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CHALLENGES AND APPROACHES TO REDUCING FOODBORNE ILLNESS

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■ **Abstract** Microorganisms have successfully adapted to changes in food production, processing, and preservation techniques, resulting in a number of new and emerging foodborne pathogens and the re-emergence of organisms that have been problematic in the past. To protect public health, science must meet the challenges that result from the remarkable adaptability of foodborne pathogens. However, not all of the challenges of preventing foodborne illness reside in the realm of science. Food safety policy must evolve in reponse to new scientific understanding of hazards in the food supply and an ever-changing food processing industry. The laws, regulations, and organizations comprising the food safety system frequently lag behind current scientific knowledge of the risks posed by foodborne pathogens. Future systemic changes to enhance food safety will require better understanding of risks associated with specific pathogens occurring in the food supply and the costs and benefits of implementing mitigation strategies.

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OVERVIEW

Microorganisms have successfully adapted to changes in food production, processing, and preservation techniques, resulting in a number of new and emerging foodborne pathogens and the reemergence of organisms that have been problematic in the past. Infectious doses vary greatly depending on the species and type of microorganism. Ingestion of only a small number of some bacteria, viruses, and parasites is required before illness occurs, with only one organism or virus particle required in some cases. Improved understanding of infectious doses would be important in improving regulatory performance standards for food products and food safety objectives for government and industry. Research is most certainly needed to improve techniques for isolating microorganisms from food matrices and patient specimens and for concentrating them before analysis as well as in the improvement of immunological and genetic methods of detection. Unknown agents—organisms either yet-to-be identified or not detected in an illness—account for approximately 81% of foodborne illnesses and hospitalizations and 64% of deaths related to foodborne illness. Issues further complicating this estimation are the number of cases that are not reported to officials, because infected individuals neglect to seek medical help, physicians do not order laboratory tests, or medical facilities simply do not report cases altogether. Although most foodborne infections are short-term, recent attention has focused on investigating chronic diseases associated with foodborne illnesses, such as Guillain-Barre syndrome following Campylobacter infection.

A battery of techniques is used in the food processing industry to reduce or prevent the introduction and survival of microorganisms in food. Physical methods of preservation can include dehydration, freeze-drying, heat treatment, or irradiation. Chemical preservatives, such as antimicrobial agents, organic acids, and salt can be added to foods to reduce the levels of contamination. All of these preventive tools work by exerting various forms of pressure on the microbial cell, leading to growth inhibition or death. Multiple agriculture practices, processing methods, and post-processing practices have to be successfully implemented and consistently adhered to in order to mount an adequate defense against microbial contaminants and effectively assure the safety of the food supply.

Its size and complexity, coupled with the rapid changes that have occurred in its organization, products, and workforce, make the structure of the food industry a challenge to improving food safety. As mergers occur and companies invest in construction of large processing facilities, they also become responsible for producing larger amounts of products that are distributed over a larger geographic area. When food safety problems occur, the probability of widespread exposure is therefore increased.

Individuals or groups who would use the food supply to poison a few or many people are a challenge to all segments of the food industry (food producers, processors, retailers, and preparers) and to state and federal governmental agencies. Product tampering is a constant, but low-frequency, challenge to food processors, retailers, and regulators and since the terrorist attacks on New York City and Washington, D.C. in September 2001, current concern is focused primarily on domestic and foreign terrorist organizations that might choose to intentionally contaminate the food supply to create fear, undermine the government, and bring attention to their cause.

A successful food safety system must have means to hold individual processors accountable both for producing safe product and for reducing the level of hazards in the food supply. In addition to the need for a common understanding of the appropriate roles and responsibilities in a food safety system for government, industry, and consumers and the need for practical accountability mechanisms, a risk-based food safety system requires the risk-based allocation of resources.

The regulatory framework to assure the availability of safe food for consumers—that is, the laws, regulations, and organization of responsibilities—and the chronic lack of resources provided to regulatory agencies pose yet another set of challenges to improving the safety of the food supply. While American consumers benefit from one of the world's safest food supplies, the existing regulatory framework is a patchwork of laws and regulations that are frequently inconsistent and lag far behind current scientific knowledge of the risks posed by foodborne pathogens and toxic chemicals.

INTRODUCTION

The U.S. food system is constantly changing and with change come challenges to the safety of food and opportunities to improve food safety. An increasing proportion of our foods are imported from other countries, the way food is processed is frequently modified, regulatory approaches and resources are evolving in response to new knowledge, and consumer lifestyles and demands for different food products are changing along with demographics. Microorganisms have successfully adapted to these changes in our society, resulting in a number of new and emerging pathogens and the reemergence of organisms that have been problematic in the past. For our food safety system to successfully address these challenges, science, food processing technologies, the structure of the food industry, and the regulatory framework must progress and meet these challenges. Reliable data are critical to mount appropriate responses to outbreaks or isolated cases of foodborne illness. Knowledge of an organism's ability to grow in certain foods under various conditions is essential to preventing these illnesses in the first place. This article will discuss some of the challenges posed by foodborne pathogens and opportunities to improve the safety of the American food supply.

SCIENTIFIC CHALLENGES

Several aspects of the most common foodborne pathogens (listed in Table 1) are the roots of scientific challenges to improving food safety. Information, including an estimate of the number of people infected annually, infectious dose, and illness associated with each pathogen, is included to illustrate the diversity of pathogens associated with foodborne illness.

Infectious Dose Estimates

The infectious dose—the predicted ingested dose necessary to cause infection or illness—provides a useful reference to the pathogenic nature of an organism and insight into the challenges posed by pathogens. Infectious doses vary greatly depending on the species and type of microorganism. Ingestion of only a small number of viruses and parasites is required before illness occurs, with only one organism or virus particle required in some cases. For bacterial pathogens, ingestion of a large population of cells is usually required for the initiation of symptoms. However, this is not the case for some of the emerging bacterial pathogens. For example, the infectious dose for *Escherichia coli* O157:H7 may be as low as four organisms (71). Other bacteria, such as *Clostridium botulinum,* are capable of producing toxins that cause serious illness when only a minute quantity is ingested (80).

The infectious doses reported in the literature are derived from volunteer human feeding studies, animal feeding experiments, or estimations from epidemiological data (68, 80). There are obvious drawbacks to these approaches. Host variability, such as age, health, gastric acidity, and immune capacity, greatly influence the infectious dose of an organism or parasite (80). Healthy, young adults used as subjects in volunteer human feeding studies are hardly representative of the physiological state of the most vulnerable populations (i.e., infants, children, the elderly, and immunocompromised individuals). Animal feeding studies provide some estimate of the infectivity of an agent, but cannot account for the variability in host/microorganism interaction that occurs when extrapolating to humans. Furthermore, data from epidemiological studies are greatly lacking in this area because it is often difficult to identify a food source as the vehicle for transmission; the pathogen population in a food source can be altered over time and can be influenced by storage conditions; and frequently, the distribution of the pathogen is not uniform in a food product, making it very difficult to determine the dose consumed by an ill individual. Statistical models have been proposed for more accurate usage

TABLE 1 Characteristics of foodborne pathogens: annual cases of human illness, incubation period, infectious dose, high-risk foods, methods for detection, and resistance to environmental stress

