

Outbreak Alert!



Closing the Gaps in
Our Federal Food-Safety Net

Center for Science in the Public Interest

Updated and Revised—March, 2004

Outbreak Alert! 2004 was researched and written by Caroline Smith DeWaal, Deliya Banda and Kristina Barlow. Deliya Banda maintained CSPI's outbreak database in 2003 and 2004. Kristina Barlow maintained the database in 2001 and 2002. We gratefully acknowledge the assistance of Lucy Alderton, Michael F. Jacobson, Leora Vegosen, Stephen Watkins, Karen Egbert, and Ken Kelly in preparing this report. We also thank the scientists in government public-health agencies who provided information and inspiration for this report.

Center for Science in the Public Interest (CSPI) is a non-profit organization based in Washington, D.C. 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 800,000 subscribers to its *Nutrition Action Healthletter* and by foundation grants.

Center for Science in the Public Interest
1875 Connecticut Avenue, N.W., Suite 300
Washington, D.C. 20009-5728
Phone (202) 332-9110
www.cspinet.org

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Sixth Edition, March 2004

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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 3,529 outbreaks, representing 118,670 individual cases, of foodborne illness that occurred between 1990-2003. The top five single-food vehicles causing outbreaks were:**
 - **Seafood and seafood dishes, with 723 outbreaks and 8,071 cases of illness.**
 - **Produce and produce dishes, with 432 outbreaks and 25,823 cases.**
 - **Poultry and poultry dishes, with 354 outbreaks and 11,894 cases of illness.**
 - **Beef and beef dishes, with 343 outbreaks and 10,872 cases of food poisoning.**
 - **Eggs and egg dishes, with 309 outbreaks and 10,750 cases.**
- **Multi-ingredient foods (such as salads, pizza, and sandwiches) where the contaminated ingredient was not identified were linked to 601 outbreaks and 18,006 cases of food poisoning.**
- **Foods regulated by the Food and Drug Administration (FDA) were the vehicles in two-thirds of the outbreaks in CSPI's database, while foods (meat, poultry) regulated by the U.S. Department of Agriculture (USDA) were the vehicles in one-fourth of the outbreaks.**

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 that spread germs from carcass to carcass and into large volumes of contaminated 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 food poisoning 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 food-poisoning outbreaks to the CDC.

In *Outbreak Alert!*, CSPI seeks to summarize what is known about outbreaks, by contacting the states for outbreak information, searching scientific and medical journals and newspapers for outbreak reports, and gathering information from the CDC, in order to compile the most complete information available about foodborne-illness outbreaks linked to specific foods. CSPI’s database identifies the food vehicles most likely to be linked to an outbreak.

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. Linking outbreaks to specific foods, as CSPI does in *Outbreak Alert!*, serves to alert consumers to food-safety hazards and gives policymakers, legislators, and public-health

officials better information to help them design risk-based hazard-control plans.

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 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 31 percent of the total federal budget for food-safety inspections.³ Because of limited funding, the FDA inspects only two percent of the estimated five 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 food-poisoning outbreaks in the U.S. today is evidence that the current food-safety system needs to be improved. In March, 2003, USDA Secretary of Agriculture Ann Veneman said that USDA was "working under a Meat Inspection Act that pre-dates the Model T."⁶

The following is a list of the most common causes of outbreaks, together with suggested food-safety interventions for each type of food. That information is followed by the findings from the 2004 *Outbreak Alert!* database and CSPI's recommendations for improving the safety of America's food supply.

Foods Most Frequently Linked to Foodborne-Illness Outbreaks

Seafood

Seafood is one of the leading causes of food-poisoning outbreaks in the U.S. Outbreaks can result from naturally occurring toxins, such as scombrototoxin and ciguatera toxin 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.⁷ 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.⁸

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 pathogenic 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, around 40 percent of the produce outbreaks identified by CSPI were caused by pathogens commonly found in meat and poultry. 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 food poisoning.

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 approximately 555 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 the larger, deadly outbreak.

