...Upfront

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Promoting Food Safety—An Economic Appraisal

Food safety has been much in the news. The past few years have seen some highly publicized outbreaks of foodborne illness, linked to such sources as *E. coli* O157:H7 in hamburger and unpasteurized apple juice, *Listeria monocytogenes* in hot dogs, and *Salmonella* in poultry products. These outbreaks and the resulting publicity have led to a heightened public awareness of food safety risks, as well as new efforts by Government, the food industry, and consumer groups to promote the safety of the Nation's food supply throughout the food system.

Promoting a safe and secure food and fiber system is one of USDA's primary objectives. Several broadly based programs and initiatives are underway to increase food safety. These efforts include strengthening the meat and poultry inspection system, establishing early warning systems to detect and monitor foodborne disease outbreaks, issuing new requirements for product labeling, promoting good agricultural and management practices to reduce microbial hazards in fresh produce, enhancing inspection of imported foods, using irradiation to control microbial pathogens in meat and poultry, and improving surveillance activities to provide better data on the scope and extent of foodborne illness.

This issue of *FoodReview* highlights research underway at USDA and other agencies to improve food safety. USDA's Economic Research Service (ERS) has been collaborating with colleagues in many agencies to provide economic analysis of food safety issues. Crutchfield gives an overview of the new Federal programs aimed at improving the safety of the Nation's food supply. Crutchfield and colleagues at ERS assess the effects of one of these policies (the new Pathogen Reduction/Hazard Analysis and Critical Control Points rule) and show that the benefits of the new meat and poultry inspection system outweigh the costs.

Data from the new "FoodNet" surveys of foodborne illness established as part of the National Food Safety Initiative are used by Frenzen, Buzby, Roberts, and our partners in the FoodNet Task Force to revise our estimates of the costs of foodborne salmonellosis. Majchrowicz discusses new technologies that could increase food safety; more uses for existing processes such as ozone and advancements in newer technologies such as ultra-high pressure offer food processors an array of pathogen treatments. Buzby and Morrison update earlier research on the costs and benefits of using irradiation to prevent foodborne disease. Buzby and Crutchfield report on new rules designed to protect consumers from exposure to microbial pathogens in fruit juice.

ERS research in the food safety area will continue to examine the costs and benefits of particular approaches to improving food safety, thereby helping to ensure that our solutions to food safety problems are cost effective and impose the least burden on consumers and producers.

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Inside...

Promoting Food Safety

Also Inside

New Federal Policies and Programs for Food Safety

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The United States excels at producing an abundant supply of safe, nourishing, and affordable food. However, some recent well-publicized incidents, such as the contamination of hamburgers and apple juice with the *E. coli* O157:H7 bacterium and contamination of frozen, sugared strawberries with the hepatitis A virus, have led to increased public concern about the possibility of illnesses caused by foods.

The Government at all levels and the private sector share this concern. Currently, at the Federal level, regulatory authority over food safety is divided among several agencies. The Department of Agriculture's Food Safety and Inspection Service (FSIS) is responsible for inspecting domestic and imported livestock and poultry products, and egg products (such as pasteurized eggs). The Department of Health and Human Services' Food and Drug Administration (FDA) is responsible for other fresh and processed foods, including eggs, fresh produce, and imported foods other than meat and poultry. On a fee-for-service basis, the Department of Commerce's National Marine Fisheries Service (NMFS) may, at industry's request, conduct inspections of seafood harvesters and producers for quality; however, FDA has responsibility for seafood inspection. The Environmental Protection Agency (EPA) is responsible for regulating agricultural chemicals used in farm production and establishing tolerances for pesticides. FDA enforces those tolerances. FDA regulates drugs and feed additives used in food producing animals.

A New System for Inspecting Meat and Poultry

New rules governing meat and poultry inspection in the United States were published in 1996. The Pathogen Reduction/HACCP rule was implemented initially on January 26, 1998, in plants with more than 500 employees, which slaughter 75 percent of U.S. meat. Plants with 10 to 500 employees were to have HACCP plans in place by January 25, 1999. Very small establishments, with fewer than 10 employees or annual sales of less than $2.5 million, have until January 25, 2000.

Four essential elements define 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 standard operating procedures 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 that the process prevents and removes fecal contamination.

HACCP Plans Identify and Reduce Hazards

USDA now requires that all meat and poultry plants develop HACCP plans to monitor and control production operations. Plants must first identify food safety hazards and

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critical control points in their particular production, processing, and marketing activities. In addition to biological hazards, such as disease-causing microorganisms (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 then establish critical limits, or maximum or minimum levels, for each critical control point. For example, the plant may determine that water or steam used for cleaning carcasses must be maintained at a minimum temperature of 180 degrees Farenheit or higher. The plant monitors the critical control point to ensure that the critical limits are met. Each plant must list its procedures for monitoring the critical control points and the frequency of its monitoring activities. HACCP also includes steps for recordkeeping and verification, including some microbial testing of meat and poultry products to ensure that the system is meeting the target level of safety. Plants have responsibility to ensure the effectiveness of the HACCP system, although FSIS will perform verification activities.

Plants Must Write Sanitation Procedures and Test for Pathogens

The Pathogen Reduction/HACCP rule required all federally inspected meat and poultry plants to have developed written sanitation standard operating procedures (SOP's) by January 27, 1997, which state how they meet daily sanitation requirements. Sanitation SOP's are 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.

FSIS testing for *Salmonella* on raw meat and poultry products verifies that plants are controlling pathogen levels. All plants that slaughter and grind meat and poultry must achieve at least the current baseline minimum level of *Salmonella* control for each type of product produced. One reason that *Salmonella* was selected to be tested as an indicator of all pathogens was because it was the most prominent cause of U.S. foodborne illnesses associated with livestock and poultry at the time the regulations were developed. New data indicate that infections caused by *Campylobacter* may now be more prevalent. Plants must meet the *Salmonella* standard on the same timetables as they meet the HACCP requirement.

Slaughter plants are 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. Plants were required to begin *E. coli* testing on January 27, 1997, regardless of plant size. Plants were given an additional 6 months to gain experience in conducting these tests before FSIS personnel began reviewing the test results as part of their inspection routine.

E. coli contamination is not directly correlated with *Salmonella* contamination, which is affected by factors other than fecal contamination, including the health and condition of incoming animals. Therefore, *Salmonella* and *E. coli* testing complement one another and will help slaughter plants and FSIS inspectors ensure that plants are preventing and reducing fecal contamination of meat and poultry products.

Enforcement Strategies

If FSIS program employees find violations of the new Pathogen Reduction/HACCP rule, 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 a product at the plant or requesting that the company recall the product.

Minor violations of an establishment's HACCP plan and sanitation SOP's will be noted by FSIS program employees. 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, FSIS program employees can stop production lines until failures in HACCP and sanitation SOP's are corrected. Program employees 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 sanctions, after due process. For example, improper maintenance or falsified records would have potentially serious

implications because accurate recordkeeping is essential to the proper functioning of sanitation and HACCP systems and to the production of safe foods. USDA will continually monitor and adjust its enforcement approach during the program transition to ensure that enforcement activities are effective, fair, and consistent.

Other Federal Food Safety Programs

In December 1995, the FDA announced a rule requiring seafood processors to adopt HACCP systems. Under the FDA rule, seafood processors are required to identify hazards that, without preventive controls, are reasonably likely to affect the safety of seafood products. If at least one such hazard can be identified, the firm is required to adopt and implement an appropriate HACCP plan. In addition to helping ensure that the food is free of contaminants, this process also helps manufacturers who subsequently have problems with their food determine how and when those problems could have occurred. Seafood processors using the HACCP system continue to be monitored under FDA surveillance and inspection programs. This rule was implemented in stages, with complete implementation effective in late 1997.

On January 25, 1997, President Clinton announced the National Food Safety Initiative, a multiagency effort to strengthen and improve food safety in the United States. The initiative included several new programs to promote food safety, including improved inspection systems and preventive measures, new tests to detect pathogens, a national education campaign for safer food handling in homes and retail outlets, and increased funding for food safety research and risk assessment activities.

The early-warning surveillance system called FoodNet was expanded in 1997 under the Food Safety Initiative to detect outbreaks of foodborne illnesses and to gather data necessary to prevent outbreaks. FoodNet is administered by the U.S. Centers for Disease Control and Prevention (CDC) (see "*Salmonella* Cost Estimate Updated Using FoodNet Data" elsewhere in this issue).

In 1998, FDA proposed new regulations requiring warning labels on all fruit juices not treated to eliminate illness-causing microorganisms. The agency also proposed that that producers of juices adopt HACCP systems to prevent microbial, chemical, and physical contamination (see "New Juice Regulations Underway" elsewhere in this issue).

The initiative calls for increased funding for FDA inspections, proposes implementation of food safety preventive systems such as HACCP, and establishes a national educational campaign to improve the use of safe food practices in homes and retail outlets. This education effort augments efforts at the farm and processing level to reduce risk of foodborne hazards; consumers and retailers are responsible for preparing and handling foods properly to prevent contamination.

The initiative also calls for research to develop new prevention techniques and tests to detect foodborne pathogens, to assess risks to the food supply, to improve response to foodborne illness outbreaks, and to improve coordination among the Federal agencies responsible for food safety.

Produce and Imported Foods Scrutinized

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. Frozen, sugared strawberries contaminated with the hepatitis A virus were served in school lunches in several States. The source of contamination was never determined. Raspberries contaminated with the *Cyclospora* parasite thought to originate from Guatemala caused many illnesses in the eastern United States and Canada.

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

- Enhanced FDA oversight for imported foods. Proposed legislation requires FDA to establish procedures to assure that foreign food systems meet the same level of protection as in the United States. Increased funding would expand FDA inspection and surveillance activities at home and abroad.
- Improved inspection activities abroad. In addition to committing more resources to FDA's international food inspection force, the initiative calls for increased efforts to assess agricultural and manufacturing processes abroad, identify gaps, and provide foreign countries with technical assistance to improve these practices when necessary.
- Guidance on good agricultural and manufacturing practices. FDA and USDA jointly developed recommendations for growers and producers on how to minimize the risk of microbial

contamination of fresh fruits and vegetables. This document is for guidance only and does not have the legal force of a regulation. The final version of this guidance document was published in late 1998 in the *Federal Register* for public comment. *Good Agricultural Practices Guidance* is available in several languages (English, Spanish, French, and Portuguese).

The steps the Federal Government is taking will help protect public health by improving the safety of the Nation's food supply. Ultimately, though, food safety is everyone's responsibility. Farmers, processors, and consumers must all do their part to ensure that our food supply is safe.

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Assessing the Costs and Benefits of Pathogen Reduction

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There has been increasing concern in recent years over the human health risks posed by microbial pathogens—bacteria, parasites, fungi, and viruses—in the food supply. Each year an estimated 6 million to 33 million cases of foodborne disease occur in the United States, and up to 9,000 people die. USDA's Economic Research Service (ERS) has estimated that diseases caused by seven major pathogens alone may cause between $6.6 billion and $37.1 billion annually in medical costs and productivity losses.

These estimated social costs of foodborne illness, while suggesting the extent of the burden of these illnesses on society, are only a starting point. Policymakers are also interested in how efforts to prevent foodborne illness can reduce this burden, and the relationship between the benefits of safer food and the costs of achieving this goal. Ideally, the costs of regulations and other efforts to control foodborne disease and to reduce pathogens will be less than the benefits of reduced medical costs and productivity losses.

Most government regulations have some sort of economic effect on producers and consumers. Regulations governing how foods are produced can raise production costs. Regulations require resource commitments, which, in turn, may raise costs and food prices. On the other hand, regulations that improve the safety of the food supply benefit consumers by reducing the number and/or severity of foodborne illnesses. Economic analysis can play an important role in the public decisionmaking process by identifying and comparing the benefits and costs of food safety policies. Currently, all regulations with an annual economic impact of over $100 million are required by Executive Order to have undergone a cost-benefit analysis to show that the expected benefits of the regulation exceed the expected costs. The cost-benefit analysis will also explain why the planned regulatory alternative is preferred.

One such regulation is the 1996 Hazard Analysis and Critical Control Points (HACCP) pathogen reduction rule for livestock and poultry slaughter and processing establishments. ERS analyzed this rule to estimate the economic costs and benefits of this new approach to meat and poultry inspection.

Meat and Poultry Inspection Modernized

Federal inspection of meat and poultry processing and slaughter plants has been in place for decades. Prior to 1996, USDA's Food Safety and Inspection Service (FSIS) program employees relied on labor-intensive examinations of each animal and carcass and its internal organs to identify obviously diseased animals. FSIS program employees also checked for unsanitary operating conditions. This inspection system removed diseased animals from the food supply and enforced sanitary standards in livestock and poultry slaughter and processing by relying on sensory methods—sight, smell, and sense of touch—to identify unsafe products. This system, however, could not detect the presence of microbial pathogens that could cause human illness.

To encourage the use of new technologies, including new methods that can detect pathogens efficiently and effectively, FSIS began to strengthen the meat and poultry products inspection process in the early 1990's. On February 3, 1995, FSIS published a proposed rule that

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would require all federally inspected livestock and poultry slaugher and processing plants to do the following:

- Adopt HACCP procedures.
- Set targets for microbial pathogen reduction.
- Require microbial testing to determine compliance with the targets.
- Establish written sanitary standard operating procedures.

