THE ECONOMICS OF IMPROVING FOOD SAFETY

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Abstract

Each year, between 6 and 33 million people become ill from foodborne diseases caused by bacteria and parasites, and up to 9,000 die. This paper discusses how economic analysis measures the costs of foodborne disease. Illnesses related to seven major foodborne pathogens cost the U.S. between $6.6 and $37.1 billion annually in medical costs and lost productivity. Efforts to prevent foodborne illness by reducing the level of bacteria and parasites in food may generate billions of dollars in cost savings. New initiatives to further strengthen the safety of the nation's food supply are also discussed.

Introduction

Americans have access to one of the most abundant, diverse, and inexpensive food supplies. The economic privilege enjoyed by the people of America in comparison to those of other nations, however, has created higher expectations by consumers about the variety and quality of their food purchases. Access to information about large outbreaks of food-related illnesses and death has also heightened consumer concerns about the safety of their food.

The Center for Disease Control and Prevention estimates that between six million and thirty-three million people contract foodborne illnesses from microbial pathogens each year and of those as many as 9,000 die.

Buzby, et. al (1996) studied the extent of foodborne illnesses caused by seven major microbial pathogens (*E. coli* O157:H7, *Salmonella*, *Listeria Monocytogenes*, *Staphylococcus aureus*, *Campylobacter*, *Clostridium perfringens*, and *Toxoplasma gondii*). Results of the study were that in 1996 there were an estimated 3.3 to 12.4 million U.S. cases of foodborne illnesses from the seven pathogens studied, and up to 3,700 associated deaths. (There are more microbial pathogens, perhaps as many as 40, for which illness and death estimates are not currently available.)

Table 1. Estimated Annual Extent of U.S. Foodborne Illness for Seven Major Pathogen, 1996

Pathogen	No. Cases	No. Deaths
Salmonella	696,000- 3,840,000	870 - 1,920
Campylobacter	1,100,000 - 7,000,000	116 - 564
E. coli O157.:H7	16,000 - 32.000	63 - 126
Listeria monocytogenes	928 - 1,767	230 - 485
Staphylococcus aureus	1,513,000	454
Clostridium perfringens	10,000	100
Toxoplasma gondii	1581	40
Total	3,300,000 - 12,300,000	1,900 - 3,700

Source: Buzby et. al, 1996.

Other sources of food safety risk include chemical contamination of food--such as nitrates in drinking water and pesticide residues on fruits and vegetables. Although scientists believe that the health risks associated with chemical contamination of food and drinking water are lower than the health risks associated with microbial pathogens, studies show that consumers still perceive these as significant risks.

The price of food, as well as its convenience, appearance, and nutritional content, have a major influence on choices made in the marketplace. Consumer concerns about food safety should have a similar impact. In the optimal market scenario, consumers make their purchase decisions possessed of a full and correct understanding about how their selections will affect their well-being, but unlike most other product characteristics, food safety is usually not discernible to consumers at the time of purchase. Therefore, consumer ignorance of the safety of their food purchases limits the degree to which demand for safer food can lead the market to enhance food safety.

Currently, the market provides few incentives for producers to provide levels of food safety beyond those mandated by government regulations or to offer the public other than the most rudimentary information about the safety of their food product. The cost of having products linked to outbreaks of food borne illness, both to reputation and sales, does provide some incentive for producers to ensure the safety of their products. However, the complexity of the process whereby food travels from farm to table makes warranting food safety risky business for producers. The liability associated with claims of 100% safety, if proven false, is a significant disincentive for producers to advertise their food as “safe.” Constrained from advertising "safe" food and thus reaping market rewards, producers have no vested interest in making information about the safety of their food product more available to consumers.

Consumer pressure necessary to impact the market in the matter of food safety will not occur until the information gap is closed. Until then, an optimal level of food safety is not likely

to be achieved within a non-regulated market. This lack of consumers' food safety information and the lack of producers' incentives to provide it leads to market failure

It would be impossible to provide a risk-free food supply. Since there are costs associated with increasing food safety, society must decide how much, if any, it is willing to spend on food safety and where these dollars will have the greatest impact. The optimum level for food safety would be where the marginal cost of creating one more unit of food safety equals its marginal benefit.

The marginal costs would be the costs to food processing plants to meet new food safety plans and the cost of government programs aimed at educating consumers, retailers, and foodservice workers about safe food handling. The marginal benefits are the reduced illness and mortality associated with a safer food supply. However, since these benefits or goods are not traded in the market, how do you assign them a dollar value?

In the next section of this paper, we show how economists have measured the costs of unsafe food. This gives us a benchmark by which to measure the benefits of programs and policies that improve food safety - the benefits being the reductions in costs associated with unsafe food.