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.⁹ 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.

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.¹⁰ 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 bad meat continued to be sold at supermarkets, served at countless restaurants, and grilled at outdoor barbecues nationwide.

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.

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.

DATABASE OF FOODBORNE-ILLNESS OUTBREAKS

To help identify food hazards linked to specific foods, CSPI maintains a database of foodborne-illness outbreaks, which is analyzed and updated periodically in this report. As of January 1, 2004, the database contains over 3,500 outbreaks that are organized by the implicated food and the agency that regulates it – the FDA, USDA, or both (available online at <http://www.cspinet.org/foodsafety/reports.html>).

Methodology

Incidents of foodborne illness were only included in CSPI's database if they met the definition of an outbreak,¹¹ had an identified pathogen and food vehicle,¹² and were reported by a reliable source.

CSPI's database was compiled from CDC's Foodborne Disease Outbreak Line Listings, 1990-2001, CDC's "*E. coli* O157 Summaries," CDC's "*Salmonella* serotype Enteritidis Outbreak Summaries," other government publications, and scientific journals. Additional outbreaks (about 9 percent) were discovered in health-department postings and in newspaper and Internet reports verified by CSPI's calls to public-health officials. Once an outbreak report was found to meet CSPI's criteria, it was further evaluated to determine whether it was already listed in the database or represented a new outbreak. If the new report simply updated information already in CSPI's database, the database was changed to reflect the most recent information. A report was added as a new outbreak, however, if it had a reliable source and did not duplicate an outbreak already included in the database.¹³ Each outbreak is sorted first by food, then by pathogen, and is given a reference number. References follow the complete listing, available online.

Outbreaks and Illnesses Not Included in CSPI's Database

For several reasons, the outbreaks included in this report represent only a small percentage of actual foodborne illnesses that occurred over the reporting period:

- CSPI's database includes only the outbreaks for which we could obtain complete information from a government, scientific, or public-health source.
- The database only includes outbreaks that could be linked to a food, so it includes fewer outbreaks than comparable CDC lists. (The CDC Line Listing for 1990-2001 included over 5,000 outbreaks that had no identifiable etiology or vehicle. Those are excluded from *Outbreak Alert!*.)

- Sporadic (individual) cases of foodborne illness are dismissed, ignored, or not investigated. That excludes most cases of several well-known food hazards, such as *V. vulnificus* in shellfish and *Campylobacter* in poultry.
- *Outbreak Alert!* includes only a small portion of total outbreaks, because foodborne illness is vastly under-reported. That is due, in part, to the number of steps involved in outbreak reporting: People who become ill may not seek medical care; doctors may not order diagnostic tests; the tests may not be sensitive enough to detect low numbers of organisms; the cause of the outbreaks may never be identified; or diagnosed illnesses may not be reported to public-health agencies. Any of those failures in the process mean that information about those outbreaks will never enter the public record and is, therefore, not included in CSPI's database.

