An Economic Assessment of Food Safety Regulations: The New Approach to Meat and Poultry Inspection. Stephen R. Crutchfield, Jean C. Buzby, Tanya Roberts, Michael Ollinger, and C.-T. Jordan Lin. Food Safety Branch, Food and Consumer Economics Division, Economic Research Service, United States Department of Agriculture, Agricultural Economic Report No. 755.

Abstract

An economic analysis of new meat and poultry inspection rules evaluates the benefits and costs of reducing microbial pathogens and preventing foodborne illness. The new rules require federally-inspected processors and slaughterhouses to adopt Hazard Analysis and Critical Control Points (HACCP) systems to identify potential sources of pathogen contamination and establish procedures to prevent contamination. The benefits of reducing pathogens, which include lower medical costs of illness, lower productivity losses, and fewer premature deaths, range from $1.9 billion to $171.8 billion over 20 years, depending upon the level of pathogen control. These benefits will likely exceed the costs of HACCP, which are estimated at between $1.1 and $1.3 billion over 20 years. Small meat and poultry processing firms may bear higher costs under the new regulations than do large firms. Non-regulatory alternatives to improving food safety, such as education, labeling, market-based incentives for pathogen reduction, and irradiation, may contribute to the goal of making foods safer, but are not a substitute for regulation. Additional research is necessary to address the fundamental uncertainties involved in estimating the economic consequences of meat and poultry regulatory policies.

Keywords: Food safety, foodborne illness, microbial pathogens, meat and poultry inspection, HACCP, cost of illness, consumer education, irradiation

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Summary

This economic analysis of new meat and poultry inspection rules evaluates the benefits and costs of reducing microbial pathogens and preventing foodborne illness. USDA is now requiring all federally-inspected meat and poultry processing plants to implement a new inspection system called Hazard Analysis and Critical Control Points (HACCP). This system strives to reduce human exposure to meat- and poultry-borne pathogens by requiring processing plants to scrutinize the critical control points in the production process—points where food safety hazards can be prevented, reduced to an acceptable level, or eliminated.

Efforts to improve the U.S. meat and poultry inspection system were spurred in part by recent outbreaks of illness traced to *E. coli* bacteria in beef products. According to the U.S. Centers for Disease Control and Prevention and the Food and Drug Administration, between 6 and 33 million people become ill each year from microbial pathogens in food, including meat and poultry, resulting in as many as 9,000 deaths.

The key economic benefit of HACCP is the money saved by reducing foodborne illnesses. Society incurs medical costs and productivity losses when people need medical care, miss work, or die prematurely from illnesses caused by microbial pathogens in their food. ERS research has estimated the annual medical and productivity costs of seven major pathogens in meat and poultry products to be between $6.5 and $34.9 billion annually.

The key costs of HACCP include spending by meat and poultry processing plants on such things as sanitation, temperature control, planning and training, and pathogen testing. USDA's Food Safety and Inspection Service estimates these costs to be from $1.1 to $1.3 billion over 20 years.

The report finds that the benefits of HACCP will likely outweigh the costs. Using conservative assumptions that HACCP reduces both pathogen levels and foodborne illnesses and deaths by 20 percent, the benefits of the new inspection system are at least $1.9 billion over 20 years. This exceeds the 20-year estimated cost of the program, which FSIS puts at $1.1 to $1.3 billion. If implementation of HACCP reduces pathogen contamination by 90 percent, the expected reductions in medical costs and productivity losses climb to as much as $170 billion. These estimates are conservative, because they encompass foodborne diseases from four pathogens for which epidemiological and cost-of-illness data exist. HACCP implementation could produce additional economic benefits by controlling other pathogens.

HACCP will likely affect some groups more than others—in terms of both benefits and costs. For instance, certain high-risk population groups—including the elderly, the very young, pregnant women, and people with HIV/AIDS or cancer—will benefit more from improved food safety than others because they are more likely to contract foodborne illnesses. On the other hand, the costs of implementing HACCP may be proportionally greater for small processing plants.

Strengthening the meat inspection system is one of several actions that can improve the safety of the Nation's meat and poultry supplies. Others include promoting the safe handling of meat and poultry by consumers, retailers, and foodservice workers and educating them how to do so; irradiating meat and poultry products; and strengthening economic incentives to produce safer food by certifying production processes that significantly reduce pathogens, or by increasing the legal options available to those stricken with foodborne illnesses.

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Introduction and Overview

American agriculture excels at producing an abundant supply of safe, nutritious food for the Nation and the world. Despite the productivity and quality of the Nation's food system, concerns remain about the safety and quality of the food we eat and the water we drink. In recent years, some well-publicized incidents, such as the contamination of hamburgers with the *E. coli* O157:H7 bacterium and residues of the pesticide Alar on apples, have led to increased public concern about the possibility of foodborne illness and exposure to potentially hazardous chemicals in the food supply. According to the U.S. Department of Agriculture's (USDA) 1991 Diet and Health Knowledge Survey, 49 percent of primary meal preparers cited bacteria or parasites in food as the food safety issue of greatest concern. An additional 26 percent cited pesticide residues in food as their greatest safety concern. In response, the USDA has begun several broad-based efforts to make further improvements in the safety and quality of the Nation's food supply.

This report discusses the regulation of meat and poultry products from the economist's perspective. Economics plays an important role in the public debate about food safety. Fundamental economic principles help explain why food safety problems may exist. Economic analysis of the costs of foodborne disease helps put the social burden of unsafe food into a broader perspective. Finally, economic analysis of food safety policies helps public- and private-sector decisionmakers rank policy options on the basis of expected costs and benefits.

The Economics of Food Safety

The food supply in the United States is generally considered healthy, nutritious, and safe. However, the modern industrial food system may result in undesired or unanticipated outcomes that pose a health hazard for consumers. Fresh or processed meat and poultry products may contain bacteria, viruses, fungal toxins, and parasites that can cause human illness if not killed by thorough cooking. Residues of agricultural chemicals may remain on fruits and vegetables, and prolonged dietary exposure to such chemicals may pose a risk of cancer or other adverse health effects. Chemical residues from fertilizers and pesticides applied to cropland may end up in drinking water supplies, again exposing consumers to potentially hazardous chemicals. Finally, microbial pathogens may enter streams and human water supplies through feedlot or pasture runoff.

Consumers make choices about the food products they purchase based on a number of factors. In addition to the price of the product, factors such as appearance, convenience, texture, smell, and perceived quality influence choices made in the marketplace. In an ideal world, consumers would make consumption decisions with full information about product attributes, and so choose the foods that maximize their well-being.

In the real world, however, there are numerous food-safety information problems, which complicate the consumer's decisionmaking. All raw meat and poultry products contain some level of microorganisms, some of which may be pathogens (bacteria, parasites, viruses, or fungi that can cause illness in humans). However, consumers generally do not know the level of foodborne-illness risk, since pathogens are not visible to the naked eye. Aside from some rather obvious indications (*e.g.*, unpleasant odor, or discoloration, both of which are more likely to be caused by non-pathogenic spoilage microorganisms), there are, in many cases, no clear-cut ways for consumers to determine if there is a health risk from pathogens or other causes (such as pesticide residues). Firms may also be reluctant to link food safety issues and their products in the minds of consumers.

Consumers do not have complete information about the safety of the products they buy because producers have no direct incentive to provide this information. Since it is not clear whether consumers can distinguish different safety levels in food products, firms may not wish to incur the extra cost of providing more than the minimum required level of safety in the food products they market. Even if firms were to attempt to provide food-safety information through product labels, there may be some concern from a consumer protection standpoint about firms' making unsubstantiated health-risk claims in labeling or advertising.

The lack of consumers' food-safety information and the lack of producers' incentives to provide such information lead to a market failure. The workings of a non-regulated market may yield greater-than-optimal levels of pathogens in the food supply and excessive human-health risk, which could result in higher levels of illness and mortality from foodborne pathogens. In such a case, the public welfare could be enhanced if society regulated the food-processing industry to reduce the level of foodborne pathogens and increased consumers' knowledge, so they could take action to reduce their risk of exposure to foodborne illness.

The economic issue of concern is how best to achieve the goal of a safer food supply. Although regulations governing the production, processing, distribution, and marketing of food products may create benefits by increasing the safety level of the Nation's food supply and reducing risk of illness, these regulations can also increase producers' costs and potentially raise food prices. The task is to ensure that the regulations maximize the net benefits of increasing food safety, equating the marginal benefits of safer food with the marginal costs of achieving food safety goals.

In the next section, we present a baseline estimate of the extent of microbial foodborne illness and associated deaths in the United States.

The Scope and Extent of Pathogen-Related Foodborne Disease

Bacteria and parasites exist to some degree in all farm animals. Many microbes that are pathogenic to animals do not cause human illness, and some human pathogens can live in food animals' gastrointestinal tract without causing animal illness. Some pathogens remaining in meat and poultry products after slaughter may cause human illness under certain conditions. Pathogens can also be introduced into meat and poultry products in slaughter plants, processing plants, grocery stores or foodservice establishments, and at home (fig. 1). Pathogens can enter the food chain through feed, manure management, processing procedures, or equipment and facility sanitation. Improper operating procedures during processing and while handling food in the home or restaurant can allow bacterial pathogens to grow, which in turn increases the risk of foodborne illness. Among the most frequent causes of foodborne disease are new product contamination, inadequate cooking, inadequate cooling, storage, and improper personal hygiene of the food handler or preparer.

