

Outbreak Alert!

Closing the Gaps in Our Federal Food-Safety Net



Center for Science in the Public Interest
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Center for Science in the Public Interest (CSPI) is a non-profit organization based in Washington, DC. Since 1971, CSPI has been working to improve the public's health, largely through its work on nutrition and food-safety issues. CSPI is supported primarily by the 900,000 subscribers to its Nutrition Action Healthletter and by foundation grants.

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EXECUTIVE SUMMARY

In the United States, foodborne illness has been estimated to cause 5,000 deaths and 76 million illnesses per year. Responsibility for food safety is divided among at least ten federal agencies involved in monitoring, surveillance, inspection, enforcement, outbreak management, research, and education. Despite recent improvements, significant gaps in the federal food-safety structure remain that put consumers at risk. To help fill one of these gaps, the Center for Science in the Public Interest (CSPI) maintains a database of foodborne illness outbreaks that have been linked to specific foods.

Findings

CSPI tracked a total of 4,486 foodborne illness outbreaks, involving 138,622 individual cases that occurred between 1990 and 2003. The food categories most commonly linked to foodborne illness outbreaks were:

- **Seafood and seafood dishes: 899 outbreaks involving 9,312 cases of illness**
- **Produce and produce dishes: 554 outbreaks involving 28,315 cases of illness**
- **Poultry and poultry dishes: 476 outbreaks involving 14,729 cases of illness**
- **Beef and beef dishes: 438 outbreaks involving 12,702 cases of illness**
- **Eggs and egg dishes: 329 outbreaks involving 10,847 cases of illness**

Multi-ingredient foods (such as salads, pizza, and sandwiches) where the contaminated ingredient was not identified were linked to 812 outbreaks and 23,126 cases of foodborne illness.

Foods regulated by the U.S. Food and Drug Administration (FDA), such as seafood, produce, eggs, and dairy, were associated with more than twice as many outbreaks as foods regulated by the U.S. Department of Agriculture (USDA), which include meats and poultry.

Recommendations

The Centers for Disease Control and Prevention (CDC) should continue to improve outbreak reporting and surveillance. The CDC has made improvements in its reporting and surveillance system, but gaps still remain. For example, seven states don't have basic laboratory capacity. Those gaps are particularly troubling, given current concerns about bioterrorism.

Congress should pass legislation to form a unified, independent food-safety agency with increased authority. Outbreaks occur, in part, because of inadequate regulatory authority, inadequate monitoring, and inadequate funding. Those problems will not be corrected until the underlying government structure is fixed. Congress needs to create a single food-safety agency, and to invest that agency with greater authority (such as the ability to recall food from the market and to penalize companies that produce contaminated products) than existing regulatory agencies have.

INTRODUCTION

In recent decades, changes in food production and consumption have had an impact on the safety of food. The food industry has evolved from being local to one in which production and processing are centralized in different parts of the country and world. Such large-scale “farms” and feedlots can be breeding grounds for pathogens that are further dispersed in fast-paced slaughterhouses and processing plants. Large-scale processing can easily spread germs into large volumes of processed food, especially meat. Improved transportation has given consumers greater access to produce imported from around the world, but that can also introduce new hazards. Furthermore, some foodborne pathogens have become more virulent, while our population is aging and increasingly vulnerable to foodborne illness.¹

Unsafe foods cause an estimated 76 million illnesses and 5,000 deaths each year in the United States.² Although people from all walks of life can develop foodborne illness, those who are most at risk include the elderly, young children, pregnant women and their fetuses, and the immuno-compromised. While most illnesses occur as isolated cases, outbreaks of foodborne illness are clusters of illness that result from ingestion of a common contaminated food. A single outbreak can affect hundreds, or even thousands, of people.

Foodborne illness outbreaks are primarily investigated by state and local health departments. These local officials sometimes call on the federal Centers for Disease Control and Prevention (CDC) to help investigate large or multi-state outbreaks. The CDC is also responsible for nationwide surveillance of outbreaks and for tracking new and emerging pathogens. But many, perhaps most, outbreaks fall through the cracks because the states are not required by law to report foodborne illness outbreaks to the CDC.

In the United States, at least ten federal agencies have jurisdiction over some aspect of food-safety regulation. That highly fragmented system divides regulatory responsibility based on food products. However, the CDC’s system for reporting outbreaks does not synchronize easily with the regulatory system. Instead of emphasizing the foods that cause outbreaks, the CDC’s lists of outbreaks are organized by pathogen and include outbreaks with unknown etiology and foods.

The primary agencies that inspect and regulate food are the United States Department of Agriculture (USDA), which oversees meat, poultry, and

processed egg products, and the United States Food and Drug Administration (FDA), which is responsible for all other foods. Although FDA-regulated foods are linked to two-thirds of the outbreaks with known causes, the FDA's budget is just 38 percent of the total federal budget for food safety.³ Because of limited funding, the FDA inspects only two percent of the estimated six million shipments of imported food each year.⁴ And while meat-processing plants are inspected by USDA daily, plants processing potentially contaminated seafood, eggs, produce, or processed foods containing less than two percent meat are inspected by FDA on average just once every five years.⁵ When foodborne illness outbreaks do occur, neither the USDA nor the FDA has the power to order recalls of contaminated food. They must ask food companies to *voluntarily* remove foods from the market, although USDA can threaten to withdraw inspectors. This system can delay the recall and increase the number of illnesses in an outbreak. In addition, recent lawsuits brought by the meat industry have curbed USDA's ability to close down plants

producing contaminated meat. The regular occurrence of foodborne illness outbreaks in the United States today is evidence that the current food-safety system needs to be improved.

Figure 1. Food Safety Expenditures FY 2005 (\$ Millions)

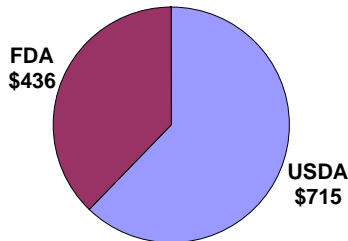
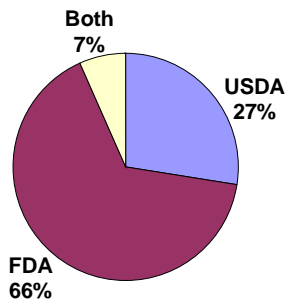


Figure 2. Percent of Outbreaks Linked to FDA- and USDA-Regulated Foods



"We are working under a Meat Inspection Act that pre-dates the Model T."

