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New Approaches To Regulating Food Safety

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The Centers for Disease Control and Prevention (CDC) states that "foodborne disease remains one of the most common and important causes of illness and deaths"—this despite progress in improving the quality of food and food handling in the United States, such as canning, refrigerating, freezing, and pasteurizing foods.

According to researchers at the CDC and the U.S. Food and Drug Administration (FDA), from 6.5 million to 33 million illnesses and up to 9,000 deaths may occur each year from foodborne microbes (namely, bacteria, parasites, viruses, and fungi). For just the few foodborne bacterial and parasitic diseases for which we have made cost estimates, medical charges and lost productivity cost society \$5-6 billion annually (see box and table 1).

In contrast to foodborne pathogens—which generally cause illness within hours or months—any toxicological effects from pesticide residues in food, in general, may take decades to manifest their chronic health effects. Such health risks are less easily tied to a particular cause. Most experts agree that pesticide residues in food pose minimal health risks.

Nonetheless, questions continue to be raised about whether such risks are adequately understood and measured. For example, a recent National Academy of Sciences study questioned whether the current assessment of dietary risks from pesticide residues adequately accounts for their effects in children. This uncertainty has contributed to continued consumer concerns about pesticide risks (also see "Food Safety: Meal Planners Express Their Concerns," elsewhere in this issue).

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Impetus for Change

Scientific advances are one factor responsible for the increased attention to food-safety regulation. New pathogen tests and improved epidemiological methods link human diseases to their foodborne sources. The *E. coli* O157:H7 outbreak associated with undercooked hamburgers in the West in early



Scientific developments should improve the efficiency of food-safety regulation. The use of risk analysis will improve identification of the causes of foodborne illnesses and deaths, associated foods, control options, and the costs and benefits of these options.

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1993 is one example. Washington State investigators discovered the outbreak, and epidemiological investigations in California, Nevada, and Idaho uncovered related outbreaks. Since then, several small *E. coli* O157:H7 outbreaks have been detected.

Improved tests for pesticide residues can now detect parts per billion of many chemical compounds, leading to more frequent findings and thereby increasing concern about the existence of pesticide residues in food and water. Even though risks to human health are extremely low at such minute levels, these findings show that consumers are exposed to a number of residues, and the risks from multiple exposures are not well understood or quantified.

The pool of highly susceptible people at risk for microbial foodborne illness is growing, as the population ages, as medical technology keeps ill people alive longer, and as chronic illnesses suppressing people's immune systems (such as AIDS) spread. An aging population also means greater consumer concern about the chronic effects from both microbial and chemical contaminants, which only become apparent with longer life spans. Thus consumers may now place a higher value on reducing risks from microbial pathogens or pesticide exposure than in the past, even though such risks are small (see "Food-Safety Policy: Balancing Risk and Costs," following this article for comparison of foodborne illness with other risks in society).

Setting New Standards

Many different Federal agencies have responsibilities for food safety (fig. 1). For example, FDA has the regulatory responsibility for most foods. The U.S. Department of Agriculture (USDA) inspects meat and poultry. The Environmental Protection Agency (EPA) sets tolerances for pesticide residues in foods. These Federal agencies are trying new approaches to food-safety regulation. Regulations by USDA, FDA, and EPA are under agency, congressional, and Presidential review and debate. Some new initiatives include:

- The Clinton Administration's initiatives to reduce pesticide use/risk and better protect children from residues,
- USDA's Food Safety and Inspection Service's (FSIS) plans to redesign meat and poultry inspection,
- FDA's proposed regulations requiring hazard-control plans for safeguarding seafood, and
- Congressional proposals for a single food-safety agency.

One element of the new foodsafety initiatives involves changing the standards for acceptable risks. EPA is responsible for setting pesticide residue tolerances (the maximum level of residue that can legally remain on the food product) for pesticides used on food crops. Presently, under the Delaney Clause of the Federal Food, Drug, and Cosmetic Act (FFDCA), carcinogenic food additives are illegal, without regard to whether the risk is "negligible" and without regard to other characteristics, such as benefits of product use. However, this "zero-tolerance" clause applies only to pesticide residues that are used or that concentrate in processed foods. For fresh foods, small risks are allowed, particularly if there are substantial benefits from product use.