Pathogen	Estimated # of cases/year[a]	Incubation period/ illness[b,c]	Infectious dose[b,c]	High-risk foods for contamination[b,c]	Methods utilized to detect organism in food[b,d,e]	Resistance to environmental stress[b,c]
Bacterial						
Bacillus cereus	27,360	6–15 hrs/watery diarrhea, abdominal cramps. Usually lasts 24 hrs.	$>10^6$ org/g of food	Meats, milk, vegetables, fish, and rice products.	Isolation on selective media followed by biochemical tests. ELISA kits are available to detect the diarrheal toxin.	Can grow under wide temp. range (10–48°C) and pH range (pH 4.7–9.3). Can also tolerate salt conc. of 7.5%. Spores resistant to heat.
Botulism toxin	58	12–36 hrs/dizziness, weakness of limbs, blurred vision, fatigue, and difficulty in swallowing.	A few nanograms of toxin	Any food that has a low acidity, low salt conc., and supports an anaerobic environment (i.e., home-canned foods, foods submerged in fat or oil).	Injection of extract of food into passively immunized mice. ELISA can also be employed to detect toxin.	The bacterium Clostridium botulinum that produces the toxin is resistant to heat, but the toxin itself is very susceptible to high temperatures. C. botulinum can grow at low temp. (3.3°C).
Campylobacter spp.	2,453,926	2–5 hrs/severe abdominal pain, fever, and bloody diarrhea with nausea. Vomiting does not usually occur. Illness self-limits in about one week.	≈100 cells	Undercooked meats and chicken. Any foods that require handling Water.	Isolation in enrichment media followed by biochemical tests ELISA.	Known to survive at low temperatures (−20°C). Grow at low oxygen levels.
Clostridium perfringens	248,520	8–24 hrs/nausea, abdominal pain, and diarrhea. Fever and vomiting are rare. Usually lasts 24 hrs.	10^8 cells	Meats, meat products, and gravy.	Isolation in selective media followed by biochemical tests. RPLA can be used to detect enterotoxin.	Spores are resistant to heat (100°C). Cells lose viability when frozen.

(*Continued*)

TABLE 1 (*Continued*)

Pathogen	Estimated # of cases/year[a]	Incubation period/ illness[b,c]	Infectious dose[b,c]	High-risk foods for contamination[b,c]	Methods utilized to detect organism in food[b,d,e]	Resistance to environmental stress[b,c]
Escherichia coli O157:H7	73,480	3–9 days/intense abdominal pain and nonbloody diarrhea that progresses within 2 days to bloody diarrhea that becomes quite severe. Vomiting and low-grade fever can occur as well.	Less than 10 cells	Undercooked ground beef, hot dogs, raw milk, vegetables, cheese, juice, and fruit.	Isolation in selective media followed by biochemical tests. ELISA kits are available as well.	Sensitive to heat but is resistant to acidic conditions. Can grow in apple cider at a pH of 3.6.
E. coli, non-O157:H7 STEC	36,740	Bloody diarrhea with pus in stools and fever.	10 cells	Raw beef and chicken.	Isolation on selective media followed by biochemical tests. Serotyping with antisera.	
E. coli, enterotoxigenic	79,420	24 hrs/gastroenteritis, traveler's diarrhea, watery stools.	100 million to 10 billion cells	A number of foods. Any food that is handled frequently.	Isolation of selective media—biochemical tests. Gene probe.	
E. coli, other diarrheaogenic	79,420	1–6 days/vomiting, diarrhea, abdominal pain, and fever.		Food and water contaminated with feces.		
Listeria monocytogenes	2,518	1 day–3 wks/may cause nausea, vomiting, and abdominal pain followed by fever. Can cause meningitis, septicemia, and encephalitis. Can also cause spontaneous abortion and stillbirth in pregnant individuals.	Fewer than 1,000 cells	Beef, pork, ready-to-eat foods, soft cheeses, delicatessen foods, milk, poultry, fruits, and vegetables.	Isolation on selective media, followed by biochemical tests. Several immunological techniques are available as well.	Has ability to grow at refrigeration temperatures (3°C) and is resistant to acid pH (4.4) and high salt concentrations (10%).
Salmonella Typhi	824	7–28 days/high fever, headache, vomiting, and diarrhea.			Isolation on selective media followed by biochemical tests. ELISA and LA also available.	

Salmonella, nontyphoidal	1,412,498	6–72 hrs/nausea and vomiting followed by nonbloody diarrhea and abdominal cramps. Illness lasts about 7 days.	10,000 or more cells	Raw meats, fish, poultry, eggs, milk, and diary products.	Isolation on selective media followed by biochemical tests. PCR can also be used.	Susceptible to heat, but resistant to both freezing and drying. Can grow at pH 4.
Shigella spp.	448,240	12–50 hrs/abdominal pain, diarrhea, fever, vomiting, blood, pus, and mucus in stools.	10 cells	Salads, raw vegetables, milk and dairy products, and poultry.	Isolation on selective media followed by biochemical tests. LA can be used to detect toxin.	Temperature range of growth: 10–45°C. Does not survive below pH 4.5.
Staphylococcus food poisoning	185,060	½–6 hrs/intense nausea, vomiting, abdominal cramps, and diarrhea. Illness lasts for about 2 days.	Less than 1.0 microgram of toxin	Meat, poultry, egg products, salads, bakery products, milk, and dairy products. Any food that requires handling.	Toxin is extracted from food by precipitation with antisera.	Toxin is resistant to boiling for 30 min. and is resistant to gastric and jejunal enzymes. *S. aureus* grows in temp. range 7–48°C.
Streptococcus foodborne	50,920	Group A: 1–3 days/sore throat, pain in swallowing, high fever, headache, nausea, vomiting, malaise.	Greater than 10^7 cells	Group A: milk, ice cream, eggs, steamed lobster, ground ham, potato salad, egg salad, custard, rice pudding, and shrimp salad.	Enumeration techniques.	
		Group B: 2–36 hrs/ diarrhea, vomiting, abdominal cramps, fever, and dizziness.		Group B: sausage, evaporated milk, cheese, meat products, pudding, raw milk, and pasteurized milk.	Lancefield group specific antisera.	
Vibrio cholerae, toxigenic	54	Watery diarrhea with rice water stools.	One million cells	Shellfish, water.	RPLA used to detect toxin.	
V. vulnificus	94	Gastroenteritis	Less than 100	Oysters, clams, crabs.	Isolation on selective media followed by biochemical tests.	Can survive at −20°C in oysters. Grow over wide pH range of 6–11.

