Recent scientific developments are changing what we know about food safety. We now have better methods for detecting dangerous substances in our food and for assessing their risks to human health. But this new knowledge, while helping to assure the public that our food is safe, has simultaneously raised concerns about food safety that were not present before. The challenge will be to incorporate this new knowledge into food safety policies that are both comprehensive and cost effective.

Potential effects of food contamination range from diarrhea to cancer and arise from a number of sources. Pathogenic (human disease-causing) microbes and chemical contaminants may enter the food chain naturally from the environment, through farm practices, such as using pesticides or animal drugs, or through food processing and handling. Some enter the food chain because they reduce the costs of producing food. Still others improve food quality in terms of taste, texture, visual appeal, or shelf life. The risks to human health depend on how toxic a substance is or how virulent a microbe is, how much is in particular foods, and how much of those foods an individual consumes. Even common and useful substances in food can be harmful if eaten in large enough amounts. However, the quantities of potentially harmful compounds that may be in food are regulated and monitored to manage the risk from unsafe foods.

Researchers from the Centers for Disease Control and the Food and Drug Administration (FDA) estimate that from 6.5 million to 33 million Americans become ill each year from microorganisms in their food. This is roughly 3 to 14 percent of the population. An estimated 9,000 of these cases result in death each year. In contrast, the Environmental Protection Agency's (EPA) worst-case estimate is that pesticides in food cause potentially about 6,000 cases of cancer each year, or 2 in every 100,000 people. Most toxicologists and food scientists believe that microbial pathogens are a more serious hazard than chemical residues in the food supply.

The Need for Regulation

To make informed decisions, consumers must know what substances are in particular foods and how these substances may affect their health. They must also be able to weigh any benefits, such as lower prices or desirable food qualities, against the risks. However, acquiring and understanding food safety information is difficult for highly trained professionals, let alone for individual consumers. Without regulation and oversight, sellers have little incentive to inform buyers of potential hazards. If they did, sales could fall or consumers might be reluctant to pay higher prices for “safer” foods with safety claims they could not easily verify. If sellers cannot recoup the extra costs of developing and producing safer foods, they will not make the products.

Liability rules that enable injured parties to sue and recover damages will not solve the problem either, because they seldom compensate victims in food safety cases. A consumer may not know whether an illness is connected to a particular food because the symptoms are often delayed. Even if a consumer can trace the cause, the proof may be gone—the food eaten or thrown out. In other cases, damages suffered by individuals may not be serious enough to justify the time and expense of litigation. Class-action suits are very difficult to organize unless there is a single, identifiable source of contamination.
As we have moved from home production of food to mass production by strangers, the need to regulate the safety and wholesomeness of our food has increased. The Federal Government has worked with State and local governments to control the amount and type of substances allowed in foods since 1906. The regulatory tools used most often by EPA, FDA, and USDA's Food Safety and Inspection Service (FSIS) are tolerances and food manufacturing process standards.

Tolerances, which are set by EPA for pesticides and FDA for other compounds, are legal limits on the amount of potentially hazardous substances allowed in commercially sold foods. The food manufacturing process standards established by FDA and FSIS include sanitation and construction requirements for packing plants and food processing establishments. FSIS is responsible for making sure that meat and poultry products intended for human consumption are safe, wholesome, and accurately labeled. FDA handles the regulation of all other food products. (For an explanation of EPA and FDA regulations as they apply to pesticides, see Changing Pesticide Regulations: A Promise for Safer Produce, and for a description of FSIS activities, see Safe Meat and Poultry.)

FDA and FSIS enforcement of tolerances and food processing standards requires an inspection system for foods and production and processing facilities. Inspections are usually done on a sampling basis, with a penalty for noncompliance. The sampling rate determines the probability of being caught in noncompliance. This probability, coupled with the penalty imposed, equals the price firms can expect to pay for violating the law. The higher the expected cost of a violation, the more violations that are deterred. For instance, if firms know that the sampling rate is high and the fines large, they are less likely to violate the regulations.

Other regulatory tools are occasionally used to enhance food safety. One example is public education programs and public health warnings, such as telling consumers to cook pork thoroughly, which will kill the parasite that causes trichinosis. Another example is label identification of food additives—colors, flavors, preservatives, artificial sweeteners, and similar substances added to foods in known amounts. Although people have a choice about consuming products with identified additives, the Government still plays an important role in ensuring that what is added is safe or poses only minor health risks, and that the label is informative. Public education and labeling may enhance the safety of food, but they do require consumers to take an active part in controlling health risks.

In 1985, the National Academy of Sciences concluded that current regulations for poultry inspection were not aimed at detecting the most common foodborne pathogens, namely microrganisms. Because testing all foods for all pathogens would dramatically raise the cost of producing food, the academy suggested using a risk-assessment approach for determining the sources of risk to human health and setting Government inspection priorities (see box). The academy report recommended that meat and poultry inspection be refocused to prioritize microbial and chemical testing, compared with traditional visual inspection methods. FSIS is giving greater attention to these areas.