Under a HACCP plan, plants must identify potential sources of food safety hazards in their operations and the critical points where controls could prevent or reduce hazards. Plants must then establish critical limits for each hazard at each critical control point. Plants are also required to develop written procedures to show how they will meet daily sanitation requirements. HACCP-related activities are to be monitored and verified, including microbial testing for *Salmonella* by FSIS, and for *E. coli* by industry. The rule was adopted in 1996 following public comment, and the regulations began to take effect in 1998. (See "New Federal Policies and Programs for Food Safety" elsewhere in this issue for a more in-depth discussion of the new HACCP pathogen reduction rule.)

Benefits of HACCP Hinge on Assumptions

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 products?
- Since HACCP will be implemented over time, what is the appropriate way to express long-term benefits in present value terms? When do benefits begin to accrue?
- How should we quantify the benefits of reducing foodborne illnesses, particularly for those who die prematurely or are never able to return to work because of a foodborne illness?

Effectivness of HACCP

In its initial assessment of HACCP, FSIS assumed that, when fully in place, the new meat and poultry inspection system would reduce microbial pathogens 90 percent across the board. Some commentors on the proposed rule asserted that this assumption about HACCP effectiveness was not scientifically justified. In the final rule, 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." Consequently, FSIS assumed multiple effectiveness estimates, ranging from 10- to 100-percent reduction in pathogen levels.

Pathogen Reduction and Foodborne Illness

The relationship between human exposure to microbial pathogens and any resulting 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 pathogens, such as *E. coli* O157:H7, are believed to be 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 our charge. Therefore, we make the assumption that HACCP will reduce illnesses and deaths in proportion to the assumed reduction in pathogen levels. In other words, if HACCP is assumed to be 50-percent effective in lowering the level of pathogens, then we assumed a 50-percent reduction in foodborne illness.

Present Value of Benefits

In our analysis, we follow FSIS' assumption that the pathogen reductions associated with HACCP will begin to accrue 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.

"Present value" expresses future payments of income or cost savings 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

Table 1
Five HACCP[1] Scenarios Illustrate Range of Benefits

Scenario	Effectiveness of pathogen[2] reduction	Discount rate	Valuation method for premature death/disability	Annualized benefits Low	High
	Percent			*Billion 1995 dollars*	
1995 FSIS analysis	90	7	Human capital	8.4	42.1
Low-range benefits estimates	20	7	Human capital	1.9	9.3
Mid-range benefits estimates	50	7	Human capital	4.7	23.4
Mid-range benefits estimates	50	3	Labor market	26.2	95.4
High-range benefits estimates	90	3	Labor market	47.2	171.8

[1]Hazard Analysis and Critical Control Point (HACCP) Pathogen Reduction Rule. [2]Pathogens included in this analysis are *E. coli* O157:H7, *Campylobacter, Staphylococcus aureus, Salmonella, Clostridium perfringens, and Listeria monocytogenes.*

estimates published in 1995 were calculated using a 7-percent discount rate, as recommended by the U.S. Office of Management and Budget. Other analysts have argued for a lower discount rate. Economists at the U.S. Centers for Disease Control and Prevention (CDC) recommend using a 3-percent discount rate to calculate the present value of HACCP benefits over time, and also looking at the size of benefits when valued at rates of 0, 5, and 7 percent.

Valuing Premature Death

Because there is no consensus on how to best value premature death, we used two approaches. The human capital approach estimates a value for a statistical life using average wages adjusted by a risk premium derived from life insurance studies. The labor market approach estimates a value based on the higher wages people demand for accepting risky jobs.

HACCP Rule Yields Social Savings

Obviously, there is no single correct estimate of the benefits of HACCP; the estimates depend on the assumptions used in the analysis. In our analysis, we chose several different combinations of assumptions about HACCP's effectiveness, the discount rate for valuing future benefits, and the value of a premature death resulting from a foodborne illness.

Our first scenario used the original FSIS assumptions of 90 percent effectiveness, a 7-percent discount rate, and the more conservative, human capital approach for valuing premature death in the cost-of-illness calculations. Next, we considered four alternative scenarios: one yielding a smaller set of benefits estimates, two yielding mid-range estimates, and one set of assumptions yielding the greatest estimate of the benefits of pathogen reduction associated with HACCP (table 1).

As expected, the benefits estimates varied widely, from $1.9 billion to $171.8 billion. No matter what the assumptions, the HACCP rule (even at low effectiveness rates) can be expected to generate considerable social savings by reducing foodborne illness.

Costs of HACCP Rule

A complete economic assessment requires a consideration of the costs of HACCP and how they compare with the expected benefits. FSIS estimated the costs of implementing the HACCP pathogen reduction rule as part of the rule-making process, including the likely costs for plants to develop and implement their HACCP plans and sanitation standard operating procedures and to comply with *Salmonella* and *E. coli* standards. These costs include the expenses involved with assessing and developing control procedures, antimicrobial treatments, record-keeping, employee training, and microbial testing. FSIS also included the cost to FSIS to administer the new rules.

To make a meaningful comparison, the costs of HACCP must be annualized in the same manner as its benefits. FSIS estimated the costs of the proposed rule to be $2.3 billion in a preliminary analysis in 1995, annualized over a 20-year period, starting in 2000 (when all provisions of the final HACCP rule become fully effective). FSIS made changes to the final rule based on public comments on the proposed rule. These changes lowered the estimated costs of the final HACCP rule to $1.1 billion to $1.3 billion, again annualized over 20 years.

Table 2
Benefits of HACCP[1] Outweigh Costs Under All Scenarios

Scenario	Annualized benefits		Annualized costs	
	Low	High	Low	High
	Billion 1995 dollars			
1995 FSIS analysis	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

[1]Hazard Analysis and Critical Control Point (HACCP) Pathogen Reduction Rule.

HACCP Rule's Benefits Outweigh Costs

Estimating the benefits and costs of the HACCP rule helps policymakers assess the economic consequences of reforming the meat and poultry inspection system. Our analysis found the benefits of the HACCP rule to be greater than the costs for all five scenarios (table 2). Even at relatively low effectiveness (20-percent pathogen reduction assumed for the low-range scenario), the new rules save at least $1.9 billion in medical costs and productivity losses, and are greater than the $1.1 billion to $1.3 billion in estimated costs. Higher pathogen reduction rates and increased cost estimates for premature death and disability widen the margin between costs and benefits.

The results of this analysis indicate that implementation of the HACCP rule will reduce medical costs and productivity losses associated with foodborne illness by an amount greater than the costs of the rule. Our benefits estimates (especially the low values) are conservative, encompassing foodborne diseases from only six pathogens for which we have epidemiologic and cost-of-illness data. Implementing the HACCP rule could likely produce additional benefits by controlling other microbial pathogens not included in this analysis.

ERS is continuing to research the benefits and costs of programs and policies to improve the safety of the Nation's food supply. Collaborative efforts are underway with the U.S. Food and Drug Administration (FDA), FSIS, and CDC to refine our estimates of the benefits of safer food using new data gathered from the Foodborne Diseases Active Surveillance Network (see "*Salmonella* Cost Estimate Updated Using FoodNet Data" elsewhere in this issue). ERS is also working with the FDA to assess the benefits and costs of efforts to improve the safety of fresh and imported produce.

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Salmonella Cost Estimate Updated Using FoodNet Data

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Salmonella infections due to contaminated food products make many people ill each year and are responsible for substantial economic costs. *Salmonella* infections are potentially serious and may be fatal, particularly for the elderly and people with weak immune systems (see box on *Salmonella* infections). However, most salmonellosis cases do not result in a visit to a medical facility and are never reported to public health agencies. The high proportion of unreported cases makes it difficult to determine the true incidence of salmonellosis, and has resulted in a wide range of estimates of the annual economic costs of foodborne *Salmonella* infections.

Many *Salmonella* infections are caused by undercooked shell eggs, which may be contaminated by hens infected by *Salmonella* serotype Enteritidis, one of the most common *Salmonella* strains. Effective August 1999, Federal regulations will require that shell eggs packed for retail sale to consumers be stored and transported at or below 45 degrees Fahrenheit to reduce the risk of *Salmonella* infections. USDA was unable to make a definitive estimate of the potential economic benefits of this rule, partly because of the uncertainty about the economic costs of *Salmonella* infections. USDA shares federal regulatory responsibility for egg safety with the Food and Drug Administration (FDA), which recently proposed requiring safe handling labels on egg cartons to warn consumers about the risk of illness associated with *Salmonella*-contaminated shell eggs.

Previous estimates of the economic costs due to foodborne *Salmonella* infections by USDA's Economic Research Service (ERS) were based on the best available estimates of the annual number of infections and the associated medical expenses and productivity losses. New information about the incidence, severity, and medical consequences of salmonellosis has since become available from the Foodborne Diseases Active Surveillance Network (FoodNet) and other sources, allowing us to refine the previous estimates.

FoodNet Monitors Foodborne Pathogens

The Federal Government and other organizations established FoodNet in 1995 to monitor illness due to certain foodborne pathogens including *Salmonella* in selected

Salmonella Infections May Cause Serious Illness or Death

Many different strains of *Salmonella* bacteria live in the intestinal tracts of domestic and wild animals and may contaminate raw meat, poultry, eggs, dairy products, or other foods. The *Salmonella* cost estimate excludes illnesses due to *Salmonella* serotype Typhi, the strain responsible for typhoid fever. Infections by other, non-typhoidal *Salmonella* strains may cause salmonellosis, an acute gastrointestinal disease usually lasting 4 to 7 days, with symptoms including diarrhea, fever, or abdominal cramps. Some people develop potentially fatal infections of the bloodstream or other parts of the body, or secondary complications such as reactive arthritis or Reiter's syndrome, a long-term chronic illness characterized by joint pain, eye irritation, and painful urination.

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geographic sites (see box on FoodNet). FoodNet's goals include estimating the annual frequency and severity of foodborne diseases, and determining how much foodborne illness is due to the consumption of specific foods such as meat, poultry, and eggs.

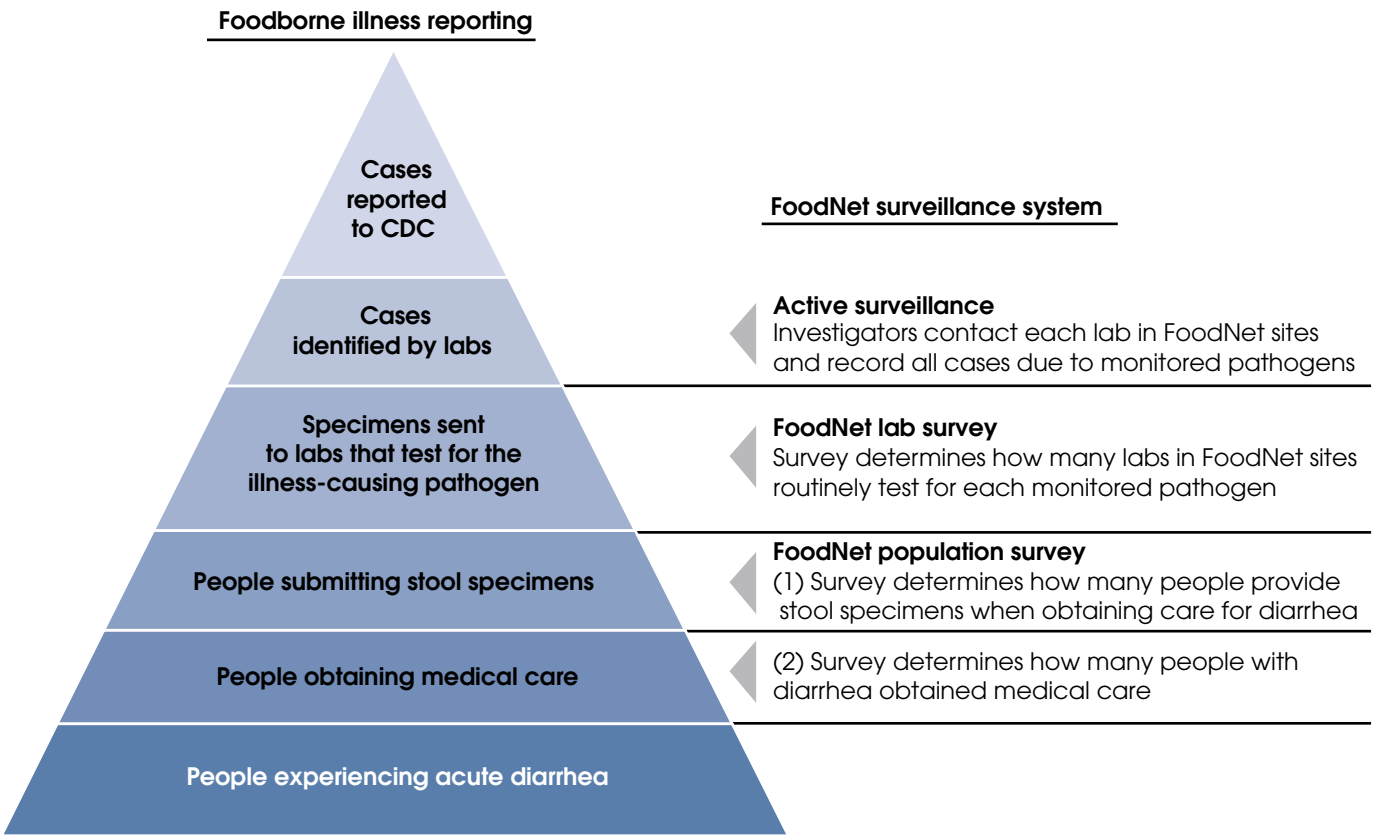
Diarrhea is the most common symptom of illness due to the pathogens monitored by FoodNet. Clinical microbiological laboratories can identify the cause of infectious diarrhea if physicians instruct patients with diarrhea to provide stool specimens for bacterial culture tests. Laboratories may then report certain illnesses (including salmonellosis) to public health agencies, depending on local reporting requirements. However, foodborne illnesses tend to be underreported for several reasons. First, most people with acute diarrhea do not seek medical care. Second, many people who obtain medical care for diarrhea do not provide stool specimens for testing. Third, laboratories do not routinely test stool specimens for every possible foodborne pathogen. Finally, laboratories may not report confirmed cases of foodborne illness to public health agencies, even when required.