(*Continued*)

TABLE 1 (*Continued*)

Pathogen	Estimated # of cases/year[a]	Incubation period/ illness[b,c]	Infectious dose[b,c]	High-risk foods for contamination[b,c]	Methods utilized to detect organism in food[b,d,e]	Resistance to environmental stress[b,c]
Vibrio, other	7,880	4–96 hrs/diarrhea, abdominal pain, nausea, vomiting, headache, fever, and chills. Duration is 2–5 days.	Over 1 million cells	Raw, improperly cooked fish and shellfish.	Isolation on selective media—biochemical tests.	Grow under alkaline conditions (pH 8.0–9.5). Have salt tolerance; found in saltwater. Can grow at low temp. (10°C).
Yersinia enterocolitica	96,368	24–48 hrs/gastroenteritis with diarrhea, fever, and abdominal pain.	Unknown	Meats, oysters, fish, and raw milk.	Isolation on selective media followed by biochemical tests.	Can grow at temp. 0–44°C.
Parasitic						
Cryptosporidium parvum	300,000	1–2 wks/severe, watery diarrhea, dehydration	About 10 organisms	Raw foods.	Microscope analysis.	Resistant to chlorination. Killed by conventional cooking procedures.
Cyclospora cayetanensis	16,264	Watery diarrhea, stomach cramps, vomiting, fever, weight loss. Illness is long term.		Strawberries and raspberries.	PCR technique established to analyze strawberries and raspberries.	Undocumented.
Giardia lamblia	2,000,000	24 hrs/diarrhea, cramps, weight loss.	One cyst	Water, raw foods, fruits, and vegetables.	Microscope analysis.	Resistant to chlorination.
Toxoplasma gondii	225,000	Attacks nervous system. Can one cyst cause abortion and stillbirth.		Pork, lamb, and beef.	Microscope analysis.	61°C or higher can inactivate cysts.
Trichinella spiralis	52	Abdominal discomfort, weight loss, nervousness. Long-term illness		Undercooked pork.	Microscope analysis.	Freezing can kill taenia cysticeri.
Viral						
Norwalk-like virus	23,000,000	10–51 hrs/vomiting, nausea, abdominal pain, and diarrhea. Self-limiting in about 1–2 days.	Unknown but very small	Salads, fruits, eggs, coleslaw, and raw shellfish.	No adequate technique available. Development of gene probes and PCR techniques under way.	Remains active after exposure to acid (pH 2.7) and heat (60°C).

Rotavirus	3,900,000	1–3 days/vomiting followed by watery diarrhea with brown, copious stools. Self-limits in 5–8 days.	10–100 particles	Raw foods, salads, and fruits.	No satisfactory method is currently available.	Can survive for days at 4°C on vegetables.
Astrovirus	3,900,000	Gastroenteritis, vomiting, nausea, diarrhea, malaise, abdominal pain, headache, and fever.	Not known, but presumed to be low	Undercooked foods that require handling.	Gene probes and PCR detection methods are currently being developed.	Resistant to pH = 3. Can remain active after 30 min. at 50°C.
Hepatitis A	83,391	14–40 days/ fever, nausea, abdominal pain, anorexia followed, in several days, by jaundice.	10–100 particles	Lettuce, delicatessen meats, fruits, juices, milk, vegetables, raw seafood, and ice cream.	RT-PCR technique available for detection in shellfish. Otherwise no satisfactory methods exist.	Stable at cold temperatures (−20°C) and low pH.

[a]From Reference 55.
[b]From Reference 80.
[c]From Reference 5.
[d]From Reference 31.
[e]From Reference 8.

Abbreviations: ELISA, Enzyme-linked immunosorbent assay; LA, Latex agglutination; PCR, Polymerase Chain Reaction; RT-PCR, Real-time Polymerase Chain Reaction; RPLA, Reverse passive latex agglutination.

of the data available, but more data and experience are needed for this approach to be fully reliable (42). Infectious dose data are important because they can be utilized as the bases for regulation and monitoring. Improved understanding of infectious doses would be important in improving regulatory performance standards for food products and food safety objectives for government and industry.

Detection of Microorganisms in Food and Patient Specimens

The identification of biological contaminants in food has proven to be more difficult and time-consuming than desirable for public health protection. Similar approaches are used to identify pathogens in food and in specimens from sick people. This process usually involves an initial step of isolating the organism from the matrix, which is frequently complicated by the low levels of contamination in foods. Enrichment media can be utilized to help isolate bacteria and increase cell numbers. Various biochemical tests, many of which are now automated, can then be employed to identify bacteria by the species and serotype. Immunological assays can be used to detect toxin production and DNA probes have been developed for most species (8). Mammalian cells are required for the growth of parasites and viruses. Detection of viruses and parasites requires an initial concentration step, followed by cell culturing. Some viruses, such as Norwalk-like virus, cannot be cultured by existing methods, however (48). Parasites and viruses are typically present in small numbers and, unlike bacteria, they do not replicate in food. Immunological techniques such as enzyme-linked immunosorbent assay (ELISA), radioimmunoassay, and DNA/RNA probes have been developed to detect viruses and parasites, but are limited by high detection limits ($>10^3$ infectious units), unavailability of reagents, and poor sample quality (48). The development of reverse-transcription polymerase chain reaction (RT-PCR) detection methods have allowed for some viruses to be identified in foods (49). As the technology for detecting viruses improves, more foodborne infections are likely to be associated with viruses.

Microscopy can be used to identify parasites in food and water, but is not practical for screening purposes in most cases, due to the low number of organisms present and the labor and expertise required. Furthermore, rapid diagnostic tests for the detection of *Trichinella*, *Toxoplasma*, and *Taenia* spp. in food—parasites that account for a number of worldwide illnesses—remain nonexistent (31).

Much remains to be learned about the microbial ecology of farms and food processing establishments, how microorganisms are initially introduced into the food supply, how (or if) they adapt and grow in food, and how various ingredients or conditions influence their virulence. Research is most certainly needed to improve techniques for isolating microorganisms from food matrices and patient specimens and for concentrating them before analysis as well as to improve immunological and genetic methods of detection.

The Emergence of New Foodborne Pathogens

In the past 25 years a number of agents have been recognized as causes of foodborne illness (4, 57, 72). Newly identified foodborne pathogens include bacteria

(*Escherichia coli* O157:H7, *Listeria monocytogenes*, *Campylobacter jejuni*, and *Yersinia enterocolitica*), parasites (*Cryptosporidium* and *Cyclospora*), and viruses (Norwalk-like virus). In addition, prions have been discovered as the cause of a fatal neurodegenerative condition in humans (Creutzfeldt-Jakob disease) and in animals (e.g., scrapie in sheep and bovine spongiform encephalopathy in cattle) (21). These emerging pathogens, organisms that are new or that existed before and are being introduced into the population for the first time, represent the cause of a number of illnesses and hospitalizations each year. Many of these pathogens possess virulence qualities that may not have been observed in the past and can cause chronic illnesses. Some of these organisms have been associated with foods that were once considered to be "safe" from the threat of foodborne illness, such as products with high acidity (e.g., tomatoes, fruit juices). These organisms have forced the scientific community to reconsider the nature and extent of foodborne illness.

Foodborne Pathogens Yet to be Identified

The identification of new biological pathogens in recent years indicates the probability that many unknown agents of foodborne illness remain to be discovered. The Centers for Disease Control and Prevention (CDC) recently estimated that unknown agents—organisms either yet to be identified or not detected in an illness—account for approximately 81% of foodborne illnesses and hospitalizations and 64% of deaths related to foodborne illness (55). Issues further complicating this estimation are the number of cases that are not reported to officials, because infected individuals neglect to seek medical help, physicians do not order laboratory tests, or medical facilities simply do not report cases altogether.

Chronic Sequelae of Infection

Although most foodborne infections are short-term, chronic illnesses are associated with foodborne illnesses as well. Acute symptoms of infection can include vomiting, diarrhea, and fever. Long-term sequelae are very difficult to link to a single infection, due to the large time gap between initial infection and the onset of symptoms of chronic illness. Chronic sequelae may occur in 2 to 3% of foodborne disease cases (52).

