

Review of the Pathogen Reduction; Hazard Analysis
and Critical Control Point (HACCP) Systems Final
Rule Pursuant to Section 610 of the Regulatory
Flexibility Act, as Amended

Food Safety and Inspection Service

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TABLE OF CONTENTS

I. INTRODUCTION

II. THE ECONOMIC IMPACT OF THE RULE

III. THE CONTINUED NEED FOR THE RULE

IV. PUBLIC COMMENTS ON THE IMPACT OF THE RULE

V. THE COMPLEXITY OF THE RULE

VI. OVERLAP, DUPLICATION, OR CONFLICTS WITH OTHER FEDERAL, STATE, OR LOCAL GOVERNMENT RULES

VII. TIME, TECHNOLOGY, ECONOMIC CONDITIONS, OR OTHER FACTORS

VIII. CONCLUSIONS AND RECOMMENDATIONS

APPENDICES

APPENDIX I Amended Schedule

APPENDIX II Request for Comments

APPENDIX III Small and Very Small Plant Owner Evaluation – Blank Form

APPENDIX IV Small and Very Small Plant Owner Evaluation – Response Analysis

APPENDIX V Structural Changes in the Meat and Poultry Industry

I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) has been delegated the authority to exercise the functions of the Secretary of Agriculture as specified in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, et seq.), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, et seq.), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031, et seq.). These statutes mandate that FSIS protect the public by ensuring that meat, poultry, and egg products are safe, wholesome, unadulterated, and properly labeled and packaged.

Section 610 of the Regulatory Flexibility Act (RFA), as amended (5 U.S.C. 601-612), requires Federal agencies to conduct a review of their rules that have a significant economic impact upon a substantial number of small entities. Agencies are required to conduct the 610 review by the end of 10 years after the implementation of such a rule. Moreover, agencies are to publish a plan of their reviews in the *Federal Register*.

The purpose of the review is to determine whether the rule should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact upon a substantial number of small entities.

Agencies are to consider the following factors while reviewing the rule:

1. the continued need for the rule;
2. the nature of complaints or comments received concerning the rule from the public;
3. the complexity of the rule;
4. the extent to which the rule overlaps, duplicates, or conflicts with other Federal rules, and, to the extent feasible, with State and local government rules; and
5. the length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule.

On January 28, 2005, FSIS published a schedule of its planned 610 reviews in the *Federal Register* (70 FR 4047)--Regulatory Flexibility Act; Amended Plan for Reviewing Regulations Under Section 610 Requirements. According to the schedule, the Agency would first review the Pathogen Reduction; Hazard Analysis and Critical Control Point (PR/HACCP) Systems final rule.

The PR/HACCP final rule (61 FR 38806) was published in the *Federal Register* on July 25, 1996. These regulations established the following requirements:

- all official meat and poultry establishments must develop and implement written Sanitation Standard Operating Procedures (SSOPs);
- regular microbial testing by slaughter establishments to verify the adequacy of the establishment's process controls for the prevention and removal of fecal contamination and associated bacteria;
- pathogen reduction performance standards for *Salmonella* that slaughter establishments and establishments producing raw ground products must meet; and
- all meat and poultry establishments must develop and implement a system of preventive controls designed to improve the safety of their products, known as HACCP (Hazard Analysis and Critical Control Point).

(Note that the PR/HACCP rule did not address egg products inspection; hence, this review does not cover egg products inspection.)

FSIS assembled a 610 review team to review the PR/HACCP rule in February 2005. The team conducted a review of the regulations implemented by the PR/HACCP rule examining the five factors enumerated by Section 610 of the RFA and also the economic impact of the rule on the meat and poultry industries.

This report is the culmination of the FSIS 610 Review team's efforts.

II. THE ECONOMIC IMPACT OF THE RULE

When analyzing the impact of the PR/HACCP Rule on the meat and poultry industries 10 years after its promulgation, it is important to remember that the meat and poultry slaughter industries have long been characterized by a high rate of entry and exit. Since 1993, the total number of plants in meat slaughter has declined, while the total number of poultry slaughter plants has fluctuated, but remained relatively constant. Free entry and exit means that there are no restrictions against new firms entering or established firms exiting the industry. A firm will enter if it believes that it can make positive profits, but will exit if it has unsustainable losses. In other words, firms do not face barriers to entry or exit. Firms will enter if they can make positive profits and will exit when losses become unsustainable.

The food industry has been undergoing structural changes and consolidation for the last 35 years with profound impacts on the firms and employees (Ollinger et al. 2005). These structural changes are the result of changes in technology and demand. While the changes benefit the consumers and society, they can harm the small-scale producers.¹

Columns 1 and 2 of Table 1 show the type, size and number of plants in the meat and poultry slaughter industries during the years 1993, 1996, 2000, and 2003. Columns 3 and 4 show the rates of entry and exit for the various size plants during the pre-HACCP period (1993-1996), the HACCP implementation period (1996-2000), and the post-HACCP implementation period of (2000-2003).

Overall, the net change (exit minus entry) for the meat slaughter plants during the pre-implementation, implementation and post-implementation periods was negative, meaning that more plants exited than entered the market place. The same was true for the poultry slaughter plants, except for the implementation period, when more plants entered than exited.

¹ See Appendix V for an elaboration of the structural changes to the meat and poultry industry.

TABLE 1 Entry and Exit Rates for Meat and Poultry Slaughter Plants (Muth, 2003)

PLANT TYPE and SIZE	NUMBER of PLANTS that ENTERED or EXITED				ENTRY RATES			EXIT RATES		
	1993	1996	2000	2003	93-96	96-00	00-03	93-96	96-00	00-03
<i>Meat Slaughter Plants</i>										
Very small plants	640	608	569	533	6.6%	9.0%	11.1%	13.0%	19.2%	17.4%
Small Plants	271	243	216	201	6.3%	5.8%	10.2%	16.6%	16.9%	17.1%
Large Plants	59	64	63	61	11.9%	0.0%	4.8%	3.4%	1.6%	7.9%
Total:	970	915	848	819	6.8%	7.5%	10.4%	13.4%	17.4%	16.6%
<i>Poultry Slaughter Plants</i>										
Very Small plants	28	27	43	47	28.6%	85.2%	53.5%	35.7%	25.9%	44.2%
Small plants	116	108	114	101	2.6%	24.1%	7.9%	10.3%	18.5%	19.3%
Large plants	140	146	144	140	5.0%	2.7%	0.7%	0.7%	4.1%	3.5%
Total:	284	281	301	288	6.3%	18.9%	11.0%	8.1%	11.7%	15.3%

Since the enactment of the PR/HACCP final rule in 1996, several research studies have been designed and conducted to study the rates of entry and exit of federally inspected meat and poultry plants prior to, during, and after the promulgation of the PR/HACCP final rule. While the meat and poultry slaughter industries are characterized by frequent plant entry and exit, several studies (Muth, 2003) suggest that small and very small meat slaughter plants were more likely to exit during the implementation period (1996-2000), compared to the pre-implementation period (1993-1996). However, the rate of meat slaughter plant exit during the post implementation period (2000-2003) declined for very small plants. Rates of entry increased modestly for all three time periods for meat slaughter plants, while entry was higher for small and very small plants compared to large plants during the implementation and post-implementation periods. (See Table 1).

In contrast to the trend for the meat industry, the results of the studies used in this report suggest that the regulation had little effect on the rate of exit for small and very small poultry slaughter plants during implementation, but may have

affected the probability of exit during the post-implementation period. Entry rates were extremely high for very small poultry slaughter plants relative to small and large poultry slaughter plants (See Table 1). The difference in results for meat slaughter and poultry slaughter is likely due to the difference in industry structure. Many poultry plants are owned by large companies that tend to have substantial food safety expertise in house for use at the plant level. This would reduce the initial HACCP training costs and make implementation seamless, since the workforce was already in place.

The change in the rate of exit for very small, small, and large plants either before or after PR/HACCP implementation was not statistically significant at the 5% level (RTI 2002). This result implies that the PR/HACCP rule was not a significant factor in explaining the exit or entry of plants in the meat and poultry industries. The factors affecting the exit of meat and poultry slaughter plants over all three time periods included slaughter volume, species slaughtered, plant age, regional competitiveness, wage rates, and livestock prices (RTI 2002). However, at the same time many small entities decided to enter the industry. During the implementation period (1996-2000), the rate of entry for very small plants in the poultry slaughter industry was 85.2% as compared to the rate of exit of 25.9% and for small plants it was 24.1% entry as compared to 18.5% for exit. The authors of the 2002 RTI study do indicate however, that smaller plants may have lacked the expertise to implement PR/HACCP and would have closed as a result of it. Thus, the rule can be said to have affected a certain number of smaller plants in that they closed rather than implement HACCP.

Previous research (Muth, 2002) indicated that PR/HACCP increased the costs of producing meat and poultry products and may have increased the likelihood of plant exit, without a substantial corresponding increase in revenue (RTI 2002, Nganje, et al., 1999). The greatest costs were attributed to plants installing additional capital equipment, hiring additional workers, and increasing training. Plants also increased their use of sanitizers, anti-microbials, water, and pathogen testing. While prices have not changed substantially, small and very small plant revenue may be up because they produce different types of products, while large plants have not changed their production mix.

