data entered into the system.

In addition to providing technical training for its inspection personnel and updating PBIS, the Agency established the Technical Service Center (TSC) in Omaha, Nebraska. The TSC was set up as a central information source for employees and industry to answer technical questions regarding any aspect of inspection. Also established was a HACCP Hotline to answer employees' and industry's questions specifically related to Phase One implementation. These resources were set up to address the need for accurate and consistent distribution of information, correlate the execution of inspection procedures and requirements, and lead the implementation of new and modified inspection programs and procedures.

This evaluation study, which began four months after Phase One implementation, was initiated to review HACCP implementation activities in large plants to improve the next stage of implementation in small plants. Additionally, this evaluation tracks the extent to which Agency employees have settled into their new roles, behaviors, and work patterns by comparing some of this study's results to those documented in the *SSOP Implementation Follow-up Study* conducted in 1997, during the initial implementation of the final rule.

Methodology

A team of Agency employees was assembled to design and conduct this evaluation. The team consisted of a Core Team, data collectors, and support staff (see Appendix B). The team was committed to designing, conducting, and completing this study in six months - January through July 1998 - so that information and recommendations included in the report could be used by policy makers and trainers to plan the next phase of HACCP implementation for small plants. This tight timeframe presented logistical challenges that resulted in the following decisions.

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[14] PBIS is designed to schedule inspection activities, record inspection findings, and take corrective action when noncompliance of the regulations is determined as documented by FSIS Directive 8800.1, June 29, 1995. The automated system of PBIS schedules work to be done by inspection personnel during each shift in meat and poultry establishments. It incorporates inspection findings into a central database and creates reports from the database that are used to support supervisory and management decision making.

[15] FSIS Directive 5400.5, Inspection Systems Activities.

First, a judgmental sample[16] was used to collect data from numerous sources described below. Second, data collection was limited to three weeks. Third, a research method known as triangulation[17] was used to strengthen the findings. This methodology relies on a synthesis of data from a variety of sources to present the most valid picture. No one source is taken as the truth.

Abiding by the method of triangulation, the team used a variety of data collection methods to address study questions including personal interviews, records examination (including a review of PBIS data[18]), and minutes from weekly meetings between industry representatives and FSIS's Administrator. Personal interviews with the inspection and compliance workforce and Headquarters management officials were conducted to receive first-hand information about Phase One of HACCP implementation. The records examination determined the accuracy and completeness of information included on Noncompliance Records (NRs)[19] and whether establishments' HACCP plans met basic regulatory requirements.[20] Minutes from weekly meetings between industry representatives and FSIS's Administrator and senior management officials were reviewed to obtain industry feedback concerning Phase One implementation.

This report reflects the synthesis of information collected throughout this study. Prior to writing this report, data collected from all sources –field interviews, records examinations, Headquarter interviews, several data analysis sessions with the evaluation team, and follow-up interviews-- were reviewed and discussed. When inconsistencies appeared, the evaluation team debated the reasons, explored possible explanations, reviewed the information from all sources, and when necessary followed up with additional interviews.

➢ *Personal interviews*

Interviews were conducted with four main groups of FSIS employees: key senior-level managers who assisted in drafting and implementing the PR/HACCP final rule and accompanying regulations; District Office personnel in District Offices[21] with HACCP plants; FSIS inspection

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[16] Judgment sampling involves drawing a sample based on expert choice or best guess. *Evaluation Counts,* Davis, B. and Humphreys, S., National Science Foundation, 1983.

[17] Originally the procedure used by surveyors to locate ("fix") a point on a grid. In evaluation, or scientific research in general, it refers to the attempt to get a fix on a phenomenon by approaching it from more than one independently based route. Triangulation provides "redundant" (really confirmatory) measurement (*Evaluation Thesaurus,* Scriven, M. and Roth, J., 1977, Edge Press).

[18] National summary of PBIS data for the ten-week period (January 26 through April 4, 1998) during HACCP implementation in large plants.

[19] Noncompliance Records (NRs) are official records of noncompliances observed by FSIS inspection personnel in establishments. NRs document each noncompliance observed and corrective actions taken by the establishment. Noncompliances are categorized on each NR using a trend indicator that documents trends in noncompliance.

[20] The purpose of on-site visits was to collect information about the implementation of the HACCP component of the final rule in large plants. Visits were not intended to be plant reviews or reviews of FSIS employees. However, teams were obligated to report to the project manager any conditions or situations observed which could cause a public health hazard, and to report any situation in which HACCP plans did not appear to meet regulatory requirements. These instances were referred to the appropriate District Manager and handled on a case by case basis.

[21] FSIS field workforce is divided nationally into 18 districts, each covering a set of specified states. Each district is further divided into circuits made up of a set of meat, poultry, and egg products establishments. Data was not collected from the Albany district because it had no operating HACCP plant.

and enforcement personnel in a sample of establishments; and facilitators of the introductory HACCP technical training program. Questionnaires were developed for each group to solicit their input on a number of different implementation issues. In total, 267 employees were interviewed.

A total of 12 senior-level managers were interviewed at Headquarters. These managers were asked questions concerning implementation of the final rule and how to improve HACCP implementation for small and very small plants based on their experience with Phase One implementation. These interviews were conducted by non-bargaining unit members of the Core Team.

Interviews were also conducted with 14 District Managers/Deputy District Managers, 20 Compliance Officers and Assistant District Managers for Enforcement (ADMEs), and 12 Processing Inspection Coordinators (PICS)/HACCP Coordinators at 17 district offices. These interviews were conducted by bargaining[22] and non-bargaining unit members of the Core Team. Additionally, 74 HACCP Facilitators were interviewed via the Agency's electronic mail system. Questions for District Office personnel and HACCP Facilitators focused on training and technical support and enforcement activities.

The majority of interviews were conducted with all levels of FSIS inspection personnel including 23 Circuit Supervisors, 36 supervisory Inspectors-in-Charge (IICs), and 76 Field Inspectors and non-supervisory IICs (GS-8s and above). Interviews were not conducted with GS-7s because they are not trained in HACCP. The sample of respondents was drawn from approximately 30 establishments which included both red meat and poultry, various types of facilities (i.e. processing, slaughter, or combination) and various processing categories (i.e. ground raw product, thermally processed, fully cooked, etc.). The sample also included establishments where enforcement actions have been taken, to assure that all steps of the regulatory process were reflected in the data collection activity.

Inspection personnel were asked questions concerning training and technical support, work assignments, noncompliance records, enforcement activities, and PBIS. Eight teams were formed to conduct interviews with inspection personnel. Each interview team consisted of two persons – a management representative, and a bargaining unit representative designated by the Council Presidents of the National Joint Council of Food Inspection Locals (NJC). Both team members participated in all interviews.

At each establishment, an effort was made to conduct interviews with all non-supervisory (GS-8 and above) and supervisory inspection personnel assigned to that establishment on both day and night shifts who perform HACCP inspection procedures. The appropriate local employee representative was invited to attend each bargaining unit employee interview. All bargaining unit employee interviews were voluntary.

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[22] Non-supervisory Food Inspectors are covered by a collective bargaining unit agreement with the National Joint Council of Food Inspection Locals (NJC).

➢ *Records examination*

In the sample of eight plants visited for interviews, a three-person team completed a records examination. The records examination consisted of the team obtaining and reviewing the establishment's HACCP plan(s) and answering a number of questions about whether the plan reflected the basic regulatory requirements. Also, the team randomly selected a minimum of 5-10 of the most current NRs, made an overall assessment of NRs in the closed file and then provided a summary judgement of all NRs. PBIS data was also examined.

➢ *Minutes from weekly meetings between industry representatives and FSIS's Administrator*

FSIS's Administrator, with the senior level management team, conducts weekly meetings with representatives from industry to resolve issues regarding implementation. The meetings provide a forum to cover a broad range of issues regarding inspection and enforcement policy, technical inspection concerns, due process questions and enforcement matters. Minutes from these meetings were reviewed to obtain industry's perspective on HACCP implementation.

Report Plan

This report contains six chapters. Chapters two through five present issues related to the main elements of Phase One HACCP implementation – new inspection procedures, enforcement procedures, introductory HACCP technical training, and on-going technical support, follow-up training and communication activities – and each concludes with a list of short-term and long-term recommendations. Short-term recommendations are those that can be implemented *before* Phase Two implementation on January 25, 1999. Long-term recommendations require more time and would be implemented *after* Phase Two implementation begins. In addition, the office(s) of primary responsibility for carrying out each recommendation is noted. Chapter six concludes the report with a road map for categorizing the wealth of information included in the previous chapters and presents Four-Steps to successful continued implementation of the final rule.

Chapter II
HACCP-based Inspection Procedures

The difficulty lies not in forming
"new ideas, but in escaping from the old ones."[23]

Preface

This chapter addresses the wide range of issues related to the implementation of new inspection procedures. Special focus is given to how inspection personnel and all levels of supervision are functioning in this new arena. These issues deal with all HACCP-related inspection activities in conjunction with FSIS personnel assigned to large establishments.

This chapter focuses on the HACCP aspects of the final rule and provides information related to verification of the implementation of different components of the regulation. Feedback related to those components will be discussed. The chapter concludes with specific recommendations that are grouped by chapter sections for easy reference to supporting text.

Background

To reduce the occurrence and number of pathogenic microorganisms on meat and poultry products, FSIS published the PR/HACCP final rule. This and corresponding regulations represent a fundamental shift in FSIS's regulatory philosophy from command-and-control to performance standards[24] for industry accountability. The philosophy also shifts inspection methodology to a "systems approach" rather than being task specific. Industry is being required by the regulation to develop HAACP plans for controlling food safety hazards that can affect their products. These plans delineate a process control system for that establishment's particular operation(s). If the plans they design are effective in eliminating food safety hazards, and if the establishment executes the plan's design properly, including taking corrective action when appropriate, then the resulting product should be safe for the consumer. Instead of FSIS determining the means by which establishments will meet their responsibility to produce safe, wholesome, and properly labeled products, FSIS sets performance standards that establishments must meet. Inspection's role is one of regulatory oversight. FSIS relies less on after-the-fact detection of product and process defects and more on verifying the effectiveness of the process control system designed to ensure food safety.

With the "systems approach" to inspection, the Agency published FSIS Directives 5400.5 and 5000.1 which contain the new inspection procedures that are being used in establishments under the PR/HACCP regulation. These are the implementing directives for verification of Parts 416 and 417 of the regulations[25]. Many changes in inspection practices are required because of

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[23] John Maynard Keynes, 1936.
[24] Performance standards tell establishments what degree of effectiveness their HACCP plans will be expected to achieve and provide a necessary tool of accountability for achieving acceptable food safety performance.
[25] 9 CFR 416, Sanitation Standard Operating Procedures; part 417, HACCP System Regulations.

policy changes. To assist inspection personnel in carrying out these changes, a plant awareness process was established which familiarizes inspection personnel with the HACCP plan and supporting documentation. In addition, Basic and Other Compliance procedures were established for defining the general categories of in-plant inspection work.

Plant Awareness Meetings

When Phase One implementation was initiated, large plants were required to develop written HACCP plans and procedures that included provisions for meeting all regulatory requirements for the types of products produced. Since HACCP plans are plant-specific, inspection personnel need to understand the establishment's HACCP plan(s) to effectively perform HACCP procedures. This activity is called the "plant awareness process" and is accomplished by conducting a plant awareness meeting.

A plant awareness meeting is conducted when a plant initiates a HACCP-based inspection program. The amount of time required for the meeting will vary according to the plant size and complexity, and scope of the plan(s). The Inspector-in-Charge (IIC) is responsible for planning and conducting the meeting. The IIC has the option of reviewing an establishment's HACCP plan(s) before holding the awareness meeting. This review helps the IIC estimate how much time will be needed. All HACCP trained inspection personnel should attend the meeting. The plant awareness meeting should cover the following topics: plant monitoring, plant verification, plant record keeping, plant pre-shipment review procedures[26], plant corrective actions, and plant validation[27]. No determinations concerning the plant's regulatory compliance can be made until the plant awareness meeting has been completed.

Supervisory IICs and Field Inspectors/non-supervisory IICs were asked to rate the effectiveness of the awareness meeting in helping them understand specific parts of the establishment's HACCP plan. Respondents felt the meeting was particularly effective in helping them identify critical control points, critical limits, and the location of the plant's records. Respondents felt the meeting was least effective in helping them understand pre-shipment reviews and corrective actions. All respondents expressed both the importance of plant awareness meetings and requested additional guidance in conducting the meetings. They also stated the necessity for all industry and HACCP-trained inspection personnel to be present.

The majority of Field Inspectors and non-supervisory IICs interviewed said they had attended the plant awareness meeting. However, several respondents implied they had attended only parts of the meeting and would like to have been included in the entire meeting. Others indicated they were not given an opportunity to attend the meeting. When those who had not attended were

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[26]9 CFR 417.5, Records, requires that prior to shipping the product, the establishment shall review the records associated with the production of that product to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. The pre-shipment review is verified using the HACCP 02 procedure.
[27] Validation of a HACCPP plan is the process by which an establishment demonstrates that what is written in the HACCP plan and implemented in the establishment actually prevents, eliminates, or reduces to a regulated and commercially feasible and appropriate level, identified microbial, chemical, and physical hazards. Validation is exclusively the responsibility of the regulated industry, 9 CFR 417.4, Validation, Verification, Reassessment.

asked to explain why, responses included: being told it was not necessary, being in HACCP training, and being a relief Inspector. Some Inspectors stated they were on the slaughter line and therefore could not attend the plant awareness meeting. Some second shift personnel were also excluded in some instances. These findings coincide with results from a survey of industry employees conducted by the American Meat Institute (AMI) and the National Turkey Federation (NTF)[28]. Industry employees reported that FSIS second shift, relief, or GS-7 personnel were not included in approximately one-third of the plant awareness meetings.

Although the length of time for the plant awareness meeting was expected to vary according to the plant size and complexity and scope of plan(s), the majority of respondents, including supervisory IICs, stated that they participated in the meeting less than four hours. Again, the AMI/NTF survey revealed similar findings. Industry employee respondents stated that the majority of plant awareness meetings lasted four hours or less, irrespective of the number of HACCP plans. This amount of time is significantly less than the general time allocation guidelines of one to four *days* presented during the Introductory HACCP Technical Training Program. This raises concerns about the amount of information conveyed during the plant awareness meeting because the amount of time spent at the meeting reflects directly on the success of implementation. In general, Phase One implementation was smoother and more successful in plants where a longer amount of time was spent in the plant awareness meeting. The variation in attendance and length of plant awareness meetings may have resulted from having the IIC determine, based upon the plant's HACCP plan(s), how long the meeting should be and who should attend. No additional guidance was given to the IIC concerning planning this meeting which is essential for understanding the establishment's HACCP plan(s) and therefore performing the inspection procedures. Respondents were asked to provide recommendations for improving the plant awareness meeting. Suggestions for improving the effectiveness of the plant awareness meeting are listed below. Similar recommendations were also voiced by industry personnel responding to Industry's Survey of HACCP Implementation.

- ensure participants have HACCP training prior to the meeting
- conduct more than one meeting if changes are made to the plant's HACCP plan(s)
- invite *all* pertinent plant management personnel and inspection personnel
- allow the IIC to run the meeting instead of the Circuit Supervisor
- schedule more time between plant awareness meeting and implementation so the plan(s) can be better understood
- ensure the availability of the HACCP plan(s) prior to the meeting.

The importance of the plant awareness meeting should be emphasized both during training and subsequently by field supervisors. Inspection personnel should be aware that the plant awareness process should be a continuing process whereby they keep the lines of communication open with plant employees concerning the content of the establishment's HACCP plan(s). The plant awareness process should continue until all essential information is conveyed and should reoccur whenever a change is made to a HACCP plan(s). An actual workshop or scenario might be warranted in the training to provide a better understanding of the expectations of the plant

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[28] Industry's Survey of HACCP Implementation. American Meat Institute and the National Turkey Federation conducted a survey from May to June 1998 of all plants that were required to implement HACCP. Approximately 100 plants (30%) responded.

awareness process. Additionally, Office of Field Operations (OFO) management needs to provide adequate time in inspection personnel's work assignments to accomplish the plant awareness process. Specific recommendations are listed in the last section of this chapter.

HACCP Plans and Procedures

➢ *Basic Compliance*

After completion of the plant awareness meeting, inspection personnel perform a basic compliance check[29] to determine if the plant's HACCP plan(s) and procedures meet regulatory requirements. Inspection personnel conduct an unscheduled procedure using the HACCP Systems-Basic Compliance Checklist[30], FSIS Form 5000-1 (see Appendix C), to accomplish this procedure initially and subsequently whenever a change is made to a HACCP plan. If a plant has more than one HACCP plan, inspection personnel use the checklist and perform the procedure for each plan. Respondents who have used the Basic Checklist requested additional training through the use of improved workshops that include realistic scenarios.

Part of basic compliance is conducting a hazard analysis to identify points at which a food safety hazard is "reasonably likely to occur" and then establish a CCP to monitor prevention of the hazard's occurrence. The Agency's stance of a required CCP in slaughter establishments to meet the regulatory requirements of zero tolerance for fecal contamination raised a number of industry concerns which were voiced at the weekly industry meetings with FSIS's Administrator (the Agency's written clarification of zero tolerance is discussed in the Communications section of Chapter V). Industry views zero tolerance as a regulation without scientific basis, quoting situations where fecal matter was swabbed and cultured with negative results for generic *E.coli*. Industry also views the requirement of a CCP for zero tolerance at a certain stage in the slaughter process as a return to command-and-control inspection, which is contrary to the new inspection philosophy. Industry voiced concerns that other contamination is being considered fecal, and zero tolerance is being applied to things that are not relevant to zero tolerance, such as a little black dot, condensation, or a speck of something. Confusion in understanding and implementing zero tolerance regulatory requirements was also evident among inspection personnel.

To complement the interview questions on Basic Compliance, a records review team examined a sample of twelve HACCP plans in eight establishments. The HACCP plans represented six of the nine processing categories. The data collectors were uncertain[31] all basic requirements had been met in two of the eight establishments. The most often mentioned concern was the failure to address measures to prevent noncompliance recurrence. Other concerns were missing signatures, initials or dates, HACCP plans in slaughter establishments that allowed a certain

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[29] HACCP Inspection Procedure 03A01, Basic Compliance Check.
[30] FSIS Directive 5000.1, Enforcement of Regulatory Requirements in Establishments Subject to the HACCP System Regulations, November 21, 1997.
[31] The team did not determine if the plan met the basic regulatory requirements. Instead, they used the Basic Compliance Checklist to identify areas in which they questioned whether the plan met the basic regulatory requirements. For purposes of this report, this circumstance was designated as being "uncertain."

number of fecal contaminated carcasses before taking action, and product names not listed that were included in a HACCP plan.

Field Inspectors were interviewed regarding the availability and completeness of HACCP plans and records. It is a regulatory requirement that HACCP plan(s) and records be readily accessible to inspection personnel when making determinations whether the establishment is following their plan. Although most of the HACCP plans and HACCP records were available within a realistic time frame, this situation was not always the case. Some inspectors commented that since HACCP records reflect a continuous process, these records should be available on a continuous basis. There is a concern that giving plants time to respond to a request for records invites the opportunity for altering records. This is an area that needs to be reinforced to inspection personnel by the immediate supervisor with support from the Circuit Supervisor.