Measuring Food-Safety Costs: The "Cost of Illness" Approach

The "Cost-of-Illness" (COI) approach measures the sum of medical expenses and lost productivity due to illness or death. Basically, this approach measures the cost of unsafe food as the costs of treating foodborne diseases plus lost productivity when victims can't work.

The advantage of the COI approach is that it employs available data that are fairly reliable and consistent over time. Because the concepts are both easy to understand and data are obtainable from market transactions, COI measures have been widely used for several decades.

The COI approach seems to be crudely "economic" in the sense that it values lost income and the associated consumption expenditures; but in fact the approach does not conform with economic theory because it fails to recognize the value that individuals may place on (and be willing to pay for) feeling healthy, avoiding pain, or using their free time. Because the COI approach explicitly ignores these valuable aspects of health, the method is generally thought to understate the true societal benefits from risk reduction. This method places a lower value on reducing risks of the elderly because they have low future earnings to forego. Also, this method attaches a rather low value to risk reduction for children, depending on the discount rate used to value future earnings of children to the present.

The Department of Agriculture (USDA) has estimated the COI for seven pathogens which are found on some meat and poultry. These estimates are calculated from the number of annual

foodborne-illness cases and deaths; the number of cases that develop secondary complications; and the corresponding medical costs, lost productivity costs, and other illness-specific costs.

Establishing incidence rates for foodborne illness was challenging due in large part to the nature of the illnesses. Many individuals do not recognize food as the cause of their illness and often even when they do, they do not consult a physician. Finally, physicians do not always recognize the illness as foodborne. As a result the number of cases of foodborne disease is vastly underreported.

Once the incidence rate was established medical costs were calculated. Included here were the cost of doctors, hospitals, medicines, and supplies. Productivity losses were calculated for time lost from work using a daily wage rate times the amount of time lost from work as a proxy for the value of lost output. Productivity losses were also calculated for those unable to return to work or who died.

The issue of how to place premature deaths in an economic context is a difficult challenge for economists. Essentially, we are asked to respond to the question of "What is a life worth?" Two approaches are commonly used. The first approach says that one measure of the economic value of an individual is the amount of income he/she earns over his/her lifetime. In other words, one measure of the costs of a premature death from foodborne disease is the current dollar value of all future income that individual would have earned had he/she not died. This is called the "Human Capital" approach to valuing premature deaths, as developed by Landefeld and Seskin (1982).

Another approach economists have used is to look at the way individuals reveal their attitudes toward risky activities through their behavior. For example, some individuals choose to take jobs which have an increased risk of death or injury in return for higher wages, such as building skyscrapers, fishing in the arctic waters off Alaska, and so forth. In principle, the value placed on an increased risk of premature death in those cases can be equated with the extra wages paid to workers to induce them to voluntarily undertake these risk. Viscusi (1993) analyzed labor market data for twenty-four high-paying, risky occupations, and estimated the extra wages paid to such workers. He found that, when pooled over a large numbers of individuals with various risks of job-related premature death, between $3 and $7 million would be paid to raise the aggregate risk of death in the labor market by one. That is, to induce enough workers to undertake risky jobs with a probability of one extra death, the extra wages paid to those workers would be between $3 and $7 million (in 1990 dollars).

In some economic analysis, then, this estimate has been used to place a dollar value on premature deaths. The Consumer Product Safety Commission uses Viscusi's range and/or a $5-million estimate per life lost in its analysis; 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 new seafood inspection systems. Buzby et. al. (1996) used the midpoint of Viscusi's range of values to place a $5 million cost on each premature death from foodborne

diseases. As can be seen in table 2, this raises the total cost of foodborne illness considerably. All told, the cost of foodborne illnesses and deaths related to the seven pathogens studied is between $6.6 and $37.1 billion annually.

Table 2--Foodborne illness costs from seven major pathogens are $6.6 - $37.1 billion per year

Pathogen	All foods (L/S) $billion/1996	All foods ($5 M/life) $billion/1996	Percent meat and poultry	Meat/poultry (L/S) $billion/1996	Meat/poultry ($5 M/life) $billion/1996
Salmonella	0.9 -3.6	4.8 -12.3	50 - 75	0.5 - 2.7	2.4 - 9.2
Campylobacter	0.8 - 5.7	1.6 - 10.1	75	0.6 - 4.3	1.2 - 7.6
E. coli O157:H7	0.2 - 0.3	0.3 - 0.7	75	0.1 - 0.2	0.2 - 0.5
Listeria monocytogenes	0.1 - 0.3	1.3 - 2.4	50	0.1 - 0.2	0.7 - 1.2
Staphylococcus aureus	1.2	3.3	50	0.6	1.7
Clostridium perfringens	0.1	0.5	50	0.1	0.3
Subtotal	3.3 - 11.2	11.8 - 27.2	--	2.2 - 7.2	6.5 - 20.5
Toxoplasma gondii	3.3	7.8	100	3.3	7.8
Total	6.6 - 14.5	19.6 - 37.1	--	5.2 - 10.4	14..3 - 28.3