In 2003, the Economic Research Service (ERS) studied the costs of food safety regulation and the PR/HACCP rule. ERS estimated that the PR/HACCP rule added one percent (1%) to production costs or approximately \$850 million. This cost expense was likely passed onto consumers in the form of a one percent (1%) increase in retail prices (Ollinger, 2003). Additionally, the 2005 RTI Bovine Spongiform Encephalopathy (BSE) report showed that owners of plants will make adjustments such as changing production rates or altering input mixes in order to pass onto consumers the cost of the BSE regulation.

Other research by RTI showed that small and very small plants increased their revenue by adding more products. Research conducted by Nganje et al., on the

impact of HACCP in the meat processor and packer industry found that although output prices did not increase significantly to cover HACCP expenses, small firms were more profitable after HACCP implementation because the HACCP technology enabled the small firms to reduce product rework and increase efficiency of labor and carcass use. With Critical Control Points (CCPs) along the process, firms were able to avoid recycling or discarding bad product at the end of the production line. They were able to correct mistakes as they occurred and thus reduce spoilage of carcasses and overuse of labor from bad end product recycling. This finding validates other findings (Nganje & Mazzocco, 1998, Muth, 2002) that HACCP increased the efficiency of small firms in the meat industry.

Plant representatives perceive that PR/HACCP initiatives have had other positive effects on plant operations, because they have raised awareness of food safety issues and have provided the plant staff with better direction and organization. Additionally, plants have made more changes that affect productivity to monitor and control microbial hazards. Overall, smaller plants have generally made less sophisticated and fewer changes than large plants (RTI 2002). The 2003 ERS study by Ollinger showed that the projected health benefits (ERS 1997) of \$1.9 billion annually exceeded the industry costs of \$623 million annually. Moreover, the industry costs are very small on a per pound basis. For example, HACCP costs have raised the meat and poultry slaughter industry's total costs by about 1/3rd of one cent per pound.

In the international arena, the United States has directly influenced the adoption of equivalent PR/HACCP systems, because it requires meat and poultry plants that export to the United States to have implemented equivalent PR/HACCP systems. Additionally, the HACCP initiatives have had spillover effects because they have influenced the adoption of HACCP systems in many meat and poultry plants that do not export to the United States, as well as many other food processing plants.

When appropriately applied, PR/HACCP is a more economically efficient approach to food safety regulation than the previous system of command and control (Unnevehr 1999) because it provides a way to overcome the high costs of monitoring outcomes and provides firms with some flexibility in their approach. As long as the cost of directly monitoring microbial pathogens remains high, HACCP will be the standard of choice because it focuses resources where they will have the greatest effect on controlling hazards.

In summary, meat and poultry slaughter plants have made significant new investments to comply with the PR/HACCP rule. However, market forces were also at work encouraging the use of more sophisticated food safety technology along with an expanded array of food safety practices. There were more changes in entry and exit rates for small and very small plants than for large plants during the three periods studied. Overall, policy makers concerned about

the effects of regulations on plant exit should direct their resources toward assisting smaller plants. FSIS' role is to ensure the safety of meat and poultry products, but government agencies must consider the effects of their regulations on small businesses. FSIS has provided and continues to provide extensive technical assistance to plants through a variety of mechanisms.

III. THE CONTINUED NEED FOR THE RULE

Market failure – lack of information and asymmetric information

In determining the need for a rulemaking to establish HACCP regulations, FSIS pointed to the existence of a market failure caused by inadequate information on the meat and poultry products being sold (61 FR 38949-38950). The Agency observed that consumers make choices about the food they purchase based on factors such as price, appearance, convenience, texture, smell, and perceived quality. Ideally, people would be able to make their purchase decisions with full information about product attributes and choose foods that maximize their satisfaction and the utility of the product.

Because all raw meat and poultry products contain microorganisms that may include pathogens, raw food unavoidably entails some risk of pathogen exposure and foodborne illness to consumers. However, a consumer cannot determine the presence and level of this risk because pathogens are invisible to the naked eye. Consumers are able to detect unwholesomeness caused by spoilage, when the odors and product deterioration are obvious; however, they are unable to determine whether foods are safe in the absence of spoilage. When foodborne illness does occur, consumers may not be able to connect the symptoms they experience to a specific food because some pathogens may not cause illness until days or weeks after consumption of unsafe food because of various incubation periods.

With sufficient information on the risk of illness attributable to a food, the consumer would be better able to make informed decisions. The consumer probably would either not purchase a relatively risky food or would insist on paying a lower price for it. But, in the absence of such information, the valuation of foods is incomplete, the burdens associated with consuming the foods are unforeseen, and unanticipated social costs may result. When these costs occur, the market has failed to enable people to maximize their satisfaction and utility. Certainly an element in the satisfaction with, and the utility of, food is preservation of health.

If the manufacturer, the wholesaler, or the retail seller of the food had information on the riskiness of the food, and the consumer did not, a condition of asymmetric information would exist, and a regulation might be needed to correct the asymmetry. However, quite often, the businesses involved in the meat trade are just as lacking in information about the riskiness of the foods as are the consumers who buy them. To the extent this happens, the information problem is more a lack of information than of asymmetry.

The lack of information applies equally to retailers, wholesalers, and small processors, for if the consumers of their food products contract a foodborne illness, the consumers may not be able to identify the source. The businesses in

turn would not then have the feedback they would need to identify and correct the cause of the illness. In fact, as FSIS noted at the time it promulgated the HACCP regulations, the widespread lack of information about pathogen sources meant that businesses at every level from farm to final sale could market unsafe products and not suffer legal consequences or a reduced demand for their product. An additional complication, in the view of FSIS, was the fungibility of raw product at early stages of the marketing chain. For example, beef from several abattoirs could be combined in a batch of hamburger delivered to a fast food chain, e.g., the ground beef that was implicated in the 1992-1993 *E. coli* O157:H7 epidemic in the Northwestern United States originated at several slaughterhouses. Painstaking investigation by public health officials in cases of widespread disease often fails to identify foodborne illness causes—either the food vehicle or the disease agent².

FSIS acknowledged that food manufacturers who market their products under nationally recognized brand names would likely be motivated to ensure that the products are safe. Nevertheless, the Agency argued, not all brand name producers manufacture their products under the best available safety controls. Also, many meat and poultry products — particularly raw products, are not brand name products and are not produced under conditions that assure the lowest practical risk of pathogens (61 FR 38949).

FSIS suggested that, in at least some respects, the information problem was one of asymmetry. The Agency asserted that the failure of meat and poultry industry manufacturers to produce products with the lowest risk of pathogens and other hazards could not be attributed to a lack of knowledge or appropriate technologies. The science and technology required to significantly reduce meat and poultry pathogens and other hazards is well established, readily available, and commercially practical (61 FR 38949-38950).

Therefore, the market failure identified by FSIS was both a general lack of information among consumers and businesses and, in some areas, an information asymmetry. That is, the industry had knowledge of the food safety characteristics of their products or of the availability of the scientific and technical means to improve the products.

The Agency listed several reasons why, in its view, much of the meat and poultry industries have not taken full advantage of available science and technology to improve process controls and improve food safety. First, management positions in the meat and poultry industries were relatively easy to attain because of the lack of training or certification requirements. Many establishment operators had

²For a discussion of this problem in connection with the CDC's FoodNet active surveillance project, see Timothy F. Jones, et al., *Limitations to Successful Investigation and Reporting of Foodborne Outbreaks: An Analysis of Foodborne Disease Outbreaks in FoodNet Catchment Areas, 1998-1999*. Clinical Infectious Diseases 38 (2004): S297-S302.

minimal scientific and technical knowledge. Second, the industry was very competitive and comprised of small firms with limited capitalization and narrow profit margins; hence, they would be reluctant to introduce HACCP to their operations. Third, the management in many establishments had little incentive to make capital improvements that would result in safer products because the results of such investment are not distinguishable to customers and therefore yield no return. In spite of the apparent lack of incentives, according to the Agency, many firms were producing products that presented a very low practical risk to health. However, uncertainty about the overall risk remained (61 FR 38950).

FSIS concluded that the lack of consumer information about meat and poultry product safety and the absence of adequate incentives for industry to produce safer products represented a market failure requiring regulatory intervention (61 FR 38950). The result of this intervention would be improved public health.

FSIS considered four possible approaches to addressing the market failure and reduce the risk to public health: market incentives, information and education, voluntary industry standards, and government standards. The Agency did not see the market as able to generate the incentives necessary to overcome the disincentives to improving industry food safety effectiveness. Also, while the Agency favored improving food safety information dissemination to consumers and food service workers, the Agency saw this approach as an adjunct to, and not a substitute for, regulatory approaches to reducing foodborne illness. The Agency did not see evidence that the industry would be interested in forming a standards-setting group analogous to the American National Standards Institute. The Agency thought such an industry-administered system would likely be more expensive and less effective than a government one. In addition, the voluntary nature of an industry system would be a further drawback (61 FR 38950).

Hence, to FSIS, the government standards approach seemed to be the most promising among the available alternatives. The Agency promulgated the Final Rule "Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems" on July 25, 1996 (61 FR 38806).

