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HACCP development and regulatory assessment in the United States of America

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Abstract

Hazard Analysis Critical Control Point (HACCP) is internationally recognized as the best method of assuring product safety by controlling foodborne safety hazards. Currently, within the USA, the FDA has mandated HACCP for fish and fishery products and is proposing mandating HACCP for fruit and vegetable juices. The USDA has mandated Pathogen Reduction/HACCP requirements for meat and poultry processing, and the NMFS Seafood Inspection Program operates a voluntary HACCP program for seafood plants. The requirements for mandatory implementation and proposed regulations represent a significant change in the manner in which foods are regulated for food safety and necessitate a new understanding of the different roles and responsibilities between the food industries and the regulatory agencies within the USA. Each agency will approach the evaluation process differently given their unique legislative authorities and programmatic operations. Nevertheless, each agency agrees that HACCP is the best food control system of choice and is committed to improve food safety requirements.

Keywords: HACCP; Food safety; Critical control points; Critical limits; Pathogen reduction; Regulatory; Risk; Verification; Validation

1. Introduction

Hazard Analysis Critical Control Point (HACCP)-based inspection systems in the United States of America (USA) first began in the low-acid canned food industry through a jointly developed industry/government regulatory program to control the threat of botulism in low-acid canned foods. This early program recognized the need to separate the necessary or the essential activities from the non-essential quality control and regulatory compliance assessment activities so that a systematic focusing of resources could be achieved to prevent major processing errors by properly identifying the hazards and addressing the critical areas necessary to control the process.

In recent years in the USA, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) indicated that HACCP has been evolving for a number of years, to the extent that there are now nationally and internationally recognized General Principles and Guidelines for their Application (NACMCF, 1992). The NACMCF has pointed out that there are distinct differences between the roles of industry and government regulatory authorities in the HACCP food safety concept.

NACMCF indicated that the role of government is to mandate the regulatory requirements for HACCP implementation; verify that HACCP plans are working in relation to the mandated General Principles and Guidelines; establish mandated critical limits when necessary; establish criteria, methods, and sampling plans when necessary; and verify that individual facility HACCP plans are adequate to assure food safety. Additional government activities should be to use epidemiological and scientific data to identify hazards and conduct risk evaluations to provide information which can be used to improve HACCP plans; support research relating to critical control points, critical limits, and monitoring procedures; cooperate with interested groups to identify new food safety hazards and identify strategies for their control; represent the USA at international meetings of government representatives where

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HACCP may be discussed; encourage and participate in educational programs to promote the use of HACCP; cooperate with industry in the development of generic HACCP plans; and finally, exercise whatever actions are deemed necessary to prevent unsafe food from reaching consumers.

In terms of industry responsibilities, the NACMCF indicated that the industry must develop, implement, and maintain an effective HACCP system, with each facility forming an HACCP team that is responsible for the HACCP plan. Further, each facility must maintain an accurate, up-to-date HACCP plan which can be reviewed by regulatory personnel. Amendments to each facility's HACCP plan are to be made when the plan has been found to be inadequate, and further, that each facility will exercise whatever actions deemed necessary to prevent unsafe food from reaching consumers.

2. Current situation

Currently, within the USA, the FDA has mandated HACCP for seafood plants and is proposing mandating HACCP for facilities producing fruit and vegetable juices (FDA, 1995). The USDA has mandated Pathogen Reduction/HACCP requirements for meat and poultry plants, and the NMFS Voluntary Seafood Inspection Program operates an HACCP program for seafood plants (USDA, 1996). Due to the different legislative authorities and product risk consideration, each agency has developed and implemented their HACCP requirements in a slightly different fashion. Regardless, each agency program has common program elements to address: (1) Good Manufacturing Practice/Standard Sanitation Operating Procedures, consideration as a prerequisite to HACCP implementation; (2) general HACCP principles; (3) verification methods of industry development, implementation, and maintenance of effective HACCP systems; (4) performance standards; (5) engagement in internal and outreach programs for education and training; and (6) sponsorship of research to improve HACCP system functionality. The following narrative describes the different USA Federal agencies' approach and experiences in dealing with HACCP from a regulatory perspective.

3. FDA activities

3.1. Purpose of assessing HACCP

Measuring the effectiveness of a "new" food safety program such as HACCP is an important consideration if regulatory agencies are to develop information on the advantage of conducting an HACCP-based audit over conducting a sanitation based inspection. Both the food industry and the regulatory agency share the same goal of ensuring a safe food supply. Nevertheless, the food processor and the regulator may have different perspectives as to how "effectiveness" should be measured because each may place different values on the benefits that HACCP provides. The second challenge is to identify measures of effectiveness that are objective and direct, and measures that have a baseline against which an assessment can be made and/or a change can be calculated.

The regulatory agencies in the USA recognize the importance of assessing the effectiveness of HACCP. For example, the Seafood HACCP Rule advises that FDA intends to evaluate key features of this program, which will include an assessment of their effectiveness. FDA recognizes that HACCP represents a pioneering program and that full scale implementation may reveal that some modifications are necessary. Developing evaluation data will also address FDA's need to provide a rational basis for HACCP regulations for other commodities. The rule explains that FDA will judge the merits of a processor's verification:

> ... through its own continuing determinations of whether the processor's overall HACCP system remains appropriate for the circumstances. These determinations will occur as a product of the Agency's ongoing inspection program.

3.1.1. Purpose of assessing HACCP from the regulatory perspective

The goals of a regulatory agency for HACCP as a means of establishing additional food safety controls are to:

- make the food supply safer through prevention of food safety problems;
- enable regulatory agencies to more efficiently utilize their existing resources devoted to ensuring food safety;
- enhance the ability of the regulatory agency to provide consumers with the assurance they seek that the food supply is safe; and
- underscore the industry's role in continuous problem prevention and problem solving.

It is too early to report on FDA's evaluation of the seafood HACCP regulation because implementation of the rule by the seafood industry only began in January 1998. However, FDA has been implementing a pilot program for foods other than seafood since 1995 and has been able to address the issue of program evaluations. FDA established from its pilot program that it is feasible to objectively measure whether HACCP is effective in accomplishing these goals. The factors that are being used in making this assessment are summarized in Table 1.