FoodNet was designed to determine the number of unreported foodborne illnesses (fig. 1). Estimates of the total number of foodborne illnesses are based on the "culture-confirmed" cases identified by the laboratories in each FoodNet site through stool culture tests. FoodNet investigators regularly contact each laboratory and record all culture-confirmed cases caused by the monitored pathogens, including cases not reported to public health agencies. The number of culture-confirmed cases is then adjusted for the factors that keep most diarrheal illnesses from being identified by laboratory tests, using multiplication factors (or "multipliers") derived from surveys of the population and laboratories in each FoodNet site.

National *Salmonella* Estimate Based on Cases in FoodNet Sites

FoodNet detected an annual average of 2,092 culture-confirmed salmonellosis cases in the FoodNet sites during 1996-97. *Salmonella* was the second most commonly detected

Figure 1
FoodNet Examines Factors Responsible for Underreporting of Foodborne Illness



pathogen, exceeded only by *Campylobacter*. The number of culture-confirmed salmonellosis cases was inflated by the appropriate multipliers, resulting in an estimate of 81,000 annual salmonellosis cases in the FoodNet sites. The multipliers account for the following factors: (1) only 12 percent of the FoodNet site population with nonbloody diarrhea and 15 percent with bloody diarrhea obtained medical care for their condition; (2) 18 percent of those obtaining medical care for nonbloody diarrhea and 100 percent of those obtaining care for bloody diarrhea submitted stool specimens; and (3) all 263 laboratories in the FoodNet sites routinely tested for *Salmonella*, although the tests used by laboratories detect only 70 percent of salmonellosis cases. (The multipliers are calculated separately for bloody and nonbloody diarrhea cases because people with bloody diarrhea are more likely to obtain medical care and submit stool specimens.)

People in the rest of the country were assumed to fall ill from salmonellosis as often as residents of the FoodNet sites, resulting in an estimate of 1.4 million annual salmonellosis cases for the United States. The average annual number of culture-confirmed salmonellosis cases reported to the Centers for Disease Control and Prevention (CDC) during the same period was 35,621, so the FoodNet estimate of U.S. cases suggests that 97 percent of illnesses due to *Salmonella* went unreported.

CDC has estimated that 95 percent of *Salmonella* infections are foodborne in origin. The FoodNet estimate of 1.4 million annual salmonellosis cases consequently includes 1.3 million cases due to consumption of foods contaminated by *Salmonella* and 0.1 million cases due to other causes.

CDC also estimated the distribution of U.S. salmonellosis cases among three of the four illness severity categories used in the ERS cost estimates: cases visiting a physician, cases requiring hospitalization, and cases resulting in premature death. An estimated 170,000 cases visited a physician, 16,400 cases required hospitalization, and 600 cases resulted in death. (The CDC estimates are preliminary, and may change when final estimates are released later in 1999.)

FoodNet Monitors Foodborne Illness

The Foodborne Diseases Active Surveillance Network (FoodNet) is the foodborne disease component of CDC's Emerging Infections Program (EIP). FoodNet is a collaborative effort by CDC, USDA's Food Safety and Inspection Service (FSIS), the Food and Drug Administration (FDA), and the eight EIP sites. FoodNet initially included five sites, and now monitors illness due to nine pathogens including *Salmonella* in eight sites (Connecticut, Georgia, Minnesota, Oregon, and selected counties in California, Maryland, New York, and Tennessee). The FoodNet estimate of annual *Salmonella* infections is based on 1996-97 data from five sites covering 6 percent of the U.S. population.

The FoodNet Working Group, which directs FoodNet, includes the following representatives of the participating Federal agencies and sites:

• **CDC**. Frederick Angulo, Thomas Van Gilder, Patricia Griffin, Robert Tauxe, Drew Voetsch, Sudha Reddy, Samantha Yang, David Wallace, Nina Marano, Paul Mead, David Swerdlow, Laurence Slutsker, Cindy Friedman, Vance Dietz, Bill MacKenzie, Kate Glynn, Thomas Hennessy, Sarah Pichette, Karen Stamey, Peggy Hayes, Timothy Barrett, Bala Swaminathan, John Hatmaker, Richard Bishop, Kathleen Maloney, Mike Hoekstra, Nancy Bean, Laura Conn, and Robert Pinner;

• **California.** Duc Vugia, Michael Samuel, Ben Werner, Kevin Reilly, Sharon Abbott, Sue Shallow, Gretchen Rothrock, Pam Daily, Alexander McNees, Nandeeni Mukerjee, Joelle Nadle, Mary Ann Davis, Lisa Gelling, and Ben Silk;

• **Connecticut.** James Hadler, Matthew Cartter, Ruthanne Marcus, Terry Fiorentino, Gazala Kazi, Robin Ryder, Patricia Mshar, Robert Howard, and Donald Mayo;

• **Georgia.** Paul Blake, Jane Koehler, Monica Farley, Susan Ray, Wendy Baughman, Suzanne Segler, Shama Desai, Matthew Sattah, Sabrina Whitfield, Molly Bardsley, Katherine Gibbs-McCoombs, and Laura Gilbert;

• **Maryland.** Kelly Henning, Peggy Pass, Lora Gay, Michael Carter, Dale Rohn, Jeffery Roche, Diane Dwyer, Althea Glenn, Jafar Razeq,Yongyu Wong, Alexander Sulakvelidze, and J. Glenn Morris, Jr.;

• **Minnesota.** Michael Osterholm, Craig Hedberg, Julie Wicklund, Valerie Deneen, Heidi Kassenborg, Jeff Bender, Kirk Smith, and John Besser;

• **New York.** Dale Morse, Perry Smith, Shelley Zansky, Nellie Dumas, Barbara Damaske, Hwa-Gan Chang, Candace Noonan, Brian Sauders, and Karim Hechemy;

• **Oregon.** David Fleming, Paul Cieslak, Bill Keene, Beletshachew Shiferaw, Maureen Cassidy, Teresa McGivern, Regina Stanton, Steve Mauvais, Stephen Ladd-Wilson, Bob Sokolow, and Vijay Balan;

• **Tennessee.** William Moore, Allen Craig, Timothy Jones, William Schaffner, and Brenda Barnes;

• **FSIS.** Kaye Wachsmuth, Phyllis Sparling, and Ruth Etzel; and

• **FDA.** Ken Falci, Wallace Garthright, and Clifford Purdy.

ERS adjusted the estimated number of physician visits and hospitalizations because CDC included some cases (such as people who saw a physician before being hospitalized) in more than one category. The adjustments were based on information about medical care for culture-confirmed salmonellosis cases in the FoodNet sites. ERS assumed that 36 percent of hospitalized cases did not visit a physician prior to hospitalization because some people first sought medical care in a hospital emergency room. ERS also assumed that 10 percent of fatal cases were not hospitalized prior to death (although all were assumed to have seen a physician) because some people in nursing homes or other settings died outside a hospital. The fourth severity category used in the cost estimates (cases not obtaining medical care) is the residual remaining after the other three categories are subtracted from the estimated total number of cases.

The CDC estimate of annual salmonellosis cases is subject to several potential sources of error, including inaccurate stool tests and the omission of stool specimens shipped to laboratories outside the FoodNet sites. Inaccurate stool tests may be the most likely source of error. Laboratories may not detect *Salmonella* in specimens from salmonellosis patients who previously received antibiotics or waited too long to submit specimens after becoming ill, or in specimens that were improperly transported.

Cost Estimate Uses New Data on Medical Costs

New information about medical care for *Salmonella* infections was extracted from the MarketScan database maintained by the MEDSTAT Group, a medical information firm. The database includes complete medical claims for 4 million persons (nearly 2 percent of the U.S. population) who belong to private health plans offered by large employers in 45 major metropolitan areas. We examined the medical claims for every individual diagnosed with a *Salmonella* infection during 1994-96.

The health plans tracked by the MarketScan database typically receive volume discounts from health care providers, so the database was used to determine the type of medical care provided for salmonellosis patients rather than the charges paid by health plans. The social costs of medical care for salmonellosis patients were determined based on the average U.S. cost for each type of care, using information from hospital and physician surveys and estimates of annual U.S. health expenditures by the Health Care Financing Administration, U.S. Department of Health and Human Services.

The salmonellosis patients in the MarketScan database were assumed to receive the same average amount of medical care as all U.S. salmonellosis patients for the purpose of the cost estimates. MarketScan patients might require less care than other patients because the MarketScan population includes only workers and their dependents, and is therefore younger and healthier than the U.S. population. Alternatively, MarketScan patients may have used more medical care because they were covered by health insurance and faced only minor financial barriers to care, unlike the 16 percent of the U.S. population without insurance.

The MarketScan salmonellosis patients were divided into those who visited a physician without being hospitalized (outpatients) and those who were hospitalized (inpatients) to match the severity categories used in the ERS cost estimates. Outpatients averaged 1.4 physician visits, 0.1 emergency room visits, and 0.3 outpatient clinic visits. Inpatients averaged 4.1 days in the hospital, plus 0.7 physician visits (on an outpatient basis), 0.3 emergency room visits, and 0.2 outpatient clinic visits. (The average number of physician visits for inpatients was less than one because some individuals were hospitalized without seeing a physician on an outpatient basis, although all received physician care while hospitalized.) Inpatients were also older on average (32 years) than outpatients (24 years), suggesting that *Salmonella* infections were more severe among older people.

Salmonella Costs Also Include Lost Productivity

The estimated medical costs of *Salmonella* infections were based on the average medical care per case for each severity category, the estimated number of cases, and the 1998 average U.S. cost for each type of medical care. National estimates of the cost of outpatient clinic visits were unavailable, so the average charge for outpatient clinic visits for MarketScan patients was substituted, possibly underestimating the social cost. Fatal cases were assumed to use the same amount of medical care prior to death as hospitalized cases.

Direct estimates of time lost from work due to *Salmonella* infections are unavailable, so indirect estimates were derived from the 1992-94 National Health Interview Survey (NHIS) (see box on survey). The lost productivity costs due to *Salmonella* infections were determined based on the average number of work days lost by employed people in each severity category, the U.S. employment rate, and the average daily compensation for U.S. workers in 1998. All calculations were adjusted for the presumed age distribution of the salmonellosis cases in each severity category, based on age information from FoodNet and the 1992-94 NHIS.

Two separate sets of cost estimates were calculated using alternative proxies for the forgone earnings of persons who died prematurely due to *Salmonella* infections. The first set of estimates is based on the "human capital" approach developed by J. Steven Landefeld and Eugene Seskin of the U.S. Department of Commerce, and uses average wages adjusted by a risk premium derived from life insurance markets. Under this approach, the cost of a premature death ranges from a maximum of $2.2 million at age 22 to a minimum of $17,000 at age 87 or older.

The second set of estimates is based on labor market studies of the higher wages for risky jobs reviewed by W. Kip Viscusi, an economist at Harvard University. ERS modified this "labor market" approach by taking the age and sex distribution of *Salmonella* deaths into account, using information from official death certificates. In effect, the implied monetary value of life for the average worker determined by Viscusi ($5.0 million in 1990 dollars) is treated as an annuity paid over the average life span for U.S. males and females at an interest rate of 3 percent. ERS also updated the value of a life to 1998 dollars. Under the modified approach, the value of a life ranges from $8.3 million for males and $8.5 million for females at birth to $1.4 million for males and $1.6 million for females at age 85 and above. The values for males and females differ because life expectancy is higher for females (79 years) than males (73 years). Nearly two-thirds of those who died from *Salmonella* infections were aged 65 or older, so the average forgone earnings per premature death were $4.1 million for males and $3.5 million for females.

Survey Estimates Time Lost From Work

The National Health Interview Survey (NHIS) investigates health conditions and the effects of illness on work and other activities in an annual sample of approximately 49,000 U.S. households. The 1992, 1993, and 1994 NHIS samples were pooled for this study to obtain more precise estimates. The NHIS estimates of health conditions are based on respondent reports rather than medical records and tend to represent symptoms, making it difficult to distinguish salmonellosis from other acute illnesses. The estimate of time lost from work was therefore based on a broad definition of acute illnesses apparently due to infectious agents, including such symptoms as vomiting and abdominal pain typically associated with salmonellosis.

The NHIS found an annual average of 16.4 million acute infectious illnesses in the United States during 1992-94, including 6.4 million illnesses among employed people. Nearly 35 percent of the illnesses among employed people were severe enough to result in a physician visit. Employed people averaged 1.6 days lost from work for each illness resulting in a physician visit, and 1.0 day for illnesses that were less severe.

Acute health conditions that did not result in medical care or at least one-half day of restricted activity were excluded from the NHIS, suggesting that 1.0 day may be an overestimate of the time lost from work by employed people with salmonellosis who did not obtain medical attention. Therefore, we conservatively assumed that these people lost an average of 0.5 day from work. Employed people with salmonellosis who visited a physician were assumed to have lost an average of 1.6 days.

The NHIS excludes hospitalized people, so we conservatively assumed that people who were hospitalized due to salmonellosis lost the same number of days from work as those who visited physicians (1.6 days), plus the average number of days spent in the hospital adjusted for a 5-day weekly work schedule (2.9 days), or a total of 4.5 days.