Social benefits

The importance of meeting the identified regulatory need with mandatory HACCP systems became apparent when the net social benefits, in the form of reduced foodborne illnesses, were calculated. The economic analysis of the final rule presented data from the Centers for Disease Control and Prevention (CDC) and other sources on the estimated number of illness cases, the estimated number of deaths, and the estimated proportion of cases that were foodborne for a list of pathogens (*Campylobacter jejuni or coli*, *Clostridium perfringens*, *Escherichia coli* O157:H7, *Listeria monocytogenes (Lm)*, *Salmonella spp.*, *Staphylococcus aureus*, and the parasite *Toxoplasma gondii*). The Agency accompanied these

data with corresponding estimates of medical costs and productivity losses attributed to foodborne illness caused by these pathogens (61 FR 38964).

FSIS calculated the benefits of the HACCP final rule from foodborne illness reductions for the three most common enteric pathogens of animal origin – *C. jejuni/coli*, *E. coli* O157:H7, and *Salmonella* – and for the environmental pathogen *L. monocytogenes*. The FSIS analysis applied the ERS cost-of-illness methodology³ in calculating the medical costs and productivity losses attributable to the pathogens. ERS took Landefeld and Seskin's⁴ conservative human capital/willingness-to-pay approach in calculating values of statistical life. While so doing, ERS recognized that higher cost-of-illness estimates could be obtained by using such alternative approaches as that of Viscusi⁵ (1993). FSIS estimated that, collectively, the four pathogens were estimated to cause from \$1.1 billion to \$4.1 billion in annual illness and death costs attributable to meat and poultry products. The HACCP rule was intended to address 90% of that cost of illness or from \$0.99 billion to \$3.69 billion annually (61 FR 38968).

Similar approach taken by Food and Drug Administration Seafood HACCP rule

The same market failure justification for HACCP regulations was offered by the Food and Drug Administration (FDA) in rulemakings contemporary to the FSIS HACCP rulemaking. FDA promulgated final regulations mandating HACCP systems for processors of seafood in 1995 (Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products; Final Rule, 60 FR 65095; December 18, 1995). In the preliminary regulatory impact analysis accompanying the proposed regulations (December 15, 1993)⁶, FDA cited as the need for the regulations the failure of private markets to provide consumers with sufficient assurance that the products sold to them were safe. FDA noted that the private seafood market was regulated by FDA at the Federal level and by relevant State and local government agencies. These regulatory bodies set a minimum standard of safety that seafood processors were required to meet. Some processors produced seafood that was safer than the minimum standard and charged consumers higher prices to cover the costs of enhanced safety. Consumers then were free to choose among products that vary in a number of

³ USDA. Economic Research Service. 1996. Bacterial Foodborne Disease: Medical Costs & Productivity Losses. Agricultural Economic Report, No. 741. Washington, D.C.

⁴ Landefeld, J.S. and Seskin, E.P. 1982. The economic value of life: linking theory to practice. American Journal of Public Health. 6:555-566.

⁵ Viscusi, W.K. The value of risks to life and health. Journal of Economic Literature, 31 (December 1993):1912-1946.

⁶ Preliminary Regulatory Impact Analysis of the Proposed Regulations to Establish Procedures for the Safe Processing and Importing of Fish and Fishery Products. <http://www.cfsan.fda.gov/~djz/cfudpria.txt>. Accessed October 17, 2005.

characteristics including price and level of safety assurance. However, FDA argued, this situation may place some consumers in a dilemma that they wish to avoid. In making their seafood purchases some consumers may not want to be faced with differently priced products with different probabilities of illness. Instead, they may prefer that regulatory bodies set a minimum standard of safety that is high enough that consumers would no longer consider the risk of illness relevant to their purchase decisions. FDA saw no reason to change its statement of the need for regulation in its December 18, 1995, final regulatory impact analysis⁷.

FDA presented a similar argument for its fruit juice HACCP regulations, which the agency proposed in 1998 following a series of illness outbreaks associated with juice products, including some affecting children. In the preliminary regulatory impact analysis, FDA stated that the market would be unlikely to adjust to eliminate the illness risks then present in juice because of the difficulty of establishing the link between the various kinds of illnesses, acute or chronic, to consumption of juice. Generally, such a link may only be established when there are large, geographically focused outbreaks of acute illness. However, research indicated that most cases of foodborne illness are sporadic and geographically dispersed, not focused outbreaks. Also, FDA asserted, there was a presumption that consumers would be willing to pay for reduced risk of illness, given the sizeable estimated benefits from the proposed rules. Finally, while industry and State governments have initiated protocols to reduce risks associated with juice, FDA believed that changes were made with the expectation of impending Federal regulation. FDA stated that it was unlikely that the market would fully adjust to reduce the risk without additional Federal action (63 FR 24255).

FDA stated that it had found that mandating a system of preventive controls – HACCP -- to be the most effective and efficient way to ensure that juice products were safe (63 FR 24255). FDA promulgated its fruit juice HACCP regulations in 2001 (“Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice; Final Rule,” 66 FR 6137; January 19, 2001).

Hazard analysis component of HACCP regulations

A particular component of HACCP systems must be highlighted. The hazard analysis is an essential element of HACCP systems because it causes plants to identify hazards before determining preventive control measures or critical limits. This point has been clear in both the FSIS and FDA HACCP regulations and was discussed specifically in the response to comments in the final rule on fruit juice

⁷ U.S. Department of Health and Human Services. Food and Drug Administration. 1995. Final Regulatory Impact Analysis: Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products. <http://www.cfsan.fda.gov/~lrd/haccpria.html> Accessed October 17, 2005.

HACCP. Thus, in the FSIS proposed rule (“Pathogen Reduction; Hazard Analysis and Critical Control Point Systems; Proposed Rule,” 60 FR 6774; February 3, 1995), in the discussion of the hazard analysis principle, the Agency stated that the first step in establishing a HACCP system for a food production process is the identification of the hazards associated with the product. The Agency stated that the information developed during the hazard analysis should enable the establishment to identify which steps in its process are critical control points (60 FR 6809). The Agency stated that because the implementation of mandatory HACCP would result in less risk of contracting foodborne illness from meat and poultry products, the identification of critical control points throughout the production process to control microbial hazards was especially important (60 FR 6810.)

In responses to comments objecting to the requirement for a written hazard analysis (66 FR 6156), FDA conceded that the seafood HACCP regulations did not require a written hazard analysis, only that the hazard analysis be conducted, but observed that a certain evolution in thinking had occurred on this point. FDA stated that even though a written hazard analysis is not required by the seafood HACCP regulations, those regulations, as well as the FSIS meat and poultry HACCP regulations, do require a systematic and comprehensive hazard analysis. In addition, FSIS’s HACCP regulations require that the hazard analysis be written. FDA stated that the additional step of recording the hazard analysis posed no significant burden, economic or otherwise, to juice processors and, on the contrary, had advantages for the processor. FDA said that a written hazard analysis provides processors with a ready record of the decisions made in conducting a safety analysis of their process, which they may use in evaluating potential changes to the system and for discussions with regulatory officials. Further, FDA pointed out that written hazard analyses are useful to processors because they help provide the rationale for critical limits and other HACCP plan components. Having the basis for such decisions available would help when processors experienced changes in personnel, especially personnel associated with the HACCP process and in responding to unanticipated deviations from critical limits (66 FR 6156). Therefore, the value of the hazard analysis in providing adequate information support to the manufacture of products is apparent.

Healthy People 2010

To gauge the overall effectiveness of HACCP systems, FSIS has looked to epidemiological benchmarks and data published by the Department of Health and Human Services (HHS). One of these, Healthy People 2010 is a statement of national health objectives designed to identify the most significant preventable threats to health and to establish national goals to reduce these threats⁸. It was released by HHS in January 2000 and outlines a comprehensive nationwide health promotion and disease prevention agenda. In the food safety component

⁸ <http://www.healthypeople.gov> Accessed October 17, 2005.

of the Healthy People program, the Government is seeking to reduce major causes of foodborne illness. For the four pathogens on which FSIS focused in its economic analysis of the HACCP final rule, the goal for reduction of *Campylobacter* infections from the 1997 baseline is 12.3 cases per 100,000 population; for *E. coli* O157:H7 it is 1.0; for *Salmonella* it is 13.7 to 6.8, and for *Lm* it is 0.25.⁹

Foodborne Diseases Active Surveillance Network (FoodNet) surveillance results

The CDC FoodNet active surveillance data show, after statistical adjustment to account for an increase in the FoodNet population and other factors,¹⁰ that between 1996-1998 and 2005, the estimated incidence of illness attributable to the four pathogens declined. The incidence in cases per 100,000 population attributable to *Campylobacter* declined 30 percent to 12.7; to *E. coli* O157:H7, 29 percent to 1.1; to *Listeria*, 32 percent to 0.30; and to *Salmonella*, 9 percent to 14.6¹¹. These declines are concurrent with the implementation of the HACCP

⁹The President's Council on Food Safety, established by Executive Order 13100, August 25, 1998, developed a strategic plan that set public health goals including, by 2005, reducing foodborne illness by 25% for some pathogens and for others to the quantitative targets established in Healthy People 2010. See <http://www.foodsafety.gov/~fsg/cstrpl-4.html> Accessed July 25, 2007.