Table 1
Factors to consider in measuring the effectiveness of HACCP from the regulatory perspective

Desired outputs	Potential yardsticks to measure outputs	Baseline data available to regulatory agency
Safer food supply through prevention of food safety problems	Incidence of out-of-control food processing	Pre-HACCP incident rate from regulatory (Federal and State) inspection files
	Incidence of violative samples	Pre-HACCP incident rate from regulatory (Federal and State) inspection files
	Incidence of consumer complaints	Pre-HACCP incident rate from regulatory (Federal and State) inspection files
	Incidence of foodborne outbreaks associated with regulated industry	Baseline incidence is not reliable because level of detection is increasing
More efficient use of inspection resources	Degree to which audits focus on safety factors	Pre-HACCP incidence of inspection reports focusing on non-safety deficiencies
	Scope and relevance of production records available for review	Type of production records available to regulatory agency before HACCP
	Incidence of enforcement actions taken for non-safety violations	Frequency that FDA took enforcement actions on basis of non-safety violations before HACCP
Enhanced industry role in problem prevention and problem solving	Incidence of violative samples	Pre-HACCP incidence rate from regulatory agency files
	Incidence of product recalls	Pre-HACCP incidence rate from regulatory agency files

FDA developed data which suggests that three of the four goals were being achieved during the pilot program. For example, FDA was able to determine with a high degree of confidence that the food produced by the pilot participants during the pilot program was safe. This was measured by the data provided by the firm's verification audits and FDA's quarterly audits which showed that every deviation from critical limits was detected, appropriate corrective actions were taken in every instance, and all products produced under the HACCP plan at each pilot firm met all safety criteria established in the HACCP plan when it left the processor.

Secondly, the pilot program showed that the HACCP audits provided for a more effective use of resources because the data being reviewed by FDA established, to a higher degree of confidence, the safety of the food being produced and marketed during the entire 1-year period of the pilot program. Under the previous GMP based inspection approach, FDA and the states had to rely upon interviews with management, observations of controls being implemented on the day of the inspection, the results of any in-process and end-product samples that FDA might have collected, and any consumer complaints submitted to FDA to make an assessment of product safety. Normally, these data only established whether preventive control and corrective actions were taken during the short period of the inspection and the period of production related to any samples collected.

3.1.2. Effectiveness of HACCP from the industry perspective

FDA learned from the pilot program that industry may have a different perspective on measuring effectiveness. The pilot firms were asked what was learned from the pilot program that can be used in measuring the effectiveness of HACCP. The pilot firms reported that they could use two types of objective and direct measurements to assess these benefits or key outputs. The first measurement used was the change in the level of product dissatisfaction. This can be derived by measuring the change in numbers of consumer complaints before and after HACCP. However, the pilot firms also advised that the vast majority of consumer complaints does not relate to food safety, and thus there are few complaints that are relevant to the HACCP program. Another related type of measurement that can be used is to assess customer satisfaction. This is more difficult since few customers provide feedback regarding their level of satisfaction beyond their reorders.

The second measurement approach used by the pilot firms was to assess changes in the product quality or production efficiency. This can be done by calculating the number of deviations from critical limits against opportunities for deviations before and after HACCP. Deviations can be measured in terms of the amount of potentially hazardous product that could have left the facility, or the number of times a firm needed to take corrective action or prepare a product safety incident report because a critical control point (CCP) was out of control. Two firms reported that they saw the amount of product thrown away substantially reduced after they instituted HACCP.

A summary of the assessment factors considered important by industry is provided in Table 2. Although this list may be useful to industry in conducting their own effectiveness assessments, its usefulness to a regulatory agency is limited. The baseline data available to

Table 2
Factors important in measuring the effectiveness of HACCP from the industry perspective

Desired outputs	Potential yardsticks to measure outputs	Criteria or measures to use as a baseline
Understanding of food safety hazards and their relationship to incoming materials and processing	Quality[a] of hazard analysis	Scientific and technical literature and case studies
	Quality of list of hazards likely to occur	Scientific and technical literature and case studies
	Validity of process flow diagram	In-plant observations
Proper designation of appropriate CCPs to control safety hazards that are reasonably likely to occur	Appropriateness of list of CCPs	HACCP guidelines and decision tree
	Changes in control points and procedures including monitoring	Number and effectiveness of control points before HACCP
	Incidence of non-compliant end-product samples	Incidence of product failing to meet specifications prior to HACCP
	Incidence of product recalls	Incidence prior to HACCP
Customer satisfaction with product and confidence in control system	Incidence of customer samples being out of specifications	Incidence prior to HACCP
	Number of customer complaints	Incidence prior to HACCP
	Incidence of third-party audits finding problems	Incidence prior to HACCP

[a] "Quality" refers to appropriateness, completeness, etc.

the firm to assess the level of product dissatisfaction, the number of deviations from critical limits, and the amount of product put at risk before HACCP would not normally be available to a regulatory agency.

3.1.3. Using end-product samples to measure the effectiveness of HACCP

An issue of importance to a regulatory agency is the role that finished product samples should play in a firm's HACCP program. FDA's experience in their pilot program provides some insight into this issue. All pilot firms used raw ingredient, in-process, and/or end-product samples to verify that hazards were being controlled as intended. These samples showed that when prerequisite program and HACCP plan controls are properly applied, food safety hazards are not detected in the finished product.

FDA did not take samples during the pilot program, and FDA does not anticipate that product samples taken to document insanitary conditions, the presence of pathogens, or the presence of chemical hazards will have a routine role in FDA's HACCP audits. Instead, FDA anticipates taking regulatory action based on the absence of preventive controls. FDA stated in the advanced notice of proposed rulemaking (ANPR) that

> if a food purveyor covered by the (HACCP) program does not adopt and implement a HACCP plan that complies with the program's requirements or does not operate the plan in accordance with the program, food prepared, packed, or held in that facility would be adulterated under section 402(a) (4) of the act and potentially subject to regulatory action by FDA.

The results of the pilot program affirm that an evaluation of the firm's HACCP plan and an audit of the prerequisite programs and HACCP records by FDA is sufficient to determine whether proper food safety controls are being provided. Further, the samples collected by the pilot firms to verify their HACCP operation which were reviewed by FDA suggest that there may be no added utility for FDA to collect and use product samples to assess the effectiveness of HACCP or to attempt to detect intermittent or indirect sources of contamination that may not be revealed by the HACCP audit.

3.1.4. Using data collecting forms as an assessment tool

HACCP provides the regulatory agency with the opportunity to more effectively utilize inspection resources if there is an adequate inspection and verification data base from which to work. Any partnership or cooperative agreements between different regulatory agencies or agencies at different levels of government must be based upon shared data that utilize a common language. This has led FDA to conclude that data collection or inspection forms are a useful tool in developing a data base that can be shared by several regulatory entities. Two types of forms have been utilized.