A range of chronic illnesses is associated with foodborne pathogens. *Campylobacter jejuni*, *Yersinia enterocolitica*, *Shigella* sp., *Salmonella* sp., and *Klebsiella pneumoniae* have all been reported causes of rheumatoid disease (35, 59, 69, 70). *E. coli* O157:H7 and other shiga-like toxin producing *E. coli* are a major cause of kidney failure, with infections progressing to hemolytic uremic syndrome (7). A number of neurological disorders can manifest from certain infections. *Campylobacter jejuni* is associated with Guillain-Barré, a syndrome that is the most common cause of neuromuscular paralysis in the world (43). Toxoplasmosis in young children due to the parasite *Toxoplasma gondii* can result in retardation, epilepsy, and slight hearing loss, which can appear many years after infection (34). Additional chronic conditions that may be caused by foodborne pathogens and a better understanding of how such conditions manifest in infected individuals await further discovery.

Antibiotic Resistance

With the widespread availability of penicillin, antibiotics were deemed as "miracle drugs," providing the cure to infectious diseases that had plagued humanity throughout time. Now, with the emergence of multi-drug resistant organisms, the currently used antibiotics are less effective against bacterial infections, making it more difficult to treat bacterial illnesses due to the decreasing options available. Multi-drug resistant strains of a number of bacteria are known, including *Salmonella* sp., *Streptococcus pneumoniae*, *Enterococcus* sp., *Klebsiella pneumoniae*, and *Campylobacter jejuni* (47, 75, 77) as well as fungi that have developed resistance to various antifungal agents. *Candida albicans*, *Aspergillus* sp., and *Cryptococcus neoformans*—all important opportunistic pathogens—have acquired resistance to a number of antifungal agents (65, 17). Furthermore, data suggest that antimicrobial-resistant strains are more virulent than susceptible bacterial strains (77).

The overuse and abuse of antibiotics in health care and agriculture has led to the current state. The CDC, for instance, estimates that more than one-third of prescriptions written to patients are unnecessary (13). Over 40% of the antibiotics produced in the United States are used in agriculture, where they are freely administered in livestock feed to promote better growth (61, 74). Many of the antimicrobial agents used in agriculture are closely related to drugs used in humans. Bacteria that develop resistance in the environment can easily find their way into the food supply and present a threat to humans. Vancomycin-resistant enterococci may have evolved from animals fed avoparcin in Europe, for instance (63). Efforts are being made by the CDC, the National Institutes of Health, and the Food and Drug Administration (FDA) to implement an action plan to control the further emergence of antibiotic resistant bacteria (13). Currently, conservative usage of antibiotics is being advocated and alternatives to antibiotics used in agriculture are being explored.

FOOD PROCESSING

A battery of techniques is used in the food processing industry to reduce or prevent the introduction and survival of microorganisms in food. Physical methods of preservation can include dehydration, freeze-drying, heat treatment, or irradiation. Chemical preservatives, such as antimicrobial agents, organic acids, and salt can be added to foods to reduce the levels of contamination. All of these preventive tools work by exerting various forms of pressure on the microbial cell, leading to growth inhibition or death. The problem is that microorganisms have remarkable adaptive mechanisms, enabling them to respond to environmental stresses, such as wide fluctuations in temperature, salt and sugar concentration, or pH. It is therefore no surprise that microorganisms have developed resistance to a number of preservative agents used in the food processing industry (9). This section will address some of the industry's primary concerns in preventing microbial contamination.

Heat/Acid Resistance

The most effective measure used to defend the food supply against microbial contamination is heat. The principal goal of heat treatment is to destroy vegetative cells, toxins, and spores of microorganisms that may either be pathogenic to humans or cause the spoilage of food. In addition to cooking, two basic types of commercial heat processing methods exist: pasteurization and sterilization. Pasteurization is basically a mild heat treatment aimed at destroying roughly 99 to 99.9% of vegetative cells. The purpose of pasteurization is to destroy most spore-forming bacteria that may be present. Sterilization involves a more intense treatment, which completely destroys a population of microorganisms.

Most cells die in response to high temperatures—heat denatures nucleic acids, structural proteins, and enzymes, and results in the loss of vital cell functions. However, various microorganisms have developed mechanisms, such as the production of heat-shock proteins, which allow them to withstand high temperatures. As a general rule, gram-positive spore-forming bacteria tend to be more resistant to heat than gram-negative bacteria. Fungi are usually the most resistant organisms of all; viruses are the most susceptible to high temperatures. Adequate cooking procedures, either during processing or in homes or institutional kitchens, are effective in killing foodborne microbes. But as the information on Table 1 demonstrates, several species of bacteria are capable of surviving at elevated temperatures for a reasonable length of time. Spores of certain bacteria, such as *Bacillus cereus* and *Clostridium perfringens*, can tolerate boiling temperatures ($>100°C$) and therefore require rigorous processing for their control (1). *Enterococcus faecalis* and *E. faecium* are examples of nonsporulating bacteria that have developed tolerance for high temperatures. Both are capable of surviving heat processing and have been implicated in spoilage of pasteurized canned hams (29).

A number of factors influence a microorganism's susceptibility to heat. These factors include the water content of the food and the water capacity of the cell; the salt, fat, protein, and carbohydrate content of the food; the number of organisms present in the food; and the age of the organism. One of the most important intrinsic parameters, however, is the pH of the food. It is well known that the microbial susceptibility to high temperature increases as the pH of the food decreases (11, 67).

Many organic acids are used to reduce the pH of foods. These acids are either present naturally, such as citric acid in fruits and benzoic acid in cranberries, or added as preservatives. Acidic pH affects microbial cells adversely by inhibiting the functions of enzymes and the transport of nutrients into the cell. Microorganisms vary in their ability to tolerate acidic conditions, with gram-negative bacteria being generally more sensitive than gram-positive bacteria and molds and yeast being the least sensitive organisms. Exceptions have been discovered in recent years, and some pathogens have been found in acidic foods and beverages never previously associated with such agents. Outbreaks of *E. coli* O157:H7 have been associated with apple cider (6) and dried fermented sausage (41) and outbreaks of salmonellosis have been linked to unpasteurized orange juice (16), tomatoes (37), and cantaloupe (58).

The relationship between low pH and bacteria survival is complex. If acid treatments are not applied properly to foods, processing effects become counterproductive. Exposure to moderate acid conditions (pH 4) can result in increased synthesis of the acid-tolerance response (ATR) elements in *Salmonella typhimurium* (28). An important feature of the ATR is the production of acid shock inducible proteins, which increase an organism's resistance to low pH. *E. coli* is capable of surviving at a pH of 2 in complex media as the result of expressing the ATR system (52). Exposure to low pH can also induce resistance to other stresses. For instance, heat shock proteins were induced in *Salmonella* cultured in mildly acidic environments (44).

Cold Tolerance and Spoilage

Unlike heat treatment, the desired effect of cold treatment is not necessarily the destruction of microbe contaminants. Instead, cold treatment or freezing slows the catalytic ability of enzymes, resulting in the deceleration of metabolic processes. Growth rate reduces as temperature decreases, with the generation time, on average, doubling for every 10°C reduction in temperature (66). Factors such as the protein, carbohydrate, fat, and water content and pH of the food are all important in determining a microorganism's ability to resist temperature decreases. Yeasts and molds are more resistant to cold temperatures (with many able to grow at temperatures below 0°C) than bacteria. Bacteria differ greatly in their capacity to tolerate cold temperatures. Some species are susceptible to the damaging effects of cold temperatures (inactivation of enzymes, cell wall and membrane injury, RNA degradation, etc.).