Premature Death Largest Component of *Salmonella* Costs

The estimated annual costs (in 1998 dollars) of medical care and lost productivity due to foodborne *Salmonella* infections were $0.5 billion, based on the human capital approach for calculating forgone earnings (table 1). Using the less conservative labor market approach, the total annual costs were $2.3 billion. Economists have not reached a consensus about the best method for determining the costs of illness. Both approaches undervalue the social costs due to foodborne *Salmonella* infections, omitting medical expenses and the value of lost productivity due to secondary complications such as reactive arthritis and Reiter's syndrome, and other costs due to pain and suffering, travel to obtain medical care, time lost from work caring for sick children, and lost leisure time.

The forgone earnings of persons who died prematurely due to salmonellosis accounted for a large share of the estimated costs of foodborne *Salmonella* infections under both the human capital approach (65 percent) and the labor market approach (93 percent). The estimated medical costs for foodborne *Salmonella* infections were $118 million under both approaches, with two-thirds of these costs due to hospital care.

The previous ERS estimate of the annual costs (in 1998 dollars) of foodborne *Salmonella* infections

Table 1
Premature Deaths Accounted for Most of the Economic Costs Due to Foodborne *Salmonella* Infections

Severity and cost category	Estimated foodborne illness costs, assuming: Human capital approach[1]	Labor market approach[2]
	Million 1998 dollars	
Severity:		
No medical care	28	28
Physician visit only	48	48
Hospitalized	82	82
Died	307	2,171
Total	464	2,329
Type of costs:		
Medical costs	118	118
Hospital care	79	79
Other medical services	38	38
Lost productivity	347	2,211
Total	464	2,329

Notes: Totals may not add due to rounding. All estimates assume that 95 percent of *Salmonella* cases are foodborne. [1]The human capital approach incorporates a willingness-to-pay multiplier, and estimates the cost of a premature death as $17,000-$2.2 million (in 1998 dollars), depending on age at time of death. [2]The labor market approach values the cost of a premature death as $1.4-$8.3 million for males and $1.6-$8.5 million for females (in 1998 dollars), depending on age at time of death. The values for males and females differ because average life expectancy is higher for females.

ranged from $0.9 billion to $3.7 billion under the human capital approach, and from $5.0 billion to $12.8 billion under the alternative labor market approach. The reduction in the estimated costs is due to several factors. Most importantly, we adopted the CDC estimate of 1.4 million annual salmonellosis cases in place of the previous range of 0.8-4.0 million annual cases, and the CDC estimate of 600 annual deaths in place of the previous range of 1,000-2,000 annual deaths.

The estimated costs of foodborne *Salmonella* infections are sensitive to potential errors in the CDC estimate of salmonellosis cases. Errors in estimating deaths are likely to have the greatest effect on the cost estimates because the average cost is much higher for fatal cases than for other cases. The estimated average cost per fatal case is $0.5 million (under the human capital approach) and $3.8 million (under the labor market approach). In contrast, the estimated average cost for other outcomes is $5,460 per hospitalized case, $315 per case visiting a physician, and $24 per case recovering without medical care, regardless of the approach for estimating forgone earnings.

The updated estimates of the annual economic costs due to foodborne *Salmonella* infections provide a new basis for assessing the potential economic benefits of measures to improve food safety, particularly those measures intended to reduce risk factors for *Salmonella* infections. Fatal cases will probably continue to account for most of the economic costs due to *Salmonella* infections. Therefore, more precise cost estimates ultimately may depend on a consensus among economists about the best method for determining the monetary value of a life.

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Innovative Technologies Could Improve Food Safety

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Gamma rays, electron beams, flash or steam pasteurization, steam vacuums, ozonation, ultra-high pressure treatment—these are some of the emerging technologies that U.S. food processors are investigating or implementing to help remove illness-causing pathogens in our food.

Many of these emerging food processing technologies are not new, but rather are innovative or expanded applications of existing technologies that had been examined, developed, or used for other purposes. For example, patents were awarded for the use of ionizing radiation to preserve food in 1905, but commercially, irradiation has been principally used to sterilize medical devices. Among disinfectants, ozone was initially used to cleanse drinking water in France in 1906 and has been used to treat bottled water in the United States since 1982. Processing food with high pressure was first examined in the United States during the late 1890's and early 1900's. However, in response to increased food safety concerns and heightened awareness of potential pathogen reduction abilities of these methods, recent advancements in many of these technologies have made them more commercially feasible in treating food.

The U.S. food processing industry in recent years has faced multiple challenges of expanding markets, increasing competition, and controlling known and newly emerging foodborne pathogens, all of which have raised concerns about the industry's ability to provide a larger, but consistently safe, food supply. Today's food processing system is vastly changed from that of the past where food was grown and sold locally. Many products now travel long distances between producer and consumer, with numerous processing points—from picking, boxing, shipping, to final preparation—separating farm and table.

Recognizing that food may be contaminated anywhere along the production chain, even on products thought to be pathogen-free, processors have realized that some form of intervention to disinfect food, perhaps at several steps, is necessary. But continued outbreaks of foodborne illnesses even after using conventional hot-water sprays, chlorine washes, and chemical treatments have led processors to examine new alternative technologies to help assure the safety of their products.

Government Regulations Boost Interest in New Technologies

Processors' interests in innovative food safety technology are driven partly by new government regulations for inspecting certain foods and controlling foodborne pathogens under the Hazard Analysis and Critical Control Points (HACCP) system. Processors of food covered by HACCP regulations are required to identify food safety hazards and indicate production steps where an intervention method can prevent or reduce these hazards. The HACCP regulations do not specify the intervention method to meet safety standards but rather places that decision with the processors, who may improve their existing processing methods or adopt a new technology, or combination of technologies, as part of their operating plan.

The HACCP system is quickly becoming a major tool in U.S. food safety efforts. HACCP was mandated for the U.S. seafood industry in 1995. The U.S. Department of Agriculture has since adopted the HACCP system for meat and poultry, which required the largest processors to have a HACCP plan in place by January 1998. All State and

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federally inspected meat and poultry slaughter and processing plants must implement HACCP by January 2000 (see "New Federal Policies and Programs for Food Safety" elsewhere in this issue).

In April 1998, the Food and Drug Administration (FDA) issued proposed rules that require the fruit and vegetable juice industry to use the HACCP system (see "New Juice Regulations Underway" elsewhere in this issue). In response to FDA's call for safer juice products, pasteurization of fruit and vegetable juices, including juice sold as fresh, has become an industry norm. On July 8, 1998, FDA published a rule requiring that unpasteurized fresh juice, which accounts for about 2 percent of all juice consumed in the United States, carry a warning label indicating that the product may contain harmful bacteria. If HACCP goes into effect for the juice industry, warning labels would no longer be needed. Many fresh juice producers, reluctant to place warning labels on their products for fear of losing sales, elected to pasteurize their products in response to the proposed HACCP regulations. Some apple juice and cider producers reported costs, based on size of the operation, ranging from $24,000 to $50,000 to upgrade their equipment to pasteurize their products.

Technologies Are Chosen Based on Benefits...

The greatest benefits to society from enhanced food safety are the reductions in the number of illnesses and deaths. But from an industry viewpoint, adopting a new food processing technology depends on the benefits for the processor versus the costs of the technology. An effective intervention method of killing dangerous foodborne bacteria, parasites, and viruses provides the most direct benefit to processors through production of a safer product, reducing risk of plant shutdowns, product recalls, and liability claims. An associated benefit of some technologies is the slowing of product spoilage, which extends the shelf-life of goods. Other benefits obtained from innovative technologies compared with existing treatment methods may include improved taste, appearance, and nutritional value of products.

...and Costs

Adopting new food safety treatments carries costs. For example, USDA's Food Safety and Inspection Service (FSIS) has estimated that initial "process modification costs" for all meat and poultry plants to comply with HACCP regulations could total between $5.5 million to $20 million. These cost estimates assumed that meat plants that did not comply with HACCP requirements would adopt steam vacuum systems and noncompliant poultry plants would implement antimicrobial rinses. Additional costs would be incurred by processors that implement innovative food safety methods. Expenses may include startup costs for equipment, operational redesign, buildings, and training, as well as variable operating costs for power, water, waste disposal, supplies, maintenance, and labor.

But limited information is available to industry decisionmakers on how to cost effectively control or reduce pathogens. A single new technology may greatly reduce specific pathogens at a cost comparable with, or less than, combinations of existing intervention methods. Other innovative technologies may affect multiple pathogens, or have a higher level of pathogen reduction, at costs higher than methods providing adequate control. Actual implementation costs are uncertain because some innovative technologies are only now starting in-plant operation, other approved methods are not yet fully embraced by industry, and still other methods are being tested onsite but lack formal approval from government regulatory agencies.

Effectiveness of Technologies Differs

Food safety technologies are based on thermal or nonthermal treatments to reduce foodborne pathogens. Thermal disinfectant technologies rely on heat, either dry or steam, to dehydrate or injure microorganisms. Heat, particularly through cooking, has long been the principal method of eliminating pathogens in food. New technologies, including steam pasteurization and steam vacuuming, continue to rely on heat to control or reduce harmful microorganisms in meat. Flash pasteurization is a rapid heating and cooling process to eliminate bacteria in fruit and vegetable juices. Nonthermal disinfectant technologies, such as chemical rinses, irradiation, ozonation, and ultra-high pressure, work without heat, affecting the composition and cellular activity of pathogens, ultimately killing them.

Which of the new food safety intervention methods are best? No single technology can be practically applied to all products and, within technologies, pathogen reduction varies among products treated. For example, a thermal intervention method may work for meat but not for heat-sensitive produce like lettuce. Where a water-based technology may effectively clean some produce, it may not be feasible for treating water-sensitive products like strawberries or raspberries. Within technologies, such factors as time of exposure, treatment temperature, and organic material levels or

acidity of treatment water affect the effectiveness of intervention methods in reducing pathogens.

Thermal Technologies

Several large beef producers in the United States and Canada have adopted steam pasteurization systems, which gained USDA approval for use on beef in December 1995. These systems pass freshly slaughtered beef carcasses, already inspected, washed, and trimmed, through a chamber that exposes the beef to pressurized steam for approximately 6 to 8 seconds. The steam raises the surface temperature of the carcasses to 190-200 degrees Fahrenheit. The carcasses are then cooled with a cold-water spray. This process has proven successful in reducing pathogens, such as *E. coli* O157:H7, *Salmonella*, and *Listeria*, without use of any chemicals.

A steam pasteurization system installed in very large beef processing plants, handling up to 400 carcasses per hour, costs approximately $1 million, according to industry sources. Limited capacity systems, with a cost of $200,000 to $250,000, are also being developed for smaller beef processors and possibly for poultry and pork producers. Steam pasteurization systems have low operating costs as expenses include only those for power to generate steam and to dispose of the small amount of waste water.

Related to the steam pasteurization system are hand-held steam vacuums used to spot clean carcasses of fecal contamination. Steam vacuums, at a per unit cost of $13,000, employ simple technology and are widely used in the meat processing industry today. But the merger of steam and vacuum concepts has led to the development of a novel device to pasteurize the surface of raw meat. The device kills bacteria by first removing through a vacuum the air surrounding the meat, exposing the meat surface to steam at approximately 280 degrees Fahrenheit for less than 1/10 second, and finally re-evaporating through a cooling vacuum the steam condensation formed on the treated meat. The initial vacuum process removes air and water acting as an insulator on the product, which allows the steam to have direct contact on the meat, improving the effectiveness of the process and shortening the treatment time. The entire process takes less than one second to complete, thus no cooking of the product occurs. This vacuum/steam process is in the experimental stages, with USDA's Agricultural Research Service and industry jointly providing research.

Flash pasteurization is a high-temperature, short-time treatment in which pourable products, such as juices, are heated for 3-15 seconds to a temperature that destroys harmful microorganisms. The product is subsequently cooled and packaged. This aseptic processing reduces the thermal stress on the product and, consequently, is said to better maintain the product's nutrients and flavor. Most drink boxes and pouches use this pasteurization method as it allows extended, unrefrigerated storage while providing a safe product.

Nonthermal Technologies

The nonthermal food decontamination technology most generally known is irradiation. FDA approved irradiation's use on wheat and potatoes during the 1960's; spices, pork, fruits, and vegetables during the 1980's; poultry in the early 1990's; and, most recently, red meats (beef, veal, lamb) in December 1997. Commercially, however, irradiation has only been used in the United States to treat spices and seasonings found in processed foods, with limited additional application for fruits, vegetables, and poultry. Irradiation of red meat awaits final performance guidelines and standards from USDA (see "Food Irradiation—An Update" elsewhere in this issue). USDA issued proposed standards for public comment in February 1999.

Recent studies estimating the costs of foodborne illnesses have helped cultivate interest in irradiation technology. Widespread use of irradiation in the food processing industry, however, is hindered by some lingering doubts, among them concerns of consumer acceptance of irradiated food and economic considerations about processing food with existing commercial irradiation systems. Commercial irradiation technology, originally designed to sterilize medical devices through use of radioactive cobalt-60, is difficult to transfer to food processing. In treating food, the necessary exposure periods to cobalt-60 gamma radiation to achieve disinfection may increase product turnaround time and discolor food. Stand-alone irradiation plants located away from the processor are economically impractical in treating perishable food because of shipping time and costs. Traditional in-house gamma ray irradiators may be feasible only for large food processors because of high startup capital costs, which exceed $5.5 million. The seasonal nature of many agricultural products presents further concerns about irradiator "down time," leading to cost considerations regarding year-long monitoring of irradiators, continuous natural loss of radioactive material processing power, and licensed-operator training and retention.