FDA developed a comprehensive inspection form for use during the pilot program. This form was based upon the recommendations of the NACMCF. The purpose of

this form was to ascertain whether the firm was applying the NACMCF guidelines which had been agreed upon as the assessment criteria for the pilot program. The form was used successfully to communicate to industry what FDA would be assessing during the audits, and to insure greater uniformity between different auditing teams at different firms.

FDA developed another type of inspection form for the seafood HACCP inspections. The assessment tool being used consists of a "mark the appropriate selection" type form that the inspector fills out and faxes to a central, dedicated fax server. The fax server holds electronically transmitted data for computer and visual verification. Accepted data are stored in a central data file that can interact with other regulatory files, and can be manipulated in various ways as needed. The system is simple and relatively inexpensive. The form is based upon the requirements of the seafood HACCP regulation, and as such, is more abbreviated than the NACMCF based form used for the pilot program.

3.2. Essential activities

FDA's seafood HACCP program provides an example of the essential activities involved in assessing a mandatory HACCP program. The following summarizes the procedures being followed to implement this regulatory program. The purpose of the program is to provide regulatory coverage of seafood to ensure a safe and wholesome domestic seafood supply. It provides policy and procedural guidance for ensuring compliance by domestic processors. The program addresses the control of pathogens, filth, decomposition, pesticides, industrial chemicals, marine biotoxins, and illegal use of food color additives in domestically processed fish and fishery products. With the adoption of the regulation requiring the implementation of seafood Hazard Analysis Critical Control Point (HACCP) systems, the 1998 regulatory priority for seafood focuses on ensuring the control of seafood safety hazards by use of an HACCP plan. Highlights of the program are as follows.

3.2.1. Approach

The FDA seafood program has a two-pronged approach for the initial year of implementation. It incorporates HACCP review for food safety by investigators specially trained in HACCP, with non-HACCP inspection activities for those areas such as filth, decomposition (other than histamine related) and parasites (non-infective to humans) that are considered potentially violative although they represent a food defect rather than an actual health hazard. The HACCP review requires investigators to be trained in auditing to review plans, records, and controls as they relate to safety hazards.

3.2.2. Categorization of risk

Within this program views products to be either to have "substantial risk potential" or "low risk potential". Substantial risk potential seafood includes the following:

- ready to eat fish or fishery products;
- scombrotoxin-forming species (tuna, amberjack, anchovies, bluefish, etc.);
- stuffed seafood products;
- fish packed in modified or vacuum packages;
- acidified and low acid canned foods; and
- raw (fresh or frozen) shellfish. Products not in these categories are considered low risk.

3.2.3. Inspection frequency

With the implementation of mandatory requirements effective since 12 December 1997, the agency is directing inspection of all fish and fishery products processors regardless of size or risk category.

3.2.4. Sample collection

A limited number of HACCP verification samples will be collected. Samples will be used as a means of judging the overall effectiveness of a firm's HACCP system. The results of these sample analyses will enable the agency to make determinations about the likelihood of the occurrence of particular safety defects in products that are produced under HACCP preventative controls. HACCP verification samples are "Official Samples" of finished products and are to be collected from processors to check "For cause" safety related samples may also be collected when it is deemed necessary by the investigator to: determine if an imminent public health hazard exists, or, to make a determination about the product controls that cannot be determined by observation (e.g., whether the salting process has resulted in an appropriate waterphase salt concentration).

3.2.5. HACCP training for FDA inspection

All investigators performing an HACCP review of firms have completed mandatory regulator training. Training includes a 3-day course developed by the Seafood HACCP Alliance or its equivalent and the 2-day FDA Seafood Regulator Training course and pass the course examination. Inspections of firms are then performed in a manner consistent with the Seafood HACCP Regulator Training manual. And, the Fish and Fishery Products Hazards and Controls Guide which is also available to processors to aid in identification of hazards and to formulate control strategies.

3.2.6. Federal/state contracts and partnerships

Contracts exist between FDA and a number of states to inspect seafood establishments. The seafood inspection program is incorporated by reference in these contracts as guidance in conducting fish and fishery

product inspections. As of 18 December 1997, all seafood inspections either under contract or through partnership agreement with states must be HACCP-based and consistent with the methods included in the Seafood HACCP Regulator 2-day course.

3.2.7. Implementing HACCP – FDA's juice initiative

On 24 April 1998, FDA published two proposals in the Federal Register dealing with juice. The Preliminary Regulatory Impact Analysis for these proposals was published on 1 May 1998. The agency is taking these actions because of the recent outbreaks of food borne illness and deaths, including some directly affecting children, associated with juice products that had not been processed to destroy pathogenic microorganisms. FDA has proposed to adopt regulations that mandate the application of HACCP principles to the processing of juices. For the purposes of this proposed regulation, processing does not include:

- harvesting, picking, or transporting raw agricultural ingredients of juice products;
- the operation of a retail establishment; and
- the operation of a retail establishment that is a very small business and that makes juice on its premises, provided that the establishment's total sales of juice and juice products do not exceed 40 000 gallons per year, and that sells such juice directly to consumers and other retail establishments.

FDA also proposed a labeling requirement for juices not under preventative control (HACCP), to provide the following warning statement:

> WARNING: This product has not been pasteurized, and therefore, may contain harmful bacteria which can cause serious illness in children, the elderly, and persons with weakened immune systems.

Comments have been sought from the public, and all pertinent issues submitted will be considered in the final rules.

3.3. Observations

3.3.1. Issues regulatory agencies currently face in assessing program effectiveness

HACCP is a type of quality assurance program that shares common characteristics with other recognized programs such as total quality management (TQM) and ISO 9000. Most food manufacturing firms will have a quality assurance program prior to developing an HACCP program and will incorporate HACCP into their pre-existing system. Many firms that have adopted HACCP report that incorporating HACCP does not represent a great departure from what was being done before and requires refinements more than substantial changes.

However, confusion can develop over integrating HACCP with pre-existing quality assurance systems because, on a practical basis, it is difficult and may seem illogical to separate controls that address food hazards from controls that address quality and productivity factors. The consumer wants safe foods that are of good quality and are provided at a low cost. A firm's system of controls to assure safety are in many respects identical to systems that assure quality and efficient production. As a result many firms find it challenging to separate safety hazards that were to be controlled at CCPs from other factors that were to be controlled at other types of control points.

Industry's propensity to incorporate HACCP into pre-existing quality assurance programs has important ramifications for a regulatory agency that is assessing the effectiveness of HACCP.