-Ann Veneman, USDA Secretary of Agriculture, March 2003⁶

The Center for Science in the Public Interest (CSPI) has attempted to address some of these gaps by examining outbreaks linked to specific foods. Such data alert consumers to food-safety hazards, allow consumers to make informed risk decisions about the foods they eat, and provide better information to government for setting priorities for food-safety resource allocation. The findings presented here are from the 2005 *Outbreak Alert!* database, and are accompanied by a list of the most common foods associated with foodborne illness

outbreaks, suggested food-safety interventions for each type of food, and CSPI's recommendations for improving the safety of America's food supply.

A DATABASE OF FOODBORNE ILLNESS OUTBREAKS

Data Collection

CSPI maintains a database of foodborne illness outbreaks, compiled largely from CDC and state health department annual outbreak line listings, reports by the CDC's Foodborne Outbreak Response and Surveillance Unit, and peer-reviewed journal articles. Since 2001, the 1990-1998 CDC outbreak data have been available as annual line listings on the Internet.⁷ Prior to 2001, the CDC outbreak data was unpublished, and obtained by CSPI via Freedom of Information Act requests. Additional outbreaks were obtained from scientific articles, federal government publications, state health department postings, and newspaper reports verified by public health officials; data from these additional sources constitute about 7% of the database. Each outbreak entry was assigned a reference number indicating the data source where the information was obtained.

Incidents of foodborne illness were only included in the CSPI database if they met the CDC's definition of an outbreak: when two or more people have consumed the same contaminated food and come down with the same illness.⁸ In addition, each outbreak must have an identified etiology and food vehicle⁹, must have occurred in the U.S. or its territories between 1990 and 2003, and must have been reported by a reliable source. Outbreak reports that met CSPI's inclusion criteria were further evaluated to determine whether they were already listed in the database or whether they represented new outbreaks. Outbreak reports from different sources may contain slightly different information about the same outbreak. When such discrepancies were discovered, a public health official at the state, local, or federal level was contacted to determine which information was correct.

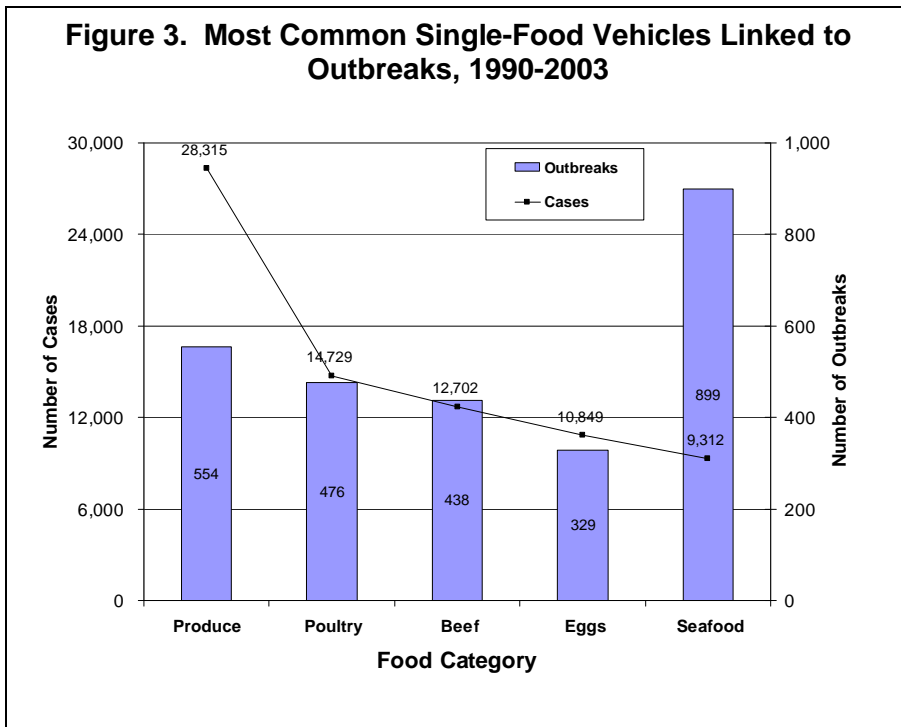
Excluded from the CSPI database were sporadic cases of foodborne illness (individual cases not linked to an outbreak), outbreaks that had no identifiable etiology or food vehicle, and waterborne outbreaks.

Food Categorization

Each outbreak in the CSPI database was categorized by the implicated food, and the regulatory agency with primary responsibility for that particular food item. In general, meat, poultry, and processed egg products are regulated by the United States Department of Agriculture (USDA), while all other foods

are regulated by the U.S. Food and Drug Administration (FDA).¹⁰ There are thirteen food categories in the CSPI categorization scheme, the majority of which were further divided into food subdivisions (see Appendix A).

Food categorization enables identification of the specific food-pathogen combinations causing large numbers of illnesses. Many of the reported foodborne illness outbreaks, however, do not have an identified food vehicle or etiology.¹¹ In addition, the majority of foodborne illness outbreaks go unreported due to their small size, long incubation period, geographic dispersion, an inability to identify the pathogen, or mild cases of illness which do not prompt individuals to seek medical care.¹² For these reasons, the outbreaks included in the CSPI database represent only a small proportion of the actual foodborne illness outbreaks that occurred between 1990 and 2003.



RESULTS

Overall Findings

A total of 4,486 outbreaks, involving 138,622 cases of illness and occurring between 1990 and 2003, were included in the CSPI database. Seven percent of these outbreaks were from sources other than the CDC. The five food categories, not including multi-ingredient foods, linked to the most foodborne illness outbreaks were seafood, produce, poultry, beef, and eggs. These five food

categories were responsible for 60% of all outbreaks in CSPI's database, and 55% of the cases. The produce category alone was linked to the largest number of foodborne illnesses associated with outbreaks, constituting 20% of all cases in CSPI's database.

FDA-regulated foods were linked to 2,954 outbreaks with 83,076 cases, while USDA-regulated foods were linked to 1,229 outbreaks with 38,577 cases.

Foods such as seafood, non-meat multi-ingredient foods, produce, eggs, dairy,

bread, and beverages were linked to more than twice as many outbreaks and cases as meats and poultry. Outbreaks due to multiple foods, including both meat (USDA-regulated) and non-meat (FDA-regulated) items, comprised 7% of the database.