For the pathogens addressed in the analysis of the HACCP rule and for which "Healthy People 2005" targets were established, the incidence of illness cases declined to the 2005 target for *Campylobacter* (12.72 cases per 100,000 population by 2005, the 2005 target being 18.5) and for *E. coli* O157:H7 (1.06, the 2005 target being 1.6) but not for *L. monocytogenes* (0.30, the 2005 target being 0.25).

¹⁰ CDC used a main-effects, log-linear Poisson regression model (negative binomial) to estimate statistically significant changes in the incidence of pathogens. The model accounts for the increase in the number of FoodNet sites and the more than doubling of the surveillance population since 1996, and for variation in the incidence of infections among sites. U.S. Department of Health and Human Service Centers for Disease Control and Prevention. Preliminary FoodNet data on the incidence of foodborne diseases—selected sites. United States. 2002. Morbidity and Mortality Weekly, vol. 51, no. 15, pp. 325-329. U.S. Department of Health and Human Services Centers for Disease Control and Prevention. 2006. Morbidity and Mortality Weekly Report, vol. 55, no. 14. Hartnett, F.P., Hoekstra, R.M., Kennedy, M., Charles, L., Angulo, F.J., Epidemiologic Issues in Study Design and Data Analysis Related to FoodNet Activities. 2004. Clinical Infectious Diseases 38 (Suppl. 3): S121-6.

¹¹ U.S. Department of Health and Human Services. Centers for Disease Control and Prevention. 2006. Morbidity and Mortality Weekly Report, vol. 55, no. 14. However, it should be noted that the decline for *Salmonella* was the shallowest of the declines among the four pathogens. Of the five most common *Salmonella* serotypes only Typhimurium has declined, and most of that decline occurred in 2001. After an increase in broiler chicken carcasses testing positive for *Salmonella* during

regulations by FSIS and FDA, the impact of which FoodNet was established to register¹². The results indicate that while substantial progress has been made toward meeting the national food safety goals for these pathogens, continuing effort is necessary.

Regulatory actions since implementation of the HACCP regulations

FSIS believes that the market failure of inadequate information would continue or could become aggravated in the absence of regulatory intervention. The Agency views HACCP as the framework within which establishments work to target and eliminate food safety hazards. The FSIS HACCP regulations contain the minimum requirements that establishment HACCP plans must meet. It has been the Agency's position that in order to be successful in ensuring food safety, HACCP must be coupled with appropriate performance criteria and standards against which the effectiveness of the controls developed by establishments can be validated and verified (61 FR 38836). The HACCP regulations require that critical limits to be met at critical control points be designed to meet applicable targets or performance standards, or other requirements applying to specific processes (9 CFR 417.2(c)(3)). The Agency has regarded HACCP plans (with performance standards) as integral to maintaining sound food safety systems. FSIS promulgated microbiological performance standards and criteria in the HACCP final rule with respect to raw products and in 1999, with respect to certain processed products (64 FR 732; January 6, 1999).

In recent years, the Agency has supplemented and strengthened the effectiveness of HACCP systems to control pathogens in meat and poultry. In 1999, with the emergence of an especially virulent strain of *Lm*, FSIS concluded that many establishments should reassess their HACCP plans. FSIS published in the *Federal Register* a notice (64 FR 28351; May 26, 1999) advising manufacturers of ready-to-eat (RTE) meat and poultry products of the need to reassess their HACCP plans to ensure that the plans were, in fact, adequately addressing *Lm*. If the reassessment revealed that *Lm* was a hazard reasonably likely to occur in an establishment's production process, the establishment would have to address the hazard in its HACCP plan.

In 2002, FSIS published a notice in the *Federal Register* urging that establishments reassess HACCP plans for raw beef products to account for new scientific data on potential *E. coli* O157:H7 contamination of ground beef. According to the Agency, the new data constituted a change that could affect an establishment's hazard analysis or alter its HACCP plans for raw beef products,

2002-2005, FSIS has had under way an initiative to reduce Salmonella in raw meat and poultry carcasses.

¹² Allos, B.M., Moore, M.R., Griffin, P.M., Tauxe, R.V. 2004. Surveillance for Sporadic Foodborne Disease in the 21st Century: The FoodNet Perspective. *Clinical Infectious Diseases* 38 (Suppl. 3):S115-20.

and that change, under the HACCP regulations, necessitated reassessment of the HACCP plans (67 FR 62325, October 7, 2002; 9 CFR 417.4(a)(3)).

In 2003, following the publication of a draft quantitative risk assessment for *Lm* in deli-and hotdog-type products (68 FR 6109; February 6, 2003), the Agency published the interim final rule “Control of *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products” (68 FR 34208; June 6, 2003). The rule requires that an establishment that manufactures post-lethality-exposed RTE meat or poultry products control *Lm* in the processing environment through its HACCP plan or prevent contamination of products by the pathogen through SSOPs or other prerequisite programs. The establishment must use any of three alternative means of controlling *Lm*, involving the use of 1) sanitation with or without a post-lethality treatment that reduces or eliminates populations of the organism, 2) an antimicrobial agent, or 3) a process that suppresses or limits the growth of the organism.

In 2004, FSIS published an interim final rule (69 FR 1862; January 12, 2004) that, among other things, requires that official establishments processing the carcasses or parts of cattle develop, implement, and maintain written procedures for the removal, segregation, and disposition of Specified Risk Materials. Establishments must incorporate these procedures into their HACCP plans, SSOPs, or other prerequisite programs.

In 2006, FSIS published a notice (71 FR 9772; February 27, 2006) announcing changes in how it reports and uses the results from its *Salmonella* verification program for meat and poultry establishments to enhance public health protection. FSIS has started to add results of individual *Salmonella* verification sample tests to reports that the Agency regularly makes to meat and poultry establishments that have asked to be informed of various test results. FSIS also posts quarterly nationwide data for *Salmonella*, presented by product class, on the Agency Web site. The Agency said it would assess each completed *Salmonella* set in light of either existing regulatory standards or recently published baseline study results, as appropriate. The Agency then will take follow-up action based on the plant’s performance.

Food safety as a credence attribute

The need for HACCP and other regulatory interventions in the food safety area persists, in part, because of the nature of food safety characteristics which are difficult to know and to communicate. Meat and poultry processors have had difficulty marketing the benefits of food safety innovations to consumers. ERS and other economists regard food safety as a credence attribute of a product, for the most part, meaning that consumers cannot evaluate the existence or quality of the attribute before purchasing or even after consuming the product^{13,14}. For

¹³ USDA. Economic Research Service. Golan, E., Roberts, T., Ollinger, M. 2004. Savvy Buyers Spur Food Safety Innovations in Meat

example, consumers cannot detect by sight, smell, or price whether raw meat or poultry is contaminated with *Salmonella*. The credence characteristics of the products are thus a cause of market failure. There is evidence that market failure can be mitigated, to some extent, by the demands of large meat and poultry buyers who are creating emerging markets for food safety through their ability to require safety standards with testing and process audits, and who reward suppliers that meet the standards and punish those that do not.^{15 16}

Additional market and regulatory incentives, from “branding” fresh meat packaged at the slaughter plant, to providing consumers with increased information on product safety, to encouraging industry appropriation of new food safety technologies within the HACCP regulatory framework, would have the long-term result of overcoming the market failure caused by the credence characteristics of food products.

Conclusion on continued need for HACCP regulation

HACCP regulation helps compensate for an information deficit — a type of market failure. It is likely that without a regulatory intervention, the information would not persist because food safety is inherently a credence attribute, one that is not evident to consumers by sensory examination of a product. Therefore, consumer demand alone would be unlikely to drive food safety improvements. The HACCP regulation, by imposing safety standards, compensates for the information deficit market failure. Moreover, a component of HACCP—hazard analysis—directly addresses the information deficit.

The absence of a viable alternative to government regulation, such as widespread industry adoption of standards set by an independent institute, which has not yet occurred, was a reason for mandatory HACCP regulation. It is

Processing,. Amber Waves, April 2004. At <http://www.ers.usda.gov/Amberwaves/April04/Features/SavvyBuyers.htm> Accessed October 18, 2005.

Roberts, T. 2005. Economic Incentives, Public Policies, and Private Strategies to Control Foodborne Pathogens. *Choices*. 2ndQuarter 2005, 20(2). At <http://www.choicesmagazine.org/2005-2/safety/2005-2-01.htm> Accessed October 18, 2005. USDA. Economic Research Service. 2004. Golan, E., Roberts, T., Salay, E., Caswell, J., Ollinger, M., Moore, D. Food Safety Innovation in the United States: Evidence from the Meat Industry. Agricultural Economic Report No. 831. Washington, D.C. Pp. 2-8.

¹⁴ The credence attributes of a good are distinguished from such other attributes as search, the characteristics of a good that can be determined before purchase, and experience, the characteristics of a good that can be determined only after purchase. See Nelson, P. 1974. Information and Consumer Behavior. *Journal of Political Economy* 78:311-329.

¹⁵ USDA. Economic Research Service. *Amber Waves*, April 2004.