The U.S. Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA)

Figure 1 - Tracking pathogens from farm to fork

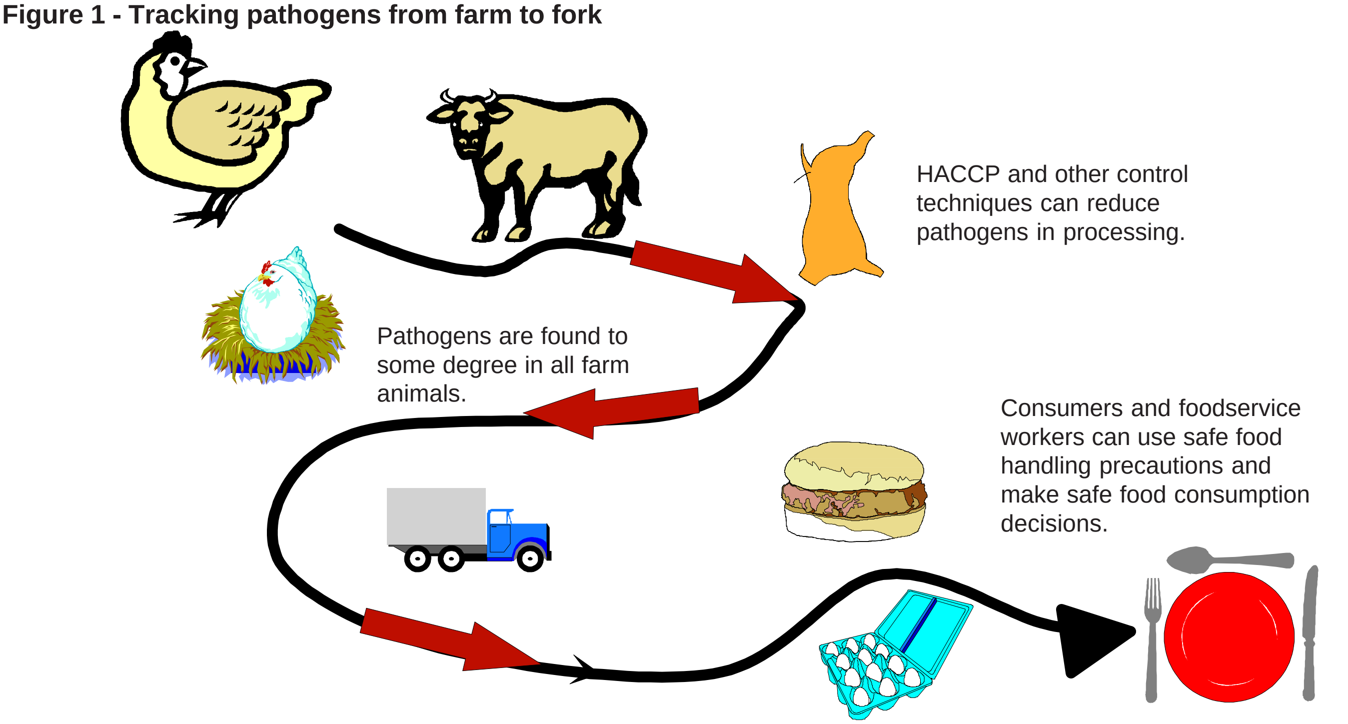


Table 1--Cases of illness and death for seven major microbial pathogens

Pathogen and disease/complication	Estimated annual cases	Estimated annual deaths	Estimated share foodborne	Foodborne annual cases	Foodborne annual deaths
	------------*Number*-----------		*Percent*	-------------*Number*-----------	
Bacteria					
Campylobacter jejuni or *coli*					
Campylobacteriosis	2,000,000-10,000,000	200-730	55-70	1,100,000-7,000,000	110-511
Clostridium perfringens					
C. perfringens intoxications	10,000	100	100	10,000	100
Escherichia coli O157:H7					
E. coli O157:H7 disease	10,000-20,000	100-250	80	8,000-16,000	80-200
Hemolytic uremic syndrome[1]	400-820	120-291	80	320-656	96-233
Subtotal	N/A	220-541	N/A	N/A	176-433
Listeria monocytogenes[2]					
Listeriosis	1,092-1,860	270-510	85-95	928-1,767	230-485
Complications	26-43	0	85-95	22-41	0
Subtotal	N/A	270-510	N/A	N/A	230-485
Salmonella (non-typhoid)					
Salmonellosis	800,000-4,000,000	1,000-2,000	87-96	696,000-3,840,000	870-1,920
Staphylococcus aureus					
S. aureus intoxications	8,900,000	2,670	17	1,513,000	454
Parasite					
Toxoplasma gondii[3]					
Toxoplasmosis	435	79	50	217	40
Complications	3,083	0	50	1,541	0
Subtotal	3,162	79	N/A	1,581	40
Total[4]	11,700,000-22,900,000	4,500-6,600	N/A	3,300,000-12,300,000	1,900-3,900

Notes: N/A = Not applicable.
[1] Kidney failure.
[2] Includes only hospitalized patients because of data limitations.
[3] Includes only toxoplasmosis cases related to fetuses and newborn children who may become blind or mentally retarded. Some cases do not have noticeable acute illness at birth but develop complications by age 17. Does not include all other cases of toxoplasmosis. Another high-risk group for this parasite is the immunocompromised, such as patients with AIDS.
[4] Totals are rounded down to reflect the uncertainty of the estimates.

Source: Buzby and Roberts, 1996.

estimate that, each year, between 6.5 and 33 million people in the United States become ill from microbial pathogens in their food; of these, up to 9,000 die (CAST, 1994). These figures are estimates based on reported outbreaks and other epidemiologic data. The actual number of reported cases is much smaller, averaging about 18,000 cases of foodborne disease for the period 1983-87 (CAST, 1994). There are several reasons why the range of estimated cases is so much greater than the number of actual, reported cases. First, many foodborne illnesses have symptoms that are similar to other gastro-enteric illnesses, and might not be reported by physicians as foodborne. Second, in some cases there is a delay of days or weeks between exposure to a foodborne pathogen and the resultant illness; many illnesses that are reported are not linked to specific foods or pathogens. Finally, many people who become ill do not seek medical care, and these cases are, therefore, not reported.

Table 1 presents illness and death estimates from all sources for seven pathogens for which we have the most reliable information: These include *Salmonella*, *Campy-*

lobacter jejuni/coli, *Staphylococcus aureus*, *Escherichia coli* (*E. coli)* O157:H7, *Clostridium perfringens*, *Listeria monocytogenes*, and *Toxoplasma gondii*. The table also presents the estimated percent attributable to foodborne sources and the resulting cases of foodborne illness cases and associated deaths.

Human illness caused by *Salmonella* is frequently associated with poultry, beef, and egg consumption (Lin, Roberts, and Madison, 1993). Symptoms generally occur 6-72 hours after eating contaminated food (Benenson, 1990), and can last from days to weeks (although most last only a day or two). Acute symptoms include abdominal pain, nausea, stomachache, vomiting, cold chills, fever, exhaustion, and, in rare cases, bloody stools. Endocarditis (infection of the heart), meningitis (infection of the brain), and pneumonia may follow the acute stage. The pathogen can also cause chronic complications such as rheumatoid syndromes, colitis, and thyroiditis. Death may result from the illness. A new strain, *Salmonella enteritidis*, can be passed to eggs before the shell forms if the hen is infected. Raw shell eggs and their products can be contaminated with *Salmonella enteritidis*. Home-made foods containing raw eggs, such as ice cream, egg nog, mayonnaise, cake frosting, lightly cooked egg dishes, and Caesar salad, are potentially risky. A recent outbreak of *Salmonella enteritidis*-related illness in the Midwest was traced to ice cream transported in containers that had previously carried unpasteurized liquid eggs.

Human illness caused by *Campylobacter* has been linked to chicken or poultry consumption. Symptoms usually begin 1-10 days after exposure to contaminated food (Benenson, 1990) and can last for days. These symptoms include malaise, diarrhea, vomiting, severe abdominal pain, (occasionally) bloody diarrhea, and fever. Other complications may follow, such as meningitis, arthritis, cholecystitis, urinary tract infection, appendicitis, septicemia, Reiter syndrome, and Guillain-Barré syndrome (GBS) -- a major cause of nontrauma-related paralysis in the United States. A small proportion of patients die.

Table 2--Populations susceptible to foodborne disease in the United States, 1993

Category	Number of individuals
Elderly (over age 65)	29,400,000
Pregnant women	5,657,900
Neonates	4,002,000
Cancer patients	2,411,000
Non-hospitalized residents in nursing homes	1,553,000
Organ transplant patients	110,270
HIV/AIDS patients	135,000

Source: Council for Agricultural Science and Technology, 1994.

Illness caused by *E. coli* O157:H7 is less widespread, but has received considerable publicity following a 1993 outbreak in California, Idaho, Nevada, and Washington attributed to undercooked hamburgers in a fast-food restaurant chain, a 1996 outbreak in Japan of unknown origin, and a 1996 outbreak related to unpasteurized apple juice in the Midwest. The pathogen has also been found in raw milk, unpasteurized apple cider, processed sausage, and home-prepared hamburgers. The latter present a particular risk; the bacteria can live on the surface of meat products and are normally destroyed by cooking. However, when meat is ground to make hamburger or sausage the organism can be distributed throughout the product, and the raw meat ground into hamburger can come from many different meat carcasses. (This can increase the probability of contamination.) If the sausage or hamburger is undercooked or eaten rare, the bacteria in the center of the meat might not be killed. It generally takes 3-7 days before symptoms occur after eating contaminated food. Acute symptoms, lasting 6-8 days, are diarrhea (often bloody), abdominal pain, vomiting, and little or no fever. Chronic consequences include hemolytic uremic syndrome (HUS), which is characterized by kidney failure and strikes mostly children under the age of 5. Some proportion of patients will die.