Source: Buzby et. al., 1996

Economic Analysis of Food Safety Regulations: The case of HACCP

These estimates of the social costs of foodborne illness, while revealing of the total burden these illnesses place on society, are only a starting point. Economists also are interested in how efforts to prevent foodborne illness can reduce this burden, and the relationships between the benefits of safer food and the costs of achieving this goal. Ideally, we would want to chose to implement regulations and other efforts to control foodborne disease only when/if the costs of pathogen reduction are less than the benefits of reduced medical costs and productivity losses. In this section of the paper, we discuss how economic analysis has been used to evaluate one such program, the recently-enacted Hazard Analysis and Critical Control Points (HACCP) pathogen reduction rule.

Federal inspection for meat and poultry processing and slaughter plants has been in place for decades. Under the system in place prior to 1996, Food Safety and Inspection Service (FSIS) inspectors relied on a labor-intensive examination of each carcass and its internal organs, with the purpose of identifying obviously diseased or spoiled meat. Inspectors also would check for sanitary operating conditions. 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 sensory methods - sight, smell, and sense of

touch - to identify unsafe products. This "poke and sniff" system, however, could not detect the presence of microbial pathogens which could potentially cause human illness.

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,
- Require microbial testing to determine compliance with the targets, and
- Establish written sanitary standard operating procedures.

(See the Appendix for a detailed description of the HACCP system)

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.

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.

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?

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 (FSIS, 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.

Economists use the concept of "present value" to express future payments of income in terms of current value. That is, a certain stream of payments extending into the future can be expressed as a given amount of money invested today at a given interest (or "discount") rate. 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.

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 methodology for valuing premature death 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 (Table 3).

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.

Table 3--Scenarios Used to Ealuate the HACCP Pathogen Reduction Rule

Description	Effectivness Pathogen Reduction	Discount Rate	Valuation Method for Pemature Death/Disability	Annualized Low	Net Benefits High
	(Percent)			$ billion (1995)	
Preliminary FSIS 1995	90	7	Landefeld/Seskin	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	$5 million/life	26.2	95.4
High-range benefits estimates	90	3	$5 million/life	47.2	171.8

Source: Crutchfield, et. al., 1997

Costs of HACCP Rule

The Food Safety and Inspection Service (FSIS) estimated the costs of implementing the HACCP pathogen reduction rule as part of the rule-making process. (For details, see Crutchfield, et. al., 1997.) To make a meaningful comparison of benefits and costs, we also need to estimate the annualized costs of the pathogen reduction rule over time (that is, the present value of costs discounted over 20 years). In the preliminary rule-making in 1995, FSIS estimated the costs of the proposed rule to be $2.3 billion, annualized over a 20-year period, starting in 2000 (when all provisions of the final HACCP rule become fully effective). Subesquent analysis lowered these costs estimates to $1.1 to $1.3 billion, again annualized over 20 years.

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 4 summarizes the 20-year annualized benefits and costs of HACCP, based on the scenarios outlined above.

Table 4 - Comparison of Benefits and Costs of the HACCP Pathogen Reduction Rule

Description	Annualized Net Benefits Low	High	Annualized Costs Benefits Low	High
	$ billion (1995)		$ billion (1995)	
Preliminary FSIS 1995	8.4	42.1	2.3	2.3
Low-range benefits estimates	1.9	9.3	1.1	1.3
Mid-range benefits estimates I	4.7	23.4	1.1	1.3
Mid-range benefits estimates II	26.2	95.4	1.1	1.3
High-range benefits estimates	47.2	171.8	1.1	1.3

Source: Crutchfield, et. al., 1997

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.

What's Next for Food Safety Policy?

As the previous discussion has shown, foodborne illness causes a signficant social and economic burden to the Nation. In addition to moves by the USDA to strengthen the meat and poultry inspection system to reduce microbial pathogens, other efforts are underway to improve the safety of the Nation's food supply.

Currently, at the Federal level regulatory authority over food safety is divided among several agencies. The Department of Agriculture has responsibility for inspection of meat and poultry products, and egg products (such as pastuerized eggs). The Food and Drug Administration (FDA) has responsibility for other fresh and processed foods, including fresh produce and imported foods. The National Marine Fisheries Service (NMFS) and FDA share responsibility for inspection of seafood harvesters and producers, and a HACCP-based inspection system has

been put in place for seafood products. The Environmental Protection Agency (EPA) has responsibility for regulating agricultural chemicals used in farm production.