➢ *Other Compliance*

Once inspection personnel determine whether the HACCP plan(s) meets the regulatory requirements through the Basic Compliance Checklist, FSIS inspection personnel are responsible for determining if the execution of the HACCP plans meet the five regulatory features:

- monitoring
- verification
- record keeping
- corrective actions
- reassessment

01 and 02 Procedures. To make determinations concerning these five features, inspectors perform *either* a procedure (01) to review a random sample of the regulatory features in operation *or* another procedure (02) that looks at the entire production process of a specific product. When performing the 01 procedure and finding a noncompliance, inspection program personnel should further verify whether the HACCP plan prevented adulterated product from being shipped. To make such a verification, inspection program personnel perform an 02 procedure. The 02 procedure focuses on the *system* in operation by making determinations about whether the establishment is following the HACCP plan.

Interviewers asked supervisory and non-supervisory IICs to describe how they track a HACCP procedure from 01 to 02. Approximately three-fourths stated that when an 01 procedure identifies a failure, they perform an 02 on the entire production process, including the pre-shipment review. This response matches instructions given in training. However, approximately one-fourth of the responses indicated an incomplete understanding of how to track a HACCP noncompliance from 01 to 02. Inspectors expressed some confusion about the definitions and differences between 01 and 02 procedures. This confusion was caused for several reasons. In the old PBIS system, 01 tasks were records evaluations and the 02 tasks were "hands-on" tasks. Under HACCP, both the 01 and 02 procedures have records and "hands-on" components. Adding to this confusion is that the term "01" can also refer to the SSOP activity while "02" also refers to the HACCP activity. Further confusion may result since SSOP 01 procedures are performed differently from HACCP 01 procedures. When HACCP was implemented, the

regulatory requirements for SSOPs remained the same, but the directives and terminology changed. Inspection personnel assigned to large establishment have stopped using a previous directive[32] and the old PBIS terms, and have started using a different directive[33] and the new PBIS terminology[34]. Some inspection personnel seem to be unclear about exactly what constitutes an 01 procedure and an 02 procedure due to the new nomenclature and confusion with the HACCP "01" and "02" concepts. Inspectors also have difficulty making the distinction between recording product contamination under SSOP 01 and facilities 06 activities of the ISP.

The ambiguity related to the terms 01 and 02[35] necessitates a high degree of precision in communication to be understood. Writers of directives, training materials and other documents, trainers, and others involved in inspection activities need to be aware of the confusion and lack of understanding that now exists and work to correct the situation.

There was also concern expressed that inspection personnel mark an 02 procedure as having been "performed" on the procedure schedule before they have finished all of the procedure. Some inspection personnel expressed concern that this could be construed as falsification of records.

Both 01 and 02 procedures have a record keeping and a review and observation component. Almost all Inspectors interviewed had performed both the 01 and 02 procedures, including the record keeping and review and observation components. Respondents were asked to consider the 01 and 02 procedures and to estimate the percentage of record keeping components compared to the percentage of review and observation components they performed over the past month. Answers indicated that inspection personnel are using both the record keeping and review and observation components of the procedures at varying frequencies. There is no correct percentage

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[32] FSIS Directive 11,100.3, Evaluating, Verifying, and Enforcing a Sanitation Standard Operating Procedure, January 27,1997.

[33] FSIS Directive 5000.1 (Part Three), Enforcement of Regulatory Requirements in Establishments Subject to the HACCP System Regulation, November 21, 1997.

[34] FSIS Directive 5400.5, Inspection Systems Activities, November 21, 1997.

[35] The term 01 could mean any of the following: (1) the SSOP Activity, (2) the SSOP basic compliance check, (3) the SSOP pre-operational procedure: review of written procedures and completed plant records, (4) the SSOP operational sanitation procedure: review of written procedures and completed plant records, (5) the HACCP Basic Compliance procedure, (6) the random procedure of HACCP processes: includes records and observation check, (7) yield/shrink, labeling, or finished product standards procedure under 04 Economic/Wholesomeness Activity, (8) *E. coli* records checks only, scheduled actual economic, or scheduled actual residue sampling procedure under 05 Sampling Activity, or (9) export, custom exempt, facilities(plant),sewage, water(certificate check only), or pest/rodent procedure under 06 Other Requirements Activity.

The term 02 could mean any of the following: (1) the 02 Reserved (slaughter HACCP) Activity, (2) the SSOP pre-operational procedure: review of written procedures and observe activities, (3) the SSOP operational sanitation procedure: review of written procedures and observe activities, (4) the verify HACCP plan procedure, either as a scheduled procedure or after finding noncompliance while performing an HACCP 01 procedure, (5) the X-percent solution or the CN/grade labeling procedure under 04 Economic/Wholesomeness Activity, (6) the observe actual E-coli sampling by the plant, the directed actual economic (not scheduled by PBIS but by HQ) sampling, or the directed actual residue (not scheduled by PBIS but by HQ) sampling procedure under 05 Sampling Activity, or (7) the facilities(reprocessing, inspection areas only), sewage, water (observe equipment), or pest/rodent procedure under 06 Other Requirements Activity.

for performing the record keeping versus the review and observation component. This will be somewhat dependent on the plant's operations. It is important that inspection personnel incorporate both components into their inspection activities. In the past, inspection determinations were made primarily by on-site measurements or tests. As part of the overall culture change within the Agency, it is important that inspection personnel understand they can make inspection determinations that could result in further enforcement actions by reviewing establishment's records or observing the establishment implementing their program. It is not necessary for inspection personnel to take a measurement of their own for making enforcement determinations. This concept needs to be reinforced with inspection personnel including supervisors.

Corrective Action and Plan Reassessment. As stated earlier, establishments operating HACCP systems must meet five regulatory features including: 1) monitoring; 2) verification; 3) record keeping; 4) corrective action; and 5) plan reassessment. Inspection personnel verify that establishments meet those features. Because the establishment must continually conduct their own monitoring, verification, and record keeping activities, inspection personnel *routinely* verify that the establishment has met those three regulatory features. Almost all Inspectors interviewed had had an opportunity to verify the monitoring, verification and record keeping features.

Inspection personnel determine if the establishment has met the requirements for corrective action and plan reassessment features *only* when there is a specific reason. Reasons include deviations from critical limits, unforeseen hazards, or positive *Salmonella* results. When an establishment deviates from a critical limit, the regulations require very specific corrective actions be taken by that establishment in response to a deviation. These four requirements for corrective actions[36] are the following:

- the cause of the deviation will be identified and eliminated
- the CCP will be under control after the corrective action is taken
- measures to prevent recurrence are established
- no product that is injurious to health or otherwise adulterated enters commerce

Inspection personnel are required to verify that the corrective actions meet all four requirements when they or the plant find a deviation. All respondents who had verified corrective action had had an opportunity to determine if all four parts of the corrective action requirements had been met.

A plant may establish alternative corrective action procedures, such as critical limits that differ from regulatory requirements, if these limits are based on sound scientific data. When asked how prepared they were to address a situation where a plant had alternative corrective actions, such as different procedures or a critical limit that was outside the regulatory limits, inspection personnel expressed reservations and requested additional training about Agency policy and practices. Some respondents contacted the Technical Service Center to obtain technical information on a small number of alternative procedures. These respondents also experienced a degree of discomfort with alternative procedures and expressed need of additional support.

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[36] 9 CFR 417.3, Corrective Actions.

Finally, inspection personnel are expected to verify execution of an establishment's immediate and further planned actions due to noncompliance. Study findings showed industry was somewhat deficient in meeting "measures to prevent recurrences." Approximately one-half of the Field Inspectors and non-supervisory IICs who were interviewed stated the plants' immediate and/or further planned actions in response to NRs were at times inadequate. Plants often gave a weak response, which was not likely to correct the problem. Sometimes plants were slow to perform the corrective action, and a few plants reportedly never performed the corrective action. Industry also has expressed frustration in meeting the requirements for corrective action. One industry representative stated that plant managers do not understand corrective action and asked that the requirements be clarified in *Qs&As*, a communication vehicle used by FSIS to address common questions raised by FSIS personnel, industry, and others. A number of industry representatives voiced concerns about inadequate corrective action, stating that a corrective action that was adequate last week may "all of a sudden" be inadequate this week, and may lead Inspectors to withhold the mark of inspection.

Pre-shipment Reviews. Establishment officials are required to take responsibility for making sure their HACCP plan has been completely and appropriately applied in the production of product leaving the establishment. This requirement can be met by the establishment performing a record verification at any point after the completion of processing, but before shipping. Pre-shipment review is defined in Regulations 417.5, Records, as:

> *Prior to shipping the product, the establishment shall review the records associated with the production of that product,… to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product.*

In practice, "prior to shipping the product" has been interpreted to mean "prior to being sold in commerce." This interpretation by industry has resulted in a variety of pre-shipment practices and has caused confusion among inspection personnel regarding how to verify completion of this task. When Supervisory and non-supervisory IICs and Field Inspectors were asked how the establishment performed the pre-shipment reviews they described various methods: at the end of each hour, shift, or day, or on a continuous basis. In addition, several respondents mentioned that the plants performed pre-shipment reviews by checking computerized records or written documents, using bills of lading. A few respondents mentioned that the plants performed tests as well. Due to the loose interpretation of "prior to shipping", some respondents confirmed that the pre-shipment review is not completed before the product leaves the establishment. Concern was expressed about how to ensure pre-shipment reviews are meeting regulatory requirements when performed in so many different ways.

To ensure a thorough understanding of acceptable practices, additional clarification on pre-shipment review verification would be useful in introductory, follow-up, and supervisory training, as well as communications with industry. The training needs to be reinforced with both industry and field personnel. Office of Field Operation's supervisors must continue to work with inspection personnel in understanding and clarifying this requirement.

One Procedure Schedule

The allocation of work generated for each assignment is called the Procedure Schedule (PS). The Performance Based Inspection System (PBIS) is the automated system that schedules the work to be done by inspection personnel in meat and poultry establishments for each assignment. Appendix A contains a detailed description of PBIS[37]. Only one PS is issued per establishment, per shift. Therefore, when the IIC is working with two or more Inspectors, it is necessary to identify who is going to do what procedure(s). Assigning work to multiple Inspectors from one PS is new with Phase One implementation. Prior to HACCP implementation, schedules were issued to individual inspection personnel, and the IIC was *not* involved in assigning work. The change to one procedure schedule occurred to reflect the philosophy that work is assigned for an establishment rather than a person, based on what is required to inspect a facility.

Since only one PS is issued per establishment, the work assignment in multiple Inspector establishments is accomplished by the IIC and Inspectors jointly reviewing and identifying the work to be done. This joint process is stated as follows in a national agreement with the National Joint Council, "when there are two or more Inspectors assigned to the plant/shift, the IIC and Inspectors will jointly review the work to be done and decide who will do the work. Should agreement not be reached, the work will be assigned by the immediate supervisor."

The *Supervisory Guideline for Pathogen Reduction/HACCP Requirements*[38] also gives instructions to supervisors on assigning work. In general, inspection personnel who handle slaughter duties will continue to perform procedures associated with slaughter activities. Similarly, inspection personnel who perform processing duties will continue to perform procedures associated with processing activities. Once this has been determined, if there are two or more slaughter or processing Inspectors, the Inspectors themselves will determine who will do what procedures. If for any reason they are unable to do so, the IIC will personally assign the procedures.

To obtain information about this new activity, IICs and Field Inspectors were asked specific questions about how the new method for assigning procedures was working. When asked how HACCP duties are being determined, the most common response was that the IIC assigns processing procedures to processing Inspectors and slaughter procedures to slaughter Inspectors. Approximately one-half of Inspectors had not provided input to the IIC for work assignment purposes. The most common response for not providing input was that, as the supervisor, the IIC scheduled the work. At the time of this study, only a small percent of IICs interviewed had received the *Supervisory Guideline* that contains written instructions for determining work assignments.

Changing from multiple schedules per plant/shift to one has caused some concern for in-plant inspection personnel in the proper and equitable distribution of work assignments. These

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[37] For a detailed discussion of the policies, procedures, forms and restrictions for PBIS under HACCP, refer to FSIS Directive 5400.5 and 8800.2.

[38] United Stated Department of Agriculture, Food Safety and Inspection Service, Supervisory Guideline for the Pathogen Reduction HACCP Regulatory Requirements, 1998.

concerns are that only certain Inspectors are given certain procedures and that Inspectors have no input into the distribution of inspection procedures.

When asked if they saw a need for improvement in the use of the Procedure Schedules, the majority of respondents said yes. Only one-quarter of respondents thought it was practical to use one procedure schedule per shift for multiple Inspectors. Most felt that the use of one PS was impractical for the following reasons: confusion, physical distance between departments, and having multiple Inspectors performing the same procedures. Concern was expressed that many times the same procedure might be performed several times on the same shift by different Inspectors and only is recorded on the Procedure Schedule one time. Other study data suggest that in combination slaughter/processing assignments the use of one Procedure Schedule can be more difficult.

To address the confusion associated with one Procedure Schedule, a multi-prong approach is suggested; additional time and information need to be incorporated in both the HACCP introductory and follow-up training on the reason for one Procedure Schedule and field supervisors need to enforce the purpose and facilitate the application. One Procedure Schedule reflects the cultural change that needs to occur throughout the Agency. Inspection personnel need to learn to work as a team.

Inspection personnel also voiced complaints about the Procedure Schedule independent of whether there was one or more. Some stated non-applicable procedures were assigned to the establishment. Inspectors also found it difficult to find a problem encountered in the plant in the *Inspection Procedures Guide*. This might be due to the condensing of over 500 ISG tasks under the old inspection system to 48 procedures under the HACCP system. Inspectors expressed concern that the procedures are too general. Clarification is needed, particularly with the 04 and 06 procedure codes. In addition, inspectors expressed confusion of what code to use when performing an SSOP procedure and finding noncompliance that is direct product contamination. HACCP-based inspection has redefined the work of inspectors as delineated in FSIS Directive 5000.1 and 5400.5. The concerns expressed by inspectors reflect that follow-up training and assistance are needed to reinforce the procedural changes that occurred as a result of this redefinition.

PBIS Scheduling of Procedures

PBIS for plants under the PR/HACCP final rule (PBIS-HACCP) schedules procedures based on a set frequency, two 02 HACCP procedures for each 01 HACCP procedure. This frequency does not vary by the number of nonconformances found. Data gathered during the first ten weeks of HACCP implementation (January 26 through April 6, 1998) show that the automated system of PBIS is scheduling procedures as intended:

- Number of HACCP 01 procedures scheduled: 15,055
- Number of HACCP 02 procedures scheduled: 29,818

Inspectors were able to perform scheduled tasks almost 80 percent of the time. Based upon past experience with PBIS data, this level of performance of scheduled tasks is considered normal.

However under PBIS-HACCP, the reason(s) for the 20 percent not being performed is no longer recorded. Inspectors may not have been able to perform some scheduled procedures either because product or processes were not being produced on the day that the procedures were scheduled.

Analysis also showed approximately 60 percent of the inspection procedures performed were unscheduled by PBIS. For example under the HACCP Activity, 46 percent of all procedures performed were unscheduled. This may be explained because if a noncompliance is found during a scheduled random HACCP 01 procedure, an unscheduled HACCP 02 procedure is performed. Also, unfinished HACCP 02 procedures are completed as unscheduled. In addition, inspection personnel may be performing procedures of their own choosing, overriding the system.

Recommendations[39]

The recommendations identified in this chapter primarily focus on short-term suggestions. Recommendations focus on improving the plant awareness meeting and the use of one Procedure Schedule, and the need for clarification of zero tolerance and pre-shipment review policies.

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[39] Short-term recommendations are defined as those recommendations that this study identified as feasible to address before Phase Two HACCP implementation. Long-term recommendations are defined as those recommendations that require more time and resources than available prior to January 25, 1999 implementation.
Primary offices of responsibility: OFO-Office of Field Operations; OPPDE-Office of Policy, Program Development and Evaluation; DIO-District Inspection Operations; HRDS-Human Resources Development Staff; LMRS-Labor Management Relations Staff; OA-Office of the Administrator, TSC-Technical Service Center, DEO-District Enforcement Operations.

Recommendations	Primary Offices of Responsibility

SHORT-TERM

Plant Awareness Meetings
- Provide guidance for topics to cover.   OFO – DIO & TSC, HRDS
- Reinforce guidelines: OFO – DIO & TSC, HRDS
    - Length of meeting
    - Attendees (industry & FSIS)
    - Topics – Chairperson (IIC or CS)
    - Follow-up
- Involve all inspection personnel assigned HACCP duties in the entire awareness process.   OFO – DIO & TSC, HRDS
- Provide time for all attendees to review the HACCP plan prior to the plant awareness meeting.   OFO & OM - LMRS
- Discuss the establishment's procedure for conducting the pre-shipment review.   OFO -HRDS
- Expand window of time for plant awareness meetings prior to implementation in order to allow the patrol inspection personnel time to arrange the meetings, meet 1+ times with each plant, provide supervisory support as requested.   OPPDE, OFO –DIO, OA

HACCP Plans and Procedures
(See Chapter V for additional recommendations.)
- Reinforce accessibility of plant records.   OFO – DIO & DMs
- Review implementation of new technologies and alternative procedures by industry.   OPPDE & OFO - DIO
- Clarify that non-food safety is still a regulatory requirement. Food safety is the highest priority but both are required by law.   OFO – HRDS, TSC & DMs
- Reinforce the following topics at training: OFO - HRDS
    - Importance of basic regulatory requirements
    - Use of the Basic Compliance Checklist
    - Zero tolerance policy and application   OFO – HRDS
    - 01 & 02 HACCP procedures.
- Clarify policy on critical limit requirements for fecal contamination.   OPPDE, OFO-DIO
- Distribute zero tolerance materials directly to in-plant personnel.   OFO - DIO & DMs
- Clarify policy and procedures for pre-shipment reviews.   OPPDE & OFO - DIO
- Clarify how every level of inspection personnel and management verifies corrective actions taken by the establishments in response to a deviation and the

Recommendations	Primary Office of Responsibility

determination that the establishment has not met the requirements of 417.3.	OFO - DIO
• Clarify terms 01 and 02 in regard to SSOP/HACCP and the ISG.	OFO

One Procedure Schedule

• Provide additional discussion in HACCP training regarding the assignment of work under one Procedure Schedule.	OFO – HRDS
• Communicate rationale for having one Procedure Schedule per establishment/shift to inspection personnel and cover in training Module 6: PBIS.	OFO – HRDS
• Encourage supervisors to explain the rationale behind the format of one Procedure Schedule.	OFO – DIO, DMs
• Include time in the implementation schedule for small plants to enable in-plant inspection personnel to complete Establishment/Shift Procedure Plan, FSIS Form 5400-5, for each shift and submit to the District Office.	OFO - DIO
• Reinforce how to use appropriate procedure code for unscheduled procedures as defined in Directive 5400.5.	OFO – TSC & HRDS

LONG-TERM

Evaluation of Next Phase

• Study ways to promote the inspection team concept in multiple Inspector and patrol assignments.	OPPDE, OFO & OA
• Assess the terms and codes (e.g., 01, 02) used to describe SSOP/HACCP procedures for duplication and clarity.	OPPDE

Chapter III
HACCP-based Enforcement Procedures

All things change – and we change with them.[40]

Preface

This chapter addresses how the enforcement program is operating during Phase One implementation of the PR/HACCP Final Rule and provides recommendations for improving HACCP implementation during Phase Two, which will begin January 1999. In this chapter, enforcement includes official activities of FSIS personnel from the time they identify a noncompliance, as well as the establishment's right to due process and employment of the appeal process. To examine this entire process, the following topics are discussed: Enforcement Policies and Practices, Noncompliance Records, Trend Indicators, Due Process, and Coordination between Inspection and Compliance Personnel. The chapter concludes with specific recommendations that are grouped by these chapter sections for easy reference to supporting text.