Several bacterial species are able to grow at temperatures of 5°C or below. These organisms are capable of replicating at refrigeration temperatures and cause the spoilage of foods. Gram-negative and rod-shaped bacteria are typically more susceptible to cold temperatures and freezing than gram-positive and cocci-shaped bacteria. Spores are resistant to cold temperatures and freezing.

Several pathogenic bacteria are cold resistant. *Listeria monocytogenes* is a nonspore-forming bacterium with remarkable tolerance for low temperatures. Freezing at −15°C and even refreezing has little effect on the organism (22). *L. monocytogenes*, along with *Yersinia enterocolytica* and *Bacillus cereus*, frequently colonize dairy products (14). *Salmonella* sp. also exhibits psychrotrophic properties. The largest outbreak of *Salmonella* poisoning in U.S. history was associated with contaminated ice cream (39).

Freezing rates are very important in dictating an organism's ability to survive at lower temperatures. Gradual freezing, as opposed to rapid freezing, is more lethal to bacteria (1). However, freezing is used by the food industry primarily to preserve the nutritional content of foods, not to destroy contaminants. Therefore, rapid freezing is more desirable, because, unlike during gradual freezing, loss of product quality is minimized (1).

Raw/Minimally Processed Foods

As consumer demands increase for more "natural," fresh, ready-to-eat products, food processing methods and packaging techniques are changing (89). Sales of minimally processed products are increasing, with about half of American food dollars going to ready-to-eat or ready-prepared foods (30). Americans are decreasing the time spent in the kitchen cooking and preparing foods. A recent study of 2000 U.S. households found that 44% of the households surveyed spent 30 minutes or less preparing meals each day during the working week (62). Ready-to-eat, minimally processed foods provide the ideal items for our busy society. These foods are exposed to more gentle/less strenuous methods of processing such as acidification, mild heating, drying, and freezing. The industry is constantly exploring new ways to process and preserve foods without altering the "natural" flavors or nutrients of the products. Many new processing methods that rely on milder heat treatment of food products have been developed in recent years (33).

Raw and minimally processed foods represent a new challenge to food safety for a number of reasons. Refrigeration temperatures are often not adequate in deterring pathogen growth, and microwave heating, which is relied upon heavily with such products, is not entirely effective in uniformly heating foods (18). Pathogenic microorganisms can survive in cold pockets in foods subjected to microwave heating. Additionally, organisms that survive processing treatments may develop increased virulence as well as an increased resistance to environmental stresses. For example, the alternative sigma factor RpoS, which regulates a number of stress response genes in gram-negative bacteria, including *E. coli*, *Shigella flexneri*, and *Salmonella typhimurium*, can be induced by many of the methods used in minimal processing (2, 20). One of the organisms of concern with minimally processed foods is *Listeria monocytogenes*. *L. monocytogenes* has been identified in a number of ready-to-eat products (19, 24, 32) and can survive the subpasteurization temperatures (60–67.5°C) used in the treatment of raw-milk cheeses (23).

Need for Multiple Interventions

Microorganisms can be transmitted to food from a number of sources and via various pathways. Pathogens and organisms that can cause spoilage can be found on the surface of seeds and plants; on the skin, hair, and in the digestive, respiratory, and genital tracts of animals and food handlers; on the scales of fish, and feathers of birds; in the soil and water; and on dust particles in the air. The facilities and equipment used for processing and preparation of foods can harbor a number of hardy organisms (76). Multiple agriculture practices, processing methods, and postprocessing practices have to be successfully implemented and consistently adhered to in order to mount an adequate defense against microbial contaminants and effectively assure the safety of the food supply.

STRUCTURE OF THE FOOD INDUSTRY

The U.S. food manufacturing system is very diverse, with tens of thousands of products being produced by many different processors each year. In 2000, for instance, more than 16,000 food processing firms were responsible for producing over 40,000 products in the United States (36). Its size and complexity, coupled with the rapid changes that have occurred in its organization, products, and workforce, make the structure of the food industry a challenge to improved food safety.

Large, Small, and Very Small Facilities

The food industry can be categorized by various types of commodities and processed food products, with each type represented by hundreds to thousands of different facilities. These processing facilities can range in size from establishments that produce hundreds of products and employ thousands of people to very small businesses that employ a handful of individuals. Obviously, these different types of food processing facilities have different resources that can be brought to bear to assure food safety. From 1992 to 1997, the number of food processing establishments increased from 20,805 to 21,835, with the largest numbers of new facilities being in baking products, sugar, beverages, and other prepared foods (36). These new establishments offset declining numbers of dairy, meat, grain mill products, and fats and oils.

In the past few years, the U.S. food manufacturing system has experienced an increase in the number of very large processing facilities. As mergers occur and companies invest in construction of large processing facilities, they also become responsible for producing larger amounts of products that are distributed over a larger geographic area. When food safety problems occur, the probability of widespread exposure is therefore increased.

Consolidation in the Food Industry

The number of food industry mergers increased throughout the 1990s with a record 813 transactions occurring in 1998 (25). Consolidation has especially affected the meat and dairy industries. The total number of processing establishments decreased in both industries from 1992 to 1997, the period in which the greatest increase in the number of mergers occurred. Today, four firms control over half of all slaughter in the United States (54). A small number of large firms account for the majority of dairy sales as well. For instance, in 1998, companies with $800 million or more in sales accounted for 69% of U.S. dairy sales (36).

Even though the number of mergers has decreased in the last couple of years, data indicates that we are still in a period of consolidation and that this trend will continue for some time as new mergers are still planned (36).

Imported Foods

As Table 2 shows, the import share of U.S. food consumed—the percentage of imported foods consumed relative to all foods consumed in the United

TABLE 2 Import shares of U.S. food consumption (percentage of total food consumed)[a]

Food groups	1981–85	1991–95	2000
Total food consumption	6.8	7.4	8.8
Animal products	3.2	3.2	4.2
Red meat	6.7	7.3	8.9
Dairy products	1.9	1.9	2.7
Fish and shellfish	50.9	56.0	68.3
Animal fat	0.5	1.4	2.8
Crops and products	9.9	10.6	12.3
Fruits, juices, and nuts	12.0	15.5	18.7
Vegetables	4.8	5.9	8.8
Vegetable oils	15.7	19.3	20.2
Grain cereals	1.6	6.7	6.3
Sweeteners and candy	19.8	9.1	8.0

[a]From Reference 50.

States—increased slightly during the last 20 years (from 6.8% in 1981–85 to 8.8% in 2000). The largest increases were observed in fish and shellfish and in fruits, juices, and nuts. Many of these foods are products that are subjected to minimal processing. Increased importation of these products occurred primarily in response to growing consumer preference for ethnic foods, improvements in shipping, and better reliability of foreign suppliers (50).

Importation of raw foods from many other nations increases the opportunity to introduce new pathogens, or to reintroduce infrequent pathogens into the U.S. food supply. For example, in 1995, *Cyclospora* outbreaks occurred in California as the result of contaminated raspberries imported from Guatemala (40). In the summer of 1998, outbreaks of *Shigella sonnei* were reported throughout the United States and Canada (12). The source of these cases was determined to be contaminated parsley, which had been imported from Mexico. Even though it has not been determined if imported foods represent a larger threat to public health than foods produced domestically, imported foods are also being distributed over much wider geographic areas, which makes it difficult to link sporadic cases of illness from these foods to a single source of contamination.