Economic theory tells us that too much regulation, or the wrong sort, can be as costly to society as too little regulation. The key to optimal regulation and oversight is determining when the benefit of additional testing—human health protection—is greater than the extra cost.

**Microbial Contamination**

One of the most worrisome developments regarding food safety is the increasing incidence of some microbial contaminants. Foodborne disease can be caused by bacteria, parasites, viruses, fungi, and protozoa that contaminate raw food and are not eliminated because of inadequate cooking or other food preservation techniques that allow the pathogen to survive or perhaps multiply. Reported cases have increased for some
Assessing Food Safety Risks

In a 1983 report, the National Academy of Sciences recommended four steps be included in any Federal program for assessing risks to the Nation's food supply from potentially hazardous chemicals or microbial contamination:

- First, identify potential hazards. Pathogens can enter the food chain at any point from the farm to the consumer. For example, Salmonella contamination most often starts at the farm, where the bacteria are a common inhabitant in animals' intestines.

- Second, develop information on infective doses associated with a particular hazard. An infective dose is the amount needed to cause disease. Studies of healthy people have shown that large doses of Salmonella are needed for them to contract salmonellosis from the microorganism. On the other hand, disease outbreaks have been associated with as few as 100 Salmonella bacteria. Special risk factors may apply for particularly vulnerable groups, such as infants, pregnant women, the elderly, alcoholics, or people whose immune systems are not working well or are weakened.

- Third, assess how many people are likely to be exposed to a hazard. Many variables are involved in determining whether people have been exposed. The factors include: identifying which foods are likely to contain a particular contaminant, quantifying the likely level of contamination in each food, and calculating the serving size and consumption of each food.

- Fourth, identify the economic and social impacts. For instance, around 40,000 cases of salmonellosis are reported annually, but epidemiologists estimate that the actual number of cases is closer to 2 million. The medical costs and productivity losses of this disease are estimated at $1 billion annually.
common foodborne illnesses, such as salmonellosis, an intestinal disease with flu-like symptoms (figure 1).

At the same time, improved scientific tests have helped identify more pathogenic organisms and trace them back to foods and feedlots. (Animal, dairy, and seafood products are the major vehicles for foodborne disease.) Understanding the latest microbial threats and where they come from is important. Not only can the pathogens be isolated, but new food production and handling practices can be evaluated for their food safety attributes.

Bacterial contamination of food is the primary cause of most identified foodborne disease. Conventional wisdom used to be that foodborne pathogens would only cause mild, brief illness, primarily diarrhea and vomiting for 1 or 2 days. But new evidence suggests that the severity is enormously variable. Factors affecting the infective dose and the severity of the illness include:

- **Virulence of the organism.** The more virulent the organism, the more serious the disease. Virulence can vary among different types and strains of bacteria. Many strains of *Escherichia coli* exist, but only a few cause serious disease in humans.

- **Food composition and use of antacids.** Stomach acids can kill the bacteria. Therefore, anything that protects the organisms, such as the fat in meat, or neutralizes the acid, like antacids, can change the infective dose.

- **Human susceptibility.** This varies with age, other diseases, pregnancy, medication, nutritional status, and immune status. *Listeria monocytogenes* is extremely hazardous to some individuals, especially fetuses, while its effects on others can be negligible.

Chronic illnesses, such as central nervous system disorders, heart complications, intestinal inflammation, or kidney disease, can occasionally result from common bacterial and parasitic diseases. An estimated 2 to 3 percent of foodborne disease cases have some kind of short-term or long-term recurring aftereffects, according to researchers Kvenberg and Archer.

Food processors typically use several techniques to control foodborne disease microorganisms. These techniques include controlling food temperature during processing, making foods more acidic, and processing foods with a high sugar content, low water content, or high salt or nitrite content. Not even these barriers will correct all product abuses or be compatible with a particular food's taste.

New convenience foods, such as precooked entrees for reheating at home or in restaurants, pose new food safety problems. Vacuum packaging hinders the growth of spoilage microorganisms but may permit the production of botulinum toxin at temperatures found in many commercial and home refrigerators. Also, precooked foods only require minimal heating, eliminating the traditional last line of defense against foodborne pathogens—thorough cooking immediately before eating. The widespread use of microwave ovens exacerbates this problem because the ovens can have cold spots where bacterial pathogens and parasites may not be killed. The increasing diversity of the American diet also adds to the potential for microbial contamination. Food never before imported into the United States, for example, may contain microbes not normally found in American food.