FDA-Regulated Foods

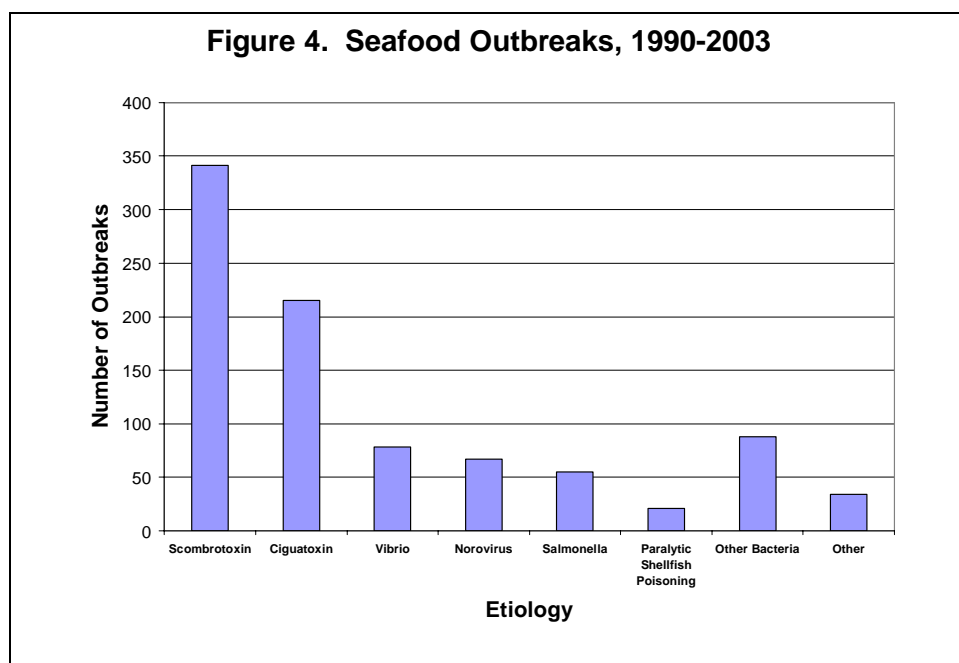
Seafood and seafood dishes. A total of 899 foodborne illness outbreaks with 9,312 cases were linked to seafood and seafood dishes. The average number of cases per seafood-linked outbreak was ten. Of the outbreaks associated with seafood, 571

outbreaks and 2,991 cases were linked to finfish such as tuna and grouper, and 135 outbreaks with 3,156 cases were linked to molluscan shellfish including oysters, clams, and mussels. Seafood dishes like crabcakes and tuna burgers were linked to 129 outbreaks with 2,400 cases. Other seafood, such as shrimp and lobster, were linked to 64 outbreaks with 765

cases. Hazards in seafood included scombrototoxin and ciguatoxin in finfish and *Vibrio* spp. and Noroviruses in shellfish. The majority of seafood outbreaks were caused by natural toxins, rather than by bacteria or viruses.

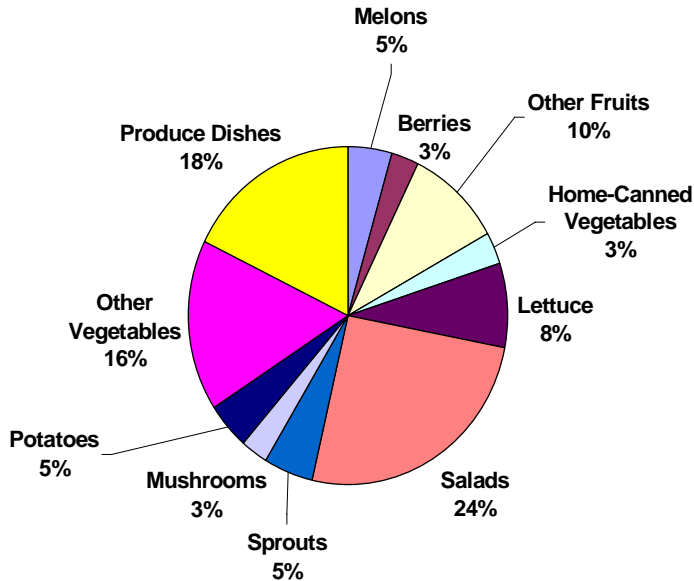
Multi-ingredient foods. A total of 812 foodborne illness outbreaks with 23,126 cases were linked to multi-ingredient foods. The average number of cases per multi-ingredient food outbreak was 28. Foods including rice, beans, stuffing, and pasta dishes were linked to 168 outbreaks and 4,301 cases.

Multi-ingredient salads such as potato salad and coleslaw were linked to 181 outbreaks with 7,841 cases, while multi-ingredient sandwiches were linked to 104 outbreaks and 2,565 cases. Sauces, dressings, and oils caused 55 outbreaks with 1,875 cases. Multi-ingredient dishes, including lasagna, tacos, sushi, and lo mein, were associated with 180 outbreaks with 3,289 cases and 124 outbreaks and 3,255 cases were linked to other foods such as soups,



puddings, and dips. *Salmonella* spp. and Noroviruses were the most common hazards associated with the multi-ingredient food category.

Figure 5. Vehicles of Produce-Related Outbreaks, 1990-2003



Produce and produce dishes. A total of 554 foodborne illness outbreaks involving 28,315 cases were linked to produce and produce dishes. The produce category had an average of 51 cases per outbreak. Vegetables were linked to 205 outbreaks with 10,358 cases, while fruits were identified as the vehicle in 93 outbreaks with 7,799 cases. Of the 93 fruit-associated outbreaks, 15 were linked

to berries and 25 were linked to melon. Produce dishes were implicated in 256 outbreaks involving 10,158 cases. In produce-linked outbreaks, *Salmonella* spp., Noroviruses, and *Cyclospora* spp. accounted for the majority of foodborne illness cases.

Eggs and egg dishes. A total of 329 foodborne illness outbreaks with 10,849 cases were linked to eggs and egg dishes. The average number of cases per egg-linked outbreak was 33. Egg-based dishes such as french toast, omelets, and egg salad were linked to 260 outbreaks with 8,764 cases, and eggs themselves were linked to 69 outbreaks with 2,085 cases. *Salmonella* Enteritidis was the most common hazard among the egg-related outbreaks, accounting for 83 percent of the egg outbreaks.