Enforcement Policies and Practices

FSIS has traditionally focused much of its effort on the plants that slaughter food animals and produce processed products. FSIS ensures that products at these establishments are produced in a sanitary environment in which Inspectors or plant employees identify and eliminate potential food safety hazards. These establishments must apply for a grant of inspection from FSIS and demonstrate the ability to meet certain pre-requisite requirements for producing safe, wholesome, and accurately labeled food products. Requirements include meeting sanitation, facility, and product standards. Now, through new requirements being implemented, establishments must have preventive systems in place to ensure the production of safe and unadulterated food. Products from official establishments are labeled with the mark of inspection, indicating that they have been inspected and passed by USDA and eligible for sale and transportation in commerce.

FSIS uses Compliance Officers throughout the chain of distribution to detect and detain potentially hazardous foods in commerce to prevent their consumption and to investigate violations of law. FSIS also works closely with USDA's Office of the Inspector General (OIG), which assists FSIS in pursuing complex criminal cases. In addition, many state and local jurisdictions have enforcement authorities that also apply to USDA regulated products. FSIS cooperates with these other jurisdictions in investigations and case preparations. FSIS also participates with the OIG and the U.S. Department of Justice in monitoring conditions of probation orders and pretrial diversion agreements or other methods developed to resolve cases. Compliance Officers do not investigate allegations against FSIS inspection personnel.

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[40] Alexander Pope.

To summarize enforcement under the new system, FSIS published its first *Quarterly Regulatory and Enforcement Report*[41] in May, 1998. The report focuses on regulatory and enforcement actions taken, including those under the new PR/HACCP regulations. The regulatory oversight provided by FSIS reflects compliance by the majority of large establishments. Plants operating under HACCP systems, since its beginning in January 1998, have a 92 percent compliance rate[42] with the regulations.

Noncompliance Records

In plants operating under HACCP, FSIS inspection personnel perform thousands of inspection procedures each day to determine whether or not official establishments are in compliance with regulatory requirements. Most procedures demonstrate compliance. However, each time performance of a procedure results in a finding of noncompliance with regulatory requirements, inspection personnel document their findings on a Noncompliance Record (NR), and as needed, initiate the appropriate product control and enforcement measures to protect consumers. It is the plant's responsibility to initiate corrective action and preventive measures.

In HACCP establishments, IICs notify plant managers of problems by completing a written NR. NRs are used to document and notify establishments of noncompliances that occur in the plant's sanitation and process control systems. The plant must take immediate corrective action to remedy the problem and prevent its recurrence. If this is done, the plant will continue to operate without interruption. Problems reported on NRs may vary from minor labeling discrepancies to serious breakdowns in food safety controls. Noncompliances are categorized on each NR using a trend indicator that documents trends in noncompliance (corrective action and plan reassessment are discussed in the HACCP Plans and Procedures section of Chapter II).

Where plants fail to develop or carry out effective future planned actions in response to NRs, FSIS Inspectors also document these findings. FSIS takes action to control products and may take an action to withhold or suspend inspection[43] when noncompliances occur repeatedly or when the plant fails to prevent adulterated product from being produced or shipped.

When a HACCP system inadequacy occurs as a result of multiple, recurring noncompliances without successful interventions, the IIC determines that the marks of inspection should be withheld. Once this determination is made, the IIC contacts the District Office (DO) and provides all the relevant information for the DO to prepare a *Notification to Establishments of*

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[41]The complete *Quarterly Regulatory and Enforcement Report* which includes a discussion of product control actions, letters of warning, administrative actions, and criminal actions can be accessed at: *http//www.usda.gov/agency/fsis/---*

[42] Data taken from PBIS database. Procedure results, including noncompliances, are recorded once, even if performed by multiple Inspectors or multiple times by single Inspectors.

[43] Withholding the mark of inspection effectively shuts down affected operations because it is illegal to sell products in interstate commerce that do not bear the USDA mark of inspection. FSIS may temporarily suspend inspection if a plant fails to present a corrective action plan to bring the plant sanitation or process control systems into compliance. As with withholding actions, a suspension shuts down all or part of the plant's operations.

Intended Enforcement Actions (see Appendix D) [44]. The Notice provides the following information:

1. Informs the establishment that the nature and scope of the noncompliances indicate that the HACCP system is inadequate as specified in the regulations;
2. States that, because of the trend, FSIS intends to withhold the marks of inspection and suspend inspection;
3. Explains the reason for the determination;
4. References each pertinent NR by number;
5. Informs the establishment that it is being afforded the opportunity to demonstrate why a HACCP system inadequacy determination should not be made or that it has achieved regulatory compliance; and
6. Provides the establishment three business days from the date of the letter to provide its response to the DO.

Based on the establishment's response, the District Manager, in consultation with District Enforcement Operations, determines further actions which include moving the withholding action to a suspension, reinstating inspection, or possibly agreeing to hold the suspension in abeyance. An abeyance agreement can occur upon receipt from the establishment of meaningful and beneficial measures to prevent recurrence. Questions were raised about how to determine when an abeyance agreement has failed.

Interviewers asked Field Inspectors, supervisory and non-supervisory IICs, and Compliance Officers (COs) specific questions about the use of NRs. The responses indicate that Field Inspectors are writing NRs and understand the significance of NRs. However, respondents in all job categories see a need for improvement in the documentation of NRs and a strong need for improving linkages of NRs. There is also a need for improving the citation of regulations and using correct procedure codes based on the data reviewed. Industry employees responding to a survey conducted by the American Meat Institute (AMI) and the National Turkey Federation (NTF) agreed that there is a need for improvements in these areas[45]. The use of incorrect procedure codes and incorrect regulatory citations were two of three reasons provided by industry respondents for appealing an inspection finding. One district developed their own form to address some of these problems with NRs. The form assists in-plant inspection personnel with consolidating information in a systematic manner to identify patterns of noncompliance in a plant (see Appendix E).

Almost all Inspectors and non-supervisory IICs interviewed have written an NR. Of those who had not written an NR, the most common reason given was working in a plant where the frequency of noncompliances is low.

Some Inspectors noted that NRs are not being changed without consent of the original author. Supervisors are using "cover sheets," when needed, to document reasons for changes to an NR.

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[44] FSIS Notice 12-98, Notification to Establishments of Intended Enforcement Actions, April 8, 1998.
[45] Industry's Survey of HACCP Implementation. American Meat Institute and the National Turkey Federation conducted a survey from May to June 1998 of all plants that were required to implement HACCP. Approximately 100 plants (30%) responded.

This correct implementation of policy indicates that Inspectors are empowered to document noncompliances, are assuming more responsibility for regulatory oversight, and supervisors are accepting this change. These are small steps toward achieving the culture change described in the preamble of the *PR/HACCP Systems Final Rule*. However, it was noted by the data collectors that this is not occurring uniformly from District to District.

Most supervisory and non-supervisory IICs stated a need for improvement in the documentation of noncompliance on NRs. The improvements cited fall into two broad categories: (1) better writing skills and (2) linkage of NRs to identify an inadequate HACCP system. In particular, Inspectors need more training on the use of trend indicators, the use of proper procedure codes and regulatory citations. However, the data showed that inspection personnel have a demonstrated ability to describe the noncompliance in a detailed, graphic manner. This is a different finding from the *Results of the SSOP Implementation Follow-up Study* which identified the ability to write descriptive NRs as an area needing improvement.

Compliance Officers interviewed also noted a strong need for improvement in the documentation of noncompliance on NRs. They suggested providing time during training for inspection personnel to practice documenting noncompliances on NRs using examples of NRs written since January 1998. They stated improvements are needed in the following areas which were also cited as weaknesses in the *Results of the SSOP Implementation Follow-up Study*:

- linking NRs/PDRs
- citing failure of the establishment's immediate/further planned actions
- citing previous or repetitive noncompliances
- citing regulatory requirements

Interviews with Headquarters staff echoed the concerns of IICs and Compliance Officers regarding documentation of NRs. Headquarters staff stated there is confusion about writing NRs and suspect that inspection personnel lack an understanding of the increased importance of record review for documentation in the HACCP environment.

A data collection team examined a sample of NRs to determine if the documentation of noncompliances is being carried out in a manner to sustain regulatory and enforcement actions. As shown in Table 1, the NRs reviewed are written clearly and adequately describe the noncompliances. Most inspectors stated they use continuation sheets for this purpose. Although Inspectors are completing NRs adequately to support withholding actions, the data collection team found that linkages to failed corrective actions are often missed. Where applicable, Inspectors generally document repetitive noncompliance and, as needed, initiate appropriate regulatory action. Only half the sample showed consistent assignment of appropriate ISP (Inspection Systems Procedure) codes as well as correct use of regulation citations. Inspectors frequently failed to link NRs to immediate and further planned action.

Table 1
Results of On-Site Records Examination of
Noncompliance Records (NRs)[46]

General Features	Yes	No	Don't Know
Clear and accurate description	91%	9%	0%
Consistency between ISP code and the noncompliance[47]	50%	50%	1%
Consistency between trend indicator and the noncompliance	70%	29%	1%
Citation of official action	47%	53%	0%
Repetitive Noncompliance Features			
Repetitive noncompliance documented	88%	12%	0%
Citation of previous noncompliance	79%	21%	0%
Linkage to failed immediate and further planned action	52%	48%	0%
Initiation of appropriate regulatory action	82%	18%	0%

Industry takes documentation of noncompliance on NRs seriously because NRs form the basis for enforcement actions and may affect the reputation of the plant. FSIS's *Quarterly Regulatory and Enforcement Report* provides generic information on the numbers of NRs issued and plant-specific information on enforcement actions. FSIS inspection personnel issued 16,102 NRs between January 26, 1998, and April 4, 1998. During this period, Inspectors performed approximately 188,000 inspection procedures at HACCP plants. Analysis of this data shows a 92% compliance rate. Industry has voiced concerns at weekly meetings with the FSIS Administrator that NRs reported are for all noncompliances, not just food safety issues. Industry representatives have requested that FSIS categorize NRs by trend indicators to separate food safety concerns from other consumer protection concerns in the report. The inspection force has voiced concern that the noncompliance rate of 8% is an under-representation because one NR may be used to capture multiple noncompliances.

Industry representatives stated that the *Quarterly Report* would be more useful and present a more complete picture of noncompliance if food safety and other consumer protection noncompliances were displayed separately. Similarly, inspection personnel are correct by noting that the actual number of noncompliances are under-represented with the present recording policy and practice. This view is related to the non-HACCP inspection systems which were deficiency oriented and generated Process Deficiency Records for each inspection task found to be deficient. Under HACCP, FSIS inspection is systems oriented. Under this concept, documentation of multiple noncompliances does not aid in the identification of inadequate systems. An important factor is the detection of a system defect, as opposed to how many times the system was defective. This culture change should be stressed to inspectors and supervisors

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[46] A review of 79 individual NRs from eight plants.
[47] Total is greater than 100% due to rounding numbers.

who may still feel that numbers of nonconformances somehow reflect upon the performance of the inspector or a measure of control by the supervisor.

Trend Indicators

With the implementation of HACCP, FSIS introduced the *Noncompliance Determination Guide*[48]. This guide allows inspection personnel to categorize noncompliance into trends using trend indicators. The purpose of trend indicators is to improve the Agency's ability to evaluate establishment performance and process control by providing information on trends of noncompliance. There are trend indicators related to SSOP, HACCP, product, facilities, and *E. coli* requirements.

While some of the Inspectors interviewed stated they are confident when selecting a trend indicator, most Inspectors commented that it is difficult to use trend indicators. They stated that trend indicators are not clearly identifiable for certain noncompliances, such as pest control recorded as a facility problem. Inspectors also perceive that trend indicators do not correspond to actual plant operations. There is confusion about which trend indicator to use when both contact and non-contact surfaces are involved. Records reviewed during the survey revealed inaccurate selection of the appropriate trend indicator. For example, many records identified the Facility/Product Based trend indicator for a noncompliance involving unclean product contact surfaces, where the proper trend indicator selection for those circumstances is SSOP.

HACCP Coordinators identified problems relating to trend indicators and the completed Procedure Schedules being returned by inspectors for data entry into the PBIS database. Some Procedure Schedules listed more than one trend indicator for the same noncompliance. Some Procedure Schedules were also marked as performed as well as having a trend indicator marked. There is also confusion about the use of the "K" trend indicator which is used for structural nonconformances but also used to delete non-applicable procedures from the establishments procedure plan.[49]

Although their purpose is to improve the Agency's ability to evaluate establishment performance and process control by providing information on trends of noncompliance, trend indicators have not been effective tools for documenting trends. They have generated significant confusion for all levels of inspection personnel and Compliance Officers. If the Agency continues to use trend indicators, they should be modified to make them clearly identifiable for all types of noncompliance. Trend indicators should be further explained during training including specific examples.

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[48] FSIS Directive 5400.5, Inspection Systems Activities, Attachment 5, November 21, 1997.
[49] FSIS Directive 5400.5, Inspection Systems Activities, Maintaining Establishment/Shift Procedure Plans.

Due Process

FSIS recently implemented the *Notification to Establishment of Intended Enforcement Action*[50] (see Appendix D), which is a provision for due process in advance of a withholding action involving system failure not associated with adulterated product. This Notice to FSIS employees provides a mechanism to inform plant managers that FSIS is prepared to withhold inspection and allows plant management an opportunity to show cause within three days about why inspection should not be withheld[51]. Under the traditional inspection systems, notice of intent was not required.

During the in-plant interviews, some respondents expressed concern that the recently implemented *Notification to Establishment of Intended Enforcement Action* diminishes industry incentive to prevent problems, since there will always be plenty of time to correct them. Some program employees reported the perception of diminished inspection authority.

They were also concerned about Agency policy for when to take an enforcement action. For example, if there is a noncompliance in the line concerning one product, but that product shares a HACCP plan with other products, are all product lines stopped? This issue may be particularly relevant to HACCP implementation in small plants where operations involve multiple process categories and one HACCP plan could cover several products.

Plants may appeal inspection findings either orally or in writing to various levels in the Office of Field Operations. A plant may appeal an inspection decision for a wide variety of reasons. According to results from an industry survey conducted by the American Meat Institute (AMI) and the National Turkey Federation (NTF)[52], the majority of plants required to implement HACCP stated that they are appealing more now than before HACCP implementation. Industry reported that half the reasons for appealing were due to disagreements with an inspector's findings or decisions. The remaining reasons were due to incorrect ISP Procedure Code and incorrect regulatory/plant citation.

Typically, the appeal begins with the Inspector or IIC and then goes to the Circuit Supervisor, to the District Manager, to the Assistant Deputy Administrator for District Inspection Operations, to the Deputy Administrator for Office of Field Operations. At the start of the appeals process, plants may provide supporting factual information and ask the Inspectors or the IIC to reconsider their findings.

FSIS recognizes that appeals are both expected and appropriate to resolve legitimate disagreements. The Agency encourages plants to make their appeals in a timely manner. A tracking system for appeals has been developed, and FSIS recently issued a letter to industry and a corresponding FSIS Notice (14-98) to the inspection force, outlining the proper appeals procedures for both industry and the inspection force.

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[50] FSIS Notice 12-98, Notification to Establishments of Intended Enforcement Actions, April 8, 1998.

[51] Immediate action may be taken to prevent shipment of adulterated product.

[52] Industry's Survey of HACCP Implementation. American Meat Institute and the National Turkey Federation conducted a survey from May to June 1998 of all plants that were required to implement HACCP. Approximately 100 plants (30%) responded.

Interviewers asked supervisory and non-supervisory IICs, and Circuit Supervisors specific questions on how the appeals process is working. All supervisory and non-supervisory IICs and most Circuit Supervisors, who have had their decisions appealed by industry, stated it is industry's right to appeal. However, inspection personnel voiced negative reactions to appeals they perceived to be frivolous or aimed at discrediting the Inspector. Some respondents expressed concern about their own liability when taking an action against industry. Several inspection personnel perceive that industry uses the appeals process to avoid initiating corrective action. Supervisory and non-supervisory IICs, Circuit Supervisors, and District Managers voiced a need for a more clearly defined appeals process. The intended purpose of FSIS Notice 14-98 was to explain FSIS's appeal policy and set up an appeals tracking system. Apparently, the Notice didn't adequately clarify the appeals process. Respondents requested a timeframe during which industry can appeal and the requirement that all appeals are submitted in writing. However, provisions of the Poultry Products Inspection Act (PPIA) and the Federal Meat Inspection Act (FMIA) do not permit the requirement that all appeals be submitted in writing.

Related to the issue of conditions for documenting noncompliance and withholding inspection is Inspector liability. Inspection personnel are concerned about their personal liability for product and production losses due to an incorrect decision they render where they are acting within the scope of their official responsibilities.

To address the continued confusion surrounding various aspects of appeals and due process policy and practices, FSIS is finalizing its Rules of Practice docket. This docket is intended to cover the constitutional provision of the right to due process of official establishments. The docket includes topics such as appeals, withholding actions, and suspensions. Headquarters and District Office management expressed the need to publish the docket at the earliest possible date to clarify these enforcement issues.

Interviewers asked Headquarters staff "What role should management play in providing technical and policy guidance on matters raised by industry with the District in handling appeals?" Respondents stated management's role is to provide consistency in communication and enforcement. One respondent explained, "Management should make sure the district offices are aware of the questions and answers that are being asked about enforcement and inspection nationwide. This will promote consistency." The Headquarters staff interviewed also emphasized the need to provide clear guidance about the appeals procedure, stating "Due process is a concern of all parties." Inspectors echoed this concern about due process. Inspectors sometimes perceive that Headquarters staff is, "quick to take industry's side over inspection in an appeal." Headquarters respondents recognize a need to improve teamwork in setting and communicating policy. "Headquarters is the final decision-maker, but to the extent possible, District Managers need to assume and take responsibility for their input on these decisions. It is not acceptable for industry to be told, we'll get back to you unless it is necessary," one respondent said. Some commented that Headquarters needs to clarify the TSC role as one of technical advice rather than enforcement decision-maker. One respondent explained, "Technical advice comes from the TSC. They do not make the final decision. But everyone can call the TSC." Inspectors also voiced a concern that the TSC keep its role as technical advisor rather than become another decision-maker.

Interviews with Headquarters supervisors also reflected management concerns to rectify the stress throughout the Agency. They recognized the extremely heavy and stressful workload of both inspection and enforcement personnel. The fact that many Headquarters and field personnel have pagers that operate 24 hours a day, 7 days a week, raises questions about the feasibility of continuing this practice.