3.3.1.1. Communicating the regulatory perspective. Training needs to focus on the different perspectives of HACCP that can develop and the practical aspects of integrating HACCP into existing food quality and safety systems. Industry needs to understand the importance of separating food safety from quality controls and that HACCP needs to be a separate subsystem to their overall quality assurance program. On the other hand, regulatory agencies need to provide industry with needed flexibility to be able to include some prerequisite program controls in their HACCP plans. No explicit criterion has been developed for determining when a control measure should be managed under a prerequisite program or elevated to the HACCP plan. In some instances, the same type of hazard will be controlled under the prerequisite programs at one firm and under the HACCP plan at another firm. Either approach can be equally effective. In most instances, however, firms tried to maximize the use of their prerequisite programs to control hazards in order to avoid the more arduous requirements of a CCP. Exceptions will arise and firms will elect to include some prerequisite program controls in their HACCP plan because it involved a quality or economic factor of great importance to the firm.

3.3.1.2. Plan review and evolution. Regulatory agencies need to provide industry with time for their HACCP plans to mature, and any assessment needs to consider this factor. For example, during the pilot program, FDA found that almost all firms changed the number of their CCPs. Over half of the firms reduced the number of CCPs. One firm, for example, reduced the number of CCPs from 80 to 16 and then from 16 to 2 by the time the pilot program was completed. A third of the firms increased the number of CCPs when additional data indicated that hazards not being controlled under the HACCP plan were likely to occur.

In each instance, the changes in number of CCPs resulted because the firms developed additional data on the likelihood of occurrence of potential hazards. These more comprehensive hazard analyses conducted by the firms increased their awareness of the significance of some potential hazards and caused them to change their control methods. Consumer and customer complaints were also useful to some firms to assess the significance of potential hazards. By the end of the pilot program, each firm had an HACCP plan well designed to meet the needs of the firm.

3.3.1.3. Prerequisite programs. Regulatory agencies also need to provide industry with time for their programs to mature, and any assessment needs to consider this factor. FDA found that over the course of the pilot program, firms made substantial changes to improve their prerequisite program controls. The purpose of these changes was to increase assurance that the hazards were being adequately controlled at "control points" and, therefore, would not need to be controlled at CCPs. In several instances, strengthening their prerequisite programs led to a reduction in the number of CCPs in the firm's HACCP plan. The firms reported that when they conducted their hazard analysis, they found that an important means of controlling potential hazards is to use raw ingredients and materials that are free of hazards. If the raw ingredients are free of hazards, the only hazards that need to be controlled by a CCP are those that may arise from within the processing operation itself. These are often only physical hazards. All the firms either had controls in place for incoming ingredient or developed additional control measures during the pilot program. These control measures, in affect, extend control of hazards backward in the food production chain to the primary producers and suppliers.

4. USDA activities

4.1. Purpose for assessing HACCP

USDA's Food Safety and Inspection Service is charged with ensuring that meat, poultry, and egg products are safe, wholesome, and properly labeled. FSIS inspects and verifies the proper processing, handling, and labeling of these products from the delivery of animals to the slaughterhouse to when the product reaches the consumer.

USDA has traditionally focused much of its effort on the plants that slaughter food animals and process products. USDA ensures that products at these establishments are produced in a sanitary environment. These establishments must apply for a grant of inspection from FSIS and demonstrate the ability to meet certain requirements for producing safe, wholesome, and accurately labeled food products. Requirements include meeting sanitation, facility, and operational standards and having 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 can be sold in interstate commerce.

The changes in the United States system for food safety over the past five years are significant. When the *E. coli* outbreak on the West Coast occurred in early 1993, HACCP was not required for any foods, other than those that were canned. The regulations covering meat and poultry were all command-and-control, and FSIS was not organized in a manner that anticipated immediate and future public health demands. All these features are undergoing major change.

4.2. Essential activities

4.2.1. USDA/FSIS requirements for Pathogen Reduction/HACCP (PR/HACCP)

The PR/HACCP regulations, published 25 July 1996, require that: (1) all federally inspected meat and poultry plants develop and implement sanitation standard operating procedures (SSOPs) and HACCP plans; (2) those establishments which slaughter livestock and birds collect and analyze samples for the presence of generic *E. coli*, and record results; and (3) those establishments which slaughter or produce ground meat or poultry products meet *Salmonella* performance standards. These new requirements are designed to help target and reduce food borne pathogens.

On 27 January 1997, all plants were required to have in place written SSOPs. SSOPs instituted a process to ensure compliance with existing Federal sanitation requirements that focus on preventing direct product adulteration. This was a major cultural change – both for industry and FSIS inspection program personnel. The implementation of SSOPs went well considering that ALL 6000 plants were required to implement SSOPs only six months after publication of the final rule. Very few had problems doing so.

FSIS believed it was very important to answer any remaining questions on the new HACCP requirements prior to the January 1998 implementation date for the largest meat and poultry plants. From December 1997 through the end of January 1998, FSIS held four nationwide "HACCP Implementation Meetings". The meetings were well attended and provided participants with necessary information on HACCP in order to be ready for implementation on 26 January 1998.

Today, HACCP is in place in large and smaller meat and poultry plants. These plants produce more than 90% of the raw meat and poultry and 55% of processed products such as frozen dinners, frankfurters, or hams,

and have the most experience with HACCP systems. The slaughter plants are testing for generic *E. coli*, and FSIS is analyzing for *Salmonella* in samples taken in plants that slaughter or grind.

4.2.2. HACCP implementation

4.2.2.1. Overview. FSIS has known that the implementation of HACCP would require a significant change in the roles and attitudes of both inspectors and industry. In the past, some plants relied on inspectors to identify deficiencies before the company would take action to correct them. Implementation of HACCP clarifies the respective roles of industry and FSIS. Businesses that produce food are accountable for its safety. They need to look at all the likely hazards, ensure their systems address those problems, and take immediate action if their controls fail.

4.2.2.2. Directives. The documents used to provide instructions to inspection program personnel on how to determine compliance/non-compliance with new regulatory requirements are called Directives. FSIS has developed two major new Directives to be applied in establishments which are now subject to the full set of PR/HACCP requirements. The agency will be operating a dual system until January 2000, but after that time these documents will be the instructions which all inspection program personnel will follow in their determination about compliance with regulatory requirements.

An advantage of these Directives is that FSIS has made every effort to be sure they are self-contained; therefore, they have many attachments including the codified language of regulations, several checklists, and specific references on which HACCP inspection procedures are based.