Dairy. A total of 153 foodborne illness outbreaks and 5,156 cases were linked to dairy products such as cheese, milk, and ice cream. Dairy products had an average of 34 cases per outbreak. Milk was identified as the vehicle in 53 outbreaks with 1,319 cases, cheese was identified in 44 outbreaks with 1,680 cases, and ice cream was identified in 38 outbreaks with 1,632 cases. Unpasteurized items were associated with 32% of the dairy-related outbreaks.

In outbreaks associated with dairy items, *Salmonella* spp. and *Campylobacter* spp. were the most common hazards.

Breads and Bakery. A total of 116 foodborne illness outbreaks with 3,493 cases were linked to breads and other bakery items. The bread and bakery category had an average of 30 cases per outbreak. Breads were associated with 27 outbreaks and 851 cases, while bakery items such as cake, pie, and cheesecake were linked to 89 outbreaks and 2,642 cases. *Salmonella* spp. and Noroviruses were the most common hazards in bread and bakery items.

Beverages. A total of 66 foodborne illness outbreaks and 2,643 cases were linked to beverages. The average number of cases per beverage-related outbreak was 40. Juices were associated with 21 outbreaks and 1,302 cases, among which almost a third were linked to unpasteurized juices. Other beverages such as alcoholic drinks, coffee, and soda were linked to 45 outbreaks with 1,341 cases. Contamination from chemicals, Noroviruses, *Salmonella* spp., and *E. coli* O157:H7 were the most common hazards in beverages.

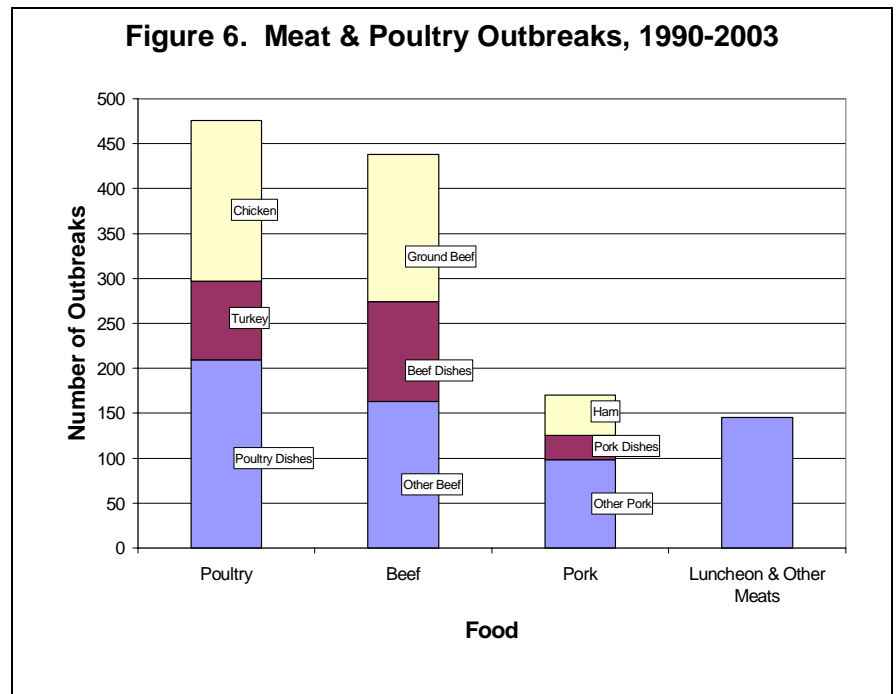
Game. A total of 25 foodborne illness outbreaks with 182 cases were linked to game. This category includes walrus, bear, moose, venison, and cougar meats. The game category had an average of 7 cases per outbreak. In game-related outbreaks, the parasite *Trichinella* was the most common hazard.

USDA-Regulated Foods

Poultry and poultry dishes.

A total of 476 foodborne illness outbreaks with 14,729 cases were linked to poultry. The average number of cases per poultry-related outbreak was 31. Chicken was linked to 179 outbreaks with 3,363 cases, while turkey was identified as

the vehicle in 88 outbreaks with 5,146 cases. Six outbreaks with 106 cases were linked to other types of poultry, such as duck, game hen, and goose.



Poultry dishes were linked to an additional 203 outbreaks with 6,114 cases. The most significant hazards in the poultry category were *Salmonella* spp., *Clostridium perfringens*, *Staphylococcus aureus*, and Noroviruses.

Beef and beef dishes. A total of 438 foodborne illness outbreaks with 12,702 cases were linked to beef. The average number of cases per beef-related outbreak was 29. Ground beef was linked to 164 outbreaks with 3,280 cases, while other types of beef such as roast beef, veal, and beef jerky were linked to 163 outbreaks with 6,111 cases. Beef dishes including casseroles, gravies, and stews were identified as the vehicle in 111 outbreaks with 3,311 cases. In beef-related outbreaks, the most common hazards were *E. coli* O157:H7, *Clostridium perfringens*, and *Salmonella* spp.

Pork and pork dishes. A total of 170 foodborne illness outbreaks with 5,859 cases were linked to pork. Ham was identified as the vehicle in 45 outbreaks with 2,105 cases. Other types of pork were linked to 98 outbreaks involving 2,991 cases. Pork dishes were linked to 27 outbreaks with 763 illnesses. The

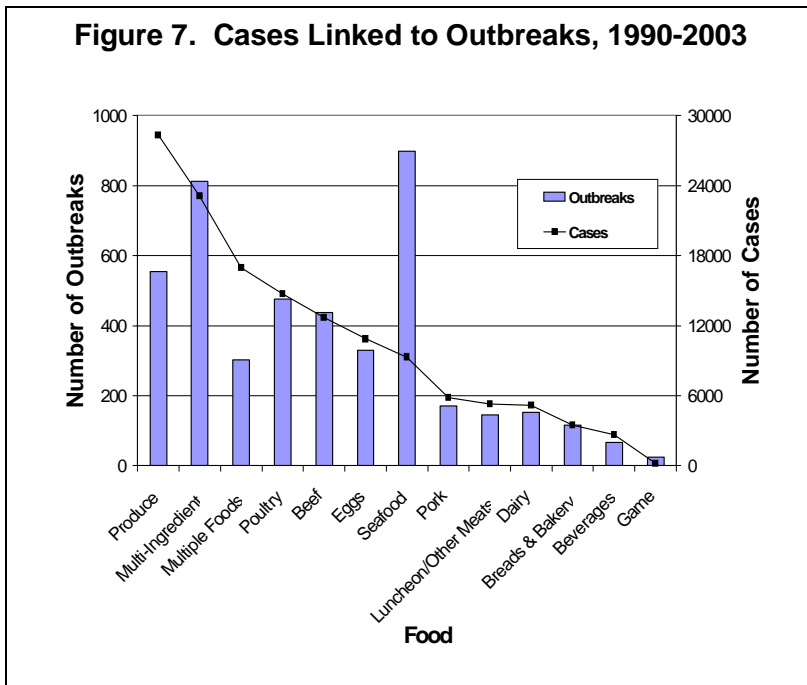
pork category had an average of 34 cases per outbreak. The most common hazard in pork was found to be *Staphylococcus aureus*.