Complexity of the Food Safety Network: From Farm to Table

The average grocery store in the United States carries over 30,000 food items (26). Many of these items contain a number of ingredients that are manufactured by many different processors. The complexity of certain products, especially many of the ready-to-eat foods, makes it very difficult to track down contamination problems, when one of a number of ingredients may be the culprit. Since the FDA and the USDA split jurisdiction along commodity lines, the ingredients in a complex food item can be regulated differently, depending on content. The statutes governing each department are different and thus the standards used by each are not always the same (60).

Workforce

The food industry workforce represents an entirely different problem for the assurance of food safety. The typical food-handling job requires a minimal education (high school at best); offers a low salary, with little to no benefits; requires long work hours which involve performing tedious, repetitive tasks; and, in some cases, is physically demanding. Injury rates in the food processing industry are among the highest in any job category—in 1999, there were 2.7 cases of work-related injury or illness per 100 full-time food-processing workers (78). Many sectors of the industry experience a high turnover rate as the result of such poor working conditions and low pay. This is most dramatically illustrated in the meat industry, where 36% of employees are seriously injured each year and annual turnover at some plants can run as high as 70% (38). Many of these jobs are filled with immigrant workers, who are willing to accept the lower wages and stressful working environment. Providing adequate training in food safety to these employees is a major management challenge. Communication is hampered due to the multiple languages spoken by employees and food safety and personal hygiene are often perceived differently among different cultures.

REGULATORY FRAMEWORK

The regulatory framework to assure the availability of safe food for consumers—that is, the laws, regulations, and organization of responsibilities—poses yet another set of challenges to improving the safety of the food supply. While American consumers benefit from one of the world's safest food supplies, the existing regulatory framework is a patchwork of laws and regulations that are frequently inconsistent and lag far behind current scientific knowledge of the risks posed by foodborne pathogens and toxic chemicals. Twelve different federal agencies share responsibilities for carrying out the authorities of 35 food safety laws. Because the federal agencies also share responsibilities with state and local governments, there is frequent miscommunication and integration of programs could be improved. The response of government at all levels—local, state, and federal—is frequently crisis-driven and reactive rather than prevention-oriented. Despite these frequently cited shortcomings, a committee of the National Academy of Sciences concluded that the current U.S. system of food safety "has many of the attributes of an effective system," although it is complex and moving toward a more science-based approach using hazard analysis and critical control points (HACCP) and risk assessment (60).

Government and Private Sector Responsibilities

U.S. laws recognize that both government and the private sector have responsibilities for food safety (81). Congress enacts statutes that establish the level of protection for the nation's consuming public. The laws are designed to achieve specific objectives; they set broad authorities but also limit regulatory actions. Executive branch agencies are responsible for implementing the laws, and they do so by promulgating and enforcing regulations. Food producers, processors, distributors, and importers are expected to market safe products; and comply with laws and regulations, and are liable if they do not. The court system is charged with rendering impartial decisions when enforcement actions, regulations, or policies lead to disputes between the private sector and government. The system also permits citizens and organizations to participate in rule making and to challenge agency decisions. They can comment on agency rules as they are being developed, petition agencies to consider different approaches, and challenge agency decisions by suing in court.

The success of this system rests on the legal duty of sellers in the United States to market safe products, a legal duty enforceable by injured consumers under state contract and tort laws, and reinforced by transparency and publicity (81). The U.S. food safety system has both "top-down" regulatory controls and "bottom-up" producer responsibility. The meshing and interplay between the authority and responsibility of regulators—and the responsibility of producers—have resulted in a food supply with a high level of consumer protection.

The responsibility of food processors to exercise caution in marketing their products is the foundation of the U.S. legal approach to food safety (81). Food processors are allowed to offer consumers only food that is safe. They may be held "strictly liable" if they fail to carry out their duty. "Strict liability" means that a processor who sells a food that causes injury to a consumer may be legally responsible even in the absence of actual knowledge of the product's hazard. The legal responsibility includes both the possibility of a private lawsuit by any injured consumers and the possibility of regulatory actions. Also, processors must have a reasonable basis for believing their products to be safe; they cannot simply assume this is so.

Divided Regulatory Responsibilities

Three federal agencies share regulatory responsibilities for the safety of food: the Environmental Protection Agency (EPA), the Food Safety and Inspection Service (FSIS), and the Food and Drug Administration (FDA). The EPA is responsible for protecting the public and environment from risks posed by pesticides and for promoting safer means of pest management. FSIS is responsible for ensuring that meat, poultry, and egg products are safe, wholesome, and accurately labeled. FDA is responsible for protecting consumers from impure, unsafe, and fraudulently labeled food other than in products regulated by FSIS. They are supported in their mission by eight other federal agencies that conduct research, surveillance, education, standard-setting, or outbreak response activities. These 12 agencies carry out the requirements of 35 laws that form the legal basis for the food safety system.

The major laws that govern the work of the food safety agencies are the Federal Food, Drug, and Cosmetic Act (FFDCA), the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act, the Egg Products Inspection Act, the Food Quality Protection Act, and the Public Health Service Act.

The paradigms that undergird the food regulatory agencies' approaches are quite different (73). While both FDA and FSIS rely on a similar requirement that food companies have the legal duty to produce foods that are not "adulterated," they differ in the authorities granted to them to oversee the food industry. FDA has jurisdiction over approximately 53,000 food producing establishments, and has authority to set standards of safety. The typical FDA enforcement activity is to remove adulterated food from commerce through requesting the company to conduct a voluntary recall or by going to court to seize the product. In contrast, the FSIS oversees approximately 6000 plants, and is required by the FMIA to conduct "continuous inspection," a term interpreted to mean inspection of every carcass passing through a slaughterhouse. The strength of this system is that government inspectors are in position to promptly detect and require correction of visible food safety and sanitation problems. Food under FSIS's regulatory authority cannot be marketed without the mark of inspection.

The challenges posed by these divided responsibilities and differing paradigms are considerable. Although the system provides a high level of safety to the consuming public, it is limited by statute in implementing practices and enforcement that are based in science (60). Both FDA and FSIS have embraced risk assessment and HACCP as the basis for regulatory approaches, but the underlying statutes present roadblocks to a truly risk- and science-based approach to food safety regulation. One major roadblock is the assignment of responsibility for meat to one agency and all other foods to another. The hazards posed by today's food supply affect many food products, and the division of responsibility has led to inequities in resources. The provisions of the FFDCA related to food sanitation remain essentially unchanged from the law's enactment 60 years ago. FFDCA also is heavily weighted toward control of the use of chemicals in food production, which to a certain extent determines allocation of resources to the neglect of food sanitation. The FMIA does not provide authority over how livestock are produced, maintained, or managed, leaving the source of many food safety hazards to states to monitor despite their limited resources.

Resources

Lack of resources is a continuing challenge to the federal regulatory agencies (73). FDA, with jurisdiction over most of the food supply, has approximately 250 inspectors who annually are expected to visit 5000 of the 53,000 food producing establishments. FSIS employs more than 7000 inspectors who are stationed in approximately 6000 meat, poultry, and egg products plants. FSIS has no authority to conduct research, and relies on the intramural research activities of the Agricultural Research Service and the extramural grants programs of the Cooperative State Research, Education and Extension Service to conduct the research it needs to fulfill its regulatory responsibilities. FDA has a small research budget, but it, too, is heavily reliant on other agencies to conduct research in support of its mandate.