Not all segments of the population are equally at risk from microbial foodborne disease. Much of the increased risk is from impaired immune systems; organisms, which a healthy immune system can fight, may pose a greater risk to some population subgroups than others (table 2). Elderly individuals may undergo a decrease in immune function as they age. The immune system of neonates (newborn children) and young children is not fully developed. Pregnancy puts the fetus at special risk of foodborne illness caused by pathogens such as *Listeria monocytogenes* and *Toxoplasma gondii*; miscarriage, stillbirth, or fetal abnormality may occur. Since, by definition, the immune systems of people with AIDS or infected by the HIV virus are damaged or destroyed, these patients are also at greater risk of foodborne disease.

Foodborne illness trends over time are not consistent across pathogens. Some illnesses may be decreasing over time, while others may be increasing. The U.S. population is increasing at a little over 1 percent each year, and part of this growth is attributed to a greater number of children and elderly people, two categories most affected by foodborne illnesses (although the proportion of children as a share of the total population is expected to decline). However, it seems clear that, as the population increases and ages and the number of immunocompromised people increases, the pool of people susceptible to microbial foodborne illness seems certain to grow. Other factors can cause an increase in overall risk as well.

Two factors critical to preventing foodborne illness are correct handling of food and cooking to appropriate temperatures. USDA, in 1994, required all fresh meat and poultry products sold at retail or handled by foodservice workers to carry labels advising safe handling and proper cooking precautions. Consumers are not always able to take precautions to prevent foodborne illness, however, when they consume food in restaurants or institutional settings. According to USDA food consumption and expenditure data, between 1970 and 1993, the proportion of the food dollar consumed away from home rose from 34 percent of total food expenditure to almost 47 percent (Putnam and Allshouse, 1996). As more food is consumed away from home, consumers will have less control over the safety of their food intake. The potential for large-scale outbreaks is greater (and the potential benefits of pathogen control are larger) when more people are eating away from home.

Options for Improving Meat and Poultry Safety

Several approaches can be taken to improve the safety of the Nation's food supply. Options are available at many points along the continuum from "farm to fork" where changes in food production, processing, distribution, handling, cooking, and consumption can reduce the health risk associated with foodborne microbial pathogens. Among these are the following:

- Strengthening the meat and poultry inspection system;
- Educating consumers, retailers, and foodservice workers, and promoting safe food handling;
- Irradiating meat and poultry products; and
- Using market-oriented approaches to food safety: labeling, branding, legal incentives, and providing food-safety information about products or production methods.

All of these options could help improve the safety of U.S. meat and poultry products. The role of economics is to identify the costs and benefits of each potential policy, rank policies on the basis of their benefits and costs, and identify the distributional consequences of such policies for farmers, food processors, retailers, and consumers. Subsequent sections of this report examine the economics of these policy options, with an emphasis on the economic consequences of proposals to strengthen the meat and poultry inspection system.

Historical Background

U.S. Meat and Poultry Inspection Before 1996

U.S. inspection of meat and poultry products began in 1891, when Congress provided for inspection of salted pork and bacon in response to European fears of trichinosis, a parasite transmitted by eating or handling raw pork. The legislation provided for inspection when required by an importing country or when requested by a purchaser, seller, or exporter (Roberts, 1983). Demand by packing houses for inspection services exceeded expectations. Consequently, USDA requested that Congress appropriate enough money to extend inspections to "cover all animals slaughtered for human food in order to protect American consumers" (USDA, Bureau of Animal Industry, 1906, p. 69).

The Congress acted on this request in 1906, in part because of conditions exposed by Upton Sinclair's book, *The Jungle*. Sinclair portrayed the Chicago stockyards as unsanitary, rodent-infested places where dead cattle were secretly butchered at night and sausages were composed of unsanitary and harmful ingredients. In response, the Congress added a meat inspection amendment to the annual Agricultural Appropriation Bill. The 1906 Act required the Federal inspection of all meat crossing State lines; the first inspection was to be conducted in the slaughterhouse, with subsequent inspections any time the meat was further processed or sold to another company.

Federal poultry inspection began as a voluntary program, on an ad-hoc basis, and was formalized under the authority of the 1946 Agricultural Marketing Act. However, the expansion of the poultry industry (from 1 million broilers raised annually in the 1930's to over 1 billion in 1957) and new scientific knowledge about the communicability of poultry diseases to workers were the principal factors leading to the 1957 Poultry Products Inspection Act. This Act mandated the Federal inspection of every poultry carcass that crossed State lines.

In 1962, motivated by a desire to lower costs, the House Appropriations Committee required the Secretary of Agriculture to survey all State inspection programs. It was thought that USDA could simply certify State inspection programs and thereby save Federal inspection dollars. At that time, however, only 26 States required inspection at the slaughterhouse (U.S. Congress, 1967). A patchwork of inconsistent and conflicting State standards and inspection practices, highlighted by the USDA survey, led Congress to mandate that State efforts be upgraded to match or equal Federal inspection efforts. Federal funding was made available to pay for half of the State inspection costs. States were also given the option of transferring their entire meat and poultry inspection programs over to the Federal Government. This resulted in a budget saving to the States, but greater Federal budget expenditures. The new regulations were enacted in two parts: the 1967 Wholesome Meat Act and the 1968 Wholesome Poultry Act.

The Acts required that all carcasses and all meat products be inspected. The 1906 Act, for example, provided for mandatory inspection of carcasses after slaughter to ensure that they were "sound, healthful, wholesome, and fit for human food." Inspection of meat products was to assure that they were "sound, healthful and wholesome, and contain no dyes, chemicals, preservatives, or ingredients which render such meat or food products unsound, unhealthful, unwholesome, or unfit for human use." Rules, as reflected in the procedures, emphasized inspection at slaughterhouses. By the mid-1990's, USDA's Food Safety and Inspection Service (FSIS) had more than 7,400 inspectors in 6,200 slaughter and processing plants (USDA/FSIS, 1996). FSIS conducted a labor-intensive examination of each carcass and its internal organs, paying particular attention to the condition of the lymph nodes -- important indicators that an infectious disease might be present. If the lymph nodes were normal and there were no other visual evidence of disease, the animal was considered suitable for human consumption. FSIS also inspected processing plants. However, unlike slaughter inspection, not all processed products were inspected; rather, the emphasis was on monitoring inspection in the plant. For smaller plants, an inspector was assigned to a circuit of several plants. Larger plants might have had one or more full-time inspectors.

In addition to checking the quality of the meat, inspectors would check the operation of equipment (such as verifying refrigeration and cooking temperatures), and they would oversee plant sanitation during processing and cleanup. Additional duties involved checking the use of labels, product net weight, and the ingredients actually used in making processed meat and poultry products.

Although this inspection system removed diseased animals from the food supply and enforced sanitary standards in meat slaughter and processing, a serious gap remained. The inspection system relied largely on organoleptic (sensory) methods -- sight, smell, and sense of touch -- to identify unsafe products. It did not adequately target and reduce microbial pathogens on raw meat and poultry. Since bacteria such as *E. coli* O157:H7 or *Salmonella* could not be detected by organoleptic inspection, they remained present in meat and poultry products delivered to distributors and consumers.

To close this gap, the FSIS began efforts to strengthen the meat and poultry inspection process in the early 1990's. On February 3, 1995, the FSIS published a proposal to mandate that all federally inspected meat and poultry plants:

- Adopt Hazard Analysis and Critical Control Points (HACCP) procedures,
- Set targets for microbial pathogen reduction, and
- Require microbial testing to determine compliance with the targets.

The FSIS also established initiatives to set standard operating procedures (SOP's) for sanitation, antimicrobial treatments, and carcass-cooling standards. The proposals included near- and long-term initiatives. The near-term initiatives required each plant to: (1) develop and maintain sanitation standard operating procedures; (2) maintain carcasses and raw-meat products at specified temperatures during handling, holding, and shipment; (3) apply antimicrobial treatments to carcasses prior to treatment; and (4) perform microbiological testing (for *Salmonella*) on each slaughter class and/or species of ground meat processed each day. The long-term initiatives added the development and maintenance of a HACCP plan for each process of each animal species. Each of these initiatives, except the application of antimicrobial treatments, requires a plan, employee training, and recordkeeping and review.

After public review of its testing plan, FSIS (May 17, 1996) published a revised version of its pathogen-reduction rules. This revision retained sanitation SOP's, modified HACCP plan and microbiological testing requirements, and dropped mandatory time and temperature requirements. FSIS also made substantial changes to the microbiological testing component of the pathogen reduction rule. Those changes included: (1) microbial testing for generic *E. coli* rather than for *Salmonella* on a production rather than daily basis, and (2) agency rather than plant *Salmonella* sampling to verify production process compliance with regulatory pathogen performance standards. If meat or poultry production processes are not in compliance with performance standards, then the plant must modify its production processes to obtain performance compliance. The next section discusses the HACCP system in more detail.

The Hazard Analysis and Critical Control Points Regulatory System

The new rules represent a comprehensive strategy on the part of FSIS to modernize the 90-year-old inspection program. There are four essential elements of this new food-safety system:

- All State and federally inspected meat and poultry slaughter and processing plants must have a Hazard Analysis and Critical Control Points (HACCP) plan.

- Federally inspected meat and poultry plants must develop written sanitation SOP's to show how they will meet daily sanitation requirements.

- FSIS will test for *Salmonella* on raw meat and poultry products to verify that pathogen-reduction standards for *Salmonella* are being met.

- Slaughter plants will test for generic *E. coli* (all types of *E. coli*) on carcasses to verify the process is under control with respect to preventing and removing fecal contamination.