The Administration's legislative proposal calls for a single healthbased standard (reasonable certainty of no harm) for risks from pesticide residues in both fresh and processed foods. This is a departure from current policy in two ways. First, concentrations of pesticide residues which pose no more than negligible risks would be allowed in processed foods, in contrast to the current zero-tolerance standard under the Delaney Clause. Second, EPA would no longer consider the benefits from lower production costs in setting tolerances for fresh foods. Changes in existing legislation are required to implement this new standard.

Standards aimed at controlling microbial pathogens are changing for meat and poultry products. FSIS is now rigidly enforcing the zero tolerance for fecal contamination on beef carcasses at the slaughterhouse to reduce the possibility of E. coli O157:H7 contamination. Similar changes in poultry slaughterhouse inspections are under consideration to control Salmonella. An interagency committee, along with academic and industry members, is investigating setting acceptable levels for other microbial contaminants.

When setting new standards, key questions for consumers are: what do we expect industry and Government to protect us from and what do we expect to do ourselves.

Often this determination hinges on the extent to which consumers can detect and control the degree of risk. Many microbial pathogens, and some pesticide residues, can be reduced by using safe food handling and cooking practices, such as those described on the newly required labels on raw meat and poultry products. From the consumer's perspective, there are tradeoffs between risk reduction and extra preparation time, changes in flavor and texture (such as from cooking meat until it is "well-done"), and the loss of food and fiber (by throwing away old food or trimming fruit and vegetables to reduce external residues and microbes).

Since neither microbes nor residues are visible to the naked eye, the consumer does not know when such precautionary behavior will

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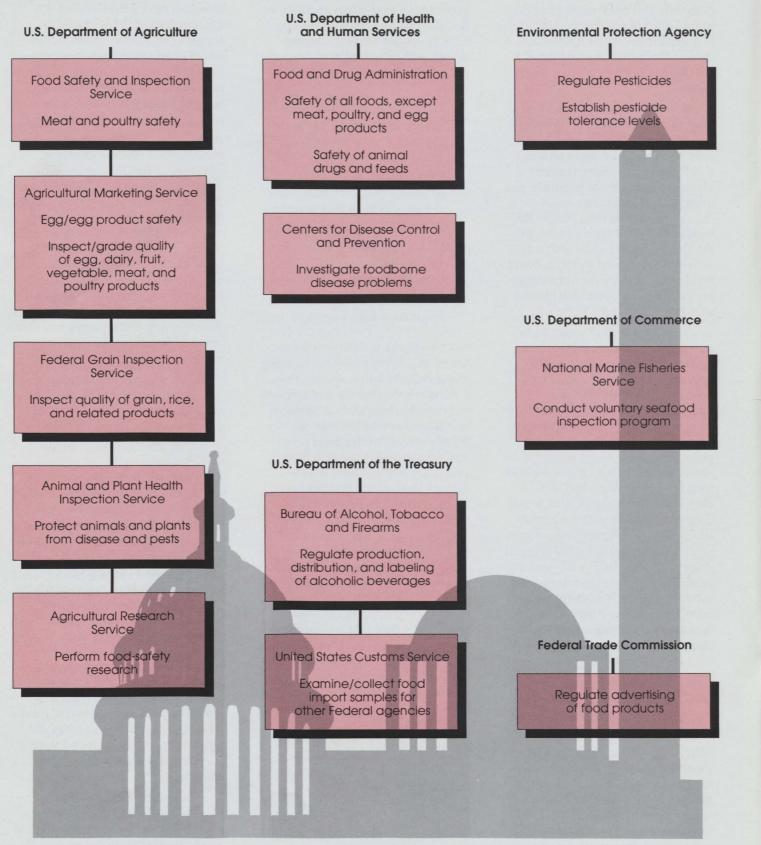
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Several Federal Agencies Involved in Food Safety and Quality



control potential risks. This lack of control is increasing as consumers purchase more prepared foods and more food away from home. For these reasons, consumers may demand greater Government intervention to reduce hazards in the food supply.

And what of those who are particularly vulnerable to foodborne disease, such as the very young, the very old, and the immunocompromised—including pregnant women? Protecting the most vulnerable, such as children or immunocompromised adults, may result in higher costs for consumers. A similar issue is whether foods could be marketed with different levels of risk to meet individual food preferences. Judgments about acceptable food-safety risks may differ widely among our increasingly diverse population.