Coordination Between Inspection and Compliance Personnel

The implementation of HACCP coupled with the reorganization of FSIS has created a greater integration of inspection and enforcement. As part of the culture change, inspection personnel and compliance personnel are expected to work collaboratively as a team. This sentiment was echoed clearly in the interviews with Headquarters managers.

Interviews were also conducted with Field Inspectors, supervisory and non-supervisory IICs, Circuit Supervisors, and Compliance Officers about their interactions between compliance and inspection personnel. Their responses indicated that very few Inspectors have worked with Compliance Officers directly. The majority stated the practice to request a Compliance Officer in their assignments is to go through the IIC. Others call the District Office directly to request a Compliance Officer or call the Circuit Supervisor directly. Some did not know the procedure. This lack of direct interaction between Inspectors and Compliance Officers might be due to a variety of circumstances such as a reliance on the familiar command-and-control strategy for communication of enforcement issues, some residual historical resistance to close cooperation, communication difficulties, or short staffing. Compliance personnel also stated that they invite the respective Circuit Supervisor to any meeting where an Inspector has requested assistance. This practice is to ensure that the immediate supervisor is aware of any discussions and advice shared with the Inspector.

The communication and coordination activities between Compliance Officers and Assistant District Managers for Enforcement (ADMEs) and inspection personnel are through the supervisory and non-supervisory IICs. Most supervisory and non-supervisory IICs have worked with a Compliance Officer before implementation of withholding actions, or "proactively." Most have also called the District Office for a Compliance Officer to react to a withholding action. However, very few supervisory and non-supervisory IICs have worked with the Compliance Officer in developing a case file. This is to be expected since case files would be reserved for the most serious administrative, civil, and/or criminal case actions.

Circuit Supervisors have a broader scope of practice than inspection personnel which affects the frequency of their interactions with Compliance Officers. Consequently, Circuit Supervisors work with Compliance Officers more frequently than other inspection personnel in developing case files. For example, more than one-third of Circuit Supervisors reported involvement with a Compliance Officer in developing a case file compared to a very small percent of Inspectors and IICs. The majority of Circuit Supervisors interviewed have worked with a Compliance Officer in a proactive manner to assist FSIS inspection personnel in documenting PR/HACCP related noncompliance. The respondents described the collaboration equally as both a positive and

negative experience. Comments from all job categories reflect a need to enhance the role of the Circuit Supervisor in the inspection-compliance team.

In weekly meetings with FSIS's Administrator, industry representatives have expressed concerns about the changing roles of inspection personnel. One representative stated Inspectors are overzealous in their new roles with respect to checking HACCP plans. Industry representatives further stated that FSIS Inspectors used the letters that FSIS issued regarding HACCP plans and CCPs as a basis to inappropriately evaluate the sufficiency of HACCP plans and threatened plants with being shut down if they did not make changes suggested by the inspector. Industry requested a letter from the FSIS Administrator clarifying the roles of the Inspector, the IIC, and the TSC on this matter. Industry has also asked questions about the role of the Circuit Supervisor, particularly in providing dispute resolution during appeals.

All job categories indicated that Compliance Officers provide same day assistance on withholding and enforcement actions. Compliance Officers and ADMEs reported an average time of 2 ½ days to complete a case file. Half of the Compliance Officers interviewed experienced barriers when documenting case files, and therefore work additional hours during withholding actions. The barriers included:

- not enough Compliance Officers
- not enough computers and computer training for field personnel
- lack of available copy machines
- relative inexperience of new compliance staff members

Interviews with District Managers strongly support the need for improvement regarding the working relationships between inspection and compliance personnel in a HACCP environment. District Managers are concerned that Inspectors do not fully understand the Compliance Officer role, and see a need for Inspectors to use Compliance Officers more proactively for assistance and advice. The data collected support these statements. Only a small percentage of Inspectors have worked with a Compliance Officer proactively, and none of the Inspectors interviewed have called for a Compliance Officer proactively. Inspectors are not clear at what point to get involved with a Compliance Officer proactively, even if permitted to do so. One way to improve the working relationship between inspection personnel and Compliance Officers is to use the "buddy system" whenever a Compliance Officer meets with plant management. The "buddy system" simply means that when such a meeting occurs, the IIC is always included so they can hear the dialogue firsthand with the Compliance Officer.

Recommendations[53]

The recommendations for improving the enforcement program begin on the following page. Additional related recommendations can be found in the HACCP-based Inspection Procedures, Introductory HACCP Technical Training Program, and Ongoing Technical Support, Follow-up Training, and Communication chapters' recommendations.

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[53] Short-term recommendations are defined as those recommendations that this study identified as feasible to address before Phase Two HACCP implementation. Long-term recommendations are defined as those recommendations that require more time and resources than available prior to January 25, 1999 implementation. Primary offices of responsibility: OFO-Office of Field Operations; OPPDE-Office of Policy, Program Development and Evaluation; DIO-District Inspection Operations; HRDS-Human Resources Development Staff; LMRS-Labor Management Relations Staff; OA-Office of the Administrator, TSC-Technical Service Center, DEO-District Enforcement Operations.

Recommendations	Primary Office of Responsibility

SHORT-TERM

Enforcement Policies and Practices

- Prepare *Qs&As* for training based on Phase One problems. — OFO – HRDS, OA & OPPDE
- Review policy and practice of 24-hour availability to industry. — OFO- DIO & OA
- Clarify if enforcement actions are taken on the product or HACCP plan. — OPPDE
- Resolve issues and publish Rules of Practice ASAP. — OPPDE & OFO – DIO
- Define failure of an abeyance agreement. — OPPDE & OFO - DIO

Noncompliance Record (NRs)

- Define system inadequacy as documented with linkages on NRs and the importance of documenting a plant's failure to implement immediate and further planned actions. Cite reference to 417.3 and 417.6. — OFO – DEO & HRDS
- Address the Inspectors' perception of loss due to the use of only one NR being created when in fact there was more than one noncompliance found. — OPPDE
- Improve application of trend indicators, regulations citation, and procedure code documentation. — OFO & OPPDE
- Emphasize that the inspection performance is not related to the number of nonconformances found. — OFO – TSC & DMs
- Emphasize the use of cover sheets by supervisors when changes to the NRs are necessary. — OFO – TSC & DMs
- Expand training on enforcement to include: — OFO – DEO & HDS, OPPDE
  - Reinforcement of specific instructions on enforcement actions step-by-step.
  - A mock withholding action
  - How to link NRs
  - Writing NRs
  - Citing regulations.

Recommendations	Primary Office of Responsibility

SHORT-TERM

Trend Indicators

- Determine the validity of the information being collected under trend indicators and whether they help to categorize *noncompliance or systems inadequacy.*   OPPDE & OFO - DIO
- Define relationship of trend indicators to system inadequacies in 417.6.   OFO – DIO, HRDS & TSC
- Clarify HACCP and SSOP trend indicators through workshops.   OPPDE & HRDS
- Conduct an assessment of trend indicators and make any necessary revisions.   OPPDE
- Expand training on enforcement: OFO – DEO & HDS, OPPDE
  - Bring in compliance officers from Phase One to share real-life examples.
  - Add training on PBIS.

Due Process

- Provide ongoing guidance about the appeals procedure to ensure the recent notices to industry and the inspection force provided adequate clarification.   OFO - DEO
- Address cultural change in terms of the appeal process (FSIS Notice 14-98). Reinforce that appeal process is not a reflection on inspection personnel.   OFO - HRDS
- Compile and distribute the questions and answers being asked by industry nationwide and share these with District Offices.   OFO -DEO
- Clarify the purpose of liability insurance. Explain phrase "covered within the scope of your employment." Provide examples of incidents covered and not covered. What if a withholding action is initiated and then reversed?   OFO –TSC & HRDS
- Clarify why plants are given three days to respond to the Notification of Intended Enforcement Action. Inspection personnel believe that their authority is weakened.   OFO - DEO

Recommendations	Primary Office of Responsibility

SHORT-TERM

Coordination Between Inspection and Compliance Personnel

- Revise sections of training modules related to Enforcement.   OFO-HRDS
  - Emphasize communication and coordination between inspection personnel and compliance officers. Discuss the cultural change.
  - Add the importance of compliance officers being proactive, e.g. participating in work unit meetings.
- Expand training on enforcement to include: OFO – DEO & HDS, OPPDE
  - A role play scenario on Inspector/CS/ DM/CO interaction.
- Encourage inspection personnel to call in Compliance Officers early in the process.   OFO - DIO
- Clarify if CO's are to be proactive and interact with inspection personnel. –When? How? Priorities?   OFO - DEO
- Conduct regular Inspector/Compliance Officer meetings to promote enforcement team work.   OFO – DM
- Recommend the "buddy system" that whenever a CO is in a plant and meets with plant management, the IIC is included.   OFO - DM

LONG TERM

Evaluation

- Conduct an evaluation to determine what information the Agency needs to continually review its regulatory activities, establishment performance, and process control.   OPPDE, OFO-DIO

Rules of Practice

- Publish as soon as possible.   OPPDE, OFO – DEO& OA
- Incorporate into introductory and follow up training materials and other communications.   OPPDE & OFO – DIO & HRDS

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Chapter IV
Introductory HACCP Technical Training Program

One must learn by doing the thing;
for though you think you know it you have no certainty,
until you try.[54]

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Preface

With the implementation of the PR/HACCP final rule in January 1997, the Agency moved away
from a command-and-control philosophy to one that emphasizes separation of Agency and
industry roles and performance standards for industry. These changes have a great effect on
Agency culture, inspection policies and practices, and the general interactions among all FSIS
employees. The diagram below[55] reflects the anticipated paradigm shifts associated with
implementation of the PR/HACCP final rule.

	From	**To**
Regulatory approach	Command-and-control	Performance standards
Identification of corrective actions	FSIS	Industry
Documentation	Not too important	Critical
Supervision of employees	Directing	Directing, coaching, supporting, delegating
Atmosphere of organization	Isolated and individual	Team work and trust
Empowerment and accountability	Chain-of-command	Lowest possible level
Identity of FSIS employees	Plant	Agency
Performance of FSIS employees	Performance tied to plant compliance	Performance independent of plant compliance

Cultural change is difficult to accomplish. It requires dedicated staff and continuing support. A
number of strategies have been utilized by FSIS to facilitate the expected cultural changes
throughout FSIS. The Agency first introduced the concept of cultural change in the Fall of 1996
and has subsequently built upon the basic principles. The Introductory Technical HACCP
Training Program which is discussed in this chapter is an eight-day course designed to provide
the basic information necessary for FSIS employees about to engage in HACCP implementation.
The course focuses on the day-to-day inspection activities required under HACCP. The
paradigm shifts noted in the diagram above are integrated into the course materials.

This chapter presents a brief overview of the Introductory HACCP Technical Training Program
followed by the results of interviews with recipients and facilitators of this training, as well as
the thoughts and opinions of Headquarters managers. The chapter concludes with
recommendations grouped by chapter sections on suggested improvements in the introductory
training for future phases of HACCP implementation. Ongoing technical support, follow-up
training and communication activities are discussed in the next chapter.

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[54] Sophocles.
[55] Diagram is taken from Module 2 of the Pre-HACCP training materials (1996).

The HACCP Technical Training Program of FSIS employees involved with Phase One implementation began in late November of 1997. The training program covered eight days primarily consisting of technical content. This video-based program was delivered to approximately 2,400 employees, including in-plant off-line Inspectors, IICs, Circuit Supervisors, Compliance Officers, District Office staff, state employees, and union officials. The Technical Service Center staff, including individuals who staffed the HACCP Hotline, also received the eight-day training. Training was organized into the following modules.

- *Module 1:*   *Overview of FSIS Food Safety Goal and Strategy*
- *Module 2:*   *HACCP Overview and Principles*
- *Module 3:*   *Steps in the Development of the HACCP System and Relationship of HACCP/GMPs/SSOPs*
- *Module 4:*   *Microbiological Testing: Salmonella and E. coli*
- *Module 5:*   *Systems Approach: Regulatory Model*
- *Module 6:*   *The Revised Performance Based Inspection System (PBIS)*
- *Module 7:*   *Basic Compliance/Noncompliance of Plans*
- *Module 8:*   *E. coli Basic and Other Compliance/Noncompliance*
- *Module 9:*   *Other Compliance/Noncompliance (Salmonella, HACCP, SSOP, Other Consumer Protection)*
- *Module 10:*   *Technical Advice and Assistance*
- *Module 11:*   *Business Relations*

Training was conducted at locations away from the establishments. Sessions were scheduled as just-in-time training[56], starting in late November and continuing through January. Each session was facilitated by a two-person team which consisted of one member of management and one bargaining unit member. The individuals on these two-person teams are referred to as the Facilitators. At the start of training, Facilitators handed each participant a binder of course materials organized by module. Reference materials, such as FSIS Directives 5000.1 and 5400.5 that include the *Inspection System Procedures Guide,* were also part of the materials.

Usefulness of Introductory Training Program

Respondents were asked to rate the usefulness of various training topics presented during the eight-day program. As shown in Table 2, the three topics rated most useful were conducting *Salmonella* sampling, using the Basic Compliance Checklist to perform the basic procedure, and knowing when to contact Compliance staff. Although the training concerning the Basic Checklist and knowing when to contact a Compliance Officer was rated as useful, employees expressed difficulties in the application of training in these two areas (see chapters II and III).

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[56] Just-in-time training means training scheduled as close as possible to the actual use of the training.

Table 2
Most and Least Useful Topics in Introductory HACCP
Technical Training Program Reported by Respondents

Most Useful Training Topics	Least Useful Training Topics
Conducting *Salmonella* sampling	Determining when there is an inadequate system
Using the Basic Compliance Checklists to perform the basic procedure for HACCP	Using the *Noncompliance Determination Guide* to select the appropriate trend indicator
Knowing when to contact Compliance	Interacting with Compliance Officers as a result of withholding actions

The topics rated "least useful" parallel the findings discussed in Chapters II and III. Inspection personnel are having difficulty with defining system inadequacy, using trend indicators, and interacting with Compliance Officers.

➢ *Determination of Inadequate System*

Comments indicated that some uncertainty remains about the criteria that should be used to make the determination that an establishment's system is inadequate. Some suggestions that typify the uncertainty were:

"Give us more concise, concrete examples of HACCP failures."
"We need training on what constitutes a systems failure."

➢ *Interaction with Compliance Officers*

Another area of some confusion was the role of Compliance Officers and their relationship with inspection personnel. The training indicated that field employees must go through the District Office in contacting a Compliance Officer. This seems to have been well understood, though practices somewhat vary across districts. There was uncertainty with regard to how inspection personnel should be interacting with Compliance Officers as a result of withholding actions. Some representative comments from Field Inspectors and others were:

"Inspectors are comfortable contacting a Compliance Officer, but there is uncertainty about what comes next."
"All Inspectors may not understand enforcement procedures once Compliance is involved, such as suspension versus withdrawal, and where the letter of warning[57] comes into play."

The idea being expressed here is that training and the interaction between inspection and compliance personnel may be improved by including more information about how in-plant employees should interact with Compliance Officers once a withholding action is taken.

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[57] A letter of warning is issued by the Agency to a plant after the plant has proposed a corrective action and a further planned action that precludes recurrence in response to a suspension.

➢ *Use of Noncompliance Determination Guide*

Confusion about the use of the *Noncompliance Determination Guide* was echoed in comments. One such comment by a District Manager stated that trend indicators "do not correspond to actual plant conditions." Comments from supervisory IICs were that more clarification on trend indicators was needed. Some felt the relationship between trend indicators and the regulations was not covered adequately in training. The issues and problems of trend indicators and their application were discussed in more detail earlier in Chapter III.

➢ *Additional Suggestions*

Respondents were also asked to identify any other changes to training that would facilitate their ability to implement HACCP. This question was asked of Field Inspectors, supervisory IICs, Circuit Supervisors, HACCP Coordinators, and District Managers. The suggestions that were offered included ideas for improving the training materials, changing the timing of the training, clarifying some policy issues, and adding to the training content.

When asked to identify additional knowledge or skills not provided during training that would facilitate HACCP implementation, respondents mentioned the following areas most frequently:

- conducting the plant awareness meeting
- understanding HACCP principles
- responding to establishment's corrective action proposals
- understanding pre-shipment review

These specific recommendations, elaborated below, and others identified in earlier chapters are summarized in the last section of this chapter.

➢ *Plant Awareness Meetings*

In terms of the plant awareness meeting, representative comments included, "We lacked a working knowledge of the purpose of plant awareness," and "we need more elaboration on the plant awareness meeting." One suggestion to improve the effectiveness of the plant awareness meeting was to develop a checklist of general items that should be covered during the meeting. Although the eight-day training program included a Basic Compliance Checklist that could be used by inspection personnel in conducting the plant awareness meeting, the importance of using this document as a tool to prepare for the meeting was not conveyed. The significance of the plant awareness meeting and mandatory topics to cover at the meeting need to be reinforced in the existing training materials covered in follow-up training and reinforced by OFO supervisors in the field. All these comments support ones heard throughout the data collection effort and discussed earlier in the report (see Chapter II).

➢ *HACCP Principles*

Some interest regarding further training in the HACCP principles was expressed by field supervisors and HACCP Coordinators. Inspection personnel were given a basic foundation in HACCP concepts, hazard analysis, and systems concept in training Modules 2 and 3. However, during the interviews, some respondents expressed an interest in gaining more knowledge. For example, District Managers stated that employees needed to understand the difference between critical control points and good manufacturing practices[58]. District Managers and HACCP Coordinators stated that they also would like more in-depth training in HACCP principles. Others interviewed stated that plant management would also benefit from a thorough understanding of HACCP principles.

➢ *Corrective Action and Pre-shipment Reviews*

Two other areas in which respondents requested additional knowledge and skills were corrective action and the pre-shipment review (see Chapter II). In terms of corrective action, the feedback from interviews indicated that the requirements are not well understood. Some clarification also needs to be provided on what an Inspector should do if uncertain that the corrective action proposed by the establishment will address the problem. For pre-shipment review, an unanswered question remains about how to handle the situation when product is going to an off-premise storage facility. Respondents noted that industry is conducting pre-shipment reviews in a wide variety of ways.

An issue that surfaced during interviews related to corrective actions and other inspection areas, concerns confusion about how to determine the adequacy of alternative operating procedures. There is confusion about what to do when the establishment incorporates procedures into their HACCP plans that do not match the regulations to the letter.

Time of Training

Study respondents were asked to give their preferences for timing of training. When asked, "Assuming that we will continue just-in-time training, how much time would you like to have between receiving training and actually implementing the skills you learned in training?" Inspectors, supervisory IICs, Circuit Supervisors, and Compliance Officers all preferred having approximately two weeks of time between training and implementation. Respondents explained that this spacing was needed to allow time to assimilate the information learned in training. Scheduling all the inspection personnel involved in the upcoming Phase Two during a two-week period obviously is not feasible. However, an effort should be made to allow at least two weeks to assimilate the training materials before start of implementation. The availability of the Hotline and immediate supervisors might be emphasized as resources to help answer follow-up questions.