To reduce the costs of irradiation, one company has designed a prefabricated unit that uses dry-stored cesium-137 as its power source. This

design eliminates the space requirements of water pools needed to shield cobalt-60 systems. These cesium-137 units, some that require only 100 square feet of floor area, would be installed as part of the production process. The cesium units, like cobalt-60 irradiators, are intended to treat fully processed and packaged foods already stacked on pallets ready for shipping. The smallest cesium-137 irradiators cost approximately $1.5 million and, according to their manufacturer, can treat as little as 20 million pounds of product per year at an average cost of 2 cents per pound. Although irradiator "down time" issues remain, cesium-137 systems lose processing power at a much slower rate than cobalt-60 systems and some designs may reduce the time and expense for operator training. USDA's Agricultural Research Service and private industry have a cooperative research and development agreement to further test and evaluate a commercial-size cesium-137 irradiator that is scheduled to be installed at a USDA research facility in late 1999.

Electron beam technology, an alternative to gamma ray irradiation, uses high-energy electrons to penetrate products in their final shipping packaging, destroying harmful microorganisms within seconds. Run by standard electrical power, electron beam technology eliminates some concerns regarding system "down time" and continuous monitoring as the system is simply shut down by turning off the power. Pathogen reduction through electron beam technology is limited by the thickness and density of the treated product. For example, ground beef can be effectively treated at a depth of 4 inches in its final retail package. Electron beam capital costs are comparable with those for gamma irradiators, estimated at $5 million for a system designed to treat 100 million pounds of product per year. However, smaller, lower cost electron beam systems that are integrated directly into a food processing plant's production line are being developed.

Ozone, a form of oxygen that acts as a disinfecting agent, was deemed "generally recognized as safe" (GRAS) to treat food by an independent panel of scientists in July 1997. Ozone, long recognized as a disinfectant for municipal water supplies, has been used to treat most U.S. bottled water since the FDA affirmed ozone as GRAS for bottled water in 1982. Application of ozone as a disinfectant in other food products will require separate FDA approval. Ozone acts as a disinfectant in either its gaseous state or when dispersed in water. As a gas, ozone is an alternative cleansing agent for water-sensitive products, such as strawberries and raspberries, and was approved by USDA for the storage of meat in 1957. Research has shown that ozonated water is effective in reducing pathogens on surfaces of meat, poultry, and vegetables. Recapturing and reozonating wash water reduces water and discharge costs, particularly for high water users, such as poultry, fruit, and vegetable processors.

Capital costs of aqueous ozone systems vary, depending on size, ranging from $150,000 for a system appropriate for large poultry operations to $25,000 for small systems. Gaseous ozone systems for a large meat processor, for example, may cost $250,000, depending on the number of ozone generators needed. As with many emerging food safety technologies, commercial use of ozone systems to treat food is relatively unproven and, therefore, identification of best applications and general adoption of the technology has been slow.

Ultra-high pressure (UHP) technology has two applications in food processing—cutting food with UHP waterjets and destroying pathogens with hydrostatic pressure. UHP waterjets have been commercially used in the food processing industry for almost 20 years. The UHP waterjet is a USDA-approved method to cut and portion products, such as chicken, fish, and pizza. Waterjets eliminate the possibility of cross-contamination of products, if bacteria are present, that can occur with traditional cutting knives.

With recent advancements in ultra-high pressure engineering, commercial interest in reducing foodborne pathogens by exposure to hydrostatic pressure has increased. Although USDA scientists initially documented the use of pressure to preserve milk, fruits, and vegetables as early as 1899, the first UHP-treated foods were commercially introduced in Japan in the 1990's. In the United States, automated UHP equipment is being developed for commercial application to treat pourable products, such as juices, dressings, soups, and salsa. Research has shown that exposure to UHP for 30 seconds to 2 minutes destroys foodborne pathogens and microbes that spoil food but does not affect flavor, appearance, or nutritional value. Processing food with pressure is more expensive than traditional heat pasteurization because of high capital costs of UHP equipment, adding approximately 10-50 cents per gallon of product according to industry sources.

Industry Faces Choices and Unknown Costs

Each emerging food processing technology has its advantages and disadvantages, and research continues on which decontamination processes, or combination of methods, provide maximum benefits for specific products. In addition to improving food safety, adoption of pathogen reduction methods by

food processors depends on developing safeguards to ensure worker safety and satisfying regulatory and environmental constraints. These concerns add to the complexity in deciding which technology to use.

Technical feasibility and regulatory approval do not guarantee that food processors will adopt a technology. Each emerging technology must also show that it cost effectively reduces or controls pathogens compared with competing treatments, thereby providing a market advantage to the food processor, before commercial adoption. Even then, commercial use of an expensive, new technology may be limited to large food processors who can afford to buy or lease innovative treatment systems. A remaining concern—consumer acceptance—is a final obstacle before industry implements a little known food processing technology.

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Food Irradiation– An Update

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Irradiation, a process that exposes products to ionizing radiation, can control or reduce microbial pathogens (illness-causing bacteria, parasites, and fungi) and can extend the shelf-life for some perishable food products, such as potatoes and strawberries. In the United States, irradiation is approved to control insects in foods, delay ripening and sprouting in fresh fruits and vegetables, decontaminate spices and dried vegetable seasonings, and control or reduce foodborne pathogens in pork and poultry.

Use of irradiation on foods requires approval by the U.S. Food and Drug Administration (FDA). USDA's Food Safety and Inspection Service (FSIS) must also grant approval for meat and poultry uses. Federal regulators have so far approved two uses of irradiation for meat and poultry: inactivating *Trichinella spiralis* (the parasite responsible for causing trichinosis) in fresh or previously frozen pork and controlling such pathogens as *Salmonella* in uncooked poultry. In December 1997, FDA approved irradiation for red meat (such as beef and lamb) to control foodborne pathogens and extend shelf life. In February 1999, USDA proposed allowing the irradiation of raw meat and raw meat products; a final rule will be published after incorporating public comment.

Under USDA's proposal, irradiation would be permitted to treat refrigerated or frozen uncooked meat and some meat products. USDA's proposal stipulates that irradiation of meat will be voluntary—no meat processor would be required to use the process.

The proposed rule requires that irradiated meat and meat products bear the radura symbol (fig. 1) and a statement indicating that the product was treated by irradiation. For unpackaged meat products, the statement and logo must be conspicuously displayed to purchasers. USDA is also proposing that irradiated meat used as an ingredient in a food product be listed as such in the listing of ingredients.

Figure 1
Radura Symbol

A Look at Benefits and Costs

While complete estimates of the costs and benefits of irradiation are not available, a 1997 *FoodReview* article examined the effects of irradiating ground beef for pathogen control. This study by USDA's Economic Research Service (ERS) estimated the medical costs and productivity losses related to two foodborne illnesses, salmonellosis and *E. coli* O157:H7 disease, associated with ground beef, as well as industry costs of irradiating ground beef. These estimates have now been updated using more recent, higher estimates of the number of illnesses from ground beef-related *E. coli* O157:H7 disease.

Estimated net social benefits (benefits minus costs) depend on the cost of irradiating ground beef and the extent of the foodborne illness prevented. If 25 percent of the 7 billion pounds of ground beef consumed in the United States were irradiated, and this treatment successfully prevented 25 percent of foodborne illnesses from *Salmonella* and *E. coli* O157:H7 in ground beef, ERS researchers estimate the net annual benefits would range from

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Table 1
Net Benefits of Irradiating Ground Beef Depend on Cost[1]

Assumed cost per pound to irradiate	Range of estimated social benefits[2]	Estimated industry costs	Range of estimated net benefits[2]
Cents	*Million 1996 dollars*		
1.6	31.8 to 203.1	28.6	3.2 to 174.5
5	31.8 to 203.1	89.3	-57.5 to 113.8

[1]Benefits and costs are in 1996 dollars and also differ from previous ERS estimates because of new data on *E. coli* O157:H7 illnesses and deaths and 1996 data on U.S. ground beef supply. Table assumes that by irradiating 25 percent of the U.S. ground beef supply, 25 percent of foodborne illnesses from *Salmonella* and *E. coli* O157:H7 in ground beef would be prevented. [2]Range is due to the uncertainty in the annual number of foodborne illnesses and the method used to value premature deaths.

-$57.5 million to $174.5 million in 1996 dollars.

Raw foods of animal origin, such as meat, poultry, seafood, dairy products, and eggs, are the most likely to carry pathogens. Ground beef poses higher food safety risks than other cuts of beef because the grinding process spreads any pathogens that may be present on the surface of the meat throughout the ground beef. An individual hamburger patty may contain meat from many cattle, increasing the risk of contamination. If the hamburger patty is insufficiently cooked, pathogens in the middle of the patty can survive. Whether a consumer gets sick depends on a number of factors, including the type and number of pathogens ingested and the health of the individual.

Data from the U.S. Centers for Disease Control and Prevention (CDC) indicate that about 49 percent of the annual cases of *E. coli* O157:H7 disease (or 9,800 to 19,600 cases) are due to consumption of insufficiently cooked ground beef. USDA estimates that roughly 3 percent of the annual cases of salmonellosis (or 23,200 to 116,000 cases) are attributed to the same cause. The annual medical costs and productivity losses from consuming ground beef tainted with *Salmonella* or *E. coli* O157:H7 was estimated between $127 million and $812.2 million. Costs varied depending on estimates of annual cases.

If 25 percent of the U.S. ground beef supply were irradiated at a cost of 1.6 cents per pound, the net social benefits range from $3.2 million to $174.5 million per year, according to ERS estimates (table 1). However, smaller volume plants and plants without onsite irradiation facilities are likely to incur higher irradiation treatment costs. At a cost of 5 cents per pound, industry costs could outweigh social benefits by $57.5 million at the lower range of estimated social benefits.

What's Ahead?

Despite scientific evidence of the effectiveness and safety of irradiation and regulatory approval of the process for specific uses, few food processors and retailers are offering irradiated products. Some processors and retailers question whether consumers will buy irradiated products and fear boycotts threatened by groups opposed to food irradiation.

Although irradiating ground beef would likely reduce foodborne illness and extend shelf-life, demand may be insufficient. To date, the market for irradiated pork has not developed, while irradiated poultry is purchased primarily by selected healthcare and foodservice establishments.

Adoption of irradiation by the food industry hinges on sufficient consumer acceptance. Also, producers, retailers, and foodservice operators will compare the cost of irradiation with other technologies for reducing pathogen contamination of foods (see "Innovative Technologies Could Improve Food Safety" elsewhere in this issue). If these factors bear out in favor of irradiation, then the food industry may further adopt the technology.

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New Juice Regulations Underway

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Each year Americans experience 16,000 to 48,000 cases of foodborne illness from fruit and vegetable juices, according to Food and Drug Administration (FDA) estimates. Increasing public concern and recent outbreaks from bacteria such as *E. coli* O157:H7 have led to new regulations designed to reduce the risk of juice contamination.

In October 1996, at least 66 people in the Western United States and Canada became ill and a 16-month-old girl died after drinking unpasteurized apple juice contaminated with *E. coli* O157:H7. The company that produced the juice pleaded guilty to violating Federal food safety laws and will pay a record $1.5 million fine.

The outbreaks from contaminated juice, particularly this 1996 *E. coli* O157:H7 outbreak, led regulators to examine the safety of juice. In April 1998, FDA proposed two regulations to increase the safety of fresh and processed juices. The first would require all domestic and foreign fruit and vegetable juice processors to use Hazard Analysis and Critical Control Point (HACCP) procedures to prevent, reduce, or eliminate hazards in juice. The second rule, requiring warning labels on all juice that has not been pasteurized or otherwise treated to control illness-causing pathogens, was finalized by FDA in July 1998. Its purpose is to provide consumers with information to lessen their risk until the HACCP rule is enacted.

Are All Juices Equally Safe?

Juice consumption in the United States has steadily increased from 5.8 billion gallons in 1987 to 7.5 billion gallons in 1997. Currently, almost all juice sold in the United States is heat pasteurized, a process that raises the temperature of the juice high enough to kill pathogenic bacteria. Only about 2 percent of juices are not pasteurized. In addition to killing pathogens, pasteurization or equivalent heat treatments destroy enzymes and naturally occurring spoilage organisms, thus making the product more shelf-stable.

Most refrigerated juice sold in bottles or cartons at grocery stores and other outlets is pasteurized. Unrefrigerated juice in bottles, cans, and laminated paperboard boxes has been heat-treated and is therefore generally considered safe. Frozen, concentrated juices are generally pasteurized during the concentration process.

Farmer's markets and cider mills often sell unpasteurized apple cider. Fresh-squeezed or pressed juice likely has not been processed to specifically control pathogens and therefore may pose some risk, despite a common belief that less-processed products are healthier. A handful of *E. coli* O157:H7 outbreaks have been linked to apple cider. *E. coli* O157:H7, which primarily strikes children, causes a wide range of health outcomes, from mild cases of diarrhea to secondary complications and sometimes premature death. The most serious complication is hemolytic uremic syndrome (HUS), which is essentially kidney failure that may require dialysis and kidney transplants and which may lead to permanent kidney failure and other health problems. Cider made from apple "drops," apples that have fallen to the ground and that might have come into contact with animal feces, such as from cattle or deer, could pose a higher food safety risk than cider made from tree-picked apples.