Steps To Identify and Control Risks

It is hard to improve food safety when it is unclear to what degree microbial pathogens and chemical residues contribute to human disease. The use of risk analysis will improve identification of the causes of foodborne illnesses and deaths, associated foods, control options, and the costs and benefits of these options.

Some parts of risk analysis may include:

- Identifying foodborne hazards capable of causing human illness.
- Estimating the total number of acute and chronic illnesses associated with each hazard that occurs annually.
- Estimating the number of deaths and illnesses, and the severity of illnesses associated with each hazard (while deaths are the most important measure, the greater number of less severe outcomes, such as ill-

ness, could impose greater costs on society).

- Identifying alternative methods of controlling foodborne hazards.
- Estimating the economic costs and benefits of the proposed control technology and the distribution of such costs and benefits.

The Administration's pesticide legislative proposal responds to the 1993 National Academy of Sciences (NAS) recommendations by requiring specific findings regarding the safety of infants and children in setting pesticide tolerances. Such findings must account for differences between adults and children in terms of body weight, dietary patterns, and vulnerability to developmental toxicity. Children consume more food per unit of body weight than do adults and consume a limited diet. Therefore, their relative exposure to particular residues can be higher than that of adults, with potentially higher risks.

NAS also recommended reducing the acceptable intake limits for pesticide residues when data on developmental toxicity are questionable or inadequate, accounting for nonfood sources of residue intake, and accounting for the combined effect of intake of multiple pesticides with similar toxic effects.

These recommendations, taken together with the application of a negligible risk standard, could result in revocation of some existing pesticide tolerances.

In contrast to pesticides, little formal risk analysis has been carried out for microbial pathogens in the past. While the U.S. Department of Health and Human Services, in its publication *Healthy People 2000*, did set targets for reduction of four bacterial pathogens (50 percent for *Campylobacter jejuni* and *E. coli* O157:H7, 29 percent for *Listeria monocytogenes*, and 11 percent for *Salmonella*), there are no de-

Salmonella), there are May – August 1994

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finitive or commonly accepted estimates of human disease and deaths caused by most bacterial, viral, parasitic, and fungal foodborne pathogens.

Improving data collection for microbial pathogens will result in more accurate risk analysis. For example, much can be accomplished by better integrating existing databases on human hospitalizations and deaths caused by specific pathogens with new FSIS data, such as their baseline studies for pathogen counts on beef, chicken, and pork. Random samples of condemned animals can be analyzed to discover the causative pathogens. More CDC studies could be funded to identify the foods associated with specific pathogens, identify high-risk population groups, standardize estimates of cases/ deaths across pathogens, and investigate the chronic diseases that may have foodborne origins. Such analysis is expensive. Yet given the \$5-6 billion in medical costs and productivity losses each year for a few microbial pathogens, even modest reductions in foodborne diseases would justify improved data collection for microbial pathogens.

Imposing New Types of Regulation

In addition to strengthening existing regulation and risk analysis, the Administration is trying new methods of regulation. These would put in place a process that reduces risk by prevention throughout the food production process, instead of primarily inspecting or testing finished products. A systems approach, such as Hazard Analysis Critical Control Points (HACCP), may reduce contaminants most effectively by identifying potential points at multiple stages of the production and marketing chain where interventions can prevent or reduce foodborne contamination.

Cost of Illness Estimates and Methodology

The annual cost of U.S. foodborne disease associated with selected bacterial and parasitic pathogens is estimated using the traditional cost-of-illness method. This analysis includes only medical costs, productivity losses, and special education/residential care because of some chronic conditions. The basis of the disease estimates is "best estimates" of the actual number of foodborne disease cases each year and is not limited to the much smaller number of outbreaks reported to the Centers for Disease Control and Prevention (CDC).

The present value of lifetime medical costs for those becoming ill in 1992 is estimated using nationwide databases, such as the published Medicare reimbursement rates and per capita expenditures on physicians' services from the Health Care Financing Administration, the National Center for Health Statis-

FDA recently proposed regulations for a HACCP system to increase seafood safety (see "New Inspection Program for the Nation's Seafood," elsewhere in this issue). FSIS is considering similar action for meat and poultry plants. This type of system can be applied to interventions anywhere in food production. Early intervention points can prevent contaminants from entering the food production/distribution system, while later interventions can eliminate certain kinds of contaminants.