HACCP Plans

USDA now requires that all meat and poultry plants develop HACCP plans to monitor and control production operations. These plants must first identify food-safety hazards and critical control points in their particular production, processing, and marketing activities. In addition to biological hazards such as pathogens, food-safety hazards include chemical and physical hazards such as chemical residues and metal fragments that may cause a food to be unsafe for human consumption. A critical control point is a point, step, or procedure where controls can be used to prevent, reduce to an acceptable level, or eliminate food-safety hazards.

As part of the HACCP plan, these plants must then establish critical limits, or maximum or minimum levels, of a hazard for each critical control point. For example, water or steam used for cleaning carcasses must be maintained at a minimum temperature of 180°F or higher. Monitoring activities are necessary to ensure that the critical limits are met. In the HACCP plan, each plant is required to list the monitoring procedures and frequencies. HACCP also includes steps for recordkeeping and verification, including some microbial testing of product to ensure that the HACCP system is meeting the target level of safety. Plants and FSIS share responsibility for verifying the effectiveness of the HACCP system.

HACCP will be implemented first in plants with more than 500 employees. Seventy-five percent of meat slaughtered occurs in large plants. The effective date is January 26, 1998, 18 months after the July 1996 rule was published. In plants with 10-500 employees, the effective date will be January 25, 1999. In very small establishments, those having fewer than 10 employees or annual sales of less than $2.5 million, the effective date will be January 25, 2000.

Sanitation Standard Operating Procedures

The Pathogen Reduction/HACCP final rule requires that all federally inspected meat and poultry plants must develop written SOP's by January 26, 1998, to show how they will meet daily sanitation requirements. This element is important in reducing pathogens on meat and poultry because unsanitary practices increase the likelihood of product contamination. Plants must document and maintain daily records of completed sanitation SOP's, and any corrective and preventive actions taken. Plant managers must make these records available for USDA inspectors to review and verify.

Testing for Salmonella

FSIS testing for *Salmonella* on raw meat and poultry products will be used to verify that plants are controlling pathogen levels. All plants that slaughter and grind meat and poultry must achieve at least the current baseline level of *Salmonella* control for the product classes produced. *Salmonella* was selected for testing because it is the most well-known cause of U.S. foodborne illnesses associated with meat and poultry. Plants must meet the *Salmonella* standard on the same timetables as they meet the HACCP requirement.

Testing for E. coli

Slaughter plants will be required to test for generic *E. coli* on carcasses to verify that they are preventing and removing fecal contamination. Generic *E. coli* was selected because of the scientific consensus that it is an excellent indicator of fecal contamination, because the analysis is relatively easy and inexpensive to perform, and because levels of *E. coli* contamination can be quantified. *E. coli* contamination is not directly correlated with *Salmonella* contamination, which is affected by other factors as well, including the health and condition of incoming animals. Therefore, the pathogen reduction standards for *Salmonella* and the *E. coli* testing complement one another.

Microbiological performance criteria will be used to help plants verify that their process controls are effectively preventing fecal contamination. These performance criteria are based on FSIS survey data on the prevalence of *Salmonella* and *E. coli* in raw products. Inspectors will also use these criteria to help assess the effectiveness of the plant's controls. These criteria are not enforceable regulatory standards, but they are intended to provide an objective point of reference that will help slaughter plants and FSIS ensure that plants are preventing and reducing fecal contamination of meat and poultry products. Plants were required to begin *E. coli* testing on January 27, 1997, regardless of plant size. Plants will be given an additional 6 months to gain experience in conducting these tests before FSIS personnel begin reviewing the test results as part of their inspection routine.

Enforcement Strategies

Implementation of the four essential elements of FSIS's new food-safety system follows a schedule. In general, larger establishments are expected to comply sooner than smaller establishments. If FSIS inspectors find violations of these new requirements, enforcement action will vary, depending on the seriousness of the problem.

USDA's first concern will continue to be preventing potentially unsafe or adulterated product from reaching consumers, which could mean detaining product at the plant or requesting that the company recall the product. Minor violations of an establishment's HACCP and SOP's will be noted by inspection personnel. A pattern of minor violations may result in intensified inspection to ensure that there is no systematic problem of noncompliance or underlying food-safety concern. For more serious violations involving adulterated or contaminated products, inspectors can stop production lines until failures in HACCP and sanitation SOP's are corrected. Inspectors can also identify specific equipment, production lines, or facilities that are causing the violations and remove them from use until sanitation or other problems are corrected.

Repeated or flagrant violations will result in other administrative, civil, or criminal penalties, after due process. For example, improper maintenance or falsification of records would have potentially serious implications because accurate recordkeeping is essential to the functioning of sanitation and HACCP systems and to the production of foods safe for human consumption. USDA will continually monitor and adjust its enforcement approach during this program transition to ensure that enforcement activities are effective, fair, and consistent.

An Economic Assessment of HACCP Regulations

Most government regulations will have some sort of economic effect on producers and consumers. Regulations governing how meat and poultry products are produced can raise costs of production. Regulations require resource commitments, which, in turn, may raise costs and product prices. On the other hand, the regulations, which improve the safety of the food supply, will generate benefits for consumers by reducing the number and severity of foodborne illnesses. Economic analysis can play an important role in the public decisionmaking process by identifying the benefits and costs of food-safety policies. Currently, all regulations that have a significant impact on society (*i.e.*, over $100 million) are required by Executive Order 12286 to be supported by a cost-benefit analysis. In this section, we assess both the benefits and the costs of HACCP.[1]

Benefits of the HACCP Rule

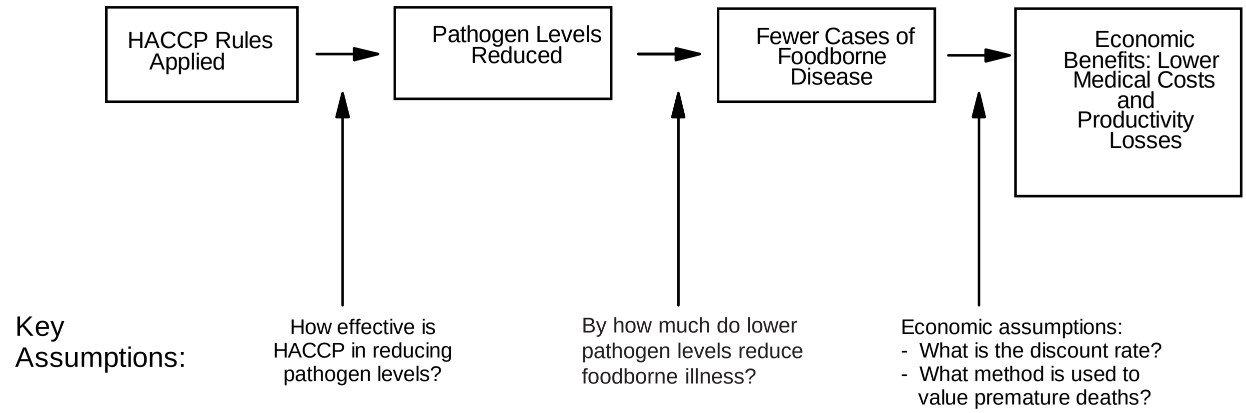
In order to evaluate the economic benefits of HACCP, we need to estimate how implementing the new inspection system will affect the level of foodborne illness. In addition, we must choose a methodology for expressing the value of improved food safety in economic terms. Figure 2 summarizes the analytic process.

Four key assumptions, which affect our analysis of the benefits of HACCP, flow from the following questions.

- How effective will HACCP be in reducing microbial pathogens in meat and poultry?
- What is the relationship between pathogen reduction and the level of foodborne illness associated with meat and poultry?
- Since HACCP will be implemented over time, what is the appropriate discount rate to use in expressing long-term benefits in present-value terms? When do benefits begin to accrue?
- What is the methodology used to quantify the benefits of reductions in foodborne illnesses; particularly regarding those who die prematurely or are never able to return to work because of a foodborne illness?

[1]Here, we use the term "HACCP" or "HACCP rule" to refer to the entire suite of rules enacted in 1996, which include not only requirements for implementing HACCP plans, but also requirements for standard operating procedures for meat and poultry plants and testing for *E. coli* and *Salmonella*.

Fig. 2--Evaluation of HACCP benefits



Source: Economic Research Service

Effectiveness of HACCP Rule in Reducing Pathogens

In its initial assessment of HACCP, the FSIS made the assumption that, when fully in place, the new meat and poultry inspection system would reduce microbial pathogens 90 percent across the board (Federal Register, Feb. 3, 1995). In comments on the proposed rule, some asserted that this assumption about HACCP effectiveness was not scientifically justified. In the final rule, the FSIS concluded "... there is insufficient knowledge to predict with certainty the effectiveness of the rule, where effectiveness refers to the percentage of pathogens eliminated at the manufacturing stage" (FSIS, 1995, pg. 297). For the final rule, the FSIS projected a range of effectiveness estimates, from 10- to 100-percent reduction in pathogen levels.

The Relationship Between Pathogen Reduction and the Level of Foodborne Illness

The relationship between human exposure to microbial pathogens and any resultant illness is very complex. A number of factors influence whether a person, once exposed, becomes ill, and the severity of the illness. Factors include the level of pathogens in the food, the way the consumer handles the product before cooking, the final cooking temperature, and the susceptibility of the individual to infection. In addition, the relationship between pathogen levels and disease varies across pathogens. Some, such as *E. coli* O157:H7, are infective at very low doses, while others require ingestion of higher doses to cause illness.