¹⁶ USDA. Economic Research Service. 2004. Agricultural Economic Report No. 831. Washington, D.C. pp. 30-35.

possible that the work of the HACCP Alliance and other industry and academic groups will have a lasting effect and that the food processing standards picture will change as a result. In the meantime, far from reconsidering the need for HACCP, FSIS has found it necessary to supplement the HACCP regulations through such actions as a notice on controlling *E. coli* O157:H7 in beef products and an interim final rule on control of *Lm* in RTE meat and poultry products.

The net social benefits resulting from the HACCP regulation appear to more than justify the costs. Initial calculations of the expected benefits were very conservative and can readily be confirmed. Epidemiological evidence suggests that government food safety initiatives are having a positive effect. CDC's FoodNet active surveillance project has revealed declines in foodborne illness concurrent with implementation of FSIS and FDA HACCP regulations. However, the results of this surveillance indicate that, while substantial progress has been made toward meeting the national illness reduction goals with respect to the pathogens selected for monitoring, continued effort is necessary.

IV. PUBLIC COMMENT ON THE IMPACT OF THE RULE

As part of its effort to satisfy the requirements of Section 610 of the RFA, FSIS published on August 12, 2005, a notice in the *Federal Register* (70 FR 47147) requesting comments on the impact of the PR/HACCP rule. The Agency also conducted a survey of nine small meat and poultry establishments in order to ensure that it received specific comments on the PR/HACCP rule from small and very small businesses affected by the rule.

A. Public Comment Elicited By the Federal Register Notice

The Agency requested comments, especially from small meat and poultry establishments, on the regulations established by the PR/HACCP final rule. Specifically, FSIS asked for comments on the continued need for the rule; the complexity of the rule; the extent to which the rule may overlap, duplicate, or conflict with other Federal rules; and the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule since its implementation.

The Agency received 19 comments from the public concerning the PR/HACCP rule.

Public Comments Summary

Almost all of the commenters noted the importance and necessity of HACCP in meat and poultry establishments to ensure food safety.

Two consumer groups submitted comments on the 610 review of the PR/HACCP final rule. Both groups noted how important HACCP and testing for pathogens are for food safety and asked the Agency not to mitigate the HACCP and pathogen reduction regulations for the sake of small businesses because of the critical role of these rules in providing public health protection.

Three trade associations also provided comments on the review. While supporting HACCP as a tool in food safety inspection, all three comments indicated that HACCP is very burdensome and expensive for small and very small plants. In addition, the industry associations offered many suggestions on how the Agency could mitigate the burden that compliance with the PR/HACCP rule places on small and very small plants.

Comment: Pathogen testing is essential to ensure food safety. HACCP has been successfully implemented by both small and large plants; therefore, small plants as well as large plants should continue operating under the Agency's HACCP regulations.

Response: FSIS agrees.

Comment: All plants must meet the same HACCP and pathogen reduction requirements to maintain food safety for the public. The Agency's outreach effort to assist small and very small plants has reduced the burden these plants face in meeting the HACCP regulations.

Response: FSIS agrees, but it plans more extensive outreach efforts to assist small and very small plants.

Comment: Although HACCP is necessary, small and very small plants find it burdensome. There is a financial burden resulting from the recordkeeping requirements, developing and redeveloping HACCP plans, and HACCP training costs. Additional problems for small and very small plants include: inspection overtime costs related to HACCP validation; a zero tolerance mentality regarding pathogens; and less-than-ideal working relationship, in some circumstances, between plants and inspectors.

The Agency should create a database "safe harbor" of scientific information for plants to use, FSIS should create standardized HACCP plans that small and very small plants could tap into.

Response: FSIS understands that HACCP creates some burdens for small and very small plants; however, the Agency believes that its outreach effort to small and very small plants regarding HACCP has reduced, and will continue to reduce, the burden. Further, the Agency is considering implementing some of the suggestions mentioned in the comment. See the Conclusions and Recommendations section of this report.

Comment: HACCP is good, but the Agency's expansion of non-scientific and regulatory HACCP is burdensome.

- FSIS field personnel are dictating reasonably likely to occur (RLTO) and Critical Control Points (CCPs) to plants;
- No scientific criteria exists for the use of professional judgment employed by FSIS personnel;
- Plants should not have to have CCPs if not indicated by sound science;
- The statistics underlying the Agency's sampling requirements are not justified;
- The expansion of the rule through additional regulations and directives that lack scientific validity; and
- Performance standards established by FSIS are not scientifically sound.

Response: It is Agency policy that its field personnel are not to dictate hazards RLTO or CCPs to establishments. Furthermore, FSIS believes that science does support its sampling and testing, performance standards, and regulations. However, regulations as an expression of Agency policy must necessarily apply the science that supports them.

Comment: HACCP deserves support as a science-based systematic approach to food safety. However, HACCP is excessively burdensome to small plants because it necessitated:

- Hiring additional employees with scientific backgrounds and HACCP professionals;
- Addition of employees to maintain HACCP records;
- Development of sampling plans and use of outside labs;
- Off-site employee training;
- Production of in-house data for supporting documents;
- Inability to hold tested product and meet customer orders;
- Capital investment for microbial intervention technology; and
- Overtime charges related to HACCP.

The commenter recommends that FSIS:

- Not require small plants to use resources to ensure that suppliers are meeting regulatory requirements;
- Develop model HACCP plans;
- Establish “safe harbors” for generic HACCP issues;
- Work with small plants to give notice when pathogen samples are to be taken so that product can be held and customer orders still met;
- Encourage and report research in the development of low-cost, easy to use pathogen reduction technologies; and
- Revamp the system of charging overtime for inspection outside of an inspector’s core hours for small plants.

Response: FSIS has taken several steps to assist small and very small plants to meet HACCP requirements. The Agency has developed model HACCP plans; established safe harbors for generic HACCP issues; encouraged and reported research in the development of low-cost, easy-to-use pathogen reduction technologies; and worked with small plants to give notice when pathogen samples are to be taken so that product can be held and customer orders still met.

Indeed, the Agency has an outreach program for small and very small plants. Information about the outreach efforts to small and very small plants is available on the FSIS Web site at [//www.fsis.usda.gov/Science/Small_Very_Small_Plant_Outreach/index.asp](http://www.fsis.usda.gov/Science/Small_Very_Small_Plant_Outreach/index.asp).

Comment: HACCP is burdensome for small and very small plants because of the paperwork and recordkeeping requirements, command and control regulations that still exist, uneven enforcement by FSIS, testing requirements, HACCP plan reassessments, HACCP training, plant modifications required, researching scientific information, and unrealistic expectations concerning zero tolerance for *E. coli* in ground beef.

FSIS should eliminate HACCP-related overtime, create a database of scientific knowledge for establishment use, and build a working relationship between FSIS inspection personnel and establishments.

Response: FSIS is considering taking further positive steps to help small and very small plants to meet HACCP requirements. See the Conclusions and Recommendations section of this report.

B. Small and Very Small Plant Owner and Operator Evaluation

In March 2005, the 610 Review team decided to administer a survey to nine small and very small meat and poultry business owners and operators in an effort to appeal for a greater range of public comment regarding the economic impact of the PR/HACCP rule on their businesses.

Study Methodology

To accomplish this task, a three member team was assembled to develop a road map. The team contacted two meat and poultry trade association representatives to request their assistance. The representatives were asked to canvas their respective organizations for individuals who would be willing to participate in an FSIS-sponsored evaluation regarding 61 FR 38806. In August 2005, a meat processing trade association volunteered to participate. In late-August 2005, the trade association sent the Agency a list of 15 owners or operators of small and very small meat and poultry product businesses willing to participate in the evaluation. The Agency then randomly selected nine

establishments regardless of their location, type of product produced, or affiliation. In September 2005, the team emailed the evaluation form to the nine selected individuals for administration. (See Appendix III.)

Evaluation participants

In an effort to get a balanced response, FSIS requested that the trade association representative only canvas and forward names of small and very small owners and operators of businesses affiliated with meat and poultry products. Consequently, the randomly selected nine individuals represented one very small and eight small businesses that produce the following products (percentages and numbers of participants involved in each process found on right. Most of the respondents cited more than one process):

- Red Meat Processing 89% (8 of 9)
- Ready-to-Eat 55% (5 of 9)
- Poultry Processing 44% (4 of 9)
- Raw Processed Products 44% (4 of 9)
- Red Meat Slaughter 11% (1 of 9)
- Poultry Slaughter 00% (0 of 9)
- Other 00% (0 of 9)

Evaluation Methodology

For consistency, the Agency used a standard set of seven questions. Five of seven questions were both open and close-ended. Two were strictly close-ended, requesting only demographic data. In addition, a comment section was included. Because of Office of Management and Budget (OMB) guidelines, the 610 Review Team was permitted to administer the evaluation to a maximum of 9 individuals. Consequently, the data collected data were limited. Therefore, FSIS qualitatively analyzed the data for patterns or trends.

The evaluation presents insight and opinions from small and very small business owner or operators regulated by FSIS. (See Appendix IV). This study did not request or document comments made by anyone other than these nine individuals.

Evaluation Analysis

The response rate for individual questions was inconsistent, with few respondents answering *all* questions.