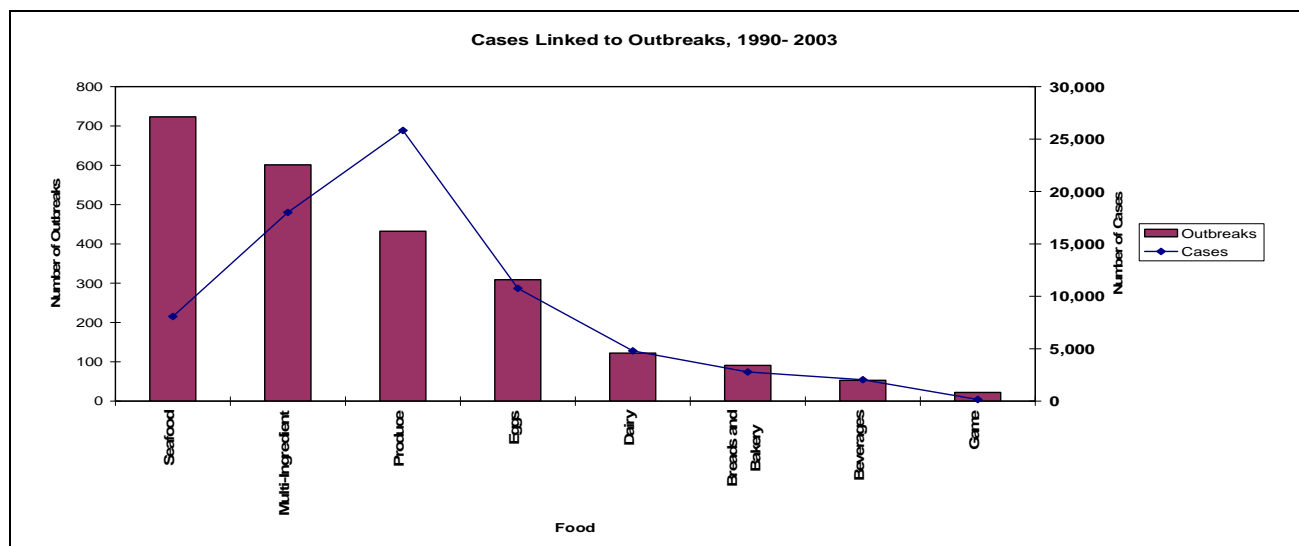
Finally, although CSPI's database includes the most current data available, outbreaks are still not reported on a "real-time" basis. Even the most recent outbreaks listed are several months old. Real-time outbreak reporting would help state and local public-health officials curb ongoing outbreaks and prevent contaminated foods from reaching the public. However, only a federal agency such as the CDC is capable of tracking and reporting on its Internet site outbreaks as soon as they are identified.

Findings

The following is a summary of findings from CSPI's database of outbreaks.

- **A total of 3,529 outbreaks, involving 118,670 cases, was recorded between 1990-2003 (see Appendix A). Those outbreaks include all of the outbreaks on the CDC outbreak listings where both the hazard and the food were identified. In addition, the database includes outbreaks separately identified by CSPI.**

Figure 1



- FDA-regulated foods were linked to 2,353 outbreaks with 72,418 cases; USDA-regulated foods were linked to 935 outbreaks with 32,427 cases; and 241 outbreaks with 13,825 cases were linked to foods regulated by both FDA and USDA.

Figure 2

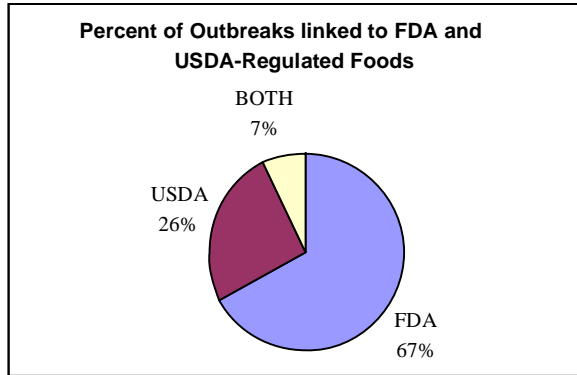
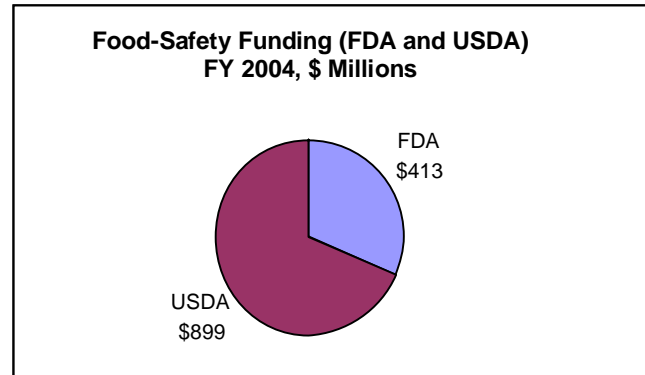