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[58] 21 CFR, Part 110, Current Good Manufacturing Practices in Manufacturing, Packaging, or Holding Human Food.

Overall, respondents found the training materials received as part of the basic eight-day program to be useful. However, they offered a variety of suggestions for improvements. The suggestions for improvement centered around inclusion of realistic concrete examples, clarification of policy, reduction in volume of material, identification of which documents are the most current, addition of other topics, and the relationship of information presented in the different modules. Specific recommendations concerning these issues are listed in the last section of this chapter. Many of these suggestions coincide with the concerns voiced by industry.

With regard to improving the training materials, the most frequent suggestion heard from District Managers, supervisory IICs, Inspectors, and Compliance Officers was to modify workshops so that they contained real life examples. Respondents were familiar with the concept of cultural change, but had not fully realized its practical application. More than likely, the reason this suggestion was made is that people relate better to examples that involve familiar situations. With one year of implementation experience, real life examples from large plants should be available. These examples would need to be adapted to the small plant environment. More poultry slaughter examples were specifically requested.

Feedback indicated that policy clarification was needed particularly related to two issues. One issue had to do with uncertainty about the Agency's policy statement that at least one initial control point would be necessary in a slaughter HACCP plan to deal with industry's compliance with the zero tolerance performance standard. The other had to do with *E. coli* sampling. With regard to zero tolerance, the comments indicated that, although the Agency has issued *Qs&As*, there is still some confusion about the Agency's policy on zero tolerance. For example, one respondent said, "we need a clear understanding of standards for zero tolerance and how it fits with HACCP" (see Chapter V). With regard to *E. coli* sampling, comments indicated that the role of the special team[59] needs to be clarified, and that some follow-up training on the rationale for sampling is needed. A representative comment by a respondent captured the point, "Inspectors need to understand the reason the establishment is collecting samples." In both cases, the comments pointed to the need for incorporating additional policy clarification into the training and a need for follow-up with employees in HACCP slaughter plants on these topics.

A number of comments were made concerning the volume of training materials and other written documents needed to understand and keep current about HACCP-related policies and practices. One suggestion was to assemble one reference book/source that includes SSOP, HACCP and pathogen reduction materials necessary for Inspectors to conduct their daily tasks. This book could also serve as a resource for those who answer technical questions. The notebook should include all the pertinent FSIS publications (e.g. directives, notices, guidelines, *Qs&As*). The resource should also include a list of all documents that have been deleted or superceded by other actions. A range of format options was suggested, such as the "Green Book" (officially known as *Sanitation Standard Operating Procedures (SSOP) Reference Guide*) or *Food Standards and Labeling Policy Book*. The *Labeling Policy Book* is a loose-leaf style notebook that allows the

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[59] The *E. coli* special team was an interim measure established to perform inspection procedures in the interval that occurred between the time when the requirements went into effect and the time when in-plant FSIS employees received HACCP training. Once in-plant employees received training, the specified team was no longer required.

reader to remove outdated information and add new, revised information as it becomes available. Regular updates are provided through a subscriber service. Several respondents also requested that the language in the "Blue Book" (officially known as *Regulatory Process for HACCP-Based Inspection Reference Guide*, January 1998) be made more user-friendly.

A final module summarizing the key points from all the modules was suggested as a means for helping participants understand the connections between the old and the new inspection methods, old and new roles of plant and inspection personnel, and changes in the regulations. Some participants had difficulty with all the materials being presented in narrative format and suggested that graphics, figures and tables would be helpful.

One module that was noted as particularly in need of improvement by respondents was *Module 11: Business Relations,* which covers the interpersonal skills needed for interacting with plant management. Respondents questioned its necessity and disliked the style of the presenter. A majority of the Circuit Supervisors and IICs said they were already using the skills included in the Module such as listening, getting feedback from subordinates, and talking with plant management. Although they were able to use the training, some negative comments were voiced about the presentation, terming it "boring" and "formal." Field Inspectors indicated that it would be more effective if the information presented was more applicable to the in-plant environment. They also suggested developing a new video to improve the presentation.

Support for HACCP Facilitators

The HACCP Facilitators were asked a variety of questions related to planning future training because of their extensive involvement in the Phase One training program. The Facilitators reported that they received adequate logistical help in planning the training and support for technical questions throughout the training sessions. In particular, the Facilitators appreciated having access to the Technical Service Center and having the District HACCP Coordinators' support scheduling participants and coordinating travel to training. The 32 hours that were set aside for Facilitators to use in reviewing materials and preparing to deliver the training was considered essential.

Another question asked Facilitators whether or not they had been used as a resource during Phase One implementation. An overwhelming majority indicated that they had been used as a resource within their District after training was completed. For example, many of them reported being contacted by peers with questions about pathogen reduction and HACCP implementation. Some had participated in public meetings and some had been members of a District Office team to answer questions during the first few weeks of HACCP implementation. Some concern was expressed by Facilitators in performing this role. The concern was due to the fact that they were not able to answer some questions adequately because they needed policy clarification on issues, such as use of trend indicators and zero tolerance. This information points to the fact that the role of Facilitators after training needs to be clarified. If the Agency continues to use them as resources, they need to be informed of any policy clarification in a timely manner.

Somewhat related to the need to be well-informed if used as resources, Facilitators need to have access to HACCP experts during training to obtain answers to participants' questions. For although the Facilitators reported that they had received adequate support in getting their questions answered during training, some training participants voiced disappointment that not all their questions were addressed.

Finally, Facilitators were asked to share ideas about how HACCP training could be improved. The Facilitators offered several suggestions for improving training:

- Start training earlier to avoid overlapping with holidays.
- Supplement workshops with real life scenarios that have detail and depth, because some of the work force tended to interpret training literally.
- Make training sessions smaller.
- Combine the *E. coli* and *Salmonella* modules (which were split between Module 6, which covered Basic requirements, and Module 9, which covered Other Compliance/Noncompliance requirements).
- Print the training materials on both sides of the page to make the amount of training material easier to manage.

Overall, the feedback from Facilitators indicates that they felt they had the support they needed to get the job done and that they reacted positively to the experience. The majority said they would like to participate again if given the opportunity. If Facilitators are going to be used as resources, as they have been during the first phase of HACCP implementation, the Facilitators need to be updated with policy clarification that occurs after the training.

Supervisory Training

Supervisors have a key role in HACCP implementation as leaders of change. To prepare them for the first phase of HACCP implementation, Office of Field Operations (OFO) supervisors received the same eight-day introductory HACCP technical training that all inspection personnel involved in HACCP implementation received, as well as specific supervisory training.

District Managers and Circuit Supervisors attended a Supervisory Conference which was a four-day meeting. This conference addressed issues of culture change, systems thinking, the role of the Circuit Supervisor, and the *Supervisory Guideline* which outlines the responsibilities of supervisors in a HACCP environment. The session was conducted by OFO Managers from Headquarters. The Circuit Supervisors were instructed to share what was covered at the conference with supervisory IICs in their circuit.

A similar conference was held for Compliance Supervisors. It covered the same material that was presented for Circuit Supervisors. Assistant District Managers for Enforcement and supervisory Compliance Officers attended. District Inspection Operations, District Enforcement Operations and Office of General Council executives were present to discuss issues specifically related to enforcement.

Results from this study indicate two main points: (1) the role of all levels of supervisors is essential to the success of HACCP implementation, and (2) all field and Headquarters supervisors involved in HACCP implementation need additional training. Due to the magnitude of the changes in inspection resulting from HACCP implementation, some supervisors still rely on a command-and-control style of management, most likely because it offers comfort in a changing environment. However, supervisors should allow inspection personnel the flexibility needed to use their own judgement when making inspection decisions. Supervisory personnel should also allow and encourage inspectors to ask questions directly to the TSC or appropriate source. Supervisors need to be clear that their primary role is to lead the change and provide coaching and support to inspection personnel.

Results from a survey of industry employees conducted by the American Meat Institute (AMI) and the National Turkey Federation (NTF) reflect similar findings[60]. Although industry employees stated that FSIS supervisors were quite knowledgeable regarding HACCP, the majority of industry personnel reported that many FSIS supervisors continue to use a command-and-control management approach.

Essential training topics for supervisors include practical approaches to team building in the various field and Headquarters settings, philosophy and practical application of culture change, and principles of management. Principles of resource management are needed to help FSIS managers address the stress that all FSIS employees have been experiencing. Interviews with Headquarters and field managers provided a forum for them to express their concerns about the stress of 24 hours-7 days a week pagers, as well as the amount of change being implemented and expectations on all personnel.

Recommendations[61]

A large number of specific suggestions for the Introductory HACCP Technical Training Program begins on the next page. The level of specificity and length of the list is a reflection of the importance respondents placed on the initial training for those involved with HACCP implementation. Many of the topics noted in the recommendations are supported by discussions throughout the earlier chapters of this report.

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[60] Industry's Survey of HACCP Implementation. American Meat Institute and the National Turkey Federation conducted a survey from May to June 1998 of all plants that were required to implement HACCP. Approximately 100 plants (30%) responded.

[61] Short-term recommendations are defined as those recommendations that this study identified as feasible to address before Phase Two HACCP implementation. Long-term recommendations are defined as those recommendations that require more time and resources than available prior to January 25, 1999 implementation. Primary offices of responsibility: OFO-Office of Field Operations; OPPDE-Office of Policy, Program Development and Evaluation; DIO-District Inspection Operations; HRDS-Human Resources Development Staff; LMRS-Labor Management Relations Staff; OA-Office of the Administrator, TSC-Technical Service Center, DEO-District Enforcement Operations.

Recommendations	Primary Office of Responsibility

SHORT-TERM

Time of Training
- Send training packet to participants prior to their scheduled training to allow time to review materials, if possible. — OFO - HRDS
- Start training earlier than December to avoid conflicts with holidays. Need to allow personnel on patrol assignments enough time to schedule and attend all plant awareness meetings in their assignment before implementation date. — OFO - DIO & OM - LMR
- Emphasize use of the Hotline to assimilate information and reinforce training before implementation. — OFO-TSC

Training Materials
- Print materials on both sides of the page to reduce the amount of material. — OFO - HRDS
- Add *Qs&As*, *Supervisory Guideline* and the *"Blue Book"* to training packet. — OFO - HRDS
- Add more real-life examples and scenarios in the workshops, particularly in Modules 9 and 11. Include examples from a variety of sources (e.g., red meat slaughter, poultry slaughter, processing). Adapt large plant experiences to small plants. — OFO - HRDS
- Include inspection personnel from Phase One to share real-life experiences. Cite success stories. Encourage more *Qs&As*. Provide practical examples of the numerous cultural changes noted from diagram (Pre-HACCP training Module 2). — OFO - DIO & TSC
- Incorporate practical examples of cultural change concepts throughout modules and materials. Need to explain the importance of cultural change in terms of a new underlying philosophy. Use concrete examples, e.g. purpose of one Procedure Schedule – team building and assignment of work and importance of inspection personnel's direct access to the TSC. — OFO-HRDS

| **Recommendations** | **Primary Office of Responsibility** |

SHORT-TERM

Revise the Following Training Modules:
- *Module 3: Steps in the Development of the HACCP System and the Relationship of HACCP/GMPs/SSOPs*　　　　　OFO – TSC & HRDS
  - Devote more time to understanding of the HACCP principles and good manufacturing practices.
  - Explain purpose and procedure for field managers to refer plant managers to the Agency resources that are available for small plants implementing HACCP. Such resources include Hotline, Small Plant Demonstrations and related materials, International HACCP Alliance, USDA National Agricultural Library, FSIS and FDA Resources Databases, etc.
- *Module 5: Systems Approach: Regulatory Model*
  - Discuss rationale for all policy and inspection activity changes.　　　　　OFO – TSC & HRDS
- *Module 6: The Revised Performance-Based Inspection System (PBIS)*　　　　　OFO – TSC & HRDS
  - Add instructions on the use of "K" code to delete non-applicable procedures from the Procedure Schedule.
  - Clarify policy related to *Noncompliance Determination Guide*, trend indicators, and use of procedure codes, especially 04 and 06.
- *Module 7: Basic Compliance/Noncompliance of Plans*　　　　　OFO – TSC & HRDS
  - Improve discussion of Basic Compliance Checklist.
- *Module 8: E. coli Basic and other Compliance/Noncompliance*　　　　　OPPDE & OFO - DIO
  - Explain the purpose of *E. coli* sampling and role of the special team.

Recommendations	Primary Office of Responsibility

SHORT-TERM

- *Module 9: Other Compliance/Noncompliance (Salmonella, HACCP, SSOP, Other Consumer Protection)*   OFO – TSC & HRDS
    - Schedule more time to cover this essential material. Show video more than once.
    - Emphasize Procedures 01 and 02 in HACCP environment.
    - Clarify inadequate HACCP system.
    - Devote more time to pre-shipment review for product going to an off premise facility.
    - Clarify zero tolerance policy and application.
    - Add workshop on trend indicators.
    - Combine or move closer the discussions of trend indicators in Module 6 and 9. Include specific examples.
    - Develop video on Compliance Officers working with Inspectors.
    - Develop checklist for completing an NR.
    - Discuss requirements to verify corrective action for SSOP and HACCP. Include information on what an Inspector is to do when uncertain about whether or not a corrective action that is proposed is adequate to meet regulatory standards.
    - Emphasize non-food safety is still a regulatory requirement.
    - Explain how inspection personnel should respond when plants initiate alternative procedures.
- *Module 10: Technical Advice and Assistance*   OFO – TSC & HRDS
    - Write a statement explaining why industry has access to the TSC and the TSC's role when interacting with industry. Incorporate statement and discussion into the training materials.
- *Module 11: Business Relations*   OFO – TSC & HRDS
    - Improve delivery of the message.
    - Develop real-life scenarios that illustrate the application of the skills covered in the video.

Recommendations	Primary Office of Responsibility

Support for HACCP Facilitators

• Continue the support that was provided to HACCP Facilitators during the first wave of HACCP implementation.	OFO-DIO & TSC
• Use as many Phase One Facilitators as possible.	OFO - HRDS
• Ensure thorough knowledge of the relationship between regulations and policy and practice; emphasize throughout training.	OFO – HRDS & TSC
• Use subject-matter experts to supplement Facilitators.	OFO –DIO & TSC
• Clarify role of Facilitators after training.	OFO – DIO & DMs

Supervisory Training

• Develop a more useful supervisory training program.	OFO - HRDS
• Provide discussion about new policies.	OFO - HRDS
• Provide practical examples of cultural change.	OFO - HRDS
• Reinforce supervisors' roles as leaders of change and coaches.	OFO – DIO, TSC, HRDS & DMs

LONG-TERM

Training Materials

• *Develop Summary Module*	OFO – TSC & HRDS

- ▪ Present an overview of HACCP and pathogen reduction activities.
- ▪ Relate inspection, enforcement, regulations, etc.
- ▪ Use graphics and figures to depict interactions.
- ▪ Demonstrate an Inspector's typical day-to-day responsibilities in a HACCP plant.
- ▪ Show how to use the regulations to clarify issues.
- ▪ Contrast a typical day under the old inspection system and the new HACCP system.

• *Develop Workshop on Interaction between Inspection Personnel and Compliance Officers*	

- ▪ Cover withholding action, i.e., identify who does what, define terms such as letter of warning, placing the withholding action in abeyance.   OFO – HRDS

Recommendations	**Primary Office of Responsibility**

- *Develop Writing Workshop.*
  - Provide time to practice writing NRs. OFO – HRDS
- *Develop Plant Awareness Meeting Workshop*
  - Cover its purpose and how to do it
    (see specifics in Chapter II recommendations). OFO – HRDS
- Have a group assess the needs of Inspectors and
  other personnel to determine how best to
  package all training materials for easy access
  and updates. Reduce volume. OFO – DIO & TSC & HRDS

Supervisory Training
- Provide additional training for all levels
  of supervisors to reinforce changing roles. OFO – DIO & HRDS

GS-7 Inspection Personnel Training
- Provide minimum training with
  computers and HACCP so they can
  perform GS-8 tasks when a staffing shortage
  occurs (see Chapter V). OFO – DIO & OM

Chapter V
Ongoing Technical Support, Follow-up Training and Communication Activities

All for one, one for all, that is our motto.[62]

Preface

To assist the individuals implementing HACCP and dealing with the day-to-day questions, a variety of support activities were initiated to provide continuing assistance during HACCP implementation. These activities followed the Introductory HACCP Technical Training Program given prior to implementation that is discussed in the previous chapter.

Some examples of the variety of technical support, follow-up training and communication endeavors that took place during Phase One include the following: (1) technical support which was provided primarily by the Technical Service Center staff; (2) follow-up training activities defined as the various types of ongoing training designed to cover information not addressed during the Introductory HACCP Technical Training Program; and (3) communications which covered a variety of conference calls, group meetings, electronic and written documents, weekly conference calls between District Inspection Operations staff in Headquarters and District Managers, work unit meetings, and printed materials. These modes of communication were provided primarily to answer questions about HACCP implementation and to clarify the application of policy, in addition to providing ongoing training and education.

The chapter describes these ongoing activities. Study respondents' comments related to each activity are noted, along with their suggestions for improving these ongoing ones and creating new ones. The chapter concludes with specific recommendations that are grouped by chapter sections for easy reference to supporting text.

Ongoing Technical Support

➢ *Technical Service Center*

The Technical Service Center opened to serve FSIS and industry in June 1997. The purpose of the Technical Service Center (TSC) is to address the need for accurate and consistent distribution of information, correlate the execution of inspection procedures and requirements, and lead the implementation of new and modified inspection programs and procedures. The TSC, which is accessible by telephone, fax, or e-mail, serves as a conduit to disseminate consistent information regarding the development and implementation of inspection programs to inspection personnel and industry. The Introductory HACCP Technical Training Program contained a module that introduced the TSC and described when and how employees should use it.

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[62] The Three Musketeers, 1844.

For those who used the TSC, the most preferred method for contacting the TSC was telephone, followed by e-mail. Very few respondents reported using a fax to contact the TSC. Respondents were nearly unanimous in saying that the TSC was available when they needed an answer. They also gave the TSC high ratings for providing answers in a timely manner. The majority said that the answers they received from the TSC were accurate and provided a user-friendly service.

There were some concerns and suggestions for improvement. A concern that surfaced in the interviews involved getting consistent answers. A perception was expressed that in some cases, different people have received different answers to the same question, or one person has received different answers when the same question was asked to more than one TSC source. There may be several reasons for this perception. One reason may be that the first answer was provided by the TSC staff before receiving policy clarification, while the second answer came after policy was clarified. Another possibility is that the questioner provided different facts when presenting the question that affected the answer that was provided. There are probably several other possibilities. To address this concern, it is important for the TSC staff to clarify any questions they have related to policy before communicating new information to field employees or to industry. Policy questions need to be discussed among representatives from OFO, OPPDE, and OPHS, as needed. It is also important for the TSC staff to conduct regular correlation meetings to ensure that they are providing consistent answers to questions.

Inspection personnel also requested formal *Qs&As*. Two sets of formal *Qs&As* had been issued. These papers listed the most common questions raised during implementation and the Agency's answers. Each set is available to FSIS employees, industry, and others. At the time of this report, one additional set of *Qs&As* is in the clearance process. It is recommended that all *Qs&As* be incorporated into the training for the next wave of HACCP implementation.