Luncheon and other meats. A total of 145 foodborne illness outbreaks with 5,287 cases were linked to other meats. Of these, 48 outbreaks with 981 cases were attributed to hot dogs and other ready-to-eat luncheon meats such as bologna and salami. Thirty-five outbreaks with 2,191 cases were linked to other meats including lamb, goat, and sausage. Meat dishes were linked to 62 outbreaks with 2,115 cases. The

other meats category had an average of 36 cases per outbreak. *Clostridium perfringens* was the most common hazard for outbreaks linked to other meats.

Foods Regulated by Both FDA and USDA

Multiple foods. A total of 303 foodborne illness outbreaks with 16,969 cases were linked to meals containing foods regulated by both FDA and USDA.



These foods included such meals as chicken served with salad, pork with coleslaw, and ground beef with potatoes. This category had an average of 56 cases per outbreak. In foods regulated by both the FDA and USDA, *Salmonella* was the most common hazard.

FOODS MOST FREQUENTLY LINKED TO FOODBORNE ILLNESS OUTBREAKS

Seafood

Seafood is one of the leading causes of foodborne illness outbreaks in the U.S. Outbreaks can result from naturally occurring toxins, such as scombrototoxin and ciguatoxin in finfish, and microbial hazards, such as *Vibrio* bacteria and Noroviruses, in shellfish. In finfish, harvesting conditions or improper handling after harvest can cause toxins to form. Once formed, the toxins are not destroyed by cooking.¹³ Shellfish can become contaminated with bacteria and viruses in harvesting beds. If not refrigerated shortly after harvest, levels of pathogens can increase. For example, the deadly bacterium *Vibrio vulnificus* can grow in shellfish to numbers 10 to 100 times higher over several hours if the shellfish are not refrigerated after harvest.¹⁴

To help keep seafood safe, the FDA should increase its inspection of processors and implement testing programs to verify that firms are controlling the hazards in their products. Consumers can help protect themselves by not eating tropical or subtropical reef fish like barracuda, by refrigerating all seafood, and by only eating cooked shellfish or raw shellfish that have been treated to eliminate hazardous bacteria.

Produce

Although diets rich in fruits and vegetables provide clear health benefits, those foods occasionally carry harmful microorganisms, including *Salmonella*, Noroviruses, and *Escherichia coli*. Pathogens can jump from animals to produce via contaminated irrigation water, direct application of inadequately processed manure to soil, or even cross-contamination from raw meats in the kitchen. In fact, approximately 30 percent of the produce outbreaks identified by CSPI were caused by pathogens commonly found in meat and poultry.¹⁵ Viruses, like Norovirus and Hepatitis A, often are transferred to produce from human sources. Pathogens can adhere to the rough surfaces of fruits and vegetables, so consumers should take precautions, such as washing produce under running water. Despite the risk posed by fruits and vegetables,

consumers should still eat plenty of produce. But with better farm-based controls, consumers could enjoy the benefits of raw produce with less risk of foodborne illness.

In November 2003, green onions imported from Mexico were the source of a multi-state Hepatitis A outbreak. The imported onions were served at a restaurant in Pennsylvania and resulted in over 500 illnesses and 3 deaths. At least 13 of the cases were restaurant employees, and 75 were residents of six other states who dined at the restaurant. Green onions imported from the same farm in Mexico had caused outbreaks in three states prior to the detection of this larger, deadly outbreak.

Poultry

Hazards commonly linked to poultry outbreaks include *Salmonella* spp., *Clostridium perfringens*, and *Staphylococcus aureus*. *Campylobacter jejuni* is a hazard frequently associated with raw poultry, however virtually all illnesses occur as sporadic cases and not as part of large outbreaks. Thus, the effects of that pathogen are not captured in outbreak data. Farm practices, such as crowding and the use of antibiotics, also can affect the safety of poultry products. Farmers and processors must recognize the critical role they play in maintaining a safe food supply. Government food-safety programs should be expanded to improve conditions on farms, as well as in the slaughter plants. During the summer of 2002, an outbreak of *Listeria monocytogenes* caused over 120 illnesses and 13 deaths. In the aftermath of that outbreak, Wampler Foods recalled 27.4 million pounds of fresh and processed poultry products, the largest recall in history. Consumers can decrease the risk from contaminated poultry by avoiding cross-contamination when handling raw poultry and by cooking all poultry thoroughly.

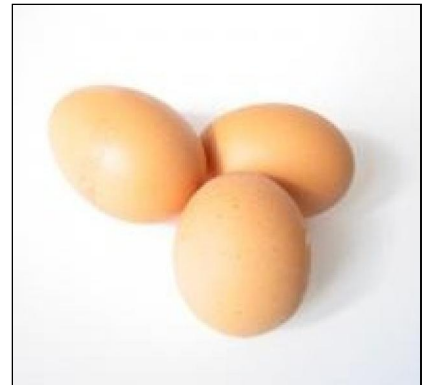
Beef

E. coli O157:H7 and *Salmonella* spp. are the biggest hazards in beef. Those bacteria live in the intestines of animals without causing illness, but if they infect humans, they can cause diarrhea, vomiting, painful abdominal cramps, and sometimes kidney failure and death. Many beef outbreaks listed in *Outbreak Alert!* might have been avoided if the government and the beef industry were more vigilant about keeping hazards out of meat, and increased their testing of beef products. Consumers can help protect themselves by cooking all beef to 160°F, using a meat thermometer, to ensure all bacteria are killed.