4.2.2.3. Future improvements. Based on comments from stakeholders, FSIS refined its HACCP implementation strategy in several specific areas: (1) establishing a team of on-call experts managed from the FSIS Technical Services Center to help the agency make prompt decisions on complex scientific and technical issues regarding a plant's HACCP system; (2) providing additional training for supervisory inspectors in systems concepts relating to HACCP; (3) expanding the cadre of FSIS HACCP experts providing ongoing advice and guidance on HACCP-related issues; (4) improving notification to plants of findings that a plant's HACCP system is not adequate; and (5) specifying the steps in the appeals process.

4.2.3. Training

The HACCP training being provided to inspection personnel is designed to equip them to carry out the inspection procedures in an HACCP-based inspection work environment. Thus, the focus is very different from what a plant would train its employees on to manufacture meat and poultry products using HACCP principles. The plant focus is on the application and use of HACCP principles to their particular manufacturing processes. The agency focus is on the application and use of inspection procedures to determine a plant's compliance/non-compliance with the PR/HACCP requirements.

4.2.3.1. HACCP technical training. A substantial amount of knowledge is required to understand and appropriately apply the changes brought about by the PR/HACCP rule. Inspection personnel cannot perform the new inspection procedures until they have completed the 11-module training program, which takes eight days. Approximately 4500 inspection personnel have completed the HACCP Technical Training Program. The 500 inspection personnel assigned to very small plants will complete the program by January 15, 2000.

4.2.3.2. Other training and educational initiatives. The agency is developing an additional training program for district managers and circuit supervisors, which will focus specifically on inspection methodology, documentation of inspection findings, and application of regulatory actions in establishments subject to PR/HACCP requirements. Information will focus on system adequacy determination versus isolated events, use of inspection data in compliance determinations, and implementation of performance management strategies when standards are not met.

FSIS is conducting an HACCP educational program for additional personnel that will focus on HACCP principles and implementation. Courses at the agency's training center in College Station, TX, will provide the agency with the depth of expertise necessary to address questions about the application of HACCP regulations in an expanded environment of thousands of plants.

In implementing HACCP to date, both industry and government have been engaged in a major change in the roles and responsibilities of both parties. This change also represents a significant change in the regulatory approach and regulatory activities of government inspectors, and has been implemented with the existing workforce.

FSIS recognizes that the inspection procedures and verification activities that have been introduced are not the only types of verification procedures and activities that may be used to ensure that industry HACCP systems are effective in controlling food safety hazards. Over time, as more of the industry comes under the HACCP regulation, and as inspection personnel gain greater experience and knowledge in regulating in an HACCP-based environment, FSIS anticipates that some changes will occur in the nature of the verification

activities that inspection personnel will be asked to undertake.

FSIS has established a Food Safety Education Program. It exposes employees to a broader and more highly developed understanding of the principles of microbiology, statistics, food chemistry, sanitation, risk assessment, and related topics in food production. The lecture components are balanced with appropriate bench laboratory time. The program runs for four weeks.

The training and education being presented to employees today are designed to begin the transition of the educational knowledge base of the workforce. This is an essential first step needed to plan further transition in regulatory responsibilities for a more highly educated workforce.

4.2.4. Resources for industry

FSIS is committed to assisting all plants in implementing HACCP – now and in the future. FSIS district managers are on call 24 h a day, seven days a week to make rapid decisions and to respond promptly to emergencies. In addition, the Technical Services Center is a valuable resource for those who have technical questions; the Technical Services Center is operating an HACCP Hotline open between the hours of 6 a.m. and 6 p.m. As of 1 May 1999, the Hotline had received about 28 000 calls, with approximately half being from industry, and half from inspectors.

To ensure open communication during the transition and adjustment to the HACCP system, FSIS has been holding weekly meetings with industry representatives to address implementation issues. These meetings are very useful, for industry and for FSIS, to learn what steps need to be taken by each party to make HACCP work better.

In order to assist very small plants in meeting the requirements of the HACCP rule by the January 2000 implementation date, agency staff are providing extensive technical assistance. Very small plants are now targeted for this assistance because many are not familiar with HACCP. FSIS has made available to the industry a number of technical guidance materials – including a Guidebook for the Preparation of HACCP Plans, a video on HACCP plan development, and draft HACCP models for 13 products and processes. So far, the agency has distributed more than 30 000 copies of these documents.

FSIS has facilitated demonstration projects around the country to help very small plants to better understand and apply the new requirements, and has held numerous meetings to find out from plants what information they need to be successful with HACCP and how to strengthen the lines of communication between FSIS and industry. The agency has also created an HACCP Training Database that is available on the Internet for plants that need information on HACCP-related services, equipment, and software.

4.3. Observations

4.3.1. Assessing the implementation and impact of HACCP

FSIS has other assessment activities planned or under development. Two significant evaluations are contemplated: the first is an evaluation of inspection activities during the first phase of HACCP implementation. Its purpose is to obtain and analyze information about inspection activities during implementation of HACCP in large plants in order to improve the implementation process in smaller plants. These general questions will be addressed:

- How are inspection personnel implementing the new inspection procedures?
- How are supervisors carrying out their responsibilities?
- How are all parties communicating?
- How is the enforcement program operating?
- How is the automated system which schedules inspection tasks working?
- How was the training?
- How are inspection personnel implementing the cultural change?
- How are the various staffs supporting HACCP implementation?

Data collection methods include in-person and telephone interviews, document examination, and database analysis and review. FSIS made this evaluation report on July 1998, so that its findings could be used in the second phase of HACCP implementation.

The evaluation of inspection activities during phase one of HACCP implementation contained over 100 recommendations and a Road Map designed to help decision-makers address the abundance of information included in the report. The report highlighted the following areas: (1) policies and terms that need clarification; (2) useful training methods and forums; (3) methods to improve communication among FSIS employees; and (4) essential inspection activities that need reinforcement. Many of these recommendations have already been used to improve planning, training, and implementation for the second stage of HACCP implementation in small plants beginning on 25 January 1999. Feedback provided by this evaluation has been very significant in that it has resulted in a smoother and more effective implementation of HACCP-based inspection nationwide.

USDA/FSIS is also planning a major impact evaluation of the PR/HACCP final rule. This evaluation will take several years to perform; it will be carried out by a third party contractor. It will be designed to provide insight on the following broad issues:

- Do HACCP systems control production safety hazards? Has there been a significant reduction in pathogens on raw carcasses leaving inspected establishments?
- Do HACCP process control systems reduce food borne illness?
- Do HACCP systems make inspection more effective?
- Do HACCP systems increase consumer confidence?
- Do HACCP systems provide an opportunity for increased productivity?