Another concern that surfaced when employees were asked to suggest improvements to the TSC was the perception that the TSC was "supporting industry." Field employees are aware the industry is able to contact the TSC for technical advice and assistance. However, they are uncomfortable with this access. This concern is likely based on misinformation or misunderstanding about how the TSC is interacting with industry contacts. To address this concern, it is recommended that the TSC develop a statement explaining why industry has access to the TSC and what the TSC's role is in interacting with industry. This statement could be included in the training for the next phase of HACCP implementation to supplement the information which addresses industry access to the TSC that is currently in Module 10 (see recommendation in Chapter IV).

Another suggestion for improvement was for the TSC to develop a chart or directory showing whom is responsible for what subject matter area as an easy reference for TSC staff. This type of resource would make it easier and quicker for TSC staff to route callers' questions to an appropriate source. It also has the potential of humanizing the service, in that names and faces could be associated with sources of information. One recommended version that the TSC can consider appears in Appendix F. In addition, to the extent possible, all calls should be transferred to the appropriate source for all callers.

➢ *Hotline*

The HACCP Hotline was initiated by the TSC staff on January 19, 1998, one week before HACCP implementation, and has been in continual operation. The TSC and the HACCP Hotline have been the major sources of technical advice and assistance during Phase One implementation. The Hotline had four stations to field incoming telephone calls. During the first week of HACCP implementation in large plants, the Hotline received 936 telephone calls. During January 26th through May 15th, the Hotline received 6,578 calls or an average of 411 calls per week from both FSIS employees and industry personnel. These calls were from a wide cross-section of field personnel: Field Inspectors, supervisory IICs, Circuit Supervisors, Compliance Officers, HACCP Coordinators, and District Managers. As shown in Table 3 below, District Managers, HACCP Coordinators, Circuit Supervisors and supervisory IICs were the most frequent FSIS users of the Hotline based on interview results.

Table 3
Percentage of Each Respondent Category
Using the Hotline/Technical Service Center

Respondent Group	Reported Usage of Hotline/TSC
District Managers	92%
HACCP Coordinators	92%
Circuit Supervisors	65%
Supervisory IICs	55%
Field Inspectors	38%
Compliance Officers	25%

The lowest percentage reporting that they used the TSC were Compliance Officers and Field Inspectors. When asked to suggest improvements for the TSC, Compliance Officers recommended that an enforcement contingent be added. This response indicates that the lack of compliance resources may have accounted for the low usage by Compliance Officers. Currently, these calls are referred to ADME's or District Enforcement Operations, Headquarters.

The low percentage of Inspectors reporting that they use the Hotline may be due to a variety of reasons. For example, it may be more difficult for them to contact the Hotline because they have limited access to the resources that allow them to make the contact: telephones, e-mail, and faxes. Another likely reason is that some Inspectors feel that they are required to use the chain-of-command to get answers to questions. Allowing Inspectors to contact the Hotline directly, without going through their supervisor differs from past practices. It requires a culture change on the part of the Inspector and his/her supervisor. In the past, supervisors were viewed as technical experts. With HACCP implementation, the supervisor's primary role is to be a leader of change and a coach.

Module 10 clearly states that the Agency policy allows anyone, including Field Inspectors, to contact the Hotline/TSC without going through the traditional chain-of-command. It further describes situations that would be very appropriate for an Inspector to contact the Hotline/TSC directly, such as when a supervisor is not available to answer a question in a timely manner and

when a supervisor is unable to answer a question. However, a simple pronouncement in a training video is obviously not enough to facilitate this culture change. As is pointed out in the *Supervisory Guideline*, Inspectors need active, verbal encouragement from IICs to feel comfortable directly contacting the TSC with technical questions. The fact that few of the Inspectors interviewed were using the Hotline indicates the need for additional work in the cultural change arena and supervisor training.

Members of the Hotline staff were also asked to provide recommendations for improving the Hotline's service. The two suggestions for improvements mentioned most frequently were to provide a larger workspace and to clarify the TSC's position on providing questions related to policy and practices. First, staff felt that they needed more room to store resource and reference materials and that they needed to have some way to diffuse the sound of other staff. Their temporary current facilities place staff in very close proximity to each other making it difficult to hear the caller. Second, staff had questions about what the maximum response time should be, how to obtain answers to policy questions, and how to handle requests for written materials. Comments from the Hotline staff, as well as FSIS managers, indicated a need for better coordination between OFO-TSC, OPPDE, and OPHS to facilitate obtaining answers to callers' questions. They expected that these questions would be worked out as they gained more experience in operating the Hotline. When asked what suggestions they had for preparing for the next phase of HACCP implementation, the Hotline staff made numerous suggestions that are listed in the recommendations section of this chapter.

Follow-up Training

As important as the Introductory HACCP Technical Training Program is for inspection personnel about to begin implementation of HACCP in small plants, follow-up training after the Introductory HACCP Technical Training Program is essential. Comments were also made that highlighted the importance of training for those involved with implementation in large plants. A number of changes and clarifications to inspection policy and practices have been provided since January 1998. These updates need to be communicated to all involved in HACCP implementation. Education is an ongoing process. The Agency faces a challenge incorporating the new policies and supporting new practices that build upon the cultural change concepts noted at the beginning of Chapter IV. Topics that need to be covered in follow-up training were identified in the previous chapter and in opening sections of this chapter.

Communications

Communication is an important source of support for HACCP implementation. The Agency used a variety of methods to communicate with those involved in HACCP implementation. The major vehicles are discussed below.

➤ *Headquarters/District Weekly Conference Calls*

One communication strategy that has been used during HACCP implementation is a weekly telephone conference call that takes place between District Managers and Headquarters staff. Its purpose is to keep the lines of communication open between Headquarters and District Managers concerning HACCP policy clarification and other related issues.

District Managers were asked to comment about this weekly call. The comments were mixed. Some said that the calls keep them abreast of new situations. Others indicated that the calls did not always meet their needs, and that they would like to have more input into the agenda. They felt that they would like to have information flowing both up and down the chain-of-command, rather than most of the information flowing down to them. District Managers requested an atmosphere where they could admit problems, raise questions and receive constructive feedback.

District Managers, and in other contexts Inspectors on patrol, stressed the need to be able to communicate with their colleagues. District Managers were interested in initiating conference calls solely for the District Managers. Patrol Inspectors requested time to share questions and experiences with other Field Inspectors. Both these groups of respondents emphasized the tremendous changes that are taking place and need to talk among themselves to obtain a better understanding of policies and practices. Means for lateral communications need to be explored.

➤ *Work Unit Meeting*

Another important communication strategy utilized during HACCP implementation is the work unit meeting. The work unit meeting has been a traditional source of communication for the field workforce. Its purpose is to share information with the in-plant inspection personnel. These meetings usually include the IIC, Inspectors, and the Circuit Supervisor. The meeting may also include inspection personnel from several plants within the circuit, the District Manager, HACCP Coordinator/PIC, and Compliance Officers.

Aware of the importance of this vehicle for communication to in-plant personnel, the Deputy Administrator for Office of Field Operations has made a commitment to members of the National Joint Council that work unit meetings be held (see current *Relationship by Objectives Agreement*, also known as *RBO*). Respondents voiced concern that the meetings have not been occurring on a regular basis due to staffing shortages and budgetary constraints. The perception is that the number of work unit meetings has been decreasing over the past few years. Respondents noted this decline as problematic since work unit meetings would provide an excellent opportunity for information sharing for both inspection and compliance personnel.

A small percent of the Field Inspectors and non-supervisory IICs reported having attended a work unit meeting. One reported that it had been over a year since a work unit meeting had been held. Less than half of the supervisory IICs said they had attended a work unit meeting since

HACCP implementation because of time constraints. A few said they had addressed HACCP-related topics during breaks, lunchtimes, and down time. Topics that were mentioned by respondents who had attended a work unit meeting were zero tolerance, trend indicators, repetitive noncompliance, record keeping, role of GS-7s, and an overview of training for the GS-7s. Similar topics were mentioned for future work unit meetings: zero tolerance, NRs, trend indicators, pre-shipment review, HACCP principles, and how to handle an 02 procedure.

District Managers, Circuit Supervisors, and supervisory IICs were also asked to list the HACCP-related topics that had been covered in work unit meetings during the first quarter of the year. Zero tolerance was the one topic mentioned by all three sources interviewed. Other topics respondents reported as being covered at work unit meetings include systems failures, documentation on NRs, pre-shipment review, appeal rights of establishments, record keeping, SSOPs, plant awareness, enforcement, trend indicators, and utilization of the GS-7s. Many of these topics reflect concerns noted in earlier chapters and address some of the follow-up training needs that have been previously identified.

When asked to recommend topics for future work unit meetings, Circuit Supervisors, supervisory IICs, and Field Inspectors suggested writing NRs and the role of GS-7s. Other frequently mentioned suggestions included the use of trend indicators, determining when an establishment's system is inadequate, and clarifying the zero tolerance policy. These are very similar to the topics that were identified throughout the paper as areas that need further clarification.

It is important to note that Circuit Supervisors, supervisory and non-supervisory IICs all addressed the need to broaden the HACCP awareness of GS-7s. Although GS-7s have no HACCP work, they are requesting information about HACCP and receiving it informally.

In summary, HACCP-related topics are being addressed when work unit meetings are held. The most often mentioned topic addressed at the meetings was zero tolerance which was also the most frequently mentioned topic for future meetings. Work unit meetings continue to serve as a useful tool to provide follow-up support to inspection personnel during implementation of a new program.   However, a concern was expressed about the effect of short-staffing on the ability to hold work unit meetings at the in-plant level. Additionally, interview responses clearly support that limited numbers of in-plant level work unit meetings are being held. An additional concern mentioned was that the next wave of implementation would include many Inspectors who are on patrol assignments. These Inspectors have limited opportunity for dialogue with colleagues in other assignments. Based on experience with the first wave, such dialogue is critical in understanding the HACCP inspection program. Work unit meetings would be one method of allowing dialogue. In light of this situation, IICs, Circuit Supervisors, and District Managers need to continually provide assistance to all inspection personnel implementing HACCP.

➢ *Computers*

Throughout interviews with all categories of respondents, the issues of computers and electronic communication were raised frequently in various contexts. FSIS employees want access to computers that are interactive and compatible with other FSIS computers. Respondents requested computer access for a variety of reasons. Primarily, the computer was viewed as an

essential means for communication. Use of a computer would allow one to receive the latest FSIS information and send/receive messages. Access to a computer would provide an opportunity to use the computer-based training (CBT) modules of which there are many covering subject areas such as inspection, HACCP, poultry and red meat slaughter, etc. Computers would also provide access to PC Dials (the Agency's library of regulations) and other reference materials.

Aware of the importance of computers in the FSIS work environment, the Agency has already made a significant commitment to providing computers to field personnel. This commitment is centered in the Field Automation and Information Management (FAIM) project which began implementation in Fiscal Year 1996. The overall purpose of FAIM is to extend automation to the field inspection workforce by delivering hardware, software, training, technical support and telecommunications. The implementation is in its third year of a five-year plan and is proceeding on schedule. FAIM has already deployed approximately 2,500 computers for FSIS inspection personnel and they have been distributed based on a pre-determined plan. FAIM computers are targeted to IICs, processing Inspectors, import Inspectors, Compliance Officers and Circuit Supervisors. GS-8 inspection personnel were not included in the original FAIM population. However, the FAIM Project Coordinator in each District Office has the authority within FAIM guidelines to send a GS-8 slaughter Inspector to FAIM training if warranted.

The FAIM policy requires any individual who uses a computer to be FAIM trained. The policy for access to computers also states that the computer belongs to the inspection assignment, not the individual Inspector, and must be available to all FAIM-trained inspection personnel in that assignment. Though the IIC might sign for the computer and complete the checklist when the computer is initially delivered, the computer appears on the District Office property list. No individual is personally liable for damage or loss to any FSIS computer, except in cases of willful and intentional abuse.

Computer training and subsequent access to computers need to occur for all inspection personnel as soon as feasible - a simple statement to which most would agree. The issue of feasibility of implementation due to resources and time constraints needs immediate attention.

➤ *Printed Materials*

FSIS prepared a variety of printed resources to provide support for HACCP implementation. These sources included the directives, regulations, the "Blue Book" titled *Regulatory Process for HACCP-Based Inspection Reference Guide*, the training materials, *Qs&As*, and the *Supervisory Guideline*. Field Inspectors, IICs, Circuit Supervisors, and Compliance Officers were asked to rate the usefulness of these reference materials. The directives and the regulations received the highest ratings.

Although the "Blue Book" was on the internet at the time of HACCP implementation and was accessible to employees at large plants, the interviewers reported that the "Blue Book" was not used as a resource as frequently as the "Green Book" for SSOP implementation. The "Blue

Book" lost its usefulness as a "how-to" reference, not only due to a writing style that was less user-friendly, but also because it was distributed several months after implementation, and in some cases, was still boxed in the IIC's office. It is recommended that this book be incorporated into the training materials used for the next wave of HACCP implementation.

Written Clarification of Zero Tolerance. On November 28, 1997, the Agency issued a Federal Register Notice[63] to ensure that industry was aware that FSIS views its existing "zero tolerance" for visible fecal material as a food safety standard. This publication described the Agency expectations for controlling microbiological contamination and requiring a HACCP plan for slaughter to ensure that no visible fecal material is present by the point of final postmortem inspection in livestock carcasses or when poultry carcasses enter the chilling tank. This publication also described that Agency verification procedures and frequencies would continue as they were prior to the implementation of HACCP. This Federal Register Notice was published after the PR/HACCP introductory training had begun for inspection personnel assigned to large establishments. This policy clarification was not available at the time the training was developed and as a result the materials did not contain information or examples related to zero tolerance.

Most of the respondents at the Circuit Supervisor level and above had received additional communications on zero tolerance. *Qs&As*[64] related to zero tolerance were distributed via electronic mail to all District Offices, Circuit Supervisors and all large establishments. Zero tolerance was also discussed at the January Supervisory Conference [65]and on numerous weekly conference calls with District Managers.

Unfortunately, these materials did not "trickle down" to the in-plant level. Most respondents felt a need for a clear definition of what the standard of *zero* means in the zero tolerance policy. This is clearly an area that must be addressed in the Agency's introductory and follow-up training programs. Zero tolerance was cited as the most frequently mentioned topic for inclusion in work unit meetings. It is essential that the Agency publish directives related to verification of zero tolerance for both poultry and livestock in a HACCP establishment. The Agency expectations for verification as well as documentation should be described in the training materials. This information should also be reinforced through at least one example for both livestock and poultry.

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[63] Federal Register Notice, Livestock Carcass and Poultry Carcasses Contaminated with Visible Fecal Material, November 28, 1997.
[64] FSIS HACCP Hotline Trends: FSIS Inspection Personnel Questions on HACCP Implementation, *Q&A Set #1*, March 1998.
[65] Field Supervisory Conference on HACCP Implementation, January 6-9, 1998, College Station, Texas.

➢ *MIS Reports*

The Management Information System (MIS) reports which are generated by the automated system of PBIS were designed to provide information to support supervisory and management decision making. As many other Agency practices which are undergoing changes to accommodate the new HACCP-based inspection program, these reports are in the process of being modified to address the new inspection activities and managers' needs. In addition, they have received limited distribution and use. Therefore, it was difficult to assess their usefulness.

What the study did discover is that it is an optimal time to assess the existing MIS Reports to determine what data are needed, for whom, and at what frequency in this new environment. As they are examined, the following comments from study respondents might be considered. Circuit Supervisors suggested the reports should help identify problem plants by identifying repetitive noncompliances and trend indicators. This information could be used in meeting with plant management. There were also suggestions that the reports include tables and graphs for each procedure for each plant, and that additional training is needed covering how to interpret the data and use the MIS reports. Others mentioned that the current MIS reports appear to offer less information than was available prior to HACCP implementation. Some reported that they had not seen a mechanism that flagged trends and problems requiring immediate attention.

The Raleigh District Manager addressed this shortcoming by developing a form to assist IICs with consolidating information in a systematic way to see trends in a plant. This form[66] was distributed to plants in the district to use on a voluntary basis when carrying out their inspection activities. Users of the form reported its usefulness in tracking noncompliances and identifying trends. A copy of the draft form appears in Appendix E. A form of this type would be useful for all IICs. An additional suggestion to improve the draft form is to add a column for documenting root cause.

➢ *Interactions with Industry*

In addition to the variety of communication mechanisms used within FSIS, the Agency initiated ongoing interactions with industry to resolve issues related to HACCP implementation. Beginning in January 1998, FSIS's Administrator and senior FSIS management conducted weekly meetings with industry representatives. These meetings are open for participation and available via conference call to all stakeholders. The meetings address the concerns of industry and provide a forum for problem solving. Public meetings are another means used by the

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[66] The Raleigh District developed a form to track nonconformances written over time in an establishment. It serves as a quick index to NRs that saves time when searching the NR file for specific cases. It also gives a quick look at the problems recurring at the establishment. Data entry, transfer and sorting are computerized within the District in the plants with Microsoft Works software.

Agency to communicate not only with industry, but also with consumer groups and the general public. Public meetings are planned periodically for HACCP start-up and ongoing implementation. To improve ongoing technical support to industry, the Agency offers the technical assistance and advice services of the TSC/Hotline to all parties. The Agency further publishes *Qs&As* and letters to clarify policy in response to industry requests.

In addition to these efforts to promote interaction with industry, the Agency has initiated the Small Plant Demonstration Project, a major effort to assist small and very small plants with planning for and implementing HACCP systems. The HACCP demonstration projects for small and very small meat and poultry plants are designed to demonstrate how these small-sized establishments can meet requirements of the HACCP final regulation. These projects will be conducted at various sites to show how HACCP systems can work for various products under actual operating conditions and will address issues unique to small and very small establishments. The goal of these demonstration projects is to provide a more extensive understanding of the problems and techniques of HACCP implementation and operation in small and very small establishments.

Recommendations[67]

Based on the study findings, participants involved in HACCP implementation were very appreciative of the ongoing support that was being provided but wanted more. A long list of the variety of ongoing technical support, follow-up training and communications that they are requesting as essential to facilitate HACCP implementation starts on the following page.

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[67] Short-term recommendations are defined as those recommendations that this study identified as feasible to address before Phase Two HACCP implementation. Long-term recommendations are defined as those recommendations that require more time and resources than available prior to January 25, 1999 implementation. Primary offices of responsibility: OFO-Office of Field Operations; OPPDE-Office of Policy, Program Development and Evaluation; DIO-District Inspection Operations; HRDS-Human Resources Development Staff; LMRS-Labor Management Relations Staff; OA-Office of the Administrator, TSC-Technical Service Center, DEO-District Enforcement Operations.