• For example, three farm practices have been effective in dramatically reducing *Trichinella spiralis* in U.S. hogs: keeping rodents out of hog production tics' National Hospital Discharge Survey, the American Hospital Association's Hospital Statistics, or Blue Cross/Blue Shield charges. The average cost to community hospitals per patient is used to compute hospitalization costs.

Productivity losses because workers were ill and missed work are approximated by the Average Weekly Earnings for nonsupervisory production workers in private nonagricultural jobs, published by the Bureau of Labor Statistics (BLS) of the U.S. Department of Labor, plus estimated fringe benefits. For those ill in subsequent years, a present value of the reduced stream of earnings is calculated. For those who die, Landefeld and Seskin's human capital/willingness-to-pay method is used. It combines elements of both methods to generate the present value of expected lifetime aftertax income and housekeeping services at a 3-percent real rate

houses, quickly taking dead hogs out of pens, and cooking all hog feed containing meat scraps or other animal byproducts.

• An example of intervention close to the consumer is the label on raw beef instructing preparers to refrigerate raw and cooked food, to wash hands, to avoid cross-contamination by washing cutting boards and knives after use, and to cook meat until it is welldone.

A similar focus on production process rather than endpoint outcomes is found in the Administration's reduced use/risk initiative of return, adjusted for an annual 1-percent increase in labor productivity and a risk-aversion premium that increases the estimates by 60 percent.

These cost estimates are based on the annual incidence of disease, rather than on the prevalence, because the goal is to develop public-health cost estimates to compare to the costs of various prevention programs. Incidence estimates are the annual increase in cases and associated disease costs. Intervention today which prevents future cases will eliminate all the economic costs of prevented cases this is the economic benefit of disease prevention.

For more detail on how the estimates are calculated, see "E. coli O157:H7 Ranks as the Fourth Most Costly Foodborne Disease" by Suzanne Marks and Tanya Roberts in *FoodReview*, Vol. 16, No. 3 (Sept-Dec 1993), pp. 51-59.

for pesticides. In the past, environmental and health risks from pesticides have been addressed by banning products. This results in the loss of pest-control alternatives. Instead, reducing the use of pesticides can prevent significant environmental and health risks while also retaining flexibility in pest control. Promoting the judicious use of chemicals within a total system of integrated pest management will be the approach to reducing use.

Use of a process standard rather than product sampling and testing could also be applied to imported foods. Certifying that production processes in an exporting country meet U.S. standards could be a

Table 1

Estimated Medical Costs and Productivity Losses for Selected Foodborne Pathogens, 1992

Foodborne pathogen	Estimated annual foodborne—		Estimated
	Cases	Deaths	total costs
	Number	Number	Million dollars
Bacteria:			
Salmonella	1,920,000	960-1,920	1,188-1,588
Campylobacter jejuni			
or coli	2,100,000	120-360	907-1,016
Escherichia coli 0157:H7	7,668-20,448	146-389	216-580
Listeria monocytogenes	1,526-1,581*	378-433	209-233
Parasites:			
Toxoplasma gondii	2,090	42	2,628**
Trichinella spiralis	131	0	0.8
Taenia saginata	894	0	0.2
Taenia solium	210	0	0.1***

Total

5,149-6,046

Note: The analysis assumes that 100 percent of human illnesses are foodborne for *Campylobacter, Escherichia coli, Trichinella*, and the Taenias and that 96 percent of *Salmonella* cases, 85 percent of *Listeria* cases, and 50 percent of *Toxoplasma* cases are foodborne. *These case estimates may be high. **Productivity losses are high for survivors who develop mental retardation or blindness as a result of toxoplasmosis. These costs exclude toxoplasmic encephalitis infections in 2,250-10,200 AIDS patients annually, which are a significant cause of premature death (50 percent of cases may also have a foodborne origin). ***Estimates do not include costs for cystericercosis, which may have an indirect foodborne transmission. Sources: M. Weiss, T. Roberts, and H. Linstrom, "Food Safety Issues: Modernizing Meat Inspection," *Agricultural Outlook*, USDA, ERS, June 1993, pp. 32-36; Centers for Disease Control and Prevention and W.K. Viscusi, "The Value of Risks to Life and Health," *Journal of Economic Literature*, Vol. 31, No. 4, 1993, pp. 1,912-1,946; and S. Marks and T. Roberts, "*E. coli* 0157:H7 Ranks as the Fourth Most Costly Foodborne Disease," *FoodReview*, Vol. 16, Issue 3, USDA, ERS, Sept.-Dec. 1993, pp. 51-59.