Conducting a comprehensive risk assessment to establish the relationships between pathogen levels, illnesses, and deaths is beyond the scope of this report. Therefore, we make the assumption that HACCP will reduce illnesses and deaths in proportion to the reduction in pathogen levels. In other words, a 50-percent effectiveness rate would result in a 50-percent reduction in foodborne illness, across all pathogens. This enables us to apply effectiveness rates to the reported incidence of foodborne illness reported in table 1 to estimate the reduction in foodborne illness associated with HACCP.

The Discount Rate Used to Estimate the Present Value of Benefits and the Timing of Benefits

In our analysis, we follow the FSIS assumption that the pathogen reductions associated with HACCP will begin to accrue starting in year 5 of the program. We also follow their analysis by estimating the benefits over a 20-year time horizon; that is, benefits begin in year 5 and extend over the next 20 years.

The initial benefits estimates (in 1993 dollars) published in 1995 were calculated using a 7-percent discount rate, as recommended by the Office of Management and Budget. However, others (*e.g.* Lind, 1990) have argued that a lower discount rate should be used. An alternative assumption would be to use a 3-percent discount rate to calculate the present value of HACCP benefits over time. Haddix et al. (1996) recommend the 3-percent rate, combined with sensitivity analyses of 0-, 5-, and 7-percent rates.

Methodology Used to Measure Benefits of Reduced Foodborne Illness

Previous ERS studies have used the cost-of-illness (COI) method to estimate the annual resource expenditures for foodborne illnesses targeted by the HACCP proposals (Buzby et al., 1996).[2] This methodology considers two components of the costs of foodborne illness: lifetime medical costs and lost productivity (e.g., forgone earnings). This estimate is a partial measure of society's opportunity cost; if foodborne illnesses were reduced, these resources could be reallocated for other uses.

Medical costs were estimated for physician and hospital services, supplies, medications, and special procedures unique to treating each foodborne illness. Medical costs reflect the number of days/treatments of a medical service, the average cost per service, and the number of patients receiving such service.

Productivity losses occur when there is a reduction or cessation of work due to premature mortality and morbidity. Although most people with foodborne illnesses miss only a day or so of work, some die or contract such physical complications that they never return to work or regain only a portion of their pre-illness productivity. ERS used the Bureau of Labor Statistics' (BLS) usual weekly earnings for full-time and part-time wage and salary earners to calculate the lost productivity for those who missed some work because of foodborne illness.

Estimating productivity losses for illness-related death and permanent disability required selecting an appropriate proxy. We used estimates of the value of a statistical life (VOSL) from the literature that encompass more than just forgone earnings. Because there is no universally accepted method to estimate the VOSL (Cropper and Oates, 1992; Hayes et al., 1995; Randall, 1993; Smith, 1992; Viscusi, 1992),[3] COI analysis frequently relies on VOSL estimates from other studies, which may use a willingness-to-pay (WTP) approach, a human-capital approach, or a hybrid of these two approaches.

Our COI analysis incorporated conservative VOSL estimates developed using Landefeld and Seskin's (LS) (1982) human capital/WTP hybrid approach. The LS approach generates the present value of expected-lifetime after-tax income and housekeeping services at a 3-percent real rate of return, adjusted for an annual 1-percent increase in labor productivity and a risk-aversion factor of 1.6.[4] The LS value of a statistical life lost is:

$$VOSL = \left[\sum_{t=0}^{T} \frac{Y_t}{(1 - r)^t} \right] \alpha$$

where T = remaining lifetime, t = a particular year, Y_t = after-tax income including labor and nonlabor income, r = household's opportunity cost of investing in risk-reducing activities, and α = risk-aversion factor. LS VOSL estimates were averaged across gender, interpolated between LS's 4-year age groups, and updated to 1995 dollars ($15,000-$1,979,000, depending on age).

The LS VOSL estimates are low compared with VOSL estimates based on the risk premium in labor markets, a willingness-to-accept measure, which theory tells us mirrors WTP.[5] Viscusi (1993) summarized the results of 24 principal wage-risk studies and suggested that most of the implied VOSL estimates ranged between $3 and $7 million in 1990 dollars ($3.6-$8.4 million in 1995 dollars).[6] Other regulatory agencies use Viscusi's VOSL estimates. The Consumer Product Safety Commission uses Viscusi's range and/or a $5-million VOSL in its analysis (Dworkin, personal communication); the Environmental Protection Agency (EPA) uses Viscusi's range in estimating the benefits of the Clean Air Act; and FDA used $5 million in its evaluation of seafood HACCP.

Baseline: Costs of Foodborne Illnesses

The benefits of pathogen reduction are the changes in foodborne illness costs. Therefore, we need a baseline of total foodborne illness costs in order to measure benefits. Total costs of foodborne illness have been estimated by Buzby and Roberts (1996) in 1995 dollars[7] for six major bacteria (*Campylobacter jejuni* or *coli, Clostridium perfringens*, *E. coli* O157:H7, *Listeria monocytogenes*, *Salmonella*, and *Staphylococcus aureus)*, and one parasite (*Toxoplasma gondii)*[8]. These estimates are based on the estimated numbers of illnesses and deaths reported in table 1. For each of these pathogens, the estimated medical costs and productivity losses have been calculated for all foodborne sources. These estimates are presented as a range, reflecting the fact that there are low and high estimates

[2] Desirable features of the COI method include its use of existing and relevant data and its flexibility to perform sensitivity analysis on estimated total cost to changes in cost subcomponents and disease severity categories of affected individuals.

[3] Four dimensions in valuing life are the duration of life, future versus present life, life in terms of social or economic productivity, and the relation of efficiency (cost-effectiveness) to equity.

[4] The LS method extends previous work by Rice (1966) by defining income more broadly and including the risk-aversion factor, based on the ratio of life-insurance premium payments to life insurance-loss payments.

[5] In essence, these values represent what employed people would pay to reduce the risks generating each additional death.

[6] One weakness is that these studies have much better data, and more usable estimates, for mortality risks than they do for morbidity risks (i.e., risk of temporary or long-term illness).

[7] Note that the COI estimates for the bacteria in the HACCP final rule (Federal Register, July 25, 1996) were in 1993 dollars, and were documented in Buzby et al. (1996).

[8] Estimates of illness cases and deaths related to *Toxoplasma gondii* are not included in our analysis of the HACCP proposal. *Toxoplasma* is a parasite found within the muscle tissue of animals, and is not subject to control through HACCP plans as are bacteria.

Table 3--Medical costs and productivity losses from foodborne and meat/poultry diseases, 1995

	All food sources		Meat/poultry[1]		Meat/poultry alone	
	Low	High	Low	High	Low	High
	Billion dollars		*Percent*		*Billion dollars*	
Landefeld & Seskin						
Salmonella	0.9	3.5	50	75	0.5	2.6
Campylobacter jejuni/coli	0.7	4.3	75	75	0.5	3.2
E. coli O157:H7	0.3	0.7	75	75	0.2	0.5
Listeria monocytogenes	0.1	0.3	50	50	0.1	0.2
Staphylococcus aureus	1.2	1.2	50	50	0.6	0.6
Clostridium perfringens	0.1	0.1	50	50	0.1	0.1
Total	3.3	10.1	n/a	n/a	2.0	7.2
VOSL = 5 million						
Salmonella	4.8	12.2	50	75	2.4	9.2
Campylobacter jejuni/coli	1.2	6.6	75	75	0.9	5.0
E. coli O157:H7	0.9	2.2	75	75	0.7	1.7
Listeria monocytogenes	1.3	2.4	50	50	0.7	1.2
Staphylococcus aureus	3.3	3.3	50	50	1.7	1.7
Clostridium perfringens	0.5	0.5	50	50	0.3	0.3
Total	12.0	27.2	n/a	n/a	6.7	19.1

[1]Data for these two columns were supplied by FSIS.
n/a = Not applicable

Source: Buzby and Roberts, 1996

for the numbers of diseases and deaths in some cases. Table 3 reports the COI estimates based on two calculations: one using the Landefeld and Seskin approach to valuing lost productivity due to premature death or permanent disability, the other using the value of $5 million per statistical life. Finally, table 3 reports the percentage shares of annual medical costs and productivity losses attributable to meat and poultry sources alone (which are, of course, the target of HACCP regulations).[9]

Benefit Estimation

Obviously, there is no single correct estimate of the benefits of HACCP; the benefits estimates depend on assumptions made (as outlined above). In our analysis, we chose several different combinations of assumptions about effectiveness, discount rates, and valuation methodology. We started with the original FSIS assumptions of 90 percent effectiveness, a 7-percent discount rate, and Landefeld and Seskin VOSL methodology in the cost-of-illness calculations. Next, we considered several alternative scenarios: one yielding a smaller set of benefits estimates, several mid-range estimates, and a final set of assumptions that yielded the greatest estimate of the benefits of pathogen reduction associated with HACCP (tables 4 and 5).

[9]Microbial pathogens can be present in foods other than meat and poultry; the 1996 outbreak of *E. coli* O157:H7 from bottled apple juice is one example.

As expected, the benefits estimates varied widely, from $1.9 billion to $171.8 billion. No matter what the assumptions, though, reducing pathogens through implementing HACCP (even at low effectiveness rates) can be expected to generate considerable social savings in terms of lower human illness costs associated with foodborne pathogens. However, a complete economic assessment requires a consideration of the costs of HACCP, and how they compare with the expected benefits.