Recommendations	Primary Office of Responsibility

SHORT-TERM

Ongoing Technical Support

- Keep Hotline staff informed of any policy change, clarification and communication about HACCP implementation in advance of communicating or issuing it to industry or field employees. — OFO - TSC
- Conduct more correlation meetings to ensure consistent and current information is being provided to callers. — OFO -TSC
- Develop a chart or directory listing the Agency's services that might be requested by Hotline callers (see Appendix F). — OFO - TSC
- Transfer calls when possible to the appropriate source. — OFO - TSC
- Increase number of telephone lines and staff to accommodate the anticipated increased number of telephone calls. — OFO - TSC
- Utilize experienced Hotline staff to the extent possible. — OFO - TSC
- Provide designated clerical assistance when needed to keep pace with data entry demands — OFO - TSC
- Improve work environment for Hotline staff. — OFO - TSC
  - Provide bookshelf near each desk for easy access and storage.
  - Provide desks with ample workspace.
  - Provide ergonomically correct chairs.
  - Continue to provide headphones.
  - Provide environment that absorbs sound.
  - Provide reference materials that belong to each work station.
- Prepare the most often asked questions and circulate with answers on an ongoing basis and keep updated – hard copy & web site. Need quick turn around. — OFO – TSC & DIO, OPPDE
- Establish policy to handle requests for written responses. — OFO - TSC

Recommendations	Primary Office of Responsibility

SHORT-TERM

Follow-up Training
- Provide clarification on the following: OFO - DIO
  - Definition of system inadequacy.
  - Inspection personnel interaction with Compliance Officers after a withholding action is taken.
  - Documentation of NRs.
  - Plant Awareness Meeting for new employees or employees new to an assignment, and when the HACCP plan undergoes significant modification.

Communications
- Continue using a variety of methods to communicate to field employees after HACCP implementation, including printed reference materials, work unit meetings, and conference calls. In particular, find a way to expedite the issuance of formal *Qs&As*, because this method of communication seems to be preferred by field employees. Coordinate communication through one central source (i.e., public affairs specialist).   OFO – DIO, OA & OPPDE
- Reinforce through channels that all pertinent information must reach the in-plant inspection personnel.   OFO – DIO & TSC
- Provide rationale for all policy and inspection activity changes.   OPPDE & OFO
- Promote communication among colleagues in the field. Encourage lateral communication among CS, patrol Inspectors, and DMs. For example, provide an opportunity for District Managers only to have their own bi-weekly conference calls – will help ensure consistency and raise common questions. Institute the 'buddy system" which requires CO to have IIC present when meeting with plant management.   OFO – DIO, DM
- Clarify that computer is for the inspection assignment and available to all FAIM-trained field personnel to allow exchange of information and access to HACCP technical training on CD ROMs.   OFO

Recommendations	Primary Office of Responsibility
SHORT-TERM	
• Improve coordination among OPPDE, OPHS, and OFO.	OA, OPPDE, OFO & OPHS
• Clarify roles & responsibilities of: District Manager, Circuit Supervisor, and HACCP Coordinator to facilitate exchange of HACCP materials to all employees.	OFO - DIO
Work Unit Meetings	
• Encourage policy of having work unit meetings. Include inspection personnel assigned to large HACCP plants to share some practical experiences. Include Compliance Officers.	OFO
• Communicate any clarifications made to training materials.	OFO – DIO, TSC &
• Use as one means of communicating information related to recommendations from this study.	OFO - DM
Communications with Industry	
• Continue public meetings, town hall meetings, small plant demonstrations to address industry's questions, such as all four parts of a corrective action, pre-shipment review 417.3 and 417.6.	OA & OM
• Schedule more town hall meetings at the local level to reach plant owners and managers.	OA & OFO
Computers	
• Enforce through a variety of means that computers are for an assignment, not solely for supervisors. Emphasize policy during Introductory HACCP Technical Training Program and Supervisory Training.	OFO – DIO & HRDS, OM - FAIM
• Support all efforts to provide computer access to inspection personnel involved in HACCP implementation.	OA, OFO, OM – FAIM
• Support PBIS Redesign Work Group efforts to develop and institute electronic PBIS schedules for sending out, entering data, sending back and analyzing data.	OA, OFO, OM – FAIM

Recommendations	Primary Office of Responsibility

Follow-up Training

- Develop interactive computer-based training modules to cover all basic areas for new inspection personnel and individuals who are promoted into a different job series.   OFO – DIO & HRDS
- Provide training to slaughter Inspectors so they understand the cultural change.   OFO – DIO & HRDS

Communications

Work Unit Meetings

- Develop a set of training materials that are interactive and cover no more than a four-hour time frame. Consider using the IIC, Circuit Supervisor, or HACCP Facilitator as resources in presenting the material and conducting workshops. Using video-taped material is optional. Consider using a conference call or site visit with TSC staff to answer questions generated by the work unit meeting. The materials can be adapted to fit the needs of Circuit Supervisors, and can be delivered at a quarterly meeting.   OFO - TSC

Computers

- Request sufficient funds to provide each inspection personnel with ready access to a computer to facilitate communication on HACCP implementation issues.   OA
- Provide some basic in-plant computer training to inspection personnel on the use of computers. Consider CBT modules and/or IIC-assisted training.   OFO, LMRS & OM-FAIM
- Continue to support computer access for all FSIS employees.   OA, OM - FAIM

MIS Reports

- Organize a task force to address the following: OPPDE, OFO & OM - FAIM
  - Define who the users are and who they should be. Who needs what at what frequency?
  - Provide training on how to interpret data.
  - Consider non-food safety reports.

Recommendations	Primary Office of Responsibility

MIS Reports (cont.)

- ▪ Consider a name change to better reflect purpose.
- ▪ Determine optimal format – tables? graphs?
- Centralize the automated system of PBIS
  that includes the network links down to
  the establishment for the electronic transmission
  of Procedures Schedules, inspection results,
  and MIS reports.   OM – FAIM
- Study the information needs to create reports to
  support supervisory and management decision-
  making.   OPPDE, OM – FAIM & OFO
- Change reporting system such that non-SSOP
  sanitation noncompliance is reflected independent of
  other noncompliance under the 06D01 procedure
  code. Prepare now for conversion from the ISG
  to the ISP in small plants to minimize the
  associated data entry downtime.   OPPDE & OFO
- Standardize the Raleigh District form.   OPPDE, OFO & OM

Chapter VI
Road Map to Next Phases of HACCP Implementation

But the point is to encourage them to try something new. To innovate. To take some chances, to try to change and evolve with the new circumstances they confront. Mistakes are then recognized as opportunities to learn. Organizations that don't learn, don't change. Organizations that don't change eventually don't work, because the world changes; change is a fact of life.[68]

Preface

This evaluation was designed to address a series of questions that focused on the major areas of inspection activities involved with Phase One HACCP implementation. The approach used throughout this evaluation was to focus on what policies and practices are going well, which ones need to be changed, and what recommendations are justified to facilitate the next phases of HACCP implementation. The previous chapters have already answered the nine questions (listed below) which were originally proposed in the first chapter.

- How are inspection personnel implementing the new inspection procedures?
- How is the enforcement program operating?
- How is PBIS working?
- How is training being applied in the field?
- How is industry's implementation of HACCP affecting inspection activities?
- How are supervisors carrying out their responsibilities?
- To what extent is the cultural change occurring with respect to inspection personnel and supervisors?
- How are the following staffs supporting HACCP implementation – the Technical Service Center, District Office, Headquarters?
- How are all parties communicating?

This chapter begins by briefly raising each question and summarizing the main study findings pertaining to each one. The last section of the chapter synthesizes the wealth of information obtained from raising these questions and presents a conceptual framework for moving to the next phases of HACCP implementation. Four over-arching issues that surfaced throughout the data collection are identified with the most promising recommendations. These four issues are proposed as four steps in a road map for facilitating implementation of HACCP throughout the Agency.

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[68] Al Gore, 1994. Remarks as delivered. Marver H. Bernstein symposium on Government Reform. Georgetown University, Washington, D.C., March 29,1994.

How are inspection personnel implementing the new inspection procedures?

Inspection personnel are implementing the new inspection procedures in the large plants operating under a HACCP system. Problems have been encountered due to a variety of policy confusions and application difficulties. Recommendations are centered in the need to clarify the following issues:

- application of zero tolerance
- definition of system concept and system inadequacy
- meaning of procedures 01 and 02 under HACCP
- use of trend indicators
- linkage of repetitive Noncompliance Records (NRs)
- linkage of failed corrective actions and future planned actions
- use of one Procedure Schedule
- clarification of pre-shipment review policy and procedure

How is the enforcement program operating?

Enforcement actions are being taken as planned under the new system. Inspection and compliance personnel are beginning to work together as a team. However, inspection personnel did voice concern about understanding their role in supporting a number of new enforcement policies and practices. Their main requests were for additional information to explain the following:

- when to take a withholding action
- what happens after withholding action is taken
- when has an abeyance agreement failed
- what to do if unclear about the establishment's corrective action and preventive measures

How is PBIS working?

PBIS-HACCP is functioning; but as any new software system, it needs additional modifications to operate as effectively as needed in a HACCP environment. The reports generated by PBIS also need to be examined for their relevance to various audiences. Concerns voiced for consideration in PBIS modifications include the following:

- large number of unscheduled procedures being performed
- concern for procedures marked performed when not completed
- usefulness of MIS Reports for various users

How is training being applied in the field?

The Introductory HACCP Technical Training Program was created and delivered to individuals involved in Phase One HACCP implementation. Participants rated the program useful, noting that it covered a wide range of essential information. They also cited a long list of recommendations for both the introductory course and follow-up training. The main recommendations concerning the Introductory HACCP Technical Program are as follows:

- Start the training early to allow time to assimilate the materials.
- Send training materials to participants prior to scheduled training.
- Provide more hands-on and experience-based training sessions.
- Discuss the changes from the old system to the new system, e.g. procedures 01 and 02.
- Train the GS-7s.
- Support follow-up training activities.

How is industry's implementation of HACCP affecting inspection activities?

Respondents expressed concern about small plants not being ready for January 1999 implementation and the effect that lack of readiness would have on both inspection and compliance personnel. Current confusion by both inspection and industry personnel about application of zero tolerance and definition of pre-shipment reviews has caused difficulties within FSIS. Suggestions included:

- Conduct more town hall meetings.
- Support the Small Plant Demonstration Project.
- Distribute materials to small plant management.

How are supervisors carrying out their responsibilities?

Supervisors are adjusting to their new roles. The following recommendations were voiced:

- Reinforce supervisors' roles as leaders of change and coaches.
- Emphasize the need for supervisors to pass information to the in-plant personnel in a timely manner.
- Develop and implement supervisory training for all levels of supervisors.

To what extent is the cultural change occurring with respect to inspection personnel and supervisors?

The cultural change is occurring at all levels to varying degrees. Cultural change is a slow process and FSIS needs to continually reinforce the underlying reasons for policy

and operational changes. To facilitate the cultural change, the following suggestions were made:

- Reinforce the policy that computers should be available to the assignment.
- Provide guidance to in-plant personnel on using one Procedure Schedule.
- Develop a supervisory training course for all levels of supervisors.
- Encourage field inspection personnel to call the Hotline and Compliance Officers directly.

How are the following staffs supporting HACCP implementation – the Technical Service Center, District Office, Headquarters?

The staffs at the Technical Service Center (TSC), District Offices and Headquarters are making efforts to support HACCP implementation. Respondents noted some areas where improvement might be made:

- Technical Service Center
  - Improve the consistency of responses.
  - Address confusion about why TSC provides support to industry and FSIS.
- District Offices
  - Address the inconsistencies in practices across districts.
- Headquarters
  - Improve communications with field personnel.
  - Reduce times that industry has information before FSIS personnel.
  - Provide avenues for two-way communication with field personnel.

How are all parties communicating?

FSIS has initiated a number of communication vehicles to reach its different audiences. While these efforts are commendable, there is much room for improvement. Noted examples are the following:

- Distribute interactive compatible computers to all assignments and make available to all FAIM-trained field personnel.
- Reinforce regular work unit meetings.
- Explore means for more communication between inspection and compliance personnel.
- Initiate lateral modes of communication, such as time for patrol Inspectors to communicate, District Manager conference calls.
- Institute the "buddy system" where a Compliance Officer only meets with plant management with the IIC present.

Road Map Steps to Next Phases of HACCP Implementation

After reviewing the information collected pertaining to each of the original study questions, consideration was given to how else the information might be meaningfully conveyed. A useful framework for capturing the main concerns expressed by all categories of respondents is proposed. This four-step roadmap is designed to help decision-makers address the abundance of information heard through study respondents. Responses were grouped into four steps, each representing a main issue area: (1) clarification of policy and terms, (2) basic understanding of key concepts and their practical application, (3) communication among FSIS employees, and (4) essential inspection activities. The four "steps to success" are discussed in the order in which they would logically need to be addressed to ensure continued success with HACCP implementation.

Step One: Clarify Policy and Terms

Inspection personnel from the in-plant level to the Headquarters managers expressed a need for further definition of the following:

- HACCP systems concept and system inadequacy
- trend indicators
- procedures 01 and 02
- pre-shipment review
- zero tolerance

As discussed in Chapter II, the HACCP systems concept is a new inspection philosophy that requires looking at system to prevent hazards in food production rather than specific tasks to examine products or processes. The inspection workforce must understand the systems concept, in addition to the technical aspects of HACCP, to be able to determine system inadequacy. Lack of understanding of the systems concept is one reason trend indicators are misunderstood, because trend indicators group specific types of noncompliance in the system. The definitions of procedures 01 and 02 are also misunderstood due to confusion with pre-HACCP inspection terminology, and possibly because the 02 procedure is a systems procedure that frequently cannot be completed in one day. Inspection personnel also need clarification on how to verify an establishment's pre-shipment review, because there is considerable latitude in acceptable methods of conducting pre-shipment review. Like all the previous terms, an understanding of the Inspector's role in pre-shipment review requires an understanding of the HACCP systems concept. The last term inspectors expressed a need for further definition is zero tolerance. Since policy clarification on zero tolerance was published after the Introductory HACCP Technical Training Program materials were developed, and since industry questions the scientific validity of the zero tolerance policy, FSIS's stance must be clearly delineated in introductory and follow-up training.

Step Two: Promote Basic Understanding of Key Concepts and their Practical Application

All respondent categories emphasized the need to understand how their daily activities relate to new policies and procedures. The challenge for the Agency is to translate the cultural change concepts to practical inspection and compliance activities at all levels. The importance of training can not be over emphasized as the primary means for conveying the new HACCP-based inspection program to all FSIS personnel. The following types of training are essential:

- introductory training
- follow-up training
- supervisory training

As discussed in Chapters IV and V, respondents requested more hands-on and experience-based examples during both introductory and follow-up training. Some suggested ways to accomplish this include: field trips to establishments that have fully implemented HACCP-based inspection, cross-training between establishments, work unit meetings based on real-life scenarios, and workshops for developing specific skills (such as linking NRs). Respondents also spoke of the importance of follow-up training to keep all FSIS personnel aware of policy clarifications and new practices. Regular updates with follow-up training for reinforcement will promote consistency in policy application. Supervisory training targeted to cultural change and leadership was cited as necessary to continue the formidable task of major organizational change.

Step Three: Improve Communications Among FSIS Employees

Respondents voiced complaints about the lack of current information being exchanged at all levels of the organization. In-plant personnel were especially vocal about the lack of up-to-date information that they received. Field managers also wanted additional avenues for communication with their colleagues. The following communication mechanisms were emphasized:

- computers
- work unit meetings
- "buddy system"

Facilitation of communications among all FSIS employees is essential for a variety of reasons: to help assimilate new information, to keep current on policies and practice, to obtain answers to questions, and to learn new skills and knowledge. Different modes of communication will provide opportunities for more individuals to receive and share information. Individuals learn in different ways and the Agency needs to use existing methods and explore new ones to reach those in need. Computers are largely an untapped resource that needs to be uncovered. Existing arrangements for conference calls, work unit meetings and other gatherings need to be used to the fullest extent possible. Written materials need to address continuing questions in clear concise language and reach in-plant personnel. The general sentiment expressed by Inspectors was that many times information was not shared with them in a timely manner. They felt that industry often hears about changes in policy and inspection procedures before inspection

personnel. In addition, both inspection and compliance personnel noted that continued efforts are needed to improve their working relationship. One possibility is to institute the "buddy system" which would be defined as whenever a Compliance Officer meets with plant management, the IIC is included.

Step Four: Reinforce Essential Inspection Activities

Respondents were still learning the new ways and struggling with implementation of the many new practices. They identified several activities that were essential to their success on the job:

- plant awareness meetings
- one Procedure Schedule
- GS-7 training
- tracking NRs

Field Inspectors emphasized the importance of the plant awareness meetings. They requested additional training on planning and conducting the meetings, noting that these meetings are fundamental in carrying out their inspection duties. Inspectors are struggling with the use of one Procedure Schedule and need additional help to understand the rationale for one schedule and information sharing with inspection personnel in establishments where it is working well. GS-7s need introductory HACCP technical training to function as part of the inspection-compliance team. In addition to promoting the team concept, this training will allow knowledgeable GS-7s to fill in for GS-8s during staff shortages.

An NR tracking system for use by in-plant inspection personnel was developed and distributed in the Raleigh District to address ongoing difficulties in this area. Consideration should be given to standardizing the form, distributing it nationwide, and computerizing its use in those districts with compatible software (see Appendix E).

Appendix A

Description of Performance Based Inspection System (PBIS)

The revised Performance Based Inspection System (PBIS) provides the structure and framework for accomplishing the Regulatory Oversight Model. The automated system of PBIS schedules work to be done by inspection personnel in meat and poultry establishments. It incorporates inspection findings into a central database and creates reports from the database that are used to support supervisory and management decision making. Two components of PBIS guide inspection program activities[69]. The first component is the Inspection Procedures Guide and the second component is the automated system. The revised PBIS approach is only used after HACCP is implemented in an establishment.

Inspection System Procedure Guide (ISP) defines the work inspectors perform in meat and poultry establishments. The ISP contains eight **activities**[70], each of which contain one or more **elements**[71]. Each element has one or more **procedures**[72] that inspectors follow to assure compliance with inspection regulations. Procedures may have two components, a recordkeeping component and a review and observation component. Currently, the ISP contains off-line slaughter and processing procedures. The procedures are designed to reinforce FSIS's regulatory oversight role and to be compatible with the systems approach of the regulatory oversight model. The procedures center on the establishment preventing problems in the process rather than inspection detecting problems. The new HACCP inspection system determines if the plant has a system in place to prevent the production of unsafe meat and poultry products. This new system emphasizes the plant's responsibility in complying with regulatory requirements and allows inspection to monitor the effectiveness of the plant's written plan and procedures. The previous PBIS system dealt with after-the-fact detection and decision making of product and process defects to ensure food safety.

The Automated System schedules work and incorporates findings from conducting inspection procedures. The following forms and activities are used to initiate and maintain the automated system. The **Plant Profile**[73] contains basic plant information, such as the establishment's address. The **Establishment/Shift Procedure Worksheet**[74] is used by inspectors to document which procedures in the ISP apply to the plant. The automated system uses this worksheet to establish an **Establishment/Shift Procedure Plan** specific to each plant produce a **Procedure**

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[69] FSIS Directive 5400.5, Inspection Systems Activities, Overview, PBIS.

[70] The activities are the following: 01 - SSOP, 02 - On-line Slaughter (reserved), 03 - HACCP, 04 -Economic/Wholesomeness, 05 - Sampling, 06 - Other Requirements, 07 - (reserved), and 08 - Emergency Elements.