Beef and beef dishes have caused many large, well-publicized outbreaks of foodborne illness and recalls.¹⁶ In July 2002, an outbreak of *E. coli* O157:H7 led to the nation's second largest recall of beef. Nineteen million pounds of beef potentially contaminated with *E. coli* O157:H7 were recalled by ConAgra Foods, Inc. On June 17 and 19, USDA test results showed that beef shipped from the ConAgra slaughterhouse in Greeley, Colorado, was contaminated. However, the USDA failed to inform ConAgra for almost two weeks. During that time, the tainted meat continued to be sold at supermarkets, served at countless restaurants, and grilled at outdoor barbecues nationwide.

Eggs

Eggs and egg dishes cause large numbers of outbreaks every year. The primary hazard associated with the consumption of raw and undercooked eggs is *Salmonella* Enteritidis (SE). The USDA estimated that in 1998, approximately one egg in 20,000, or about 2.3 million eggs annually, contained SE.¹⁷ To better protect consumers, government oversight should be increased on the farm, including ensuring that chicken flocks are tested for SE, increased immunization of flocks, and ensuring that eggs from SE-contaminated flocks are pasteurized prior to sale. In the meantime, consumers can protect themselves by fully cooking eggs and egg dishes; by avoiding foods containing raw eggs, such as Hollandaise sauce and raw cookie dough; or by using pasteurized eggs.



Multi-Ingredient Foods

Multi-ingredient foods, including pizza, salads, and sandwiches, cause a large number of outbreaks. Pathogens of concern include *Salmonella* and Noroviruses. Many practices in home and restaurant kitchens can make multi-ingredient foods hazardous, including cross-contamination, under-cooking, inadequate cooling and storage, and worker contamination. Some states and counties have adopted grading systems to inform consumers about restaurants' compliance with health codes and to encourage restaurants to improve their practices. At home, consumers can protect themselves by cleaning all cutting boards, utensils, hands, and other surfaces that touch raw meat before using them to prepare or serve other foods; by cooking foods thoroughly; and by refrigerating leftovers promptly.

RECOMMENDATIONS

With the continuing occurrence of foodborne illnesses and more recent concerns about bioterrorism, bovine spongiform encephalopathy, and avian influenza, changes are needed in government systems to increase public health protections. Implementing the following recommendations would help close holes in the federal food-safety net and, ultimately, decrease the number of illnesses and deaths caused by contaminated food.

The CDC Should Continue To Improve Outbreak Reporting and Surveillance

Outbreak information serves several important functions. It can alert consumers to food safety hazards and help policymakers and public health officials to (1) identify emerging problems, (2) evaluate existing programs, and (3) set goals and priorities for food safety. Having a timely and comprehensive inventory of foodborne illness outbreaks would allow food regulators to monitor trends, issue consumer alerts, and improve production practices. Historically, the CDC's foodborne illness outbreak reporting and surveillance programs have fallen short of meeting those goals, but in the past several years, CDC has made several improvements.

- The CDC has dramatically increased its use of the Internet to gather foodborne illness outbreak reports. The agency's website offers state public health officials an outbreak investigation tool kit and online reporting forms.
- The CDC has resumed publishing its line listing of foodborne illness outbreaks, a practice that was ended in the mid-1980s due to funding constraints.¹⁸ In the past four years, the CDC has published new outbreak information on its website, including new line listings for 2003 and an *E. coli* O157:H7 Summary for the same year, representing several thousand outbreaks.
- Reporting by the states has also increased. As a result, the CDC updated its line listings for 1990-1997 to include over 500 outbreaks that were not on the older version of the listings.¹⁹
- The CDC has expanded systems such as FoodNet and PulseNet, which provide information needed for faster nationwide tracking of foodborne illness.

Those improvements are important, but the CDC also should mandate reporting by states, provide real-time reporting of outbreaks, and organize outbreaks by food hazard to increase the utility of its information. Those gaps are particularly troubling, given the new threat of bioterrorism to our food supply.

While better monitoring and reporting of foodborne illness outbreaks are important, the most important goal is to develop a preventative system that reduces the toll of foodborne illnesses.

The Recipe for Safe Food: A Unified, Independent Food-Safety Agency

Currently, food is regulated by at least ten different federal agencies and 35 different statutes. A single, independent food-safety agency – administering a unified statute – could better address the problems with food-safety inspection and regulation, including gaps in consumer protections, inadequate coordination, conflicting public health standards, regulatory redundancies, and slow approvals of new technologies. A strengthened food-safety net should help decrease the numbers of foodborne illnesses and provide better protection against bioterrorism. A 1998 Institute of Medicine (IOM) report on food safety called for the consolidation of food-safety responsibilities under a single statute, with a single budget and single leader. The IOM report concluded that the “current fragmented regulatory structure is not well equipped to meet the current challenges.”²⁰ In October 2001, the General Accounting Office reported that:

“[O]ne official should be responsible for federal efforts in food safety and have control of resources allocated to food safety.”

- Institute of Medicine, Report on Ensuring Safe Food from Production to Consumption, 1998

A single food-safety agency responsible for administering a uniform set of laws is needed to resolve the long-standing problems with the current system; deal with emerging food-safety issues, such as the safety of genetically modified foods or deliberate acts of contamination; and ensure a safe food supply.²¹

Making the transition to a new and more effective federal agency that would offer more comprehensive protections to public health requires both organizational and statutory changes.

Organizational Changes

The Bush Administration and Congress should unify all of the federal food-safety activities within a single, independent agency – the Food Safety

“We can do much better by consolidating food safety into one single agency, where research, monitoring, risk assessment, and enforcement can be coordinated and improved.”

- Rep. Rosa DeLauro (D, 3rd-CT), co-chair of the Congressional Food Safety Caucus²²

Administration (FSA). Legislation to create a unified agency has already been introduced in Congress by Senator Richard Durbin (D-IL) and Representative Rosa DeLauro (D, 3rd-CT). That agency would be responsible for setting food-safety and labeling standards, approving new food technologies, conducting food-safety inspections, and enforcing the relevant laws. A presidentially appointed, congressionally confirmed Administrator should lead the new agency. The FSA should integrate units from numerous federal departments, including:

- USDA’s Food Safety and Inspection Service and the egg inspection program of USDA’s Agricultural Marketing Service;
- FDA’s food regulatory components (including the Center for Food Safety and Applied Nutrition, the human food-safety components of the Center for Veterinary Medicine, and the food-related laboratory and field resources of FDA’s Office of Regulatory Affairs);
- Environmental Protection Agency’s pesticide tolerance setting program; and
- Department of Commerce’s voluntary seafood inspection program.