Costs of HACCP Rule

Table 5 identifies the FSIS-estimated costs of the preliminary and revised FSIS pathogen reduction rules. It also indicates the costs of a similar HACCP plan estimated by the Institute for Food Science and Engineering at Texas A&M University (IFSE). FSIS labor estimates (for recordkeeping, record review, plan development, etc.) are based on agency experience. Wage rates are based on existing wage rates. Labor wage and time estimates yield a labor cost. Material, equipment, and testing costs are based on current market prices and pathogen-reduction performance standards. IFSE gives

Table 4--Scenarios used to evaluate HACCP rule and benefits estimates

Scenario/description	Effectiveness: pathogen reduction	Discount rate	Valuation method for premature death/disability	Annualized net benefits[1] Low	High
	------*Percent*------			-------- *$ billion (1995)* -----	
Preliminary FSIS 1995 proposal	90	7	Landefeld & Seskin[2]	8.4	42.1
Low-range benefits estimates	20	7	Landefeld & Seskin	1.9	9.3
Mid-range benefits estimates I	50	7	Landefeld & Seskin	4.7	23.4
Mid-range benefits estimates II	50	3	VOSL[3]= 5 million	26.2	95.4
High-range benefits estimates	90	3	VOSL = 5 million	47.2	171.8

[1]Benefits begin to accrue five years after the HACCP rule is enacted, and extend over 20 years.
[2]Landefeld and Seskin VOSL estimates after averaging across gender and updating to 1995 dollars using BLS usual weekly earnings.
[3]VOSL = Value of a statistical life

Source: Economic Research Service

Table 5--Comparison of HACCP rule costs

Intervention	FSIS preliminary cost Initial	FSIS preliminary cost Yearly	FSIS revised cost Initial	FSIS revised cost Yearly	IFSE cost Initial	IFSE cost Yearly
			Million Dollars			
Sanitation SOP[1]	3.0	16.7	3.0	16.7	-	-
HACCP planning and training[2]	61.0	-	95.0	4.0	136.4	142.8
HACCP recording[3]	-	54.1	-	54.1	-	260.3
Temp. control[4]	15.9	16.7	-	-	-	-
Antimicrobial treatments[5]	-	19.8	-	-	-	-
Testing[6]	24.0	68.0	3.0	16.9	-	550.0
Modify process[7]	-	-	-	5.5-20.0	-	-

[1]**FSIS Preliminary and Revised**: identical. The initial cost includes plan development and training. The annual cost includes recording, recording review, and record storage.
[2]**Preliminary**: one plan for each process of each animal species; same training as revised. **Revised**: one comprehensive plan; 3-day training course for each employee, additional updates. **IFSE:** no guidance on plant; $10,000-per-plant training cost.
[3]**Preliminary and Revised:** based on time and the number of critical control points, shifts, and production lines. **IFSE:** no guidance.
[4]**Preliminary:** cold storage capacity to hold newly chilled meats; planning, recording, reviewing, and training costs for operation.
[5]**Preliminary:** assumes industry will use hot water with no cabinet system in meat plants and a chlorinated water system in poultry plants to treat carcasses.
[6]**Preliminary:** requires each plant to test each slaughter species and ground meat product each day for *Salmonella*. Costs include sampling, training, and sampling plan development costs. **Revised**: requires the use of *E. coli* testing for slaughter plants on a production basis. FSIS does *Salmonella* testing. **IFSE**: assumes daily composite samples of ground products, weekly composite samples of subprimals, and at least nine other samples of either carcasses or production areas weekly.
[7]**Revised**: meat slaughter plants use steam vacuum system and poultry producers a TSP rinse to reduce pathogens.

Source: Economic Research Service, based on data from: USDA, FSIS; Institute for Food Science and Engineering, Texas A&M University

no rationale for HACCP plan costs and assumes a far greater number of microbial test samples would be required to assess process control of the plant production process.

Table 5 indicates far higher cost estimates from IFSE than from FSIS. The FSIS estimates for sanitation SOP's and HACCP plan development appear to be more reasonable than the IFSE estimates because: (1) FSIS is providing considerable plan development and implementation support; (2) plants currently maintain production records, and can easily add additional records; and (3) few differences exist between the preliminary and revised FSIS estimates, suggesting that FSIS, industry, and outside experts agree on the costs.

Some uncertainty exists about the effectiveness of microbiological testing. A review by USDA's Office of Risk Assessment and Cost Benefit Analysis (ORACBA) suggests that the *E. coli* and *Salmonella* sampling tests have a low probability of detecting whether *E. coli* or *Salmonella* are present on the carcass. Additionally, ORACBA suggests that sampling should be based on the incidence of *Salmonella* within species and species class; is skeptical that *E. coli* testing can verify a *Salmonella* reduction; and believes that not enough information is available to assess process modification costs (USDA/ORACBA, 1996).

There are also questions about the cost estimates of process modifications. FSIS claims that, since many low-volume producers use bed-kill slaughtering processes, better training and closer monitoring alone can be used to meet pathogen reduction goals.[10] However, Dr. David Swerdlow of the CDC indicates that meat from bed-kill operations tends to have higher pathogen levels than meat from online processing facilities, suggesting that plants with bed-kill operations may require more, not fewer, process modifications than online plants. Moreover, the costs of one type of modification, antimicrobial treatments, may be higher for the bed-kill operations than for the larger online plants because the treatment must be applied in a batch rather than in an inline automated system (Swerdlow, personal communication).

To make a meaningful comparison of benefits and costs, we also need to estimate the annualized costs of the FSIS pathogen reduction rule over time (that is, the present value of costs discounted over 20 years). Table 6 compares the costs of the initial proposal and the final rules, annualized over a 20-year period, starting in 2000 (when all provisions of the final HACCP rule become fully effective).

The changes made to the preliminary pathogen reduction rule appear to have come mainly from concern about the costs imposed on small plants. ERS estimated that small plants would have borne about 45 percent of new regulatory costs, while producing only about 1 percent of annual slaughter and processed meat and poultry output under the preliminary HACCP plan.

The cost disadvantage of small plants in the preliminary pathogen reduction rule stems from the requirements for one HACCP plan and microbial test for each process of each animal species. Small plants tend to slaughter more animal species than large plants and have a similar number of processes per species as large ones (Ollinger et al., 1996). Consequently, the preliminary FSIS pathogen reduction plan required a far greater number of microbial tests and imposed higher HACCP recordkeeping costs per pound of output for small plants relative to large plants. By requiring only one HACCP plan per plant and placing microbial testing on production rather than on the daily schedule, the revised pathogen reduction rule greatly lowered the cost disadvantage of small plants relative to large plants.

The ability of a plant to remain profitable depends on its cost disadvantage relative to competitors and the product market in which its sells its products. Using Longitudinal Research Database (LRD) data at the U.S. Bureau of the Census, we provide estimates of plant regulatory costs per pound of output by industry for very small, small, and large plants in table 7. Beef slaughter plants are those plants producing carcasses, boxed beef, boneless beef (including hamburger), and edible organs (SIC 20111). Pork, chicken, and turkey slaughter plants have products identified in SIC 20114, 20151, and 20153.

Table 7 contains cost estimates of both the preliminary and revised FSIS pathogen reduction rule for plants in seven slaughter and processing industries and the three plant size categories identified by FSIS. The pathogen reduction rule is more costly for small plants than for large ones. However, the revised plan greatly reduced costs in general and the cost disadvantage of small plants in particular. For example, pathogen reduction costs for very small beef plants dropped about 66 percent, while pathogen reduction rule costs for very small pork processing and sausage plants dropped about 99 percent.

Although industry classifications in table 7 are based on particular product lines, they do not show geographic or service considerations that may confer market advantages on small plants relative to a large one. Additionally, Ollinger et al. (1996) found that from 60 to 90 percent of small (less than 25 employees) beef/pork slaughter and pork processing and sausage plants failed to survive to the next census year (5 years) after entry. Given the modest differ-

[10]Bed-kill processing is where small numbers of animals are slaughtered one at a time in one location, as opposed to assembly-line slaughter processes.

Table 6--Estimated 20-year annualized costs of HACCP rule

Regulatory component	Proposal	Final rule
	--------*Millions of dollars (1995)*--------	
Sanitation SOP's	175.9[1]	171.9
Time/temperature requirements	45.5	0.0
Antimicrobial treatments	51.7	0.0
Microbial testing	1,396.3[2]	171.4
Compliance with *Salmonella* standards	NSE	55.5 - 245.3[3]
Compliance with generic *E. coli* standard	n/a	NSE
HACCP		
Plan development	35.7	54.8
Annual plan reassessment	0.0	8.9
Recordkeeping (recording reviewing, and storing data)	456.5	440.5[4]
Initial training	24.2	22.7[4]
Recurring training	0.0	22.1[4]
Additional overtime	20.9	17.5[5]
Subtotal - industry costs	2,206.6	968 - 1,156.0
FSIS costs	28.6[6]	56.5
Total	2,235.2	1,024.5 - 1,212.5

[1]The preliminary analysis included a higher cost estimate for sanitation SOP's ($267.8 million) that resulted from a programming error. The cost estimate of $175.9 million is based on an effective date of 90 days after publication.
[2]The preliminary analysis was based on the premise that microbial testing would be expanded to cover all meat and poultry processing after HACCP implementation. The proposed rule only required sampling for carcasses and raw ground product. Thus, the cost estimate of $1,396.3 million was higher than the actual cost of the proposed sampling requirement.
[3]The preliminary analysis accounted for some of the cost of complying with the new standards under the regulatory components of microtesting, antimicrobial treatments, and time and temperature requirements.
[4]These costs are slightly different from the proposal because of changes in the implementation schedule.
[5]FSIS added costs for recurring training based on review of public comments.
[6]Based on the current estimates for the cost of training, inspector upgrades, and $0.5 million for annual HACCP verification testing.
NSE - Not separately estimated
n/a - Not applicable

Source: Economic Research Service, using data from USDA, FSIS (1996)

Table 7--Comparison of HACCP rule costs for different size slaughter plants

	Preliminary[1]			Revised[2]		
Meat	Small plant	Medium plant	Large plant	Very small plant	Small plant	Large plant
			Dollars per pound			
Beef	0.0189	0.0012	0.0001	0.0062	0.0002	0.00006
Pork	d	0.0027	0.0004	d	0.0003	0.00003
Chicken	d	0.0044	0.0036	d	0.0008	0.00090
Turkey	d	0.0021	0.0011	d	0.0012	0.00120

The slaughter classes refer to five digit SIC codes 20111 (beef), 20114 (pork), 20151 (chicken), and 20153 (turkeys).
d=Shares that could not be disclosed due to confidentiality restrictions.
[1]**Preliminary estimate:** small plants have sales of less than 2.5 million; medium plants have 2.5-50 million in sales; large plants have over 50 million in sales.
[2]**Revised estimate:** very small plants have sales of less than 2.5 million or less than 10 employees; small plants have 10-500 employees; and large plants have more than 500 employees.