The findings are as follows:

From July 1996 – July 2001: All of the respondents (9 of 9) stated that PR/HACCP had an economic impact on their businesses, but only 33% (3 of 9) categorized the impact as significant. The majority of the respondents stated that they had to dedicate personnel, training and man hours to create, implement, and administer their programs.

From August 2001 – Present: All of the respondents (9 of 9) stated that HACCP had an economic impact on their business, but only 22% (2 of 9) categorized it as significant.

All of the respondents (8 of 8) stated that PR/HACCP regulations have not complicated efforts for them to comply with other mandated Federal regulations.

89% of respondents (8 of 9) stated that it is not difficult for them to comply with the PR/HACCP regulations. 11% (1 of 9) stated it is difficult for them to comply with the regulations. Most of the respondents stated that three issues arise with compliance: 1) it is time consuming, 2) it involves a financial commitment and, 3) it is difficult to keep up with changing regulations.

Only 6 of 9 individuals provided additional comments. 50% of respondents (3 of 6) felt that the regulations are sound. 33% of respondents (2 of 6) stated that HACCP is a necessary regulation to maintain public safety, yet they felt their efforts are in vain because hotels, restaurants and retail are not held to the same standard. Additional comments were for “some” FSIS Inspection Program Personnel to apply the regulations more uniformly and improve their attitude.

Based on limited findings, it appears that most of the individuals evaluated feel that the PR/HACCP rule is a necessary regulation to ensure that meat and poultry products are safe and wholesome. All of the owners and operators stated that Pathogen Reduction/HACCP regulations placed additional economic burdens on their companies. Only 22% of respondents (2 of 9) would categorize the regulations as significant. In addition, only 11% of respondents (1 of 9) stated that it is difficult for them to comply with the regulations.

VI. THE COMPLEXITY OF THE RULE

Because there is no objective measure of complexity in government regulations, it is difficult to ascertain the complexity of the PR/HACCP rule. However, there is no doubt that the PR/HACCP rule is complex in contrast to the command and control meat and poultry regulations that it replaced. The requirements to conduct and update a hazards analysis, to maintain a HACCP plan with critical control points, and to verify certainly constituted a greater complexity than the regulations that were in place before the Agency promulgated the HACCP regulation. However, the complexity of the rule is inherent to HACCP and the use of pathogen testing. In short, there could be no great simplification of the regulations without compromising its benefits.

VI. OVERLAP, DUPLICATION, OR CONFLICTS WITH OTHER FEDERAL, STATE, OR LOCAL GOVERNMENT RULES

This section focuses on a possible regulatory overlap between FSIS and the FDA as it pertains to the PR/HACCP Rule.

The U.S. General Accounting Office (GAO) compiled reports to identify overlaps that may exist in the Federal food safety system. They defined the category of rulemaking/standard-setting as activities related to food safety policy decisions, development of regulations, and administration of regulatory review processes. In GAO report 05-213, GAO cited overlapping of the HACCP rules of USDA and FDA and duplicative inspection activities. Specific examples in the report of overlap that may have negative impact on small entities included:

- United Fresh Fruit and Vegetable Association's member companies are primarily inspected and regulated by FDA, but companies that sell fruit and vegetables to school meals programs are also inspected by USDA (but not FSIS) and additional expenses are incurred due to these USDA inspections. The expenses were not described in the report.
- A facility that produces USDA- and FDA-regulated foods on three different production lines must maintain different sets of paperwork for each food product the company processes in order to meet USDA and FDA HACCP and sanitation requirements.
- A facility that cans soup and bean products received contradictory instructions from USDA and FDA in regard to sanitation/food safety concerns. USDA inspectors did not want the company to paint its sterilization equipment because of possible food product contamination from paint chips. FDA inspectors wanted the equipment painted for identity of sanitation problems. The company manager said they had to paint and remove paint to satisfy both inspectors.

Positive impacts reported by businesses in the report included:

- American Frozen Food Institute noted that USDA and FDA provided complementary expertise in scientific assessment, research, and education in addressing food safety issues.
- A Quality Assurance manager of a company producing smoked salmon liked having a "second pair of eyes" conducting food safety inspections on a high risk food.
- The American Meat Institute reported that the Federal agencies' programs do not overlap because USDA and FDA have specific, defined areas of responsibility for their industries.

FSIS comments of March 9, 2005 clarify that while the HACCP regulations may be similar, the work of the two agencies is necessarily different because the food specific hazards differ greatly by product and process, and the GAO report seems to confuse HACCP general principles with food specific hazards. When the food hazards are different, the rules must be applied to the specific set of circumstances and environment, as in the case of FSIS inspectors in meat or poultry slaughter/processing plants vs. FDA inspection in a fruit juice producing establishment. Hazards related to a specific food production or process require HACCP plans to target that process, technology, and equipment.

The FMIA, the PPIA, and the EPIA set forth vastly different inspection responsibilities from those outlined by FDA's statutory authority. The significant differences between FSIS and FDA regulated industries under HACCP dictate the necessity of distinctly different regulations based on those different statutory authorities.

State inspection of meat and poultry occurs at facilities that are under the State and not Federal inspection. However, State inspection programs must be "at least equal to" the Federal meat and poultry inspection program. Local public health agencies focus on restaurants and retail outlets.

VII. TIME, TECHNOLOGY, ECONOMIC CONDITIONS, OR OTHER FACTORS

Section 610 of the RFA requires that agencies consider the length of time since the rule has been initially evaluated, and the degree to which technology, economic conditions, or other factors have changed in the areas affected by the rule.

Time

More than a decade has passed since the promulgation of the PR/HACCP final rule in July 1996. Since that time numerous advances in food safety research and available technologies have occurred. Moreover, the economic landscape of the meat and poultry industry has also changed. Yet the need for the PR/HACCP rule has neither diminished nor abated.

Technology

New technology¹⁷ has enabled the food industry to create a wider variety of food products, to process them faster, and to distribute them more efficiently than ever before. Small establishments produce and process a substantial proportion of meat and poultry in the United States, and the safety of their operation affects the integrity of the entire food chain.

FSIS recognizes the unique contributions and needs of small establishments operating under the Federal inspection program. The Agency tries, where possible, to accommodate small entities and to respond to their special circumstances. FSIS has met its goals in demonstrating its commitment to assisting small businesses through comprehensive compliance and technical assistance, training, communications, and other outreach efforts.

Research¹⁸ on food safety and technologies associated with food production in small plants indicates that success in developing, installing, monitoring, and verifying a successful HACCP system is contingent on a multifaceted mix of managerial and technical vigilance. While it is apparent that HACCP is present

¹⁷ A new technology is defined as new, or new application of, equipment, substances, methods, processes, or procedures affecting the slaughter of livestock or poultry or processing of meat, poultry, or egg products. The application of a new technology can help protect product from physical, chemical, or biological hazards, reduce or eliminate such hazards on product, and thereby improve the quality of the product.

¹⁸ Eunice Taylor, "HACCP in small companies: benefit or burden" Lancaster Postgraduate School of Medicine and Health, University of Central Lancaster, Preston, UK.

and used effectively in large establishments, its proper implementation and use are somewhat relaxed in small establishments because small companies are less likely to invest in new technology. One study suggested that HACCP implementation in small companies decreased proportionately as the number of employees decreased.¹⁹

In an attempt to estimate the costs associated with the introduction of HACCP in small plants, and whether the associated costs contribute to the exit of small businesses from the meat and poultry industries, consider that the industry is typified by frequent plant entries and exits, and that this trend is true for small and large plants alike. Some small plants have exited the market because of regional indicators and demand or export bans or have switched to State inspections. Others have merged with other companies and moved out of the small establishment category all together. Moreover, it is apparent from market trends that some small plants are vulnerable from inception, and that any one setback (e.g., an FSIS recall, problems associated with the physical environment, equipment failures, temporary plant closures by government officials, death or illness of a key employee, employee turnover, skill level of employees, an employee strike, or bad publicity due to an outbreak) can cause an exit from the industry.

While it is true that the adoption of the HACCP regulations required most small plants to adopt an entirely new system of managing food safety, research²⁰ has shown that most small establishments have a busy day-to-day operation without any one person designated to get involved in just food safety and HACCP, and that they often fail to allocate sufficient time to develop a HACCP plan because it takes away too much time from production. Small establishments also tend to feel burdened by the paperwork requirements related to documentation, since many small businesses rely on verbal communication as a successful management tool.

Though FSIS provides training for small establishments, time spent away from the business drew criticism because for small businesses time is money. Reportedly, many small businesses had to close their businesses to attend HACCP training. Correspondingly, they also complained that the requirement to submit to periodic reviews to verify that the plant is producing safe food is just another process that takes up unnecessary time and money that the small plant feels it cannot spare.

Many small businesses initially regarded HACCP as a financial burden and set out to minimize the burden with an improvised plan at a minimal cost that ultimately required more time and money to correct. In comparison, small companies that worked diligently through the period of establishing a HACCP

¹⁹ Ibid.

²⁰ Ibid.

plan gained a thorough understanding of HACCP and food safety and experienced an increased confidence and satisfaction in their products.