The non-regulatory, foodborne illness surveillance program of the CDC should remain separate to provide ongoing information on the nature and magnitude of food-safety hazards. Similarly, food-safety research activities conducted by the National Institutes of Health, Agricultural Research Service, and other research agencies should not be incorporated into the FSA, but should provide research responsive to the needs of that agency.

Statutory Changes

The food-safety and inspection provisions of the Federal Food, Drug and Cosmetic Act, the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act need to be replaced by a unified and modernized food-safety statute. The new statute would build on the strengths of the existing laws, while modernizing the mandates and

authorities of the new FSA. The unification of the food-safety system should be accomplished over several years, with full participation by many stakeholders, including the food and agriculture industries, scientists, and public health experts. Key elements would include:

Clear definition and empowerment of the roles of government, consumers, and the food industry, including: (1) the food industry's responsibility to produce safe products by using up-to-date preventive process controls; (2) the government's authority to establish and oversee compliance with food-safety standards, such as limits on pesticide residues and performance standards for reducing microbial pathogens; (3) the government's responsibility to use its regulatory tools in ways that systematically reduce the risk of foodborne illness; and (4) consumers' right to transparent government decision-making and accountability.²³

A modernized mandate for food inspection to: (1) require that inspection resources be allocated across the food supply based on risk; (2) set a minimum frequency of inspection for food-production establishments, taking into account the food-safety risks and companies' past performances; (3) establish a statutory mechanism to ensure that inspection resources are increased as needed to allow for risk-based reallocation and that future funding levels are adequate to meet the modernized inspection mandate; and (4) coordinate inspections and resource allocation with state and local food-safety agencies.

Enhancement of enforcement authorities and other tools of accountability, including: (1) authority to mandate recalls of contaminated food; (2) adequate civil and other penalties for repeat or egregious violators of food-safety standards; and (3) citizen-suit provisions to enforce food-safety statutes.

Strengthened oversight of imported foods to ensure they are at least as safe as U.S.-produced foods, including: (1) authority to ensure that imported foods meet U.S. safety standards; (2) increased inspection of foreign food-production establishments, especially in countries whose food-safety regulatory systems have not been demonstrated to be equivalent to the U.S. system; and (3) increased border inspections of imported food.

Refinement of the procedures for evaluating and approving new food technologies, for example, carcass treatments to reduce bacteria, in order to: (1) maintain high scientific standards; (2) increase opportunities for public participation; (3) expedite the availability of technologies that can improve food safety.

A mandate to regulate animal production practices that cause or contribute to human illness, including (1) the authority to require feedlots, factory farms, and other producers to raise and transport livestock in ways that prevent or minimize pathogen contamination; and (2) a broad mandate to address the misuse and overuse of antibiotics in livestock production.

While creating a single food-safety agency with new authorities must be done thoughtfully, it also must be done expeditiously. Gaps in current systems are leaving consumers vulnerable to outbreaks of foodborne illness from both bioterrorism and unintentional contamination. Consumers cannot afford to wait years or even decades for the agencies to resolve their competing agendas. It is time for the government to enhance CDC programs and create a single food-safety agency that enforces a modernized and unified food-safety statute.

APPENDIX A: SUMMARY OF FOODBORNE OUTBREAKS AND CASES, 1990-2003

FDA-Regulated Foods			
Category	Subdivision	Outbreaks	Cases
Beverages	Juices	21	1,302
	Other Beverages	45	1,341
	Beverages Total	66	2,643
Breads & Bakery	Bakery	89	2,642
	Breads	27	851
	Breads & Bakery Total	116	3,493
Dairy	Cheese	44	1,680
	Ice Cream	38	1,632
	Milk	53	1,319
	Other Dairy	18	525
	Dairy Total	153	5,156
Eggs	Eggs	69	2,085
	Egg Dishes	260	8,764
	Eggs Total	329	10,849
Game	Game Total	25	182
Multi-Ingredient Foods	Rice/Beans/Stuffing/Pasta Dishes	168	4,301
	Salads	181	7,841
	Sandwiches	104	2,565
	Sauces/Dressings/Oils	55	1,875
	Multi-Ingredient Dishes	180	3,289
	Other Foods	124	3,255
	Multi-Ingredient Foods Total	812	23,126
Produce	Fruits	93	7,799
	Vegetables	205	10,358
	Produce Dishes	256	10,158
	Produce Total	554	28,315
Seafood	Finfish	571	2,991
	Molluscan Shellfish	135	3,156
	Seafood Dishes	129	2,400
	Other Seafood	64	765
	Seafood Total	899	9,312
FDA Total	FDA Total	2,954	83,076

USDA-Regulated Foods			
Category	Subdivision	Outbreaks	Cases
Beef	Ground Beef	164	3,280
	Beef Dishes	111	3,311
	Other Beef	163	6,111
	Beef Total	438	12,702
Luncheon & Other Meats	Luncheon	48	981
	Meat Dishes	62	2,115
	Other Meats	35	2,191
	Luncheon & Other Meats Total	145	5,287
Pork	Ham	45	2,105
	Pork Dishes	27	763
	Other Pork	98	2,991
	Pork Total	170	5,859
Poultry	Chicken	179	3,363
	Turkey	88	5,146
	Poultry Dishes	203	6,114
	Other Poultry	6	106
Poultry Total	476	14,729	
USDA Total	USDA Total	1,229	38,577

Multiple Foods			
Category	Subdivision	Outbreaks	Cases
Both	Both Total	303	16,969

All Foods	Total Outbreaks	Total Cases
Grand Total	4,486	138,622

ENDNOTES

¹ The terms “food poisoning” and “foodborne disease” are often used interchangeably. However, the term “foodborne disease” reflects three kinds of causes: foodborne intoxications (from ingestion of foodborne poisons); foodborne infections (caused by foodborne pathogenic microorganisms such as *Salmonella* that, when ingested, cause infections); and foodborne toxicoinfections (from foodborne pathogens such as *E. coli* O157:H7 that, once ingested, produce harmful toxins). Satin M. *Food Alert! The Ultimate Sourcebook for Food Safety*. New York: Checkmark Books; 1999. p.16-17.