Divided Federal, State, and Local Responsibilities

State and local governments also have important responsibilities for food safety that are complementary to the federal responsibilities. States have responsibility for public health surveillance, and the local or state health department is the first investigator of disease outbreaks that may be foodborne. States also have authority over food-service establishments that include restaurants, fast-food establishments, grocery stores and delicatessens, and sidewalk food vendors. About half the states run inspection programs for establishments that slaughter and/or process meat and poultry products sold only within the state. Although FDA and FSIS have advocated for years that states adopt a uniform food code, health and agriculture departments in the same jurisdiction are usually governed by different statutes, use different methods and standards, and have different cultures that affect their regulatory stance (60).

Calls for Change

Because of the shortcomings of the current system, Congress requested that the National Academy of Sciences (NAS) review whether the current government structure and laws were providing adequate protection to the public, and in 1998, immediately after the report was issued, President Clinton established a Council on Food Safety to develop a strategic plan as the NAS report recommended and to better coordinate the budgeting and planning that the federal food safety agencies conduct (64).

The report contains a number of important findings (64, 88). With respect to the question of whether the Federal government should reorganize its food safety structure, the Council found that the current structure reflects the food safety laws that were enacted over nearly 100 years. The current structure allows for diverse agency input on matters of controversy, but it reduces the ability to allocate resources on the basis of risks posed by the food supply and impedes coordination.

Reorganization by itself would not improve public health protection, the Council concluded. Statutory reform coupled to implementation of the actions of the strategic plan is needed in order to improve public health. The Council also concluded that the strategic plan could be implemented under any of the organizational structures it considered, and that none of them offered the perfect solution to how to organize for improved food safety.

The Council recommended that Congress should enact some near-term legislative proposals and that the Council should oversee near-term efforts to strengthen agency coordination. The Council also recommended that Congress should enact comprehensive unifying legislation followed by an organizational reform plan.

The Council report provided some general criteria for comprehensive legislative reform, but it did not go into any detail about changes to the existing authorizing legislation. The general criteria call for a risk-based, prevention-oriented system for all food. Also, the criteria include allowance for risk assessment, the use of science-based preventive controls, allocation of resources based on risks, use of modern enforcement tools, and measurement of results. Most importantly, the Council made clear that future legislative reform should not weaken the existing food safety statutory authorities.

INTENTIONAL CONTAMINATION

Individuals or groups who would use the food supply to poison a few or many people are a challenge to all segments of the food industry (food producers, processors, retailers, and preparers) and to state and federal governmental agencies. Since the terrorist attacks on New York and Washington, D.C. in September 2001, concern has been focused primarily on domestic and foreign terrorist organizations that might choose to intentionally contaminate the food supply to create fear, undermine the government, and bring attention to their cause. However, the food industry is also vulnerable to individuals who would intentionally contaminate food products for criminal purposes including murder, extortion, or revenge. Individual criminal acts of food contamination are called product tampering.

The importance of agriculture to the American economy and the essentiality of food to life make the food supply a vulnerable target for terrorists (87). The American food system accounts for a significant portion of our gross domestic product—about 15%—and is a major positive contributor to our balance of trade. In the major agricultural states, agriculture and related industries can account for a quarter or more of the state's economy. In Iowa, for example, agriculture accounts for $13.5 billion per year, more than 90% of the land area is engaged in agriculture, and almost one out of every four jobs is directly or indirectly related to agriculture.

The ease of procurement of pathogens, the simplicity of producing them in large quantities, the relative ease of dissemination with low technology, and the potential to cause mass casualties or extensive economic harm make the introduction of pathogens into food or agriculture an attractive opportunity (51). Countries have invested in the development of biological agents to be used against crops and livestock (10). The former Soviet Union, Iraq, and South Africa are all known to have had biological weapons research programs and to have produced and stockpiled numerous biological agents that are capable of causing illness in people and livestock (i.e., zoonotic agents such as anthrax or brucellosis) as well as agents capable of inflicting major crop losses (3). Whether terrorist organizations have obtained access to the agents or to the technology to produce them worries agriculturalists.

Recognition of the threat posed by intentional contamination of food poses additional challenges to the industry and regulatory agencies. To what extent should the food regulatory agencies require that food producers and processors have systems in place to prevent intentional food contamination? How does the risk of intentional food contamination stack up against the "natural" risks encountered daily? How should decision makers in state and federal food regulatory agencies move to a more risk-based and science-based food system? These are all questions that are under debate in Congress and in the agencies, but for which no definitive answers have emerged.

APPROACHES TO REDUCING ILLNESS

Public health and food safety experts realize that pathogen control remains the Achilles' heel of the food safety system. As early as the mid-1980s when the National Academy of Sciences issued a study of the meat inspection system, the scientific community began to call for the modernizing of federal inspection programs to address the presence of pathogens in food products.

Population Surveillance and Better Outbreak Detection

Better information about the incidence of foodborne illnesses is a necessary factor for planning interventions to reduce those illnesses. The CDC has played a leadership role in developing two new systems that are providing much needed information: FoodNet and PulseNet.

FoodNet is an active system of disease surveillance designed to provide information about the incidence of foodborne illnesses and to serve as the framework for case control and other epidemiological studies. With sites in nine states (California, Colorado, Connecticut, Georgia, Maryland, Minnesota, New York, Oregon, and Tennessee), FoodNet's catchment area includes 10% of the U.S. population. FoodNet collects data on the laboratory-confirmed occurrence of seven bacterial organisms (*Campylobacter*, *E. coli* O157:H7, *Listeria monocytogenes*, *Salmonella*, *Shigella*, *Vibrio*, *Yersinia enterocolitica*) and two parasites (Cyclospora and Cryptosporidium). FoodNet's purpose is to monitor the population and to identify sources of foodborne illnesses. It does so through descriptive epidemiology, estimating the frequency and severity of foodborne illnesses, and conducting studies to link illnesses with specific foods. In addition, FoodNet collects information on the occurrence of hemolytic uremic syndrome (a serious consequence of *E. coli* O157:H7), Guillain-Barre syndrome (a consequence of *Campylobacter* infection), and toxoplasmosis.

FoodNet data have proven to be extremely useful in improving estimates of the incidence of illnesses attributable to specific foodborne pathogens and the overall burden of foodborne illnesses (55). FoodNet data have also been used as the framework for case control studies that provide insights into specific foods and food practices associated with outbreaks of illnesses.

PulseNet is the common name for the National Molecular Subtyping Network for Foodborne Disease Surveillance. It was designed to speed the identification of outbreaks of foodborne illnesses by permitting laboratories access to an electronic system for matching "molecular fingerprints" obtained by pulsed field gel electrophoresis analysis of pathogens isolated from patients or food samples. Public health laboratories in all 50 states and 4 localities participate in PulseNet along with FDA and FSIS laboratories. Currently, five bacterial pathogens are included: *Campylobacter*, *E. coli* O157:H7, *Listeria monocytogenes*, *Salmonella*, and *Shigella*.

PulseNet's benefits are twofold: quicker identification of outbreaks, and faster response to outbreaks. CDC epidemiologists have used PulseNet to identify outbreaks of *Listeria monocytogenes* and *E. coli* O157:H7 in several states that probably would have taken much longer to determine in its absence. Linked to product recalls with widespread publicity, PulseNet is helping to reduce the extent of outbreaks because regulatory agencies and food companies can initiate product recalls sooner and thus prevent a larger number of illnesses.