Consumers tend to underestimate the risk of microbial foodborne disease. FSIS sampling of chicken over the last
two decades has consistently shown that about 35 percent of the carcasses were contaminated with Salmonella bacteria when they left the slaughterhouse, according to researcher Green. However, 16 percent of homemakers questioned in a one-time survey, conducted in 1974 by economists Jones and Weimer, thought Salmonella contamination was not at all likely, 47 percent said not too likely, 24 percent said somewhat likely, and only 12 percent said very likely. These figures may be different today. Recent media attention and Congressional activity may be increasing the public's awareness of microbial foodborne disease risks. However, some of the risks are controllable with thorough cooking and better sanitation practices.

The costs of foodborne disease from any source fall upon individuals who become ill, their families and coworkers, their employers, the food industry, and the public health sector. Individuals' costs include medical bills, time lost from work, pain and inconvenience, and higher health insurance premiums. The food industry faces losses due to the possibility of product recalls, plant closings and cleanup, product liability insurance, and reduced product demand. Public health costs include the expense of maintaining a disease surveillance system, investigating outbreaks, and handling their cleanup.

Medical costs and time lost from work for individuals are estimated at around $1 billion annually for salmonellosis. Campylobacteriosis, an intestinal disease similar to salmonellosis, also has medical and productivity costs of around $1 billion a year. A third disease, congenital toxoplasmosis, which causes mental retardation in fetuses, is conservatively estimated to cost $215-$323 million annually. Individuals' medical costs and productivity losses for all foodborne diseases could reach several billion dollars a year.

### Pesticide Residues

All pesticides must have EPA approval before they can be sold in the United States. However, EPA okayed many widely used pesticides when less was known about their long-term hazards, such as their potential to cause cancer. Beginning in 1978, an amendment to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) imposed new requirements on what must be known about the chronic toxicity of pesticides before EPA can approve their use on specific crops. Consequently, pesticides introduced in the last decade have faced greater scrutiny.

Tougher scrutiny, however, has not always resulted in a safer food supply, according to a 1987 report by the National Academy of Sciences. This paradox arises because even though some new pesticides are significantly less carcinogenic and pose substantially fewer health risks than some older compounds, EPA has not always been able to register them under current law. Thus, in some cases, older, potentially more toxic pesticides continue to be used even though safer ones could be available.

One reason for this is the Delaney Clause in the Federal Food, Drug, and Cosmetic Act. The clause prohibits the establishment of a tolerance for a pesticide residue in processed foods if the compound has been shown to induce cancer in humans or laboratory animals and if the residues can be shown to concentrate during processing. In the past, the Delaney Clause was seldom applicable because little scientific data existed on the ability of low levels of pesticide residues to induce tumors or on the degree to which residues concentrated during food processing. However, recent scientific developments enable estimation of even very small risks and detection of more minute quantities. Consequently, EPA...
has to apply the Delaney Clause to new pesticides that have very low cancer risks even though they would be safer than pesticides already on the market.

Another paradox is that there are two different standards for regulating pesticide residues in food. The Delaney Clause only applies to pesticide residues that have been found to concentrate during food processing. Tolerances for pesticide residues that do not concentrate or are found in raw foods must be set at a level that protects public health and allows for an abundant and economical food supply—sometimes referred to as a risk-benefit standard. For example, a pesticide residue in applesauce is subject to the Delaney Clause if it concentrates above the residue level of the same pesticide found on raw apples. If it does not concentrate, the risk-benefit standard applies to both the applesauce and the raw apples. There is no public health reason for making this distinction, according to the National Academy of Sciences. The focus should be on the level of risk, not where it occurs.

The academy study concluded that the double standard of applying the Delaney Clause only to pesticide residues that concentrate in processed foods, but not to pesticide residues in raw foods, results in greater cancer risks than a policy that would allow tolerances for both raw and processed foods for pesticides that pose a negligible risk of cancer. The study also stated that, while applying the Delaney Clause to pesticide residues in both processed and raw foods would eliminate 100 percent of the risk, a policy of allowing negligible risk would eliminate 98 percent of the cancer risk and would have significantly less impact on the availability of pesticides and hence on food prices.

The costs of living with the Delaney Clause as it is currently written could be very large. FIFRA requires EPA to reregister old pesticides as new data become available about their health effects. In 1981, EPA put out the call for these new data, and studies are now complete or partially complete for at least 25 percent of the 289 pesticides currently registered for use on food crops. Amendments to FIFRA passed by Congress in 1988 speed up the process.

At the time of the National Academy of Sciences study, EPA had classified 53 registered pesticides as oncogens (substances tending to cause tumors, whether benign or malignant). The agency is now reviewing these compounds. The 53 pesticides account for 90 percent of all fungicide use, 38 percent of herbicide use, and 40 percent of insecticide use. The situation is particularly acute for fungicides. Few good substitutes are being developed. Fungicides are also widely used on fruits and vegetables that are often processed, meaning the Delaney Clause would apply. Consequently, producers of these crops could be facing substantially higher pest-control costs over the next decade.