In 1995 and 1999, there were outbreaks of salmonellosis from unpasteurized orange juice, a product normally considered safe from such bacteria because of its high acidity. Over time, bacteria can develop

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resistance to inhibitory environments (for example, more acid resistance), making food safety precautions even more essential. Most juice-related outbreaks have been from fruit juices, though a 1993 illness from *Clostridium botulinum* in homemade carrot juice was reported in Washington State.

Prior to July 1998, the only mandatory identification for juices was a labeling requirement for pasteurized orange juice; no other juices had to be marked as pasteurized. Consumers of unlabeled juice had not known if they and their families were taking the risk of drinking an unpasteurized product.

Two Regulations Designed To Make Juice Safer

In December 1996, FDA held a 2-day public meeting to review manufacturing practices, science, and technology relating to fresh juices and to consider measures to provide safer fruit juices to the public. After this meeting, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), an independent advisory panel guiding FDA and the U.S. Department of Agriculture on food issues, concluded that juice, particularly unpasteurized juice, poses some safety concerns. The panel recommended that juice processors adopt Hazard Analysis and Critical Control Point (HACCP) procedures.

HACCP procedures use science to identify the steps in the food production chain where food hazards are most likely and to put controls in place to prevent contaminated food from going to the marketplace. The seven principles of HACCP are to (1) conduct a hazard analysis, (2) determine the critical control points, (3) establish critical limits for hazards, (4) establish monitoring procedures, (5) establish corrective actions, (6) establish verification procedures, and (7) establish recordkeeping and documentation procedures.

FDA used the NACMCF input and additional comments from the public and the juice industry to propose two regulations to increase the safety of both fresh and processed fruit and vegetable juices. These proposals were released in April 1998. The first proposed regulation requires all fruit and vegetable juice processors to use HACCP systems to control hazards in juice. There are already existing and soon-to-be-implemented HACCP regulations in the United States for meat, poultry, fish, and fishery products. FDA will evaluate all comments on the proposal and use this information to develop a final HACCP rule for juice, if such a rule is supported by the record.

The second rule concerning juice warning labels was proposed to cover the phase-in time necessary to implement the HACCP regulation. Although the time schedule for the HACCP rule was extended, FDA finalized and published the labeling rule in the *Federal Register* on July 8, 1998, in time for the fall apple cider season, the season when most unpasteurized juice is consumed. This rule requires warning labels on all juice that has not been pasteurized or otherwise treated to prevent, reduce, or eliminate illness-causing pathogens. Both rules target microbial pathogens, such as illness-causing bacteria, though the HACCP rule also controls for physical and chemical contamination.

The Proposed HACCP Regulation

The proposed HACCP regulation targets manufacturers of packaged fruit and vegetable juice. Packaged juice is any container of juice intended for retail sale for consumption outside the retail environment. Therefore, the regulation excludes fresh juice squeezed for consumption on a firm's premises (for example, by the glass), such as juice sold and served in juice bars and restaurants. One part of the proposed HACCP rule requires that packaged juice and juice products be processed in a manner that will produce, at a minimum, a five-log reduction (a decrease of the pathogen by 100,000-fold) in the most resistant pathogen of public health significance likely to occur in juice, for a period at least as long as the shelf life of the product when stored under normal and moderate abuse conditions. The NACMCF recommended the use of *E. coli* O157:H7 or *Listeria monocytogenes* as the target pathogen, though other pathogens such as *Salmonella* may be appropriate. To date, FDA has not stipulated particular pathogens for the proposed regulation; the selection may depend on the type of juice and the growing region. For example, oranges grown in California may be more or less likely to be contaminated with a particular pathogen than those grown in Florida.

Heat pasteurization will achieve the required five-log reduction. However, processors can choose what risk-reducing methods they want to use—pasteurization, another food safety precaution, or a combination of precautions. For example, processors may reach a five-log reduction in citrus juice through careful culling and sanitizing of the fruit followed by appropriate extraction of the juice.

Processors affected by this proposal include both farms and manufacturers that make packaged juice products. Retailers of packaged juice, growers and transporters of raw products, and small retail processors who sell less than 40,000 gallons of fresh juice per year directly to consumers and other retail establishments may be exempt from this rule. The proposed phase-in period for this regulation varies by firm size, with larger firms

expected to comply earlier than smaller firms.

Warning Labels on Unpasteurized Juice

The warning label regulation targets packaged fruit and vegetable juice. Unpasteurized juice or juice that does not meet the five-log reduction must carry the following warning label:

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

People with weakened immune systems include people who have AIDS, organ transplants, cancer, and other significant health problems. As 98 percent of all juice sold in the United States is pasteurized, the labeling regulation affected roughly 2 percent of juice produced. According to a spokesperson at the U.S. Apple Association, small manufacturers were disproportionately affected because of their inability to afford pasteurization equipment.

The compliance dates for warning labels depend on the type of juice. Following publication of the final labeling rule on July 8, 1998, manufacturers of packaged apple juice and apple cider had until September 8, 1998, to comply, whereas manufacturers of all other unpasteurized juices had until July 8, 1999. However, some juice companies filed agreements with FDA requesting additional time, beyond November 5, 1999, to comply with the warning label requirement. All manufacturers of packaged juice, regardless of size, may temporarily comply by using signs or placards posted at the point of sale for up to 1 year from their respective compliance dates. This temporary alternative gives firms time to make label changes and deplete existing label inventories. According to the U.S. Apple Association, many firms producing unpasteurized juices began pasteurizing their juice instead of opting to use the warning label.

What Firms Are Affected?

Both the proposed HACCP rule and the final labeling rule target juice manufacturers that sell packaged juice in the United States. Neither rule covers firms that squeeze and sell fresh juice for consumption on their premises (by the glass), such as juice bars and restaurants. Grocery stores, health food stores, and other retail outlets that sell fresh-squeezed juice for offsite consumption do not have to specifically treat their juice to control pathogens, but they must use warning labels.

FDA estimates that if both rules are adopted, up to 40 million additional gallons of juice would be pasteurized each year. FDA's preliminary regulatory impact analysis (PRIA) estimates that pasteurization would kill all *Salmonella* and *E. coli* O157:H7 in juice and that 14 percent of all unpasteurized juice would be exempt from the proposed HACCP regulation. FDA estimates that 86 percent of the 4,000 *Salmonella* cases and 1,700 *E. coli* O157:H7 illnesses attributed to juice each year would be prevented by the proposed HACCP regulation; however, only 9 percent of the 2,800 annual *Bacillus cereus* cases from juice would be prevented. Pasteurization and other heat treatments are less effective against *Bacillus cereus* as its heat-resistant spores may produce illness-causing toxins. The PRIA also estimates that the interim labeling regulation would result in a 5- to 16-percent decline in juice consumption and associated juice-related foodborne illnesses. The PRIA concludes that the $3 billion-$4 billion in savings from averted medical costs and lost productivity from the proposed rules outweigh the $240 million cost of implementing the rules.

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U.S. Firms Invest in Mexico's Processed Food Industry

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The 1994 North America Free Trade Agreement (NAFTA) between the United States, Canada, and Mexico was established to enhance trade. The successful increase in trade was accompanied by an even more important sharp increase in foreign direct investment (FDI) between the partners, especially between the United States and Mexico.

U.S. exports of processed foods to Mexico, mostly processed meats, poultry, animal fats, and vegetable oil, increased from $1.1 billion in 1990 to $2.8 billion in 1998. U.S. processed food imports from Mexico grew from $1 billion to $2.5 billion in the same years, and were mostly malt beverages, prepared fresh and frozen fish, and distilled spirits (table 1).

At the same time, foreign direct investment (FDI) between the United States, Canada, and Mexico increased sharply, paving the way for a regional food system. FDI, or substantial ownership investments in foreign businesses, allows the investing firm to exercise control over the use of those assets (unlike foreign portfolio investment, which is passive and does not seek control over decisionmaking).

The $6.5 billion in sales generated by U.S. food processing affiliates in Mexico overshadowed U.S. exports of processed food products to Mexico by more than a 2-to-l ratio in 1998, making FDI more responsible than direct exports for the increasing presence of U.S. food processing firms in Mexico (fig. 1). U.S. FDI in Mexico's $47 billion processed food industry increased from $210 million in 1987 to $5 billion in 1997 (fig. 2).

Mexico is now the third largest host country for U.S. FDI after the United Kingdom and Canada. Nearly three-fourths of the U.S. FDI in Mexico's food processing sector is in firms producing a wide variety of highly processed foods including snack foods, edible vegetable oils, mayonnaise and salad dressing, meat and poultry, concentrates and flavorings, confectionery products, and pasta and related products. About one-tenth of the U.S. FDI is in flour mills or bakery product companies; about 15 percent is in breweries and soft drink bottlers. Less than 5 percent is in fruit and vegetable processors.

Investor-Friendly Laws Increase FDI

This increase in FDI continues a trend that began prior to the enactment of NAFTA, when the Mexican Government changed many FDI rules in the late 1980's. In 1988, Mexico reformed its most important FDI law to allow foreign investors to own a larger than 49-percent share of investment properties. NAFTA strengthened the rights of foreign investors to get back their initial investment and profits by granting equal treatment under the law for foreign and domestic investors and by prohibiting new laws that could change the status of existing foreign investments.

Through an exchange with Mexico's Department of Agriculture and other government agencies under the Mexico Emerging Markets Exchange Program, administered by USDA's Foreign Agriculture Service, researchers at USDA's Economic Research Service gained new insight into U.S. investment in Mexico's food processing and agribusiness. About $1.6 billion of the $4 billion of FDI inflows into Mexico's food and beverage industries that occurred during 1994 to 1998 came from the United States. Canada, the United Kingdom, the Netherlands, and France also made significant direct investment in Mexico's food indus-

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Table 1
Processed Food Trade Between the United States and Mexico Is a Two-Way Street

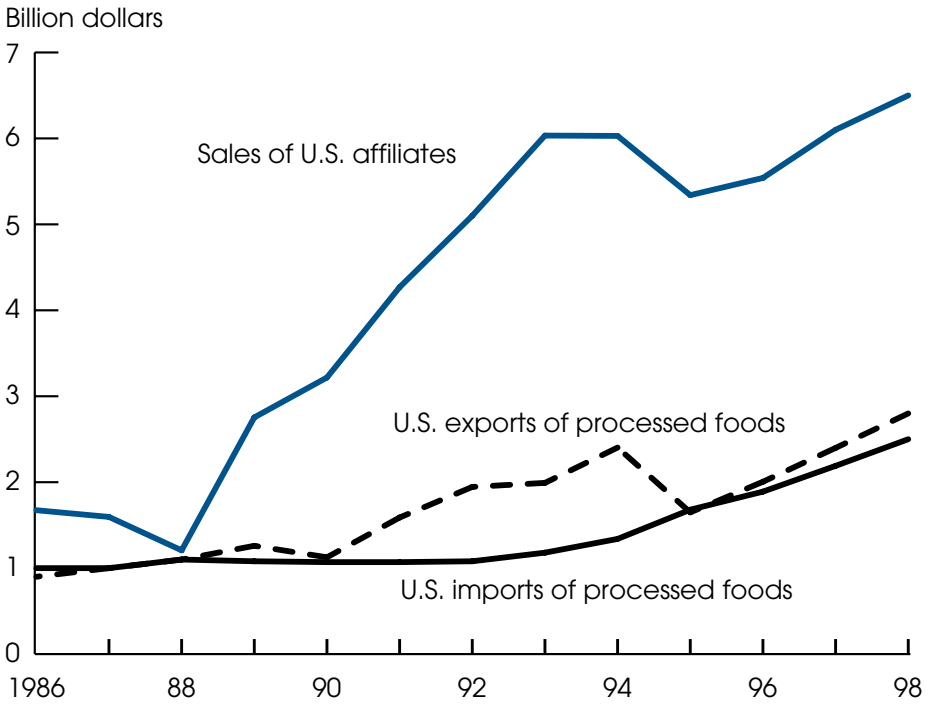
U.S. exports to Mexico		U.S. imports from Mexico	
Processed food industry	1998 sales	Processed food industry	1998 sales
	Million dollars		*Million dollars*
Meat processing	798	Malt beverages	551
Vegetable oils	314	Prepared fresh and frozen fish	437
Poultry slaughter	242	Distilled and blended spirits	150
Animal and marine fats	192	Canned fruits and vegetables	126
Wet corn milling	153	Salad dressings	93
Dry and condensed milk	132	Bottled and canned soft drinks	83

Source: USDA/ERS Processed Food Trade data set.

try (fig. 3). The largest foreign direct investments to Mexico are in companies that produce beer, soft drinks, and snack foods (table 2).

U.S. FDI continued to flow into Mexico's processed food industry in 1998; the largest investments were by Coca-Cola in Mexico's beverage industry. The U.S. firm Corn Products Incorporated expanded its interest in a joint venture with Arancia-CPC, Mexico's largest corn product processor, which makes corn oil, starches, and inverted sugars that are used in a variety of processed foods and industrial products. Mission Produce, a U.S. produce company, is opening its second avocado processing plant in Mexico. The U.S. meat company Smithfield Foods is negotiating to buy Grupo Alpro, Mexico's largest pork processing company. Many U.S. food companies, such as Campbell Soup, General Mills, Ralston Purina, and PepsiCo, have had plants in Mexico for decades.