[71] For example, the elements for the HACCP Activity are the Basic Compliance Check (03A) plus the nine HACCP processes: Raw Product-Ground (03B), Raw Not Ground (03C), Thermally Processed/Commercially Sterile (03D), Not Heated Treated-Shelf Stable (03E), Heat Treated-Shelf Stable (03F), Fully Cooked-Not Shelf Stable (03G), Heat Treated but Not Fully Cooked (03H), Product with Secondary Inhibitors-Not Shelf Stable (03I), and Slaughter (03J).

[72] There are three types of procedures: sample collection, SSOP record verification, and verification procedures. The number of verification procedures varies for each element. SSOP record verification procedures only pertain to record checks while the other verification procedures involve record checks, hand-on measurements, and direct observations.

[73] See FSIS Form 5400-1.

[74] See FSIS Form 5400-5.

Schedule (PS) [75] using the frequencies and inspection priorities assigned to each element to schedule the procedures inspectors are to follow during each shift at the establishment. There is only one Procedure Schedule per establishment shift. If there is more than one inspector assigned to a shift, the Inspector-in-Charge (IIC) uses the PS to assign specific procedures to the inspector(s)[76]. The PS is also used by inspectors to document (1) compliance with procedure performed; (2) noncompliance with procedure performed; and (3) not performed procedure. When a noncompliance is found, inspection personnel use the **Noncompliance Determination Guide (NDG) /Trend Indicators** and **Noncompliance Records (NR)** to determine and document that the establishment failed to comply with one or more regulatory requirements. The **NDG**[77] provides guidance on the selection of trend indicators in establishments. **Trend indicators**[78] are groupings of specific types of noncompliance identified in establishments covered by HACCP. The **NR** is the form[79] used by inspection personnel to document noncompliance with a written description and the appropriate trend indicators. Finally, the **Management Information System (MIS)**[80] activity of PBIS produces reports used to evaluate establishment noncompliance (including trends) and used to support supervisory and management decision making. Summary reports are also provided to establishment management.

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[75] See FSIS Form 5400-2.

[76] Supervisors of multiple inspector assignments are required by negotiated agreement to allow inspectors to participate in the process of assigning work.
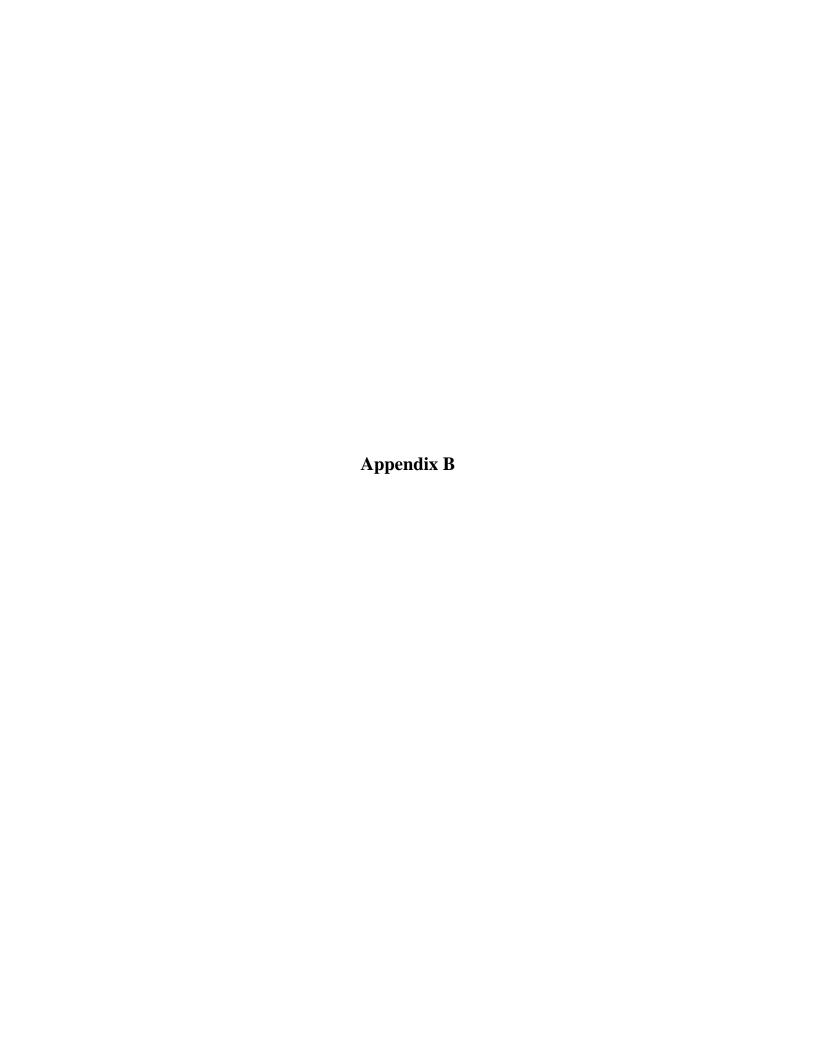
[77] The *Noncompliance Determination* Guide is Attachment 5 to FSIS Directive 5400.5, Inspection Systems Activities.

[78] Trend indicators describe noncompliance with the regulations. There are trend indicators specific to each Activity. For example the SSOP Activity has five trend indicators-monitoring, corrective action, record keeping, implementation and basic food safety noncompliance. The HACCP Activity has five trend indicators-monitoring, corrective action, record keeping, verification, and basis food safety noncompliance. The NDG documents trend indicators and how these are used to document noncompliance.

[79] FSIS Form 5400-4

[80] There are nine reports available from the automated system of PBIS. These are the following: the Procedure Schedule, Procedure Schedule Summary, Activity Summary Condition, Establishment Element Condition, Daily Procedure Establishment Results, Weekly Summary Condition, Element Summary Condition, Procedure Summary Condition, and the HACCP Feedback NOT Entered Report. National reports are being developed by the Technical Service Center, some of which were used in this report.

Appendix B

List of Team Members – Evaluation of Phase One of HACCP Implementation

Project Leaders
John Carlson	Director, OFO, TSC
Jane Roth	Director, OPPDE

Core Team
Don Delozier	*Staff Officer, OFO, TSC*
Peggy Frankel	*Program Analyst, OPPDE*
Cheryl Green	*Program Analyst, OPPDE*
Martin Hickman	*Compliance ADME, OFO*
Edie Kelly	*Program Analyst, TSC, OFO*
Karlease Kelly	*Program Analyst, TSC, OFO*
Dave Kroeger	*President of Midwest Council, NJC*
Steve Lalicker	*Program Analyst, TSC, OFO*
Barbara Masters	*Branch Chief, OFO, TSC*
Mike Micchelli	*Program Analyst, OPPDE*
Herb Ostach	*Inspection Liason Officer, OFO*
Bobby Palesano	*Staff Officer, TSC, OFO*
Chris Robinson	*SVMO, OFO*
James Vernon	*President of North Central Council, NJC*
Randy Wurtele	*President of Western Council, NJC*
Cynthia Williams	*Program Analyst, OPPDE*

Data Collection Team
Lou Bratkiewiez	*Food Inspector, OFO*
George Carnes	*Staff Officer, OFO, TSC*
Velmer Chipps	*Staff Officer, OFO, TSC*
Robert Hess	*Staff Officer, OFO, TSC*
F.A. Khan	*Staff Officer, OFO, TSC*
Ron McDaniels	*Staff Officer, OFO, TSC*
Darrell Pritchard	*Food Inspector, OFO*
William Rocheleau	*Food Inspector,* OFO
Larry Sharp	*Food Inspector, OFO*
Eldon Sharpley	*Food Inspector, OFO*
Mary Suntken	*Compliance Officer,* OFO
Denise Turner	*Food Inspector, OFO*
Darrell Wagner	*Staff Officer, OFO, TSC*
Pat Walters	*Food Inspector, OFO*
Muhammad Zia	*Review Staff Officer, OFO, TSC*

Support Team
Linda Brown	*Secretary, OFO, TSC*
Peachie Burlin	*Staff Officer, OFO, TSC*
Michael Craig	*Staff Officer, OFO, TSC*
Linda Eggers	*Secretary, OFO, TSC*
JoAnn Gnat	*Office Automation Clerk, OFO, TSC*
Kris Murthy	*VMO, OPPDE*
Mike Ricketts	*Office Automation Clerk, OFO, TSC*
Zig Sala	*Program Manager, OFO*
Mary Shropshire	*Office Automation Clerk, OFO, TSC*
Madge Stone	*Management Analyst, OFO*
Linda Sullivan	*Program Analyst, OFO, TSC*
Ralph Terry	*Staff Officer, OFO, TSC*

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*Acronyms for team members' titles and office affiliations:
OFO – Office of Field Operations
TSC – Technical Service Center
OPPDE – Office of Policy, Program Development and Evaluation
SVMO – Supervisory Veterinary Medical Officer
VMO – Veterinary Medical Officer

Appendix C

HACCP SYSTEMS BASIC COMPLIANCE CHECKLIST

ESTABLISHMENT NAME	ESTABLISHMENT NO.	PROCESS

PRODUCTS COVERED BY PROCESS

IMPLEMENTATION DATE	NEW PRODUCT	REASSESSMENT DATE *(Yearly: Check for dated signature only)*

Use this checklist to document findings of noncompliance with the requirements set out in FSIS Directive 5000.1, Part Two, Paragraph II.B.

1. HAZARD ANALYSIS AND HACCP PLAN DEVELOPMENT

REQUIREMENT	YES (✓)
INITIAL HAZARD ANALYSIS (§ 417.2 (a))	
The establishment has not conducted a hazard analysis or had a hazard analysis conducted for it.	
The hazard analysis	
does not include food safety hazards that are reasonably likely to occur in the production process, or	
does not identify the preventive measures the establishment can apply to those food safety hazard (s)	
The hazard analysis does not include a flow chart that describes (diagrams) the steps of each process and product flow in the establishment.	
The hazard analysis does not identify the intended use or consumers of finished product (s).	
INITIAL PLAN DEVELOPMENT (§ 417.2 (c) (4), § 417.3 (a) (2), and § 417.4 (a) (1))	
The establishment's hazard analysis revealed one or more food safety hazards that are reasonably likely to occur, and the establishment does not have a written HACCP plan for each of its products (§ 417.2 (b) (1); § 304.3 (c) or § 381.22 (c)).	
The establishment has not conducted validation activities to determine that a HACCP plan is functioning as intended.	
The establishment's records do not include	
multiple results that verify the monitoring of CCP's and conformance with critical limits, or	
after a deviation from a critical limit (if any), subsequent results that support the adequacy of corrective action (s) in achieving control at the CCP.	
SUBSEQUENT ANALYSIS AND PLAN DEVELOPMENT	
HAZARD ANALYSIS REASSESSMENT	
After an establishment's hazard analysis revealed no food safety hazards that are reasonably likely to occur, there was a change that could reasonably effect whether a food safety hazard exists, the establishment did not reassess the adequacy of the hazard analysis (§ 417.4 (b)).	
NEW PRODUCT (§ 304.3 (c) or § 381.22 (c))	
(1) Before producing new product for distribution, the establishment did not conduct a hazard analysis (or have a hazard analysis conducted for it), or	
did not have an applicable HACCP plan for the product.	
(2) The establishment began distributing a new product more than 90 days ago, and it has not validated the HACCP plan that covers the new product.	

REQUIREMENT	YES (✓)
MULTIPLE PRODUCTS A HACCP plan covers more than one product and the products are not all within one of the nine processing categories specified in § 417.2 (b) (1), § 417.2 (b) (2).	
FOOD SAFETY HAZARD (S) The HACCP plan does not list the food safety hazard (s) identified in the hazard analysis (§ 417.2 (c) (1)). (Exception: A HACCP plan for thermally processed/commercially sterile products produced in accordance with part 318, subpart G, or part 381, subpart X, need not address food safety hazards associated with microbiological contamination (§ 417.2 (b) (3)).)	
HAZARD CONTROL The HACCP plan does not list CCP's for each food safety hazard (§ 417.2 (c) (2)).	
The HACCP plan does not list critical limits to be met at each CCP (§ 417.2 (c) (3)).	
MONITORING The HACCP plan does not list the procedures to be used to monitor each CCP <u>and</u> the frequency with which these procedures will be performed (§ 417.2 (c) (4)).	
CORRECTIVE ACTIONS The HACCP plan does not identify the corrective action to be followed in response to a deviation from a critical limit at a CCP (§ 417.2 (c) (5)).	
VERIFICATION PROCEDURES The HACCP plan does not list the procedures that the establishment will use to verify that the plan is being effectively implemented <u>and</u> the frequency with which these procedures will be performed (§ 417.2 (c) (7)).	
The HACCP plan's recordkeeping system does not document the monitoring of CCP's and/or does not include records with the actual values and observations (§ 417.2 (c) (6)).	
ACCEPTANCE AND REASSESSMENT (§ 417.2 (d)) The responsible establishment official did not sign and date the HACCP plan (1) upon initial acceptance, or	
(2) at least annually thereafter upon required plan reassessment.	
MODIFICATION The HACCP plan was modified, and the responsible establishment official did not sign and date the plan (§ 417.2 (d) (2) (ii)).	

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2. CONTENTS OF HACCP PLAN (S)

3. RECORDKEEPING

4. DATED SIGNATURE

Appendix D

# FSIS NOTICE	12-98	4-8-98

NOTIFICATION TO ESTABLISHMENTS OF INTENDED ENFORCEMENT ACTIONS

This notice explains FSIS's process for notifying establishments of intended enforcement actions related to HACCP system inadequacy determinations.

If the Inspector-in-Charge (IIC) determines that there may be a HACCP system inadequacy because an establishment has multiple, recurring noncompliances as specified in 9 CFR 417.6 and has failed to adequately implement immediate and further planned actions as documented on the Noncompliance Record (NR) (FSIS Form 5400-4), the IIC should discuss this developing trend at the weekly meetings held with establishment management. If the IIC subsequently determines that the trend of multiple, recurring noncompliances without successful interventions has led to a HACCP system inadequacy and that the marks of inspection should be withheld, he or she shall contact the District Office (DO) and provide all the relevant information for the DO to prepare a "Notice of Intent to Suspend Inspection." The Notice shall:

1. inform the establishment that the nature and scope of the noncompliances indicate that the HACCP system is inadequate as specified in 417.6 of the regulations;

2. state that, because of the trend, FSIS intends to withhold the marks of inspection and suspend inspection;

3. explain the reason for the determination;

4. reference each pertinent NR by number;

5. inform the establishment that it is being afforded the opportunity to demonstrate why a HACCP system inadequacy determination should not be made or that it has achieved regulatory compliance; and

6. provide the establishment 3 business days from the date of the letter to provide its response to the DO.

Based on the establishment's response, FSIS will determine further actions.

If at any time inspection personnel determine that adulterated product was shipped, they should proceed in accordance with FSIS Directive 5000.1 part II. paragraph III. C.
 /sig/
Margaret O'K. Glavin

Deputy Administrator
Office of Policy, Program Development
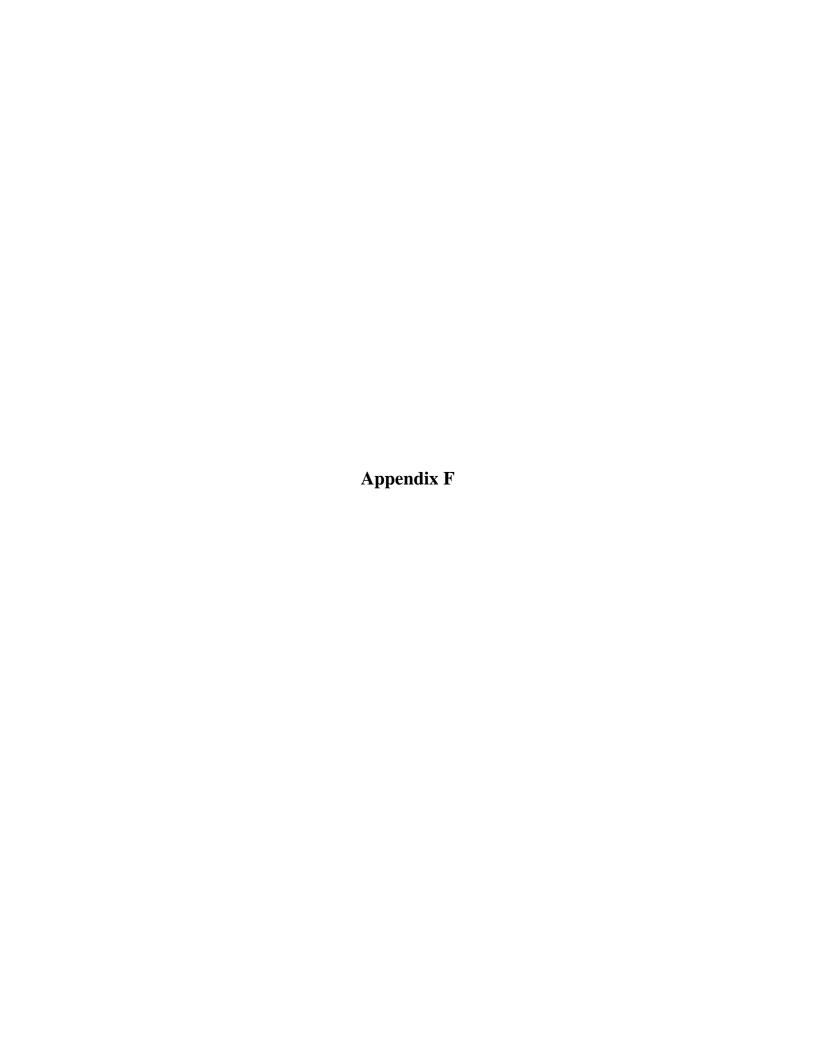 and Evaluation

DISTRIBUTION: Inspection Offices; T/A Inspectors; Plant Mgt; T/A Plant Mgt; TRA; ABB; PRD; Import Offices	NOTICE EXPIRES: 4-1-99	OPI: OPPDE

Appendix E

Noncompliance Record (NR)/Process Deficiency Record (PDR)
PLANT SUMMARY SHEET*

Plant/Shift Number	Date	NR/PDR Number	ISP/ISG Code	Trend Indicator	NR Summary	Corrective Action	Preventive Action

*The Raleigh District Manager developed this form. An additional column for documenting root cause is suggested.

Appendix F

Guide to Contact Persons by Subject Matter In
Response to Calls to TSC

Subject Matter	Office/Branch	Contact Person(s)	Phone Number
Labor Management Issues	LMR		
Compliance	DEO		
FSIS Directives	OPPDE		
E. Coli Sampling	OPHS		
Inspection Policy	OPPDE		
Salmonella Sampling	OPHS		
Imports	TSC		
HACCP	TSC		
Processing	TSC		
Slaughter	TSC		
PBIS	TSC		
Labeling	TSC		
Facilities and Equipment	TSC		
Noncompliance Determination Guide	TSC		
Inspection System Procedure(s) Guide	TSC		
State Programs	TSC		
Egg Products	TSC		
Training	TSC		
Canning	TSC		
Irradiation	TSC		