Source: Economic Research Service, using the Longitudinal Research Database (LRD) at the Center for Economic Studies, U.S. Bureau of the Census

Table 8--Estimated benefits and costs of HACCP rule over 25 years[1]

Benefit Scenario	Benefits Low	Benefits High	Costs Low	Costs High
	Billion dollars (1995)			
Preliminary FSIS 1995 proposal	8.4	42.1	2.3[2]	2.3[2]
Low-range benefits estimates	1.9	9.3	1.1[3]	1.3[3]
Mid-range benefits estimates I	4.7	23.4	1.1[3]	1.3[3]
Mid-range benefits estimates II	26.2	95.4	1.1[3]	1.3[3]
High-range benefits estimates	47.2	171.8	1.1[3]	1.3[3]

[1]Benefits begin to accrue in 2000 and extend for twenty years
[2]Initial cost estimates from table 6, updated to 1995 dollars using the CPI.
[3]Final cost estimates from table 6, updated to 1995 dollars using the CPI.

Source: Economic Research Service

ences in regulatory costs across plants as shown in table 7, possible geographic and service marketing advantages of small plants and the low survival rates of small plants, it would be difficult to distinguish the impact of pathogen reduction rule costs from the natural economic forces affecting plant survival.

Comparison of Benefits and Costs

Having estimated both the benefits and costs of HACCP, we can now assess the economic consequences of reforming the meat and poultry inspection system. Table 8 summarizes the 20-year annualized benefits and costs of HACCP, based on the scenarios outlined above.

Clearly, the benefits of the HACCP rule are greater than the costs for all scenarios considered.[11] Even at relatively low effectiveness (20 percent pathogen reduction assumed for the low-range scenario), the savings in medical costs and productivity losses of at least $1.9 billion are greater than the $1.3 billion in estimated costs, with the new rules. As we changed our assumptions to reflect higher pathogen reductions and increased the costs of premature death and disability, the margin between costs and benefits becomes even more pronounced.

The results of this analysis indicate that implementation of HACCP will contribute to U.S. economic and social welfare by reducing foodborne illness, medical costs, and productivity losses in excess of the costs. Our benefits estimates (especially the low values) are conservative. They encompass foodborne diseases from only six pathogens for which we have epidemiologic and cost-of-illness data; implementation of the HACCP rule could likely produce additional benefits by controlling other microbial pathogens not included in this analysis.

Even though application of the HACCP rule appears to be economically justified, there are other approaches to improving meat and poultry safety. Although a complete assessment of the costs and benefits of all food safety policies is beyond the scope of this report, we briefly outline some of these approaches.

Alternatives to Regulation

As discussed earlier, there are many places along the path from farm to table where pathogen reduction is possible. Consumers, retailers, and foodservice workers can take actions to reduce the likelihood of food contamination or illness from microbial pathogens in meat and poultry. These actions fall into three broad categories: time and temperature control, proper cooking, and proper handling.

Education About and Promotion of Safe Food Handling by Consumers, Retailers, and Foodservice Workers

Storing uncooked meat and poultry products at room temperature allows bacterial pathogens that may be in the products to grow and multiply, thereby increasing the risk of illness when the products are consumed. It is essential, then, that foods be properly chilled and kept

[11]We treat costs as point estimates and benefits as a range. It is likely that the HACCP rule may impose additional costs on firms that are not included in the FSIS cost estimates, or that some firms are already applying HACCP procedures, in advance of the new rules, in which case costs could be lower.

cold during processing, distribution, sale, and storage. Meat and poultry products should be kept refrigerated until just prior to cooking. In addition, USDA recommends that frozen products be defrosted in the refrigerator, rather than at room temperature.

Microbial pathogens can be destroyed by cooking foods to a proper temperature. For example, *E. coli* O157:H7 is killed when foods are cooked to 160^{o}F. Pathogens present on the surface of meat or poultry products are killed by broiling or baking. Ground food such as hamburger and sausage, however, may contain pathogens throughout the product; failure to thoroughly cook hamburger patties and other ground meats increases the probability that pathogens will pose a health risk when the food is eaten. Insufficiently cooked hamburgers served at a fast-food restaurant were the cause of a widely publicized outbreak of *E. coli* O157:H7 illnesses in four Western States in 1993. Experts recommend that hamburgers be cooked until the juices run clear, no evidence of pinkness remains, and the patty is firm when poked.

Finally, proper handling of uncooked meat and poultry products can reduce the possibility of contamination by microbial pathogens. Bacteria present on the surface or in the juices of raw products can be spread through contact with other foods or contact with utensils or preparation surfaces. For example, if hamburger patties are prepared on a cutting board, which is then used to chop vegetables for a salad, pathogens may be spread to the salad. If utensils and preparation surfaces are not kept clean between uses, this cross-contamination may lead to potentially dangerous exposure to microbial pathogens.

Consumers can take action to prevent foodborne illnesses by following recommended practices for safe food handling and preparation. Since 1993, the USDA has required that all packaged meat and poultry products include a label providing information on safe handling and preparation. In addition, USDA tries to educate the public on the importance of safe food handling and how consumers can protect themselves from the risks of foodborne illness (call 1-800-535-4555 for the hotline).

There is some evidence that recent efforts in this area have had some effect. A study by Neis and van Laanen (1995) showed that when consumers were educated about food safety principles, the number of people consuming rare or pink hamburgers fell by 73 percent and other unsafe behaviors decreased. A study by Tamplin et al. (1995) of 33 cancer patients before and after a food-safety education program showed that after patients were exposed to food-safety information, the prevalence of unsafe practices decreased as well. The public probably also responds to news stories highlighting food-safety outbreaks. ERS research has found that the percentage of people who cook hamburgers rare or medium fell from 23 percent in 1993 to 18 percent in 1996. This may be a response to publicity about the 1993 *E. coli* outbreak (Lin and Ralston, 1996).

New data from the Food Marketing Institute (FMI) present a mixed picture. In its most recent survey of consumer attitudes in the supermarket, FMI asked shoppers about the impact of safe-handling labels on safety awareness. Among those who were aware of safe-handling labels, 65 percent said the labels made them more aware of food safety issues, while 34 percent said their awareness of food safety had not changed. Forty-three percent of shoppers reported changing their behavior in response to the labels, while 57 percent did not. The most prevalent changes reported were washing/disinfecting counters, cooking areas, utensils, etc., after contact with meat (41 percent). Other changes included washing hands before or after handling meat or washing hands more frequently (19 percent), cooking properly or cooking to correct temperatures (19 percent), and not allowing meat to thaw on the counter (11 percent) (FMI, 1996).

Ideally, if everyone adopted safe food handling and preparation practices, the risk of foodborne illness would be substantially reduced. However, it is not certain that labeling, education, and provision of information can completely eliminate the health risks from microbial pathogens. To be effective, the labeling and education must change consumer behavior, and this change must be permanent if the health benefits are to persist.

Given exposure to risk information, the consumer must then pay attention to the information, understand its meaning and personal relevance, remember and retrieve it when needed, and act in accordance with the recommendation. If any one of these steps is not successfully completed, the information provided is not sufficient to change behavior.

Several factors could reduce consumer adoption of recommended food handling and consumption practices:

- Consumers may not view themselves as being at risk. Research by ERS shows that when respondents are asked “compared to other men/women who eat as many hamburgers as you do, what would be YOUR chances of getting sick, sometime in the next 12 months, from a hamburger patty because of the way it is cooked,” 52 percent of respondents chose “my chances are smaller than average,” while 8 percent chose “larger than average” (Lin and Ralston, 1996). This perception may be reinforced for consumers who have been consuming undercooked food or using unsafe preparation practices for years and have not become ill (or not realized that the food had made them ill).

- Consumers may view the probability of contamination as being small. If consumers do not believe they have ever become ill from food or feel they are not at risk, then they may be prone to believe that the risks are small.

- Consumers may inappropriately believe that, because meat and poultry are inspected by the USDA, the risks of foodborne disease are minimal. The public may believe that efforts to strengthen meat and poultry inspection have eliminated the risk of foodborne illness, and hence the need to practice safe food-handling procedures is no longer necessary.

- Consumers may feel that proper cooking of foods makes them less appealing. Some individuals may prefer the taste and texture of rare hamburgers, even if they realize that rare foods may pose a greater safety risk.

- Consumer habits are ingrained. Behavioral choices are strongly influenced by past behavior and experience. If consumers have eaten undercooked foods for years and have not become ill, they could be reluctant to make long-term changes in food preparation and consumption practices.

All of these factors suggest that consumer education on safe food handling and consumption could face a difficult challenge in changing behavior to reduce foodborne risk. Although necessary and useful, education and labeling alone may not prove an acceptable substitute for other efforts to reduce foodborne disease.