FSIS is planning for a series of final reports on various aspects of the impact of the rule. Several reports are planned, to be released each June, beginning in the year 2000. The final reports issued in June 2003 will include overall impacts of the rule on the public, the industry, and USDA/FSIS.

This major evaluation will use a number of techniques, including data review and laboratory analyses. These may include the use of interdisciplinary audit teams which could review in-depth the HACCP plans of selected establishments. FSIS has been interested for some time in using this technique as a means of reviewing a cross section of establishment HACCP plans to get a better sense of how HACCP is proceeding, but has not had the resources to devote to such an effort. For this reason, in particular, USDA/FSIS appreciates the leadership of other countries and the work of FAO/WHO during this consultation.

4.3.2. In-depth verification reviews of HACCP systems

USDA/FSIS has developed an In-Depth HACCP Verification Review protocol designed to supplement the day-to-day activities of its in-plant inspection personnel. In-Depth Verification Reviews are designed to have a different and more distantly located team of technically qualified personnel provide a detailed review of the regulatory compliance and scientific validity of a company's HACCP systems. Such reviews might be performed on various occasions – in response to problems or routinely, as a means of checking on the status of HACCP systems across the industry.

A multidisciplinary team is used, drawing on the agency scientific and technical expertise which is determined to be most relevant to the establishment under review and the processes it conducts. The standards used in conducting the review are twofold. The scientific/technical standards arise from the published HACCP literature, especially the work of the NACMCF, and the professional expertise of team members, such as food microbiologists. The regulatory standards are the FSIS HACCP regulations found at 9 CFR Part 417.

An In-Depth Verification Review consists of two parts; a Documents Review, which is confined to written materials only, and System Review, which includes an examination of any or all elements of the system in operation. An In-Depth Verification Review is conducted much like an audit: multiple reviewers are used and more than one performs each examination; only negative observations are reported; significant findings are determined by a consensus process involving the entire team; instances of potential regulatory non-compliance encountered by the review team are referred to the in-plant inspection team for appropriate action.

5. National Marine Fisheries Service (NMFS) HACCP program – NMFS approach

5.1. Purpose for assessing HACCP

In 1986, at the request of the US Congress, the NMFS was tasked to develop a new mandatory inspection system based upon the HACCP concept (US Congress, 1986). In addressing that legislative challenge, NMFS added further requirements that such a program should be pragmatic, address consumer hazards associated with the consumption of seafoods, and must also treat imports and exports equitably. The agency was also tasked to perform an economic analysis on what the recommended mandatory HACCP program design would cost the government in terms of operation as well as the projected economic impact on the industry to be regulated. The study was initiated in 1987 and was titled the Model Seafood Surveillance Project (MSSP).

As the HACCP concept was initially examined, it was quickly determined that historically there have been eight regulatory pitfalls when attempting to implement HACCP in food control systems. These included: (1) understanding the HACCP concept; (2) choosing a definition for a "Critical Control Point"; (3) incorporation of sanitation controls in the HACCP system; (4) agency resource commitment; (5) inspector acceptance; (6) consumer acceptance; (7) the regulatory approach to industry; and (8) training (Garrett & Hudak-Roos, 1991).

HACCP guidance for developing and conducting the MSSP study was heavily premised upon the advice of a 1985 National Academy of Science report which indicated that HACCP must be an industry-driven program with the role of the regulatory agency being primarily that of mandating the use of HACCP, approving the industry's basic HACCP design, on-site verification, and conducting training in the HACCP regulatory requirements (NAS, 1985).

During the MSSP a strategy was developed that would minimize the aforementioned regulatory pitfalls by providing the industry an opportunity to come together and design an HACCP program for their individual commodity segments by holding a series of 49 industry HACCP application workshops around the country on a commodity-by-commodity basis. At those workshops, industry personnel defined and determined

what the proposed regulatory HACCP model should be for their given commodity (Garrett & Hudak-Roos, 1990). Each workshop proposed a regulatory generic HACCP model that contained the seven following elements: (1) hazard analysis, (2) identification of sanitation CCPs, (3) identification of process CCPs, (4) industry controls, (5) regulatory controls, (6) a research focus to support such a program, and (7) consumer educational requirements necessary to close the loop in food protection (Garrett & Hudak-Roos, 1990). Following the workshops, each model was tested in more than 200 plants and aboard 80 vessels throughout the USA, the Caribbean, and the Pacific Trust Territories to determine system concept with the summarized results being submitted to an industry steering committee to review and modify each model where necessary. Following the steering committee action, the NMFS staff integrated all data and information into proposed regulatory HACCP generic models for use in a new mandatory seafood inspection program. During this process the NMFS staff was not bound by the steering committee action and could upgrade or downgrade individual CCPs in the proposed regulatory generic HACCP models. During the study, 20 proposed regulatory generic HACCP models were developed dealing with Aquaculture; Blue Crab; Breaded Fish and Specialty Items; Breaded Shrimp; Cooked Shrimp; Crawfish Processing; Fishing Vessels; Food Service and Consumer Education; Imported Products; Lobster; Molluscan Shellfish Processing; Non-state Insular Areas (Territories); Raw Fish; Raw Shrimp; Retail; Sampling Considerations; Scallops; Smoked and Cured Fish; West Coast Crab; and Wholesalers, Distributors, and Seafood Auctions (NMFS, 1989a, b, c; 1990a, b, c, d, e, f, g, h, i; 1991a, b, c, d, e, f, g).

Ninety-five percent of the participants who participated in this process agreed or strongly agreed on how the HACCP concept could work in their given seafood industry commodity, and it is commonly believed that the ease in which mandatory HACCP is being introduced into the seafood industry, in part, results from these early HACCP application workshops (Garrett & Hudak-Roos, 1991).

5.2. Essential activities

5.2.1. Current status

Since completion of the MSSP study, NMFS has elected to offer HACCP-based inspection services through the NMFS Voluntary Seafood Inspection Program on a reimbursable basis (CFR, 1992). The NMFS voluntary HACCP-based inspection scope currently covers seafood processing facilities, vessels, retail and food service operations and training. The NMFS HACCP-based inspection system has eight principle components dealing with requesting the service; HACCP plan development, review and approval, label review, proposed participant production pre-validation activities, HACCP certification of facility personnel, NMFS on-site validation, selected product laboratory analysis and predetermined frequencies for NMFS on-site HACCP systems audit of facilities.