² Mead PS, Slutsker L, Dietz V, McCaig LF, Bresee JS, Shapiro C, Griffin PM, Tauxe RV. Food-related illness and death in the United States. *Emerg Infect Dis* 1999; 5(5): 607-625.

³ U.S. Department of Agriculture. *FY 2005 budget summary*. p. 65. Available at <http://www.usda.gov/agency/obpa/Budget-Summary/2005/FY05budsum.pdf>; U.S. Food and Drug Administration, Office of Financial Management. *FY 2006 budget summary and budget in brief: comparable all purpose table, program level*. Available at <http://www.fda.gov/oc/oms/ofm/budget/2006/HTML/Tables/compAPTPL.htm>.

⁴ Hearing on FY 2005 Food and Drug Administration Appropriations for Programs Under its Jurisdiction Before the Subcommittee on Agriculture, Rural Development, and Related Agencies of the House Committee on Appropriations. April 1, 2004. Testimony of Lester M. Crawford, Acting Commissioner, Food and Drug Administration, Department of Health and Human Services; FDA News. *FDA proposes additional rules to ensure the safety of imported food*. Press release P04-47. April 26, 2004.

⁵ United States General Accountability Office. *Overseeing the U.S. food supply: steps should be taken to reduce overlapping inspections and related activities*. Statement of Robert A. Robinson, Managing Director, Natural Resources and Environment. Testimony before the Subcommittee on the Federal Workforce and Agency Organization, Committee on Government Reform, House of Representatives. GAO-05-549T. Tuesday, May 17, 2005. p.4.

⁶ Remarks of Secretary of Agriculture Ann M. Veneman, Food Safety Summit and Expo, Wednesday, March 19, 2003, available at www.usda.gov/news/releases/2003/03/0092.htm.

⁷ Centers for Disease Control and Prevention. *U.S. foodborne disease outbreaks*. Last accessed on August 29, 2005 at http://www.cdc.gov/foodborneoutbreaks/us_outb.htm.

⁸ Centers for Disease Control and Prevention. *Foodborne illness: general information*. Last accessed on August 3, 2005 at http://www.cdc.gov/ncidod/dbmd/diseaseinfo/foodborneinfections_g.htm#whatoutbreak. Before 1992, the exception to this rule was botulism where one illness was considered an outbreak. After 1992, the CDC started omitting outbreaks of botulism with only one case from its line listings. CSPI's database reflects these changes.

⁹ The CDC's U.S. Foodborne Disease Outbreaks, 1990-2003 contained over 7,000 outbreaks with unknown etiology or food vehicle that were not included in CSPI's database. Outbreaks were included in CSPI's database if a suspected vehicle was identified.

¹⁰ United States General Accountability Office. *Oversight of food safety activities: federal agencies should pursue opportunities to reduce overlap and better leverage resources*. Report to Congressional Requesters. GAO-05-213. March 2005.

¹¹ Jones TF, Imhoff B, Samuel M, Mshar P, Gibbs McCombs K, Hawkins M, Deneen V, Cambridge M, Olsen SJ, for the Emerging Infections Program FoodNet Working Group. Limitations to successful investigation and reporting of foodborne outbreaks: an analysis of foodborne disease outbreaks in FoodNet catchment areas, 1998-1999. *Clin Infect Dis* 2004; 38 (Suppl 3): S297-S302.

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- ¹² Olsen SJ, MacKinnon LC, Goulding JS, Bean NH, Slutsker L. Surveillance for foodborne disease outbreaks – United States, 1993-1997. *MMWR* 2000; 49 (SS01): 1-51.
- ¹³ Food and Nutrition Board Institute of Medicine. *Seafood Safety: Committee on Evaluation of the Safety of Fishery Products*. Ahmed FE, editor. Washington, DC: National Academy Press; 1991. p. 88.
- ¹⁴ Center for Science in the Public Interest, Petition for Regulatory Action to Establish a Standard for *Vibrio vulnificus* in Raw Molluscan Shellfish of Undetectable Levels 10 (1998), citing Letter from Patricia S. Schwartz, Food and Drug Administration, to Ken B. Moore, Interstate Shellfish Sanitation Conference, Aug. 17, 1995.
- ¹⁵ Pathogens with animal reservoirs include *Salmonella* spp., *E. coli*, *Campylobacter* spp., and *Yersinia* spp.
- ¹⁶ In July 2002, there was a 19 million pound recall and at least 38 illnesses due to *E. coli* O157:H7 in ground beef.
- ¹⁷ Food Safety and Inspection Service, USDA: *Salmonella* Enteritidis Risk Assessment. Shell Eggs and Egg Products. 1998 Available at <http://www.fsis.usda.gov/OPHS/risk/index.htm>.
- ¹⁸ Telephone conversation with Dr. Patricia Griffin, Chief of Foodborne Diseases, Foodborne and Diarrheal Branch, Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention, Atlanta, GA, January 14, 1999.
- ¹⁹ CSPI obtained the older, unpublished version of the 1990-1997 line listings by submitting a Freedom of Information (FOIA) request to the CDC.
- ²⁰ Institute of Medicine National Research Council. *Ensuring Safe Food From Production to Consumption: Committee to Ensure Safe Food From Production to Consumption*. Washington, DC: National Academy Press; 1998. p. 12, 97.
- ²¹ Food Safety and Security: Fundamental Changes Needed to Ensure Safe Food: Hearings Before the Subcommittee on Oversight of Government Management, Restructuring and the District of Columbia of the Senate Committee on Governmental Affairs (testimony of the General Accounting Office), October 10, 2001, p. 1.
- ²² U.S. House of Representatives, Congresswoman Rosa L. DeLauro (D, 3rd-CT). *Durbin, DeLauro introduce Safe Food Act of 2004*. Press release. October 7, 2004.
- ²³ Although foodborne illness victims and their families can sue food firms for product liability, most do not because of the difficulty of linking the illness to a definitive food source, according to the U.S. Department of Agriculture's Economic Research Service. Jean C. Buzby *et al.*, Economic Research Service, *Product Liability and Microbial Foodborne Illness* 24 (2001). Citizen suits, in which citizens or citizen groups sue firms that violate laws or regulations, might be a more effective remedy. Such provisions also allow citizens to sue the government for neglect of certain duties. While the major environmental statutes (including the Clean Water Act, 33 U.S.C. §1365) authorize citizen suits, none of the food laws contain such provisions.