Figure 1
Sales of U.S. Affiliates in Mexico More Than Double the Value of U.S. Exports of Processed Food to Mexico

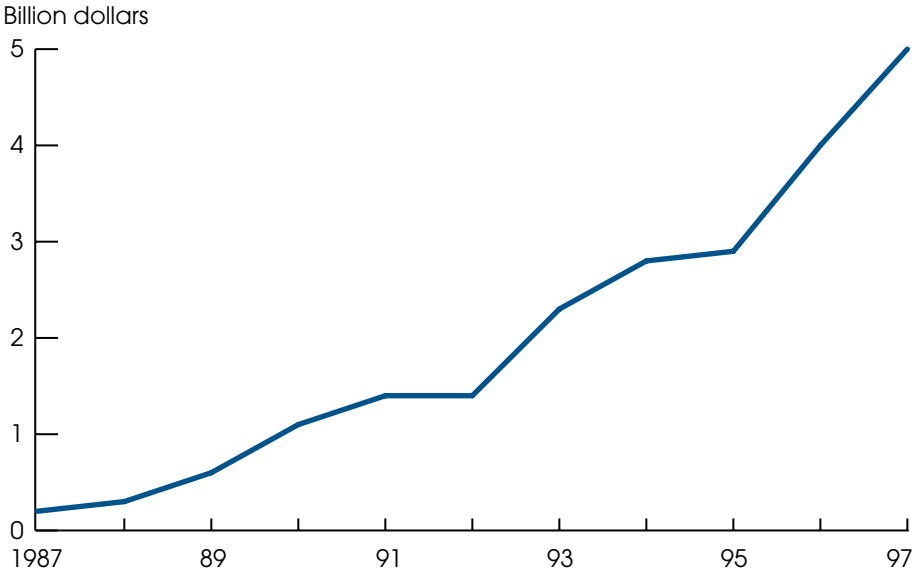


Source: USDA/ERS Processed Food Trade data set and Bureau of Economic Analysis, U.S. Department of Commerce data.

Economic Growth Also Increased FDI

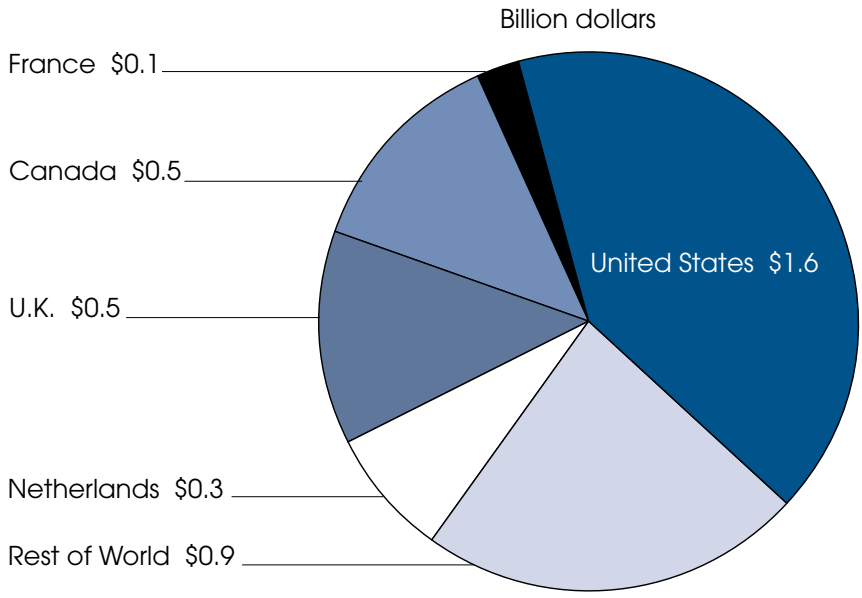
U.S. food processing affiliates in Mexico export an average of only 2.5 percent of their sales to the United States. Because most of the processed foods produced in Mexico stay in Mexico, Mexican economic growth has been the principal macroeconomic prerequisite for FDI. Except for a downturn in 1995 and slow growth at the close of 1998, the Mexican economy generally experienced healthy economic growth since 1990. Even with 1995's setback, Mexico's economy, as measured by its gross domestic product (GDP), has grown an average of 3.5 percent a year between 1990 and 1998. This economic growth led to a 9-percent raise in inflation-adjusted per capita income in Mexico from $3,100 in 1990 to $3,389 per year in 1998. (Based on relative retail prices in the United States and Mexico, this $3,389 has buying power in

Figure 2
U.S. FDI in Mexico's Processed Food Industry Grew 25-fold Between 1987 and 1997



Source: Bureau of Economic Analysis, U.S. Department of Commerce.

Figure 3
United States Leads in FDI in Mexico's Processed Food Industry
New FDI in Mexico's food processing totaled $4 billion during 1994-98



Source: Secretaria de Comercia y Foment Industrial, Mexico.

Mexico equal to $7,700 in the United States.) Mexico's GDP is forecast to grow 2 to 3 percent in 1999, and should grow faster than that predicted for the U.S. and Canadian economies during the coming decade.

Higher incomes have increased food demand by Mexican consumers and sales for Mexican food processing companies. Overall sales in Mexico's food and beverage industry grew from $37 billion in 1990 to $47 billion in 1997, a 26-percent increase. Higher sales in the Mexican food processing industry encouraged increased investment, including investment by foreign firms.

NAFTA helped Mexico's economy to grow, leading to increased investor confidence in Mexico. A synergy between investment and trade developed as U.S. firms located food processing plants by comparative advantage based on shifting production and marketing costs. As long as the Mexican business environment was stable, U.S. firms could do business in a country with low labor costs relative to the United States and a depreciating currency relative to the U.S. dollar. The strengthening of the dollar vis-à-vis the peso during the 1990's made purchase of Mexican companies less expensive to U.S. investors.

Some U.S. products, such as vegetable oil, dried milk, and flavorings, are exported to U.S. affiliates in Mexico for further processing into mayonnaise, salad dressings, bakery products, and beverages. Most U.S. beef and poultry exports are sold directly to wholesalers and retailers (such as Wal-Mart's Mexican affiliates in the case of beef) and some is further processed. The devaluation of the Mexican peso lowers labor and related costs in terms of dollars, so that the cost of the finished food product made in Mexico is often less

than if the finished product had been exported from the United States, again making FDI attractive for expanding markets.

Smaller U.S. Investment in Mexico's Farm Sector

U.S. companies have also invested in Mexico's farmland, poultry farms, and other production agriculture, but not to the same extent as in the processed food sector. Mexico has limited irrigated land attractive to U.S. companies wanting to invest in higher value production agriculture, such as vegetables. U.S. companies account for 78 percent of the total FDI in Mexico's production agriculture, which amounted to $45 million from 1994 to 1997.

Nearly three-fourths of the U.S. investments in Mexico's agricultural sector center on fruits, vegetables, and flowers. Minor interests are in livestock and poultry production. FDI has often been combined with contract farming, where U.S. processors and distributors contract with Mexican growers to deliver products to packing or processing facilities. In the vegetable industry, U.S. firms often invest in Mexican packing sheds rather than in farmland. Mexico's poultry industry has both contract farming and FDI by U.S. firms.

United States Also Hosts Mexican FDI

Mexican firms have also increased their investments in U.S. processed food companies. Sales from Mexican affiliates in the United States amounted to $664 million in 1996 compared with nearly zero in 1990. The two largest Mexican companies with interests in U.S. food processing, the bread baking company GIBSA (see box) and Gruma, a flour, tortilla, and bread maker began exporting products for the U.S. Hispanic market. Minsa, a Mexican corn milling company with six plants in Mexico, now has two corn milling operations in Texas and Iowa. Mexico's DESC acquired Authentic Mexican Food Incorporated, a processor of Mexican-style food based in Texas.

Owning plants in the United States as a hedge against currency fluctuations has been particularly important for companies like GIBSA that import most of their inputs, such as U.S. wheat and vegetable oil, for their Mexican plants. The Mexican peso crisis in 1995 increased GIBSA's costs for imports. Even GIBSA's earnings in Mexico were cut in terms of dollars by the peso devaluation. Using the dollars earned in its U.S. plants, GIBSA could pay for imports for its plants in Mexico. GIBSA and Gruma represent the modern Mexican food

Table 2
Mexican Beer and Malt Industries Are Leaders in New Foreign Direct Investment Since 1994

Processed food industry	1994-98 investments
	Million dollars
Beer and malt	1,115
Nonalcoholic beverages	719
Corn chips and other snacks	426
Other miscellaneous foods	363
Corn milling	271
Products from sugar	104

Source: Secretaria de Comercia y Foment Industrial, Mexico.

GIBSA Expands in the United States

Mexican companies, such as Grupo Industrial Bimbo S.A. (GIBSA), have targeted their sales to certain segments of the U.S. market, especially Hispanics. GIBSA, a leader in Mexico's breadmaking industry, has more than 60 plants in Latin America, Mexico, and the United States, with 57,000 employees and worldwide sales of more than $2.3 billion. In addition to making bread, GIBSA produces other baked goods, wheat and corn flour, snack foods, confections, and frozen fruits and vegetables. GIBSA also produces inputs that are used in the baking industry, such as machinery and plastics.

GIBSA initially exported products from its Mexican plants to the United States, especially to cities with a large concentration of people of Mexican origin. Now, GIBSA has a number of plants that produce bread and tortillas in California, Texas, and Ohio and has a distribution system that covers 16 States, principally in the South and Pacific regions.

Firms such as La Tapatía, C&C Bakery, Pacific Pride, La Fronteriza, Fabila Foods, Suandy Foods, National Foods, Proalsa Trading, and Bimar Foods are among GIBSA's subsidiaries in the United States. One of GIBSA's principal acquisitions during 1998 was Mrs. Baird´s, a leader in the bread-baking industry in the Southwestern United States with sales of more than $300 million. In March 1999, GIBSA further expanded in the United States by acquiring the Four-S Baking Company in Los Angeles with sales of about $40 million.

processing industry, which also includes industrial giants Cerveceria Modelo, FEMSA Cervesa, and Compania Nestlé, all of which have sales in excess of $1 billion.

FDI Enhances Choices, Employment, and Trade

Two-way FDI and trade are further integrating the U.S. and Mexican economies, with capital being provided by U.S. and, to a lesser extent, Mexican firms. Eventually this integration could mean more efficiency in providing food to consumers, as the NAFTA partners become a regional food market. Increased fruit and vegetable trade between Mexico and the United States has extended the season for particular fruits and vegetables. Consumers in both countries have more choices in foods and beverages. U.S. affiliates, for example, lead in the production of deboned chicken and chicken parts in Mexico, while Mexican affiliates have added tortillas, salsa, and other Mexican-style foods to U.S. supermarket shelves.

FDI often encourages more uniformity in food quality in response to purchasers' requirements. For example, Wal-Mart's affiliates in Mexico require a particular grade of beef cut to Wal-Mart's specifications. Uniform supply and quality speed further development of the supermarket and foodservice industries that demand these services.

FDI has increased employment in Mexico by U.S. affiliates and increased investment earnings from U.S. investments abroad. Nearly 84,000 persons earning $772 million were employed by U.S. affiliates in the food industry in Mexico in 1996, compared with 50,000 persons earning $174 million in 1986. U.S. affiliates' net income in Mexico's food processing industry was $288 million in 1996, bringing in a source of reinvested capital for further growth in Mexico's food industry. Mexican-owned food processing affiliates in the United States also have grown and by the end of 1996 employed 5,500 persons.

FDI also increases two-way trade. U.S. exports have increased recently partly because many U.S. affiliates in Mexico import products from the United States for further processing in Mexico. Partially processed products from the dairy, poultry, corn milling, and vegetable oil industries are among the United States' largest food exports to Mexico. Instead of replacing trade, FDI has often successfully fostered trade between Mexico and the United States.

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Breastfeeding: Health and Economic Issues

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Breastfeeding is widely believed to be the most beneficial method of feeding for the health and well-being of most infants. Although not recommended for all mothers (such as those who use illegal drugs, are receiving cancer chemotherapy, or have tested HIV positive), breastfeeding is endorsed by many public health experts as the preferred infant feeding method. Most recently, the American Academy of Pediatrics issued a policy statement recommending that women breastfeed infants throughout the first year of the infants' lives.

The U.S. Department of Agriculture (USDA), which oversees the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), has promoted breastfeeding, both inside and outside WIC, including establishing a Breastfeeding Promotion Consortium to exchange information and collaborate on breastfeeding promotion activities. USDA initiated in August 1997 an ongoing national campaign by Federal, State, and local WIC programs to promote breastfeeding to WIC mothers and to support all women who choose to breastfeed. The "Loving Support Makes Breastfeeding Work" National WIC Breastfeeding Campaign encourages WIC participants to begin and continue breastfeeding, increases referrals to WIC clinics for breastfeeding support, builds general public acceptance of and support for breastfeeding, provides support and technical assistance to WIC professionals in promoting breastfeeding, and calls on friends, neighbors, relatives, the medical and health community, and others to support breastfeeding mothers.

The Surgeon General aims to increase the proportion of mothers who breastfeed their babies in the early postpartum period to 75 percent nationally by 2000 and to increase the proportion who continue breastfeeding until their babies are 5 to 6 months old to at least 50 percent. Breastfeeding generally refers to feeding from the breast but also may refer to feeding breastmilk from a bottle. In 1997, about 62 percent of women giving birth in the hospital report initiating breastfeeding, and approximately 26 percent report continuing breastfeeding at 6 months. Women in lower socioeconomic groups are less likely to breastfeed and breastfeed for shorter lengths of time than higher socioeconomic groups and, thus, are far removed from the Surgeon General's goal. Recent data from a 1996 national survey, for example, indicate that only 42 percent of women from households with incomes less than $10,000 breastfeed at all and only 12 percent breastfeed for 6 months.