Irradiation of Meat and Poultry Products

Another option for controlling pathogens in meat and poultry is irradiation. Irradiation is a process that exposes products to ionizing radiation. The radiation harms or kills the cells of insects, molds, or microbial pathogens that could be present in the product. The radiation is measured in units called "kilograys" (kGy). Doses of 2.5 to 3.0 kGy are sufficient to kill many foodborne pathogens, such as *E. coli* O157:H7.

Irradiation offers advantages over other methods of treating foods for insects, molds, and microbial pathogens. Unlike chemical or heat treatments, which can leave residues or alter a food's texture, color, or flavor, irradiation achieves its effects without significantly raising the food's temperature, leaving the food closer to its unprocessed state. Some studies have found that irradiation at higher doses can create off-flavors, odors, and discoloration in beef and chicken, although other studies found no such effects. Irradiation dose, product temperature, and packaging used during irradiation can affect the results. (Morrison et al., forthcoming)

Irradiating foods requires FDA approval; in addition, FSIS approval is also required for red meat or poultry. Currently, irradiation is allowed for two uses in meat and poultry -- inactivating *Trichinella spiralis* (the parasite that causes trichinosis) in fresh or previously frozen pork, and for controlling *Salmonella* and other pathogens in uncooked poultry. Treatment is allowed on fresh or frozen uncooked whole carcasses and parts but not on cooked or cured poultry parts or those containing added ingredients. The product must be packaged prior to treatment, and labeled with a statement saying "Treated with Radiation" or "Treated by Irradiation." A petition to irradiate red meat is under review by the Food and Drug Administration.

To date, irradiation has seen limited application in the United States. Although irradiation of pork to control *Trichinella spiralis* was approved in 1986, no commercial applications have appeared in this country. One firm, FOOD TECHnology Service of Plant City, Florida, has been irradiating poultry products for the retail market and hospitals since 1993. Currently, all of its irradiated poultry goes to health care and foodservice outlets.

Despite scientific evidence of the effectiveness and safety of irradiation and regulatory approval of selected uses of the process, few food processors and retailers are offering irradiated products. Some processors and retailers are uncertain about whether consumers will buy irradiated products and fear boycotts from groups opposed to food irradiation.

Consumer resistance to irradiated products may be reduced through education about the safety benefits of irradiated foods. A survey by the Food Marketing Institute in 1996 indicated that nearly half of the respondents knew nothing about irradiation. However, among those who had some knowledge of irradiation, a clear majority indicated that they were willing to buy "a food product like strawberries, poultry, pork, or beef, if it had been irradiated to kill germs or bacteria" (FMI, 1996). A 1993 survey by the American Meat Institute Foundation found 54 percent of respondents willing to buy irradiated meat after being told that irradiation can kill the bacteria that cause foodborne illness if present in raw meat (AMI, 1993).

In February 1997, irradiated chicken was sold in a supermarket in Manhattan, Kansas. Fox and Olson (1997) reported that at the same market price as unirradiated product, 43 percent of consumers purchased the irradiated chicken breasts. When information about the public health protection benefits of irradiation was supplied, irradiated chicken purchases increased to 80 percent. Fox and Olson found that 30 percent of shoppers were willing to pay a 10 percent premium for irradiated chicken breasts.

For the foreseeable future, widespread adoption of irradiation as a solution to microbial pathogens in meat and poultry is unlikely. However, irradiation can be expected to play a limited role, perhaps for products in niche markets (i.e., targeted for individuals at higher risk of foodborne illness).

Market-Oriented Approaches to Food Safety: Economic Incentives

As discussed earlier, food safety problems flow from market failure due to lack of consumer information about food safety and from few incentives for private producers to provide this information. One possible approach to correcting this market failure would be to strengthen market mechanisms for promoting safer food. For example, property rights to safe food and product liability could provide a strong incentive for producing safe food.

A case in point is how the British Food Safety Act of 1990 changed the domestic and international food safety relationships among producers, retailers, and traders (Hobbs and Kerr, 1992). This statute changed the liability laws for companies selling in the UK by adding a “due diligence” defense clause. Food firms can protect themselves from liability by increasing compliance monitoring and by increasing vertical quality control. However, Viscusi (1989) argues that tort liability cannot provide the economic incentives necessary to reach the optimal level of health and safety because of the high information requirements for documenting liability suits. Establishing a cause-and-effect relationship among illness, food product, and producer remains problematic.

Still, HACCP could provide economic incentives that either augment or substitute for incentives found in the private marketplace and other regulatory programs. Pathogen reduction was a prominent issue in the meat industry prior to the HACCP regulations. Public outrage over the 1993 *E. coli* O157:H7 outbreak motivated the beef industry to increase research on pathogen control. Klepper (1996) stresses the importance of demand factors “in shaping the rate and direction of technological change” (p. 563).

Foodservice companies and restaurant chains (institutional markets) have strong economic incentives to avoid publicized outbreaks, product liability suits, and brand image deterioration. Lower pathogen levels provide other benefits, such as less product spoilage, longer shelf life, access to more distant markets, and fewer customer complaints about product quality.

U.S. companies with internationally recognized HACCP programs will be more competitive. The 1996 Russian ban on U.S. chicken because of alleged food safety concerns illustrates potential market losses. Other countries expect that pathogen control will expand their export markets (Roberts et al., in press). For example, New Zealand has a HACCP program for sheep slaughter, largely to protect its export market. Similarly, the Dutch Government and food industry instituted an Integrated Quality Control system for slaughter pigs to regain its export market.

HACCP will likely improve economic incentives for innovation, by clarifying firms’ responsibility for food safety, by setting public health targets, and by removing regulatory obstacles. New and affordable tests are improving pathogen monitoring and are permitting new production options, thus expanding production opportunities. An incentive to develop new technology is the first-mover advantage, whereby the first firm that markets a safer product will gain new markets and increase market share (Porter, 1983). If producers were able to prove claims of food safety through verification and testing, then certain products could develop a reputation for safety. Labeling foods or establishing brands with a reputation for safety would allow firms to capture some of the consumer demand for safer food.

As an example, certification by FSIS’s Technology Assessment and Research Coordination Division that a production process significantly reduces pathogens reduces the purchaser's cost of information about safety performance. Processors’ legal liability decreases because they are using the best pathogen reduction processes for meat and poultry slaughter and processing. And, it enables equipment purchasers to advertise foods as produced using the latest pathogen-reducing technology.

New technologies are becoming available that producers can adopt to reduce pathogen incidence in slaughter plants, and the new HACCP pathogen reduction rules may accelerate adoption of these technologies. In December 1995, Frigoscandia’s steam pasteurization process became the first process to receive FSIS approval for significantly reducing pathogens. Before sides of beef go into the chiller, they are treated with steam to kill pathogens. A large unit can process 410 head/hour, is fully automated, and costs about $750,000. Frigoscandia has installed it in Excel/Cargill's large plants and another 60 units have been ordered by U.S. and international firms. Capital costs are minimal in a large plant and less than a half a cent/pound of beef in the smallest plants. Other options include increased hand trimming for lots with high pathogen counts, steam vacuums on the kill line in the plants, and chemical dehairing of animals. As firms respond to the new rules, we may see different plants adopting different methods to achieve pathogen reduction.

As with education and labeling, market-based incentives for safer food may prove a useful addition to regulatory efforts to promote food safety. As market trends lead to more consolidation and vertical integration in the food sector, we can expect more efforts by firms to use food safety as a marketing opportunity.

Conclusions and Suggestions for Further Research

This report gives an economic appraisal of the meat and poultry regulatory system in the United States, with a particular emphasis on the new HACCP systems for meat and poultry inspection. For most assumptions about the effectiveness of HACCP in reducing foodborne pathogens, the new inspection system will likely reduce medical costs and productivity losses from foodborne disease, and these benefits of pathogen reduction will outweigh the costs of HACCP. In addition, the report highlights some distributional considerations: Certain segments of the population (the elderly, the very young, pregnant women, people with HIV/AIDS or cancer) may benefit more from improved food safety, while the costs of implementing HACCP can be proportionally greater for some small processing plants.

Additional research is necessary to increase our understanding of the economic consequences of meat and poultry regulation. First, we need more comprehensive and accurate data on the scope and incidence of foodborne illness in this country. There is still no agreement among the scientific community on the annual number of foodborne illnesses and associated deaths. Second, this report considers only six pathogens, while as many as 40 different pathogens in meat and poultry can cause foodborne illness (CAST, 1994). We also considered only a limited number of diseases. Certain chronic conditions, which can be secondary complications of foodborne illnesses (such as arthritis) were not included in our cost-of-illness estimates. More consensus is also needed on the choices economists make estimating the costs of premature death. Finally, we need to consider the effects of efforts to control other sources of microbial pathogens, such as shell eggs and egg products (Roberts et al., in press).

As USDA strengthens the meat and poultry inspection system, other initiatives are underway to promote food safety. The FDA, which also has responsibility for monitoring food safety, is implementing a HACCP system for inspection of seafood products. A governmentwide effort is underway to promote safer food through increased surveillance of foodborne illness outbreaks, increased data collection on the incidence of foodborne disease, more complete risk assessments to track foodborne pathogens from farm to table, and increased efforts to educate consumers and food handlers about safe handling practices. USDA, FDA, and CDC, along with State officials and private concerns, are examining the possibility of HACCP systems for eggs and egg products targeted at reducing the incidence of *Salmonella enteritidis*, one of the leading causes of foodborne illness in the United States. Over the next few years, these changes and improvements in our food-safety regulations and inspections are expected to improve the safety of the Nation's food supply.

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