5.2.2. NMFS HACCP Submission Guide

To ease facilitation for entering into the NMFS HACCP-based program, a facility HACCP Plan Submission Guide has been developed and distributed to current NMFS program users or potential applicants. Included in these guidelines are the NMFS requirements for the participating firm to furnish a facility organizational chart, narrative description of personnel functions and requirements, as well as a description of the fishery products handled in the facility. Additionally, for each fishery product form, a process flow chart must be depicted in which each critical control point must be identified relative to its location, hazards or defects to be controlled, preventive measures and critical limits required to be met accompanied with all monitoring procedures, corrective actions, and record names being described. A copy of all forms associated with each critical control point must be furnished.

Further requirements for the NMFS program include a full description of all record keeping and verification procedures, copies of sanitation operating procedures as well as descriptions of recall and consumer complaint procedures and copies of all labels and processing specifications.

Additional requirements include: (1) Employment of Certified HACCP-based Inspection Person(s): Each facility must employ a NMFS-certified person knowledgeable in the HACCP program's principles to be present during all processing times and (2) the certification must be kept on file and available to NMFS at all times. Verification Procedures consist of: (1) periodic end-item verification of product compliance to program requirements must be performed by the firm. Frequencies and end-time requirements must be agreed upon by both the firm and NMFS, (2) samples for analytical testing must be collected and tested at least once per year as part of their verification procedures (Jahncke Tennyson & Garrett, 1996). The level of analytical sampling per lot must be comparable to that found in Tables 1 and 2 (NMFS, Part I).

5.2.3. Prevalidation, validation, and system scope

Prior to a firm's participation in the NMFS Voluntary Seafood Inspection Program, the firm must operate in a "prevalidation phase" using the plant generated NMFS-approved HACCP plan for a specified time period. This provides the subsequent NMFS validation team with the necessary information to confirm the firm's ability to follow their own written procedures.

Table 3
System audit frequency schedule

Facility rating	Audit frequency	Number of deficiencies			
		Minor	Major	Serious	Critical
Level I	One visit every six months	0–6	0–5	0	0
Level II	One visit every two months	0–6	0–5	0	0
Level III	One visit every month	$\geqslant 7$	6–10	1–2	0
Level IV	One visit every two weeks	N/A	$\geqslant 11$	3–4	0
Level V	Daily	N/A	N/A	$\geqslant 5$	$\geqslant 1$

Note: For a facility of Level II, no more than 10 combined "Major" and "Serious" deficiencies can exist. If the combination of "Major" and "Serious" deficiencies exceeds 10, then the facility will be rated as Level III.

Following this specified "prevalidation" phase, an on-site NMFS "validation team" will determine whether all the hazards and CCPs have been identified by the firm, and whether the HACCP operation is effectively controlling the identified hazards. Validation includes industry paperwork reviews, recording of sanitation and in-process observations, and inspection of samples of finished products. Product evaluations are determined by conducting a combination of statistical reviews of the firm's records and finished product sample examinations. All reviews are preformed by using acceptable auditing practices. Firms are rated by inspectors using a "system audit check list." Those that rate a Level IV (requiring an inspection audit every two weeks) or higher can qualify as a participant in the NMFS HACCP-based inspection program.

Following successful validation, participating plants, vessels, retail facilities, and food service establishments are entered into the inspection system at a Level IV to build a compliance history which may result in a change of the inspection frequency subject to subsequent system audits.

The scope of the NMFS on-site system audits is twofold in that it determines the facility's HACCP plan adherence, and formally rates the facility's sanitation program. In terms of HACCP plan adherence, the on-site system audit focuses on records, adherence to required stated procedures, selected product examinations and laboratory analysis, and other factors such as execution of unapproved HACCP plans or procedure modifications. The facility sanitation audits relate to 11 items dealing with pest control, structure and layout of the facility, maintenance, cleaning and sanitizing, personnel, rest rooms, water supply, ice, chemicals, ventilation, and waste disposal procedures. Both aspects of the NMFS on-site systems audit which deal with adherence to approved HACCP plans and facility sanitation are rated as being either minor, major, serious, or critical with allowable differences depending upon whether the facility is producing low or substantial risk products. The individual system audit facility rating or score determines the amount of NMFS inspectional effort which can range from a daily visit to one visit every six months in accordance with Table 3.

The end-product audit intensity is a percentage of the total lots produced by the firm since the last system audit and HACCP level of the firm. For example, for a Level I or II firm, 2% of the lots would be audited while other levels would require more intense product examination.

During HACCP system audits, commodities are divided into substantial or low risk categories for either microbiological or chemical analysis. The reasons for these analyses are not for determination of individual lot compliance, but rather for HACCP verification system surveillance purposes to determine how well both the industry driven HACCP system and the NMFS regulatory verification procedures are meeting the US food safety regulatory requirements.

A firm rated at Level V has demonstrated difficulties in administering their HACCP plan. Firms which fall to Level V at any time will be subject to the following procedures: (1) if a Consumer Safety Officer believes that a facility has fallen to Level V rating, he/she will contact the Regional HACCP Activities Coordinator and the officer's Supervisor, (2) the three together will decide whether or not to recommend that the facility should drop to Level V. If so, the Regional HACCP Activities Coordinator will contact the National HACCP Activities Coordinator. Facilities who fall to Level V have a period of thirty days to obtain a rating of Level IV or higher. Failure to do so will result in the facility's removal from the NMFS HACCP-based Inspection Program.

Daily auditing will be acceptable to NMFS under the following conditions: The firm must submit a corrective action plan to the NMFS Consumer Safety Officer detailing how they will correct the problem and obtain a Level IV. The corrective action plan must include, at a minimum, detailed descriptions of the following: (1) a statement of the problem, (2) identification of the person or persons handling the situation, (3) the methods to be used to correct the problem, (4) a schedule which details the time frame to correct the problem and (5) a state-

ment with signatures of top management attesting to their commitment to correct the deficiency. The corrective action plan must be written in sufficient detail to provide NMFS with all necessary information for its approval or disapproval.

The NMFS Consumer Safety Officer will review the corrective actions identified by the firm and send a copy to the Regional Inspection Branch and NMFS Headquarters.

NMFS Headquarters will approve or disapprove the corrective actions and notify the Regional Inspection Branch who will contact the firm. At this time, NMFS will discuss with the firm how long they must remain on daily auditing. In any case, daily auditing will be granted for only 30 calendar days.

Firms who have been dropped from the HACCP-based Inspection Program may submit a request for reapplication into the program after a period of three calendar months. Application will be accepted by NMFS only if evidence of a change in management philosophy can be provided.