On May 12, 1997, Vice President Gore announced the **National Food Safety Initiative**. This initiative is a multi-agency effort to strengthen and improve food safety in the U.S. Among the features of this initiative are:

- Improved inpections and expanded preventive safety measures. The initiative calls for increased funds for FDA inspection activities, implementation of HACCP-type systems for fruit and vegetable juice industries, and proposes implementation of HACCP systems for egg products.

- Accelerated research to develop new tests to detect foodborne pathogens and to assess risks to the food supply.

- Establishment of a new early-warning surveilliance system to detect and respond to outbreaks of foodborne illnesses, and to gather the data necessary to prevent future outbreaks. This system is called "FoodNet", and is administered by the Centers for Disease Control and Prevention (CDC)

- Establish a national educational campaign that will improve food handling in homes and retail outlets. This reflects the fact that prevention at the farm and processing level will probably never eliminate foodborne risks - consumers and retailers too have a responsibility to prepare and handle foods properly to prevent disease.

- Strengthen and improve coordination among Federal agencies responsible for food safety, including USDA, CDC, FDA, and EPA.

In the past few years, there have been some highly-publicized cases of foodborne disease outbreaks linked to fruits and vegetables, in some cases linked to imported foods. Strawberries contaminated with the Hepatitis A virus were served in school lunches in several states. Raspberries contaminated with the *Cyclosopora* parasite thought to originate from Guatemala caused many illnesses in the eastern U.S. and Canada. Unpasteurized apple cider contaminated with the *E. coli* O157:H7 bacterium caused several illnesses and at least one death.

In response, the Adminstration announced the **Produce and Imported Food Safety Iniatiative** on October 2, 1997. This initiative aims to upgrade domestic food safety standards and to ensure that fruits and vegetables coming from overseas are as safe as those produced in the United States. Key features of this initiative are:

- Enhanced FDA oversight for imported foods. Legislation is being proposed to require FDA to halt imports of fruits, vegetables, and other food products from any foreign country with food safety systems and standards that are not on par with those of the U.S.

Increased funding is proposed to expand FDA inspection and surveillance activities at home and abroad.

- Improved monitoring and inspection activities abroad. In addition to committing more resources to FDA's international food inspection force, the initiative calls for increased efforts to monitor agricultural and manufacturing processes abroad, and to assist foreign countries to improve these practices when necessary.

- Development of Guidance on Good Agricultural and Manufacturing Practices. The FDA and USDA are jointly developing recommendations to growers and producers on how to minimize the risk of microbial contamination of fresh fruits and vegetables. It is interesting to note that this is a guidance document only, it does not have the legal force of a regulation. The final version of this guidance document is about to be published in the *Federal Register* for public comment.

- Although not part of this initiative per se, the FDA has recently announced new regulations requiring heatlh warning labels on all unpasteurized fruit juices, and requirements that producers of fruit juices adopt HACCP systems to prevent microbial contamination.

It should be noted, of course, that regulations and public programs to reduce the risk of foodborne disease are not the only answer to the food safety problem. Food safety is everyone's responsibility. Consumers and food handlers can help reduce risk by following recommended safe handling practices: washing cleaning surfaces and utensils, limiting contact between raw meat and other food products, cooking foods thoroughly, and following proper storage guidelines (for example, thawing meat in the refrigerator instead of the countertop).

Future Research in Food Safety Economics

There are two sources of uncertainty which affect our estimates of the costs of foodborne illness and the benefits of policies to control microbial pathogens. The first is uncertainty as to the number of cases of foodborne illness, the nature and severity of these illnesses, their underlying causes, and the health outcomes of these illnesses. The second is our imperfect knowledge about the sources of risk along the food chain and how these might be addressed by pathogen control options. In the first case, our estimates of the overall social cost of foodborne illness can only be expressed as ranges with wide confidence intervals. In the second, our efforts to estimate the benefits and costs of options to reduce foodborne illnesses are hampered by lack of knowledge about how pathogen control efforts will eventually affect public health.

The Economic Research Service is working in collaboration with the Centers for Disease Control and Prevention to update our estimates of the social burden caused by foodborne disease. We will be using data from the FoodNet surveillance system to revise and update our estimates of the number of illnesses and deaths attributable to the seven microbial pathogens already studied. We will be developing new estimates of foodborne disease costs for additional

pathogens studied in the FoodNet surveillance system. Finally, we will be working with risk assessors and other scientists in government, academia, and the private sector to develop better ways to model the relationship between food production, microbial contamination, and human health outcomes. Our goal is to develop more accurate and concise estimates of the social cost of foodborne disease, and better estimates of the benefits and costs of efforts to improve public health.

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Appendix

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 degrees 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 was 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 required 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.