more efficient way of ensuring the safety of the rapidly growing U.S. food imports than would be testing each product at the border. FDA is employing this concept for some imported produce, for example. New Zealand is ensuring for some of its exported produce that pesticide use follows U.S. registered pesticide uses and, therefore, the produce should meet U.S. pesticide residue limits.

Using Economic Incentives

Vice President Gore's *Report of the National Performance Review* proposed ways to make the Federal Government more efficient and more responsive. Among other things, the report advocates using incentives to reward firms with strong safety records and enforcement to punish firms with poor performance.

Economic incentives are a very efficient mechanism for sending signals to the market and encouraging production of products with desirable characteristics, such as safety. In the short run, firms can increase testing for contaminants and buy from suppliers whose quality-control procedures demonstrate compliance with requisite standards. In the long run, research on new production practices is encouraged as is research to develop new, safer products. Existing food-safety regulations were designed to provide safe food for the average consumer. The safety standards set in the Federal Meat Inspection Act and Poultry Products Inspection Act have become, in effect, a floor and a ceiling for the degree of safety that meat and poultry products are expected to attain. Similarly, pesticide tolerances set under the FFDCA are uniform for each crop/chemical combination; that is, there are no differences in tolerances for children's foods.

Doctors, however, are warning some individuals at increased risk for microbial foodborne disease, such as pregnant women and AIDS patients, not to consume certain

fresh seafood, meat, or dairy products and instead substitute medical, canned, and well-cooked foods. It may make sense to offer these high-risk individuals more choices for the fresh products as well. Irradiated chicken is a start and is being sold in a few markets. But, there may be other methods of reducing pathogen levels on fresh meat, poultry, seafood, and dairy products. Regulators could stipulate what product-safety targets must be met for such products, let approved products carry a special label, and thereby give industry an incentive to discover innovative methods to reduce pathogen levels.

U.S. dairy producers have already discovered that market incentives can be positive as well as negative. Prices received by farmers for their milk are partially tied to somatic cell, standard plate, and preliminary incubation counts for bacteria. Low test results are indicators of both longer product shelflife and reduced levels of bacteria, some of which may cause human illness.

Dutch producers have proposed obtaining premium prices for pork produced under hygienic codes to reduce foodborne pathogens. These codes are currently being tested in actual production situations and are expected to be implemented in 1995. "Safer" products need a grade, symbol, or label on products for the final consumer, who will choose whether to alter purchasing patterns based on foodsafety considerations (also see "Consumers Want Reduced Exposure to Pesticides on Food," elsewhere in this issue).

Another way to provide incentives is to encourage the development of safer products. EPA has moved to provide incentives for development of reduced-risk pesticides and biological alternatives through streamlining the registration process and removing unnecessary data requirements for biologicals. The Administration's pesticide legislative proposal would provide further incentives for development of reduced-risk alternatives, by giving them priority in the registration review and allowing temporary and conditional registrations prior to completion of all required tests.

Continued Challenges in the Next Decade

Scientific developments should improve the efficiency of foodsafety regulation. Epidemiology is improving our ability to identify acute and chronic human illnesses caused by foodborne pathogens. We will have better estimates of the medical and economic burdens associated with specific pathogens and chemicals. Continued development of inexpensive, rapid tests will allow detection of contaminants in foods and permit statistically based testing. Economic incentives for improving food safety will be better understood and utilized in designing regulations.

Demand for food-safety regulation may grow due to changes in food demand and demographics. An older and more affluent population may be more willing to pay for health attributes of food. The growing popularity of convenience foods further reduces consumers' control over food preparation and may alter the nature of foodborne illness risks. A growing population of high-risk consumers means that for a given number of pathogens in food, more people are likely to get sick. Whether these changes will result in a market response from industry or greater demand for regulation remains to be seen.

All these forces will challenge regulators to develop food-safety strategies that are scientifically and economically sound.

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