The NMFS HACCP-based inspection program also applies to retail stores or chains with a similar system audit frequency of processing establishments. An interesting modification to the retail program, however, relates to auditing retail chains, each of which may have numerous stores within the corporate structure. In those instances, a sliding scale is used to determine the number of individual stores to be audited by the NMFS system with actual audit frequencies depending upon the number of facilities within the chain and their level of performance to program requirements.

Throughout the agency HACCP-based inspection process, NMFS has engaged in numerous information transfer activities. Among these is a Joint Federal/State Seafood HACCP Alliance which developed training curriculum and materials to train federal and state HACCP verification inspectors. Also, NMFS participates with the National Center for Food Safety and Technology and the Conference for Food Protection in their various activities. Likewise the agency has personnel who participate in relevant WHO/FAO activities and serve on the NACMCF. To date NMFS has conducted more than 100 HACCP training workshops and have trained/certified more than 4000 persons nationally and internationally through these workshops.

5.2.4. NMFS HACCP inspection observations

During the five years of operating an HACCP-based inspection system, the agency has observed and experienced difficulties and successes. Major difficulties for NMFS have included the management of stresses related to staff development. These problems have been associated with institutional changes that have been a result of programmatic paradigm shifts and organizational culture transitions being made to maintain our position on the leading edge of regulatory compliance.

In terms of detriments in participating in an HACCP inspection program, the major concerns focused in not realizing the expected costs savings, difficulty in executing the program, having sufficient employees trained and certified to do the HACCP training. Likewise, some participating industry members have informed NMFS that the expected cost conversion to HACCP would be written off quickly, perhaps in one year, however no one achieved that goal. All recognized that implementation of HACCP brings about a demonstrable shift of costs to the processor from the federal government. In terms of program execution, several have pointed out that as with any new start, misinterpretations of program requirements occur by different inspectors.

Another industrial problem which surfaced during HACCP implementation was the difficulty of getting plant floor personnel trained and certified. To the seafood industry's credit, most plants desire to have far more personnel trained and certified in HACCP than our agency requires, and many want not only managers or supervisors certified, but also lead floor personnel as well. It was pointed out that while these latter persons are well qualified in the manufacture of the product, oftentimes due to education and language skill limitations, they do not test well in the NMFS certification testing requirement (NMFS requires passing a test at the conclusion of the HACCP training), particularly when words like "preclude," "sporadically," and "alleviate" are used in certification testing.

Aside from experiencing programmatic difficulties, NMFS measured new successes in their HACCP inspections. Smaller scale companies tell us that the decreased costs associated with the NMFS HACCP program over traditional program costs, now allow them to economically participate in NMFS inspection system which provides for new widespread access to institutional purchasers which require our inspectional services. Further, HACCP has provided for an employee empowering processes that stimulate better work ethic and job performance. In terms of product quality, several participants have pointed out that while their quality of a product was very good before entering into the NMFS HACCP program, the quality has been improved in that less rework is required and there is much more control over raw materials and the manufacturing processes. Several reported more customer satisfaction with HACCP produced products evidenced by less rejection due to failure to meet purchasing specifications.

Consumer understanding of HACCP appears mixed and probably is extremely insufficient. It is imperative that individual consumers and their organizations do not come to view HACCP as some "benign industry self-certification system" with "watered-down" regulatory requirements for product monitoring and laboratory

analysis. It is also equally imperative that consumers understand they have individual HACCP responsibilities as well, and that they must enforce the individual consumer HACCP critical control points dealing with Food Acquisition, Handling, Preparation and Serving, and Storage of Leftovers. Finally, training is a fundamental requirement of HACCP. Further attempts at harmonization are necessary but these attempts should be undertaken with the understanding that differential knowledge circumstances may require different training requirements and approaches.

In summary, NMFS is convinced that HACCP will succeed if the regulatory agencies can collectively overcome the regulatory pitfalls. It should be understood that while there is general unity on the general principles of HACCP, the verification procedures by which official regulatory officials choose to verify industry or facility compliance to the general principles of HACCP are still evolving and that evolution can be expected to take some time and further effort.

6. Conclusions

The mandatory, regulatory inspection programs for HACCP in the USA are in such an early state of implementation that conclusions are preliminary and result from limited observations. Therefore, thorough evaluations of programmatic activities are underway relative to training inspector standardization, and policy review. Since the implementation of mandatory HACCP in the USA, the working relationships between the mandatory, regulatory agencies and those operating voluntary HACCP inspection and certification programs have not been finalized and are under discussion. Likewise, the use of non-governmental, third party organizations has not been determined (Garrett, Jahncke & Tennyson, 1997).

The requirement for mandatory implementation of HACCP in meat, poultry, and seafood plants, and proposed regulations for juice plants represents a significant change in the manner in which such foods are regulated for food safety and necessitates a new understanding of the different roles and responsibilities between the food industries and the regulatory agencies within the USA. Mandatory HACCP, beyond that mandated for low-acid commercial food, is in its infancy and is still evolving and can be expected to be improved. Regardless, experience to date, by all the Federal agencies, has been positive and rewarding. All agencies have not only recognized the need for but have also provided for an extended timeline for mandating HACCP implementation so that the regulated industry can meet the HACCP requirements. Further, all agencies have noted implementation difficulties in some industry segments because of a lack of understanding in each of the HACCP general principles.

Each agency has assisted in the development of industry commodity HACCP alliances for training and educational outreach activities. Further, each agency has engaged in both the development and implementation of specific internal and external HACCP educational and training programs to facilitate the ''cultural change'' required for both the regulated food industry and the Federal and State food inspectors necessary to achieve the full food safety benefits of HACCP. As with any new regulatory program, there have been difficulties, but in the main, those have been understandable and from an industry operational perspective relate to hazard identification HACCP plan development and execution, personnel training, and non-standardization of regulatory inspections.

Regulatory agencies have managed ''institutional change'' which is always difficult when program paradigms change. Despite these difficulties, however, numerous HACCP program successes have occurred. These include successful implementation of Standard Sanitation Operations Procedures in 6000 meat and poultry plants and a significant reduction in the prevalence of *Salmonella* on poultry carcasses leaving large poultry plants which have implemented HACCP. Likewise, reduced production costs and improved product quality due to less rework and more control of raw material acquisition and manufacturing operations have been cited by some food processors. Recognizing that HACCP, from a regulatory perspective, is in its infancy, HACCP inspection in the USA will be evaluated thoroughly for its effectiveness through governmental internal processes and external mechanisms. Each agency will approach the evaluation process differently given their unique legislative authorities and programmatic operations. Nevertheless, each agency agrees that HACCP is the best food control system of choice and is committed to improve food safety requirements.

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