As small plants put a HACCP system in place, some began to express displeasure that their entire food operation was placed under a microscope²¹. This spotlight resulted in favorable outcomes such as waste reduction, better use of employees, and less paperwork and documentation once the system was operating properly. Essentially, once small plants understand that filtering out trivial controls allows them to focus on the critical control points emphasized in HACCP, they can concentrate on those concerns that bear most directly on the company's survival and growth.

One of the conspicuous advantages of HACCP implementation in a small plant is that it allows small companies to gain state-of-the-art food safety management skills at a minimal cost to the company. Another asset of HACCP is that small companies interested in expanding their markets will now have the prerequisite well-documented HACCP system that large retailers require from their suppliers.

Research indicates that small establishments are no more likely to exit the industry because of the demands associated with HACCP than they were before the introduction of HACCP. Many small plants that exited during HACCP's dawn period had other pending issues contributing to their closing, and the smaller the company, the bigger the obstacles. Since small companies tend to negotiate with companies that are also small, they are at greater risk for shutting because of a setback.

In essence, technological advances in the meat and poultry industries have not lessened the need for the regulations associated with the PR/HACCP final rule.

Economic Conditions

Over the past 10 years, the economy has gone through natural economic fluctuations. While these booms and slumps divert the economy from a smooth growth path, they are only temporary. The key business cycle variables over the last 10 years have included lower interest and inflation rates, low unemployment rates, the bursting of the dot.com and related stock market bubble, the outsourcing of jobs, oil price spikes, large trade deficits, high healthcare costs, and a more service-oriented economy.

None of these key economic variables has had a direct significant impact on food safety regulation; however, food safety indirectly affects healthcare costs. By ensuring that the U.S. food supply is the safest in the world, we are able to take steps to keep down the skyrocketing costs of healthcare. Healthcare costs in the United States are affected when people become ill from foodborne pathogens. Many of these foodborne pathogens also cause acute and chronic diseases,

²¹ Ibid.

further increasing healthcare costs. Justification for keeping HACCP in place is that it ensures a safer food supply.

With the growth in two-worker households, increased time constraints have been placed on consumers. Consumers are now turning to convenience foods and eating out more often. As a result, supermarkets, a key segment in the food marketing system, have begun to compete both with restaurants and fast-food outlets, as well as with large discount retailers. The loss of food market share to restaurants and large discount retailers has led, beginning in 1996, to financial pressures for a rapid pace consolidation in supermarkets. These pressures in turn, resulted in changes in market structure and market share. There are various reasons for this supermarket consolidation, but the main point is that regardless of economic conditions, there is an increasing demand for food safety; HACCP is the key component in ensuring that the consumer is protected regardless of where their food is purchased.

VIII. CONCLUSIONS AND RECOMMENDATIONS

In the PR/HACCP final rule, FSIS stated that the implementation of PR/HACCP would have a serious financial impact on a substantial number of small and very small meat and poultry plants. The Agency, however, considered that the potential benefits of HACCP outweighed the burdens associated with it. Despite the difficulties encountered by small and very small plants with the implementation of PR/HACCP, the 610 review shows that, more than ever, the public health and food safety benefits of HACCP justify the burdens that accompany it.

Because HACCP and pathogen testing are essential for a modern, effective food safety system, FSIS neither can nor will mitigate its application for small and very small plants. However, the 610 review shows that FSIS needs to take several steps to enhance and strengthen its outreach to small and very small businesses regarding HACCP and pathogen reduction efforts.

The Agency needs to fully implement the recommendations of the ad hoc task force in the FSIS Strategic Implementation Plan for Strengthening Small and Very Small Plant Outreach—available on the FSIS Web site. Implementing these recommendations will assist small and very small plants in compiling with HACCP regulations by:

- Providing one-stop service and easy access for obtaining information
- Providing a full range of technical assistance
- Developing new materials to meet unmet needs, including an electronic HACCP plan development tool that will assist small and very small plants in developing a HACCP plan
- Providing access and resources to support training for small and very small plants and to ensure that FSIS employees and partners have training to assist them in outreach activities
- Strengthening partnerships to support and enhance the effectiveness of outreach strategies
- Identifying small and very small plants' needs through regular and on-going needs assessment
- Conducting regular evaluations of outreach activities
- Leveraging existing resources

By taking the above-mentioned steps, FSIS will strengthen its HACCP program and further enhance food safety for meat and poultry products.

APPENDIX I

Regulatory Flexibility Act; Amended Plan for Reviewing Regulations Under
Section 610 Requirements

[INSERT Federal Register notice]

url: www.fsis.gov/OPPDE/rdad/FRPubs/04-040N.pdf

APPENDIX II

Request for Comments

[INSERT Federal Register notice.]

url: www.fsis.usda.gov/OPPDE/rdad/FRPubs/05-024N.pdf

APPENDIX III

**610 Review Committee
Evaluation – 61 FR 38806 (Pathogen Reduction/HACCP)**

In accordance with Section 610 of the Regulatory Flexibility Act, the Food Safety and Inspection Service (FSIS), U.S. Dept. of Agriculture (USDA) is reviewing regulations promulgated by the Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) System, final rule 61 FR 38806. FSIS is looking for public comment on the effects of the rule and how any of its burdens can be minimized. The Pathogen Reduction; HACCP Systems rule mandated that all official meat and poultry establishments develop Sanitation Standard Operating Procedures and a HACCP plan. In addition, there are sampling and analysis requirements for certain species of *E.coli* and *Salmonella*.

Please take a few minutes to complete this evaluation. Your responses will assist FSIS by determining where we should focus our attention. Please follow the instructions for each question. To assure confidentiality, no individual identification is requested. If you have questions or concerns, please contact Jeff Tarrant at: jeff.tarrant@fsis.usda.gov or 202.690.6497.

01.	<p>Immediately after Pathogen Reduction/HACCP regulations were promulgated in July 1996, was it difficult for you to comply with the regulations? <i>(mark one)</i> ___ Yes ___ No</p> <p>Please explain:</p>
02.	<p>From July 1996 – July 2001, did the Pathogen Reduction/HACCP regulations have a “significant economic impact” on your business? <i>(mark one)</i> ___ Yes ___ No</p> <p>Please explain:</p>

08.	Other comments pertaining to the Pathogen Reduction/HACCP Rule:
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Thank you for completing the evaluation.

APPENDIX IV

Small and Very Small Plant Owner Evaluation—Response Analysis

610 Review Committee 61 FR 38806 (Pathogen Reduction/HACCP) Evaluation Analysis – Appendix A

1. Immediately after Pathogen Reduction/HACCP regulations were promulgated in July 1996, was it difficult for you to comply with the regulations? (mark one) ___ Yes ___ No

With regards to this question, 78% of respondents (7 of 9) stated, “No.” 11 % of respondents (1 of 9) stated, “Yes.” One of 9 stated “Not applicable, started business in 2002.”

The majority of respondents stated that they had to dedicate personnel, training and man-hours for HACCP to be initially set-up. One was quoted as stating, *“I wouldn’t categorize the compliance as difficult, [but] required personnel time dedication was significant.”*

As a positive reflection of the Agency, 2 of 9 respondents stated that compliance wasn’t difficult because of FSIS assistance. One stated, *“It wasn’t difficult because of the extensive training received from various HACCP training seminars and local inspectors.”* Another stated, *“We had a lot of help from the local inspector explaining what was needed. Also, the classes were great in explaining what was expected from an establishment.”*

2. From July 1996 – July 2001, did the Pathogen Reduction/HACCP regulations have a “significant economic impact” on your business? (mark one) ___ Yes ___ No

With regards to this question, 33% of respondents (3 of 9) answered, “Yes.” 44% of respondents (4 of 9) stated, “No.” Two of 9 did not answer the question.

All of respondents (who answered the question) stated that there was an economic impact on their business, but only 33% stated that it was “significant.” For instance, one individual who responded “yes” stated, *“It did have a significant negative economic impact on our company. This impact did not affect our company until a few months prior to the deadline for small establishments became effective.”* But, another was quoted as saying, *“The impact was not significant although it did cost the company financial resources to create, implement and administer the program and train personnel.”*

3. From Aug 2001 – Present, did the Pathogen Reduction/HACCP regulations have a “significant economic impact” on your business? (mark one) ___ Yes ___ No

With regards to this question, only 22% of respondents (2 of 9) answered, “Yes.” The remaining 78% of respondents (7 of 9) stated, “No.”

All of the respondents stated that HACCP had an economic impact on their business. But, only 22% of respondents (2 of 9) stated that it was significant. One of the “Yes” respondents was quoted as saying, *“The Pathogen Reduction/HACCP regulations put significant additional economic burdens on our business due to the personnel time requirement to write the plans and implement the plans on a daily basis.”* In counterpoint, one of the “No” respondents stated, *“It does have an impact, but it is not significant. It costs the company financial resources in ongoing training, modifications and daily procedures.”*

4. In your opinion, have the Pathogen Reduction/HACCP regulations complicated efforts for you to comply with other mandated federal regulations? (mark one) Yes No

Regarding this question, all of the respondents who answered the question (8 of 8) stated, “No.” One respondent did not answer the question.