Breastfeeding Trends Have Fluctuated

Breastfeeding was the most common way to feed infants well into the 20th century United States. In the last 50 years, however, infant feeding has markedly changed. After World War II, with the development and large-scale manufacture of infant formula, formula feeding became the standard. The breastfeeding rate fell by half between 1946 and 1956, and by 1967, only 25 percent of American infants were being breastfed at the time of hospital discharge. The percentage of infants being breastfed when they left the hospital began to increase steadily from 1971 to 62 percent in 1982, declined approximately 16 percent from 1982 to 1990, and has increased slowly again to hover around 62 percent (fig. 1). Breastfeeding at 6 months has paralleled breastfeeding initiation, although at a considerably lower rate.

A number of reasons have been suggested for why more mothers don't breastfeed: aggressive formula

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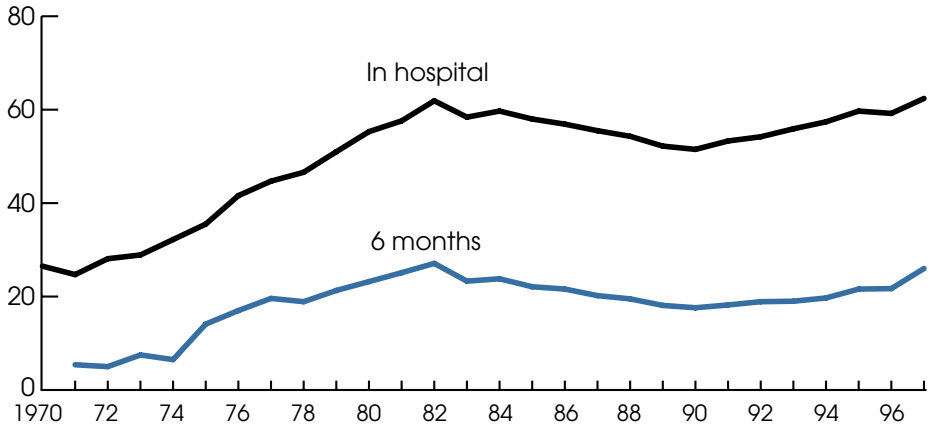
Figure 1
Breastfeeding in the United States Rebounded From Low Rates in the 1970's
Percent



Source: "Mothers" Survey, Ross Products Division, 1997. Note: The percentage of infants being breastfed at 6 months was not measured in 1970.

product marketing, lack of support from family and friends, insufficient knowledge among medical professionals of breastfeeding techniques and hurdles, maternity hospital practices (such as emphasis on short maternal stays), religious beliefs, cultural attitudes, and lack of public acceptance. All or some of these factors may come into play, but it is interesting that the increase in formula feeding parallels a rapid increase in the number of women entering the formal work force.

Breastfeeding and working outside the home are commonly believed to be incompatible. For a woman working outside the home to provide her baby with breast milk, she must have the place and time to nurse the baby or express and store her milk for bottle feeding. Increased female participation in the labor force is frequently blamed for the relatively low duration rates of breastfeeding.

The increase in the number of working women since World War II has been one of the most significant social and economic trends in modern U.S. history. In the United States between 1950 and 1985, for example, female participation in the labor force increased by 178 percent, while the number of men in the work force increased by only 47 percent. By 1997, 59 percent of women (16 years and older) were in the work force, compared with 28 percent in 1940. In 1995, 41 percent of the women employed in the labor force had children under 18 years old, with 55 percent of this group returning to the workplace before their children were 1 year old. Many workplaces seem to lack policies supporting breastfeeding or pumping at job sites, inhibiting continuation of breastfeeding after women return to work.

Breastfeeding Provides Health Advantages

Although some past studies have provided conflicting results about the protective effects of breastfeeding (see box), more recent studies have conformed to important methodological standards and better document the protective effect of breastfeeding against a variety of health problems during infancy and early childhood. Endorsement of breastfeeding from the prestigious American Academy of Pediatrics and American Dietetic Association, among others, reflects two decades of research that shows that breastfeeding improves infants' general health, growth, and development and significantly decreases risk for a large number of acute and chronic diseases. As reported in a 1997 policy statement issued by the American Academy of Pediatrics, research in the United States, Canada, Europe, and other developed countries suggests that breastfeeding decreases the incidence and/or severity of diarrhea, lower respiratory infection, otitis media (ear infection), bacterial meningitis, botulism, urinary tract infection, and necrotizing enterocolitis. For example, breastfeeding is estimated to reduce the incidence of otitis media by one-fourth to one-third in breastfed infants as compared with formula-fed infants (table 1).

According to the Academy, a number of other studies show a possible protective effect of breastfeeding against sudden infant death syndrome, insulin-dependent diabetes mellitus, Crohn's disease, ulcerative colitis, lymphoma, allergic diseases, and other chronic digestive diseases. Breastfeeding also has been related to possible enhancement of cognitive development. A number of studies indicate possible health benefits for mothers—specifically, a reduction in hip fractures in the postmenopausal period, less postpartum bleeding, and reduced risk of ovarian cancer and premenopausal breast cancer.

Economic Benefits Difficult to Accurately Quantify

In addition to individual health benefits, breastfeeding may provide significant economic benefits, both to the individual families and to the Nation. Breastfeeding provides mostly primary and, to a lesser

Table 1
Breastfeeding Has Protective Effects

Illness	Estimated reduction in breastfed infants[1]
Gastrointestinal/diarrhea	1/3-1/2
Otitis media	1/4-1/3
Urinary tract infection	1/5
Bacterial meningitis	1/4-1/16
Necrotizing enterocolitis	1/10

[1]Compared with the rates of occurrence for formula-fed infants.

extent, secondary prevention. Primary prevention is any activity that prevents a disease from ever starting while secondary prevention cures or reduces the severity of a disease. As described above, breastfeeding provides primary and some secondary protection against viral, bacterial, and allergic diseases.

Further study could more accurately assess the economic advantages of promotion and support of breastfeeding initiation and early intervention to help women extend breastfeeding duration. Estimating and comparing costs and benefits of a particular method of infant feeding poses methodological challenges. The health benefits of breastfeeding can extend across a number of conditions, with both benefits to the child and maternal benefits and costs. Several significant economic considerations factor into breastfeeding.

Costs of Breastfeeding Versus Formula

Breastfeeding may bring direct economic benefits to the family by significantly reducing or eliminating the cost of purchasing infant formula. Formula prices rose more than 150 percent during the 1980's, and several studies compared breastfeeding and formula costs. A study reported in a 1993 medical journal article, for example, found that feeding an infant formula costs approximately $260-$400 extra a year than breastfeeding the infant. This differential included the cost of extra food that mothers require for lactation.

USDA's WIC Program is the largest purchaser of infant formula, buying approximately 40 percent of all formula sold in the United States. The cost of infant formula distributed to WIC mothers in 1997 was $567 million after formula company rebates of about $1.2 billion to WIC. Advocates of breastfeeding contend that if more of these women breastfed, overall WIC food costs would decrease.

A 1989 reauthorization of the WIC Program, providing both a mandate and funding, has allowed States to substantially increase breastfeeding promotion. Note, however, that WIC is explicitly promoting breastfeeding because of its health benefits, not because of its possible effects on food costs.

In 1993, the General Accounting Office (GAO) studied the extent that the WIC Program promotes breastfeeding and examined the effects of increased breastfeeding on WIC food costs for a year. Estimating the effect of increased breastfeeding on overall WIC food costs was complicated by a number of factors, including the amount of supplemental formula breastfeeding infants sometimes use, the cost of food packages given to different participants (food packages provided to breastfeeding women often cost more), and the number of women served.

GAO concluded that if WIC were fully funded and serving all eligible recipients, any increases in breastfeeding would decrease total food costs as long as formula-supplemented breastfed infants received no more than 25 percent of the monthly amount of formula given to formula-fed infants. GAO estimated total WIC food costs for fiscal year 1992, using 16 scenarios under varied assumptions. For one scenario, for example, GAO estimated that a 10-percent increase in breastfeeding rates, with breastfed infants receiving 25 percent of the monthly amount of formula given to formula-fed infants, would save the WIC Program almost $408,000. If breastfed infants received 10 percent of the formula allowed to formula-fed infants, a 10-percent increase in breastfeeding rates would save the program approximately $750,000.

Health Care Benefits

Given that breastfeeding decreases the incidence and/or severity of specific illnesses in infants, it may significantly defray or reduce health care costs. An economic analysis of the health care savings of breastfeeding and formula feeding would be complex. Several of the illnesses that breastfeeding and formula feeding purportedly affect are chronic, with costs and savings that could accrue over several years and, in some cases, over a lifetime. Otitis media, for example, if recurrent or not promptly treated, may lead to hearing loss, tinnitus, and brain abscess. Another problem is obtaining comprehensive data on treatment costs (hospital or outpatient) for various childhood illnesses for which breastfeeding may help to defray. Existing studies relate to specific illnesses and locales—for example, local

clinics, a local hospital, a survey of local physicians. Therefore, extrapolating national estimates would be necessary.

Other Benefits and Costs

When considering the economic benefits of breastfeeding versus formula feeding, the cost of mothers' absenteeism from work should be considered in addition to those incurred by the health system. Many women return to work while their infants are less than 6 months old. When these women miss work, it is often because their infants are ill. As breastfed infants have been shown to be less likely to catch common infectious illnesses than formula-fed infants, it is possible that mothers who breastfeed may have to miss fewer days from work to care for a sick child than mothers who are formula feeding. Attributing costs to time and wages lost by mothers (and fathers) attending to a sick child should be considered when estimating the possible economic benefits of breastfeeding.

Relatively few studies in the United States have attempted to assess the economic benefits of breastfeeding. The few studies reported in the literature generally looked at the economic effect of breastfeeding within the context of a WIC program operating at a specific State site, with net savings expressed either in terms of reduced overall Medicaid expenditures for infants, reduced formula purchases, or decreased infant morbidity and health care costs associated with a specific illness (gastrointestinal problems and ear infection). For example, a 1997 study looked at whether breastfeeding of infants enrolled in WIC was associated with a reduction in Medicaid expenditures during the first 6 months of life. The two researchers found that, compared with formula feeding, breastfeeding each infant enrolled in Colorado's WIC Program saved $478 in WIC costs and Medicaid expenditures during the first 6 months of the infant's life, or $161 after considering the formula manufacturer's rebate.

Comprehensive Assessment Needed

Proponents of breastfeeding view promotional efforts and active support systems as key components in a strategy to improve the well-being and health of both mothers and infants. A number of approaches have been suggested to increase breastfeeding: promotional campaigns to correct misconceptions about or overcome barriers to breastfeeding; increased training for physicians and professional health care providers who, in turn, could more actively promote breastfeeding; hospital and/or professional home support visits to expecting mothers or mothers in the early postpartum stage; and enlightened employer practices that reduce possible conflicts between maternal employment and day-time lactation (for example, breastfeeding or breast-pumping breaks, onsite day care, or telecommuting).

Despite the health benefits to both mothers and their infants, some policymakers remain skeptical about the cost effectiveness of breastfeeding promotion and support efforts. Policymakers may be reluctant to

Past Studies Conflict on Merits of Breastfeeding

Some studies contradict one another and have contributed to the controversy about the importance of breastfeeding to public health. A number of the earlier studies used small samples and inappropriate statistical analyses. Some of the following methodological and analytical limitations of some earlier studies (particularly those conducted between 1970 and the mid-1980's) resulted in ambiguous findings:

Lack of control of confounding variables. Short of random assignment to be breastfed or formula fed, which is not ethically or practically feasible, it is important to match the groups as much as possible for as many potentially confounding variables that may independently affect infant health, such as family size, maternal education, socioeconomic status, parental smoking, and use of day care. In some earlier studies, groups were not carefully matched by these important variables.

Problems related to the definition and duration of breastfeeding. Explicit definitions of breastfeeding practices are important for understanding and comparing studies. In some studies, infants have been classified as "breastfed" if they received any amount of breastmilk at any time in their lives. As a result, groups of "breastfed" infants may have included infants who were offered breastmilk only once or twice in the hospital as well as those who were exclusively breastfed for 4-6 months. Such a mixing of treatment groups could mask the protective effects of breastfeeding.

Problems related to "assignment" or reverse causality. In studies of infant feeding and health, this bias can stem from the fact that infant health can affect infant feeding. So, if the mode of feeding is measured after an illness has already begun, it may not be clear whether a formula- fed infant, for example, experienced that illness as a result of formula feeding or whether previous breastfeeding was curtailed as a result of the illness. The illness in question, then, must be unambiguously associated with the feeding method used just ***before*** the onset of illness.

fund breastfeeding promotion and support activities and may need proof that breastfeeding will help the "bottom line" or is cost effective. Support for breastfeeding must be balanced against an organization's potential financial costs and benefits of an increase in the number of breastfeeding patients/clients/employees. Mothers who continue breastfeeding report fewer infant illnesses and less absenteeism than do mothers who do not breastfeed when they return to work. Mothers who receive support for continued breastfeeding as they re-enter the workplace tend to return earlier after their babies' births. An employer might want to balance these benefits against such factors as costs related to the time spent by working mothers to express milk onsite and the costs of providing the facilities (breastpump, private room, cold storage). Without health and cost-benefit studies, the Nation's employers, health and life insurance companies, and Federal health policymakers may not provide financial incentives to employees and insurance subscribers to breastfeed or to health providers to support and competently care for breastfeeding mothers.

A principal mission of USDA's Economic Research Service (ERS) is to provide an economic framework for examining public policy issues. ERS intends to comprehensively assess the economic benefits of breastfeeding, information that is critical to performing cost-benefit analyses of breastfeeding promotion and support efforts.

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