In October 1988, EPA announced it would begin to apply negligible-risk criteria in setting tolerances for residues of carcinogenic pesticides in processed foods. The new policy responds to the problems created by applying different safety standards to new and old pesticides. However, the policy does not completely address the paradox of different standards for pesticide residues in processed versus raw foods. Members of Congress have recently introduced bills to address this issue. (See Food and Nutrition Legislation for more information.)

Animal Drug Residues

All animal drugs must have FDA approval before they can be sold in the United States. To ensure that residues of these drugs in meat are within the tolerances set by FDA, FSIS randomly tests for drug residues as part of its meat and poultry inspection program.

Like pesticides, many approved animal drugs were registered for use on the basis of safety evaluations that are now considered obsolete. As new data become available, the toxic effects of many drugs widely used to promote weight gain and prevent disease in livestock may be questioned. For example, the safety of sulfa drugs—which are widely used in swine and veal production—is now being debated. Sulfa drugs have long been recognized as causing allergic reactions in some sensitive individuals. In addition, recent studies by FDA's National Center for Toxicological Research indicate that sulfamethazine may cause tumors as well. Based on preliminary risk assessments, FDA has warned the pork industry that the agency
may either lower the tolerance for sulfamethazine in swine or ban its use.

Adequate, timely detection methods do not exist for approximately 70 percent of the animal drug residues in meat, milk, and eggs that FSIS is responsible for monitoring, according to a congressional report. Tests are currently being developed by public and private researchers to ascertain the presence of animal drugs in food. FSIS has made considerable progress in detecting antibiotic and sulfa drug residues.

Continuing problems with illegal residues of antibiotics and sulfa drugs in meat reflect some major constraints FSIS faces in making the cost of violating the law greater than that of complying with it. To deter future violations, FSIS could raise the probability that illegal residues will be detected, the size of the penalty, or both. However, that is not so easy to do.

Increasing the rate of detection would be extremely costly and difficult. Millions of animals are slaughtered each year, so not all of them can be individually tested. Instead, FSIS samples animals to estimate the average violation rate for each species and type of drug. If the violation rate is very low and the risk to human health is insignificant, no further action is taken. If the violation rate exceeds 1 percent, FSIS takes rigorous action and searches for the likely source and reason for the violations. This effort requires costly and time-consuming research to identify the producers who are violating the tolerances and why. If the producers can be pinpointed, FSIS, in conjunction with FDA, monitors them until the problem is eliminated.

But problems can be eliminated only if FSIS is able to make sure that violating the law costs more than complying with it. This is difficult because FSIS cannot simply fine violators. The agency can condemn and seize carcasses or initiate criminal procedures. But these actions, based on detecting residues, may be hampered by the complexity and slowness of tests requiring tissue samples. In some cases, by the time a violation is found, the carcass may have already been processed, sold, and consumed, resulting in little penalty for producers selling animals with illegal drug residues.

Another constraint FSIS faces is that the marketing system often makes finding who produced an animal difficult. Except for swine, the United States has no mandatory animal identification system. Thus, in some cases, neither slaughterhouses nor FSIS is able to inform producers that they have violated the law or to subject their future marketings to followup testing. Consequently, shifting the liability to problem-causing producers is not easy. To help overcome this dilemma, FSIS, in cooperation with USDA’s Animal and Plant Health Inspection Service, recently adopted a mandatory swine identification system. Furthermore, USDA’s Packers and Stockyards Administration has suggested a procedure that would enable slaughterhouses to charge sellers the price paid for animals condemned for illegal residues.

Science Raises New Issues

While new tests and better risk-assessment methods have raised concerns about the safety of some traditional foods, new technologies have enhanced our ability to ensure food safety. New production and handling methods, better monitoring and handling procedures, and new ways of tracing foods through the production, processing, and marketing system all can help increase the safety of our food.

Progress has been made, but much remains to be done. Research is needed that will:

- Develop more rapid tests to monitor microorganisms and chemicals in foods.
- If food has been consumed before laboratory test results are available, regulatory possibilities are limited. However, tests completed in hours or in 1 to 2 days boosts the likelihood of recalling a product before it leaves the plant and increase the amount likely to be recovered.
- Identify all microbial or chemical agents that pose serious human health hazards.
- Measure significant risks to human health from foodborne disease.
- Improve the statistical framework from which to develop tolerance levels.
- Reduce risks by determining where intervention in the food chain could lower the danger.

Changes in science, technology, and lifestyles will continue to challenge policymakers, the food industry, and consumers when dealing with the problems of food safety. To reduce public confusion, risks need to be communicated clearly. To achieve a public consensus, the benefits of alternative food-producing technologies need to be understood.

References

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