As a positive reflection of the regulation, two respondents provided positive statements. One stated, “*I feel that we have a better understanding of mandated federal regulations and our own procedures due to Pathogen Reduction/HACCP regulations.*” Another stated, “*We haven’t experienced any conflicts between HACCP and other regulations. If anything, I think that it complements other mandated regulations.*”

5. Currently, is it difficult for you to comply with Pathogen Reduction/HACCP regulations? (mark one) Yes No

Regarding this question, 89% of respondents (8 of 9) stated, “No.” 11% of respondents (1 of 9) stated, “Yes.” Most of the respondents stated that it isn’t difficult to comply, but there are three issues that arise with compliance; 1) It is time consuming, 2) It involves a financial commitment and 3) it is difficult to keep up with changing regulations.

One of the respondents stated, “*Internal systems have been established to make compliance relatively smooth. However, staying current on the changing regulations is the most difficult aspect of complying with HACCP regulations.*” Another was quoted as stating, “*The only problems we have are with the continual changes in policy. As a producer you don’t know what will be the policy from month-to-month.*”

6. The following best describes my affiliation: (mark all that apply)

- | | |
|--|---|
| <input type="checkbox"/> Red meat slaughter | <input type="checkbox"/> Poultry slaughter |
| <input type="checkbox"/> Red meat processing | <input type="checkbox"/> Poultry processing |
| <input type="checkbox"/> Ready-to-Eat (RTE) processed products | <input type="checkbox"/> Raw processed products |
| <input type="checkbox"/> Other _____ | |

Red Meat Processing –	89% (8 of 9)
RTE –	55% (5 of 9)
Poultry Processing –	44% (4 of 9)
Raw Processed Products –	44% (4 of 9)
Red Meat Slaughter –	11% (1 of 9)
Poultry Slaughter –	00% (0 of 9)
Other –	00% (0 of 9)

7. If you are affiliated with a meat, poultry, RTE or raw processed products firm, what is the size of your establishment (by applying PR/HACCP regulatory criteria)? (mark one)

- Very small (1-9 employees) Small (10-499 employees) Other () employees

Small –	89% (8 of 9)
Very Small –	11% (1 of 9)

8. Other comments pertaining to the Pathogen Reduction/HACCP Rule:

Unfortunately, due to the low response rate (6 of 9 respondents offered comments), it was difficult to detect any distinct trends or patterns.

But, 2 of 6 respondents stated that HACCP is a necessary regulation to maintain public safety, yet they felt their efforts are in vain because hotels, restaurants and retail are not held to the same standard. One respondent stated, *“I think the Pathogen Reduction/HACCP Rule is a very important regulation because it is good for public safety and I think the industry needed a change. However, I have a problem understanding why we are so tightly regulated, and an end user such as a Hotel, Restaurant or Institution, which we serve, does not have to follow the same rules and regulations. No matter what we do, no matter how hard we try to maintain temperature and keep pathogen reduction to a minimum, if they don’t follow the same rules and regulations, I feel that all we do is just wasted time and money. I understand that USDA does not have jurisdiction over restaurants and hotels, but I feel that something needs to be done.”* Another respondent stated, *“Overall, I know the HACCP and SSOP programs are necessary in order to continue to create a safe environment to produce a wholesome product under a national standard. The problem is we don’t have a good program in place to protect the consumer at the restaurant and retail level. That being said, all our efforts to protect the end user are in vain.”*

With regards to positive comments, 3 of 6 respondents felt that the regulation is sound. One of the respondents stated, *“As a quality orientated processor of smoked meats I believe that HACCP has been instrumental in maintaining the high degree of integrity of our products.”*

Additional comments were in regards to “some” FSIS Inspection Program Personnel applying the regulations more uniformly and improving their attitude. One respondent was quoted as stating, *“We would like to see improved attitude from some, not all, of the USDA inspectors. Why can’t the inspectors approach implementing the regulations on a “combined effort” with the establishment rather than a “USDA vs. plant attitude?”*

APPENDIX V

Structural Changes in the Meat and Poultry Industry

Consolidation, vertical integration, and structural changes in the food industry have had profound impacts on firms, employees, and communities in many parts of the United States. Large economies of scale have caused consolidation into larger plants and firms, thus reducing the number of small and very small plants, while technology has played a dominant role in food processing industries. Economists generally attribute structural changes as these to rising or falling demand and shifts in technology (Scherer, 1980).

Consolidation

When market demand is growing slowly the increase in consolidation (larger plants and firms) can lead to an increase in concentration (fewer competitors). While the role of scale economies and technology changes has driven the consolidation, the summary indicator of the structural changes can be seen in the four firm concentration ratios (CR4). The CR4 measures the share of output held by the top four producers in an industry.

With a decline in the per-capita consumption of red meat, a drop in the number of plants, and a sharp increase in plant size, the cattle slaughter industry experienced a 50% increase in the (CR4). Today 80% of cattle slaughter is performed by the top four producers. Such structural changes can harm small scale producers and cause worker dislocations, but may benefit consumers and society if lower costs lead to lower prices.

Decreased per capita consumption of meat products during the 1980s meant that growth in sales volume could occur only if one firm took market share from another. For firms competing in markets for semi-processed goods, such as meat packers and processors, this meant that plants had to compete on selling prices, putting pressure on their own wage and operating costs. This encouraged firms to employ larger plants with more sophisticated equipment designed to handle much greater throughput, but with nonstop production. In the process, highly competitive meatpacking and processing industries emerged.

At the same time, the reduction in demand for red meat led to a large increase in demand for poultry products. To accommodate this increase in demand, there was a rapid change to larger poultry slaughter plants. Since fewer plants existed, the concentration changed very little.

Industry consolidation includes more than just concentration and plant size. Other dramatic changes affect 1) product and input mix, 2) industry location, and 3) organization and compensation of workforces at slaughter plants.

In meat slaughter, the product mix changed from carcasses to boxed beef and ground beef products. There were also location changes where concentration intensified in certain geographic areas.

Declining unionization and increasing employment of immigrants resulted in declining real wages. Contraction in plant numbers and workers lowered wages for meatpacking and processing employees by at least a third. Workers in other industries realized little change in wages. The reduction in wages combined with gains in output per worker meant that labor costs per unit of output dropped dramatically. Although likely cost reductions were passed onto consumers in the form of lower prices, the price impact was probably small because labor costs are only a small part of the cost of food processing.

Throughout the 1970s, larger plants paid higher wages. This generated a monetary scale diseconomy that largely offset cost advantages that technology changes offered larger plants. The larger plants' wage premium disappeared in the 1980s and technology changes created larger and more extensive technology scale economies. As a result, large plants realized growing cost advantages over smaller plants and production shifted to larger plants, further harming the small and very small establishments. The largest slaughter plants in 1992 held a significant cost advantage over smaller plants. However, large plants quickly lose this cost advantage if they cannot operate at a near full capacity.

Only the poultry slaughter and processing industries added workers, and that development was attributed mainly to a shift from producing primarily whole birds to producing a variety of processed products like deboned poultry parts, poultry hot dogs, turkey hams, as well as a dramatic increase in exports.

In the hog industry, small family farm breeders are being replaced by large highly sophisticated breeder companies who will often develop specific genetic lines for large producers own breeding herds, causing harm to small and very small establishments (Schrader, 1997). Pork industry structural changes were also characterized by advances in technology, economies of scale, changing methods of vertical integration, and gains in production efficiencies.

Vertical Integration

Production contracts and vertical integration in the broiler industry facilitated rapid adoption of new technology, improved quality control, and assured market outlets for broilers. Chicken consumption grew because of reduced real chicken prices and the industry response to changing consumer preferences. Additionally, the broiler industry responded to an increase in consumer demand for convenience and nutritious foods which was spurred by information linking diet and health.

Contracts and vertical integration have helped increase broiler supplies, reduce chicken prices, and improve product quality and consistency. Vertical integration between production and processing activities resulted in further gains in coordination between chicken production and demand. Innovations have increased the size of production units to achieve economies of scale and resulted in substitution of capital for labor which was harmful to small and very small establishments. Innovation in production has lowered costs for firms operating at higher levels of output, which favors larger plants over small and very small plants. As the broiler industry has grown, contracts and vertical integration have played an important role in the adoption of new technology and coordination of products with consumer preferences.

Contracts between growers and feed company integrators became a means of quickly harnessing new technology by reducing capital constraints. By facilitating adoption of new technology, improving risk management and stabilizing flows of uniform broiler supplies into processing plants, these arrangements provided a means for lower production costs, increased production, lower retail prices, and the ability to control quality. The arrangements also transferred price and production risk to the integrator who could better manage risk. Vertical integration of feed, hatchery and processing stages enabled firms to maintain large volumes and control the flow of broilers at each stage to capture economies of scale. In the early years of the broiler industry development, large capital requirements provided significant barriers for broiler growers. Contractual arrangements with feed dealers reduced the growers' financial burden and facilitated the adoption of new cost-saving technology.

Rapid changes in methods of vertical integration in the pork industry are associated with new technology, substantial growth in geographical areas of production, and scale economies. By reducing the likelihood of opportunistic behavior associated with specific assets, larger investments may be made in cost-reducing and quality-improving technology.

Economic theory suggests that in markets characterized by imperfect competition (monopoly, monopsony, or oligopoly) firms may contract or vertically integrate to increase profits. In most cases, vertical integration increases output, lowers consumer prices, and increases social welfare.