As both these systems continue to expand coverage of foodborne pathogens, they will provide additional insights that will help to frame interventions to prevent foodborne illnesses.

Prevention-Based Regulatory Approaches

Government regulatory agencies have changed their philosophical approach to food safety away from being prescriptive and toward being results-oriented. The new regulatory approaches favor setting performance standards for the industry and allowing companies (who know their products and processes best) the freedom to innovate to meet the standards.

The best example of this approach is the Hazard Analysis and Critical Control Points (HACCP) system, which is now required for meat, poultry, juice, and seafood. HACCP requires a food processor to analyze the hazards reasonably likely to occur in its process and to design and implement a system to eliminate those hazards or reduce them to an acceptable level (87). Regulators reasoned that a regulatory intervention tool that eliminates or reduces foodborne hazards would lead to a reduction in foodborne disease. A recent report by the Institute of Food Technologists reflects this reasoning: "HACCP is a management tool used by the food industry to enhance food safety by implementing preventive measures at certain steps of a process. When HACCP principles are properly implemented, microbiological hazards that have the potential to cause foodborne illness are controlled, i.e., prevented, eliminated or reduced to an acceptable level" (45). In addition to the mandatory HACCP programs that have been put in place for seafood, meat and poultry, and juice, many food processors have voluntarily implemented HACCP systems for other food products.

When HACCP is used in a regulatory context, companies are required to have a control plan for hazards that are reasonably likely to occur in their processing operations. Government inspectors working in HACCP systems then have the responsibility to monitor food processing establishments' adherence to their HACCP plans, and if pathogen or other performance standards are established, they collect product samples for laboratory testing to determine compliance with standards.

Information and Education

In addition to providing information to consumers through labeling, the federal food regulatory agencies have sought to educate the public about the safe handling of foods. In 1997, a national campaign called Fight Bac!™ was formed by the Partnership for Food Safety Education, consisting of representatives from industry, government, and consumer groups (82). Through Fight Bac! consumers were informed about the four steps they can take to protect themselves and their families from foodborne illness: to clean their hands, utensils, and surrounding areas before preparing foods; to avoid cross-contaminating raw products with other items; to properly chill foods when storing them; and to make sure that foods are cooked to the proper temperature.

The Thermy™ campaign was launched in 2000 by the Food Safety and Inspection Service (FSIS) of the USDA as a national effort to promote the use of thermometers in the cooking of meat, poultry, and egg products. The campaign was inspired by a study conducted at Kansas State University in 1995 that indicated that judging the safety of ground beef by color change alone is not safe, because it can turn brown before internal temperatures high enough to kill bacteria are reached (27). As with the Fight Bac! campaign, a cartoon character (Thermy)was designed and a slogan ("It's Safe to Bite When the Temperature is Right") was coined to symbolize and summarize the central idea of the campaign.

So, is there any evidence that indicates that these efforts to inform the public are effective? While the answer to this is unknown as yet, results from recent studies are reassuring. Surveys indicate that the public has become more aware of food safety issues and has taken measures to improve in most areas (85). Nevertheless, consumer surveys and outbreak surveillance data suggest that education efforts should continue to focus in the areas of personal and kitchen hygiene, adequate cooking, and avoiding cross-contamination (56).

Toward a More Risk-Based System

To successfully address the public health goal of reducing illnesses and deaths associated with foodborne illnesses will require research to develop more effective prevention strategies, and the application of all of the approaches outlined above along with changes in the allocation of scarce resources. To do this most effectively will require moving to a more risk-based system for food safety. While the current U.S. food safety system has many strengths, important questions concerning the goals of the system, allocation of responsibilities within the system, accountability, and optimal resource allocation need to be considered if the system is to succeed in reducing the burden of foodborne disease.

Translating public health goals into requirements for individual processors is crucial to meeting the public health goals (87). Achieving this translation requires defining the appropriate roles and responsibilities of government, industry, and the consumer in assuring a safe food supply. FSIS addressed the issue in its 1995 Pathogen Reduction/HACCP rule for meat and poultry when it set performance criteria and performance standards that must be met by plants producing raw meat and poultry. FSIS attempted in the rulemaking to define an acceptable level of pathogens on raw meat and poultry, a translation of the public health goal of reducing foodborne disease into a regulatory requirement for individual processors.

A different approach to translating public health goals into requirements for individual food processors is proposed in an Institute of Food Technologists Expert Report, "Emerging Microbiological Food Safety Issues" (45). The authors propose using the concept of Food Safety Objectives as an approach to achieve public health goals, and state that Food Safety Objectives offer "a practical means to convert public health goals into values or targets that can be used by regulatory agencies and the industry." The report describes a Food Safety Objective as "a statement of the maximum frequency and/or concentration of a microbiological hazard in a food at the time of consumption that provides the appropriate level of protection." This approach provides a way to arrive at specific targets that can be used by regulators and applied to individual food processors.

A successful food safety system must have means to hold individual processors accountable both for producing safe product and for reducing the level of hazards in the food supply. The government-mandated HACCP programs place responsibility on the individual food processor to identify and control hazards, with government ensuring that processors are addressing the hazards that are of public health concern.

In addition, a risk-based food safety system requires the risk-based allocation of resources. Given finite resources, who decides which risks are to be targeted? What factors ought to be considered in making this determination? Should the hazard that causes the most illnesses or the hazard that results in the most deaths receive the most resources? Is the severity of illness a factor that should be considered? How should those deciding resource allocation consider the disparities in how a hazard affects different populations? Should the general population or the most vulnerable be the focus?

Comparative risk rankings are a first step, but risk-based resource allocation also requires systematic approaches to comparing the effectiveness of available risk reduction interventions. This is an area where little data exist and few tools are available. Until risk-based allocation tools are available to decision makers, HACCP cannot fully meet its promise to reduce foodborne disease.

HACCP is an important tool in the existing food safety system and has the potential to bring that system to a new level of public health protection. A comprehensive dialogue on expectations of the system and the appropriate roles and responsibilities of government, industry, and consumers in assuring a safe food supply would help policy makers to design enhancements to realize the full potential of HACCP. Accountability within an HACCP-based system also must be addressed. Performance standards such as the *Salmonella* performance standard in the FSIS Pathogen Reduction/HACCP rule are one approach to accountability, but the legal authority for this approach has been challenged. HACCP without accountability will remain just a process control system and not an engine for significant improvements in food safety.

CONCLUSION

Challenges to our ability to reduce the incidence of foodborne illnesses arise from incomplete scientific knowledge of pathogens and lack of effective control mechanisms as well as from such nonscientific sources as the structure of the industry and outmoded regulatory approaches. In addition to pathogens naturally occurring in food, individuals or groups who would intentionally contaminate food pose new challenges for producers, processors, and regulators. The regulatory framework to assure the availability of safe food for consumers—that is, the laws, regulations, and organization of responsibilities—and the chronic lack of resources provided to regulatory agencies pose yet another set of challenges to improving the safety of the food supply. The existing regulatory framework is a patchwork of laws and regulations that are frequently inconsistent and lag far behind current scientific knowledge of the risks posed by foodborne pathogens and toxic chemicals. American consumers benefit from one of the world's safest food supplies, but the estimated 76 million illnesses we experience annually are costly and largely preventable. New science- and risk-based approaches should lead to better allocation of resources to reduce the burden of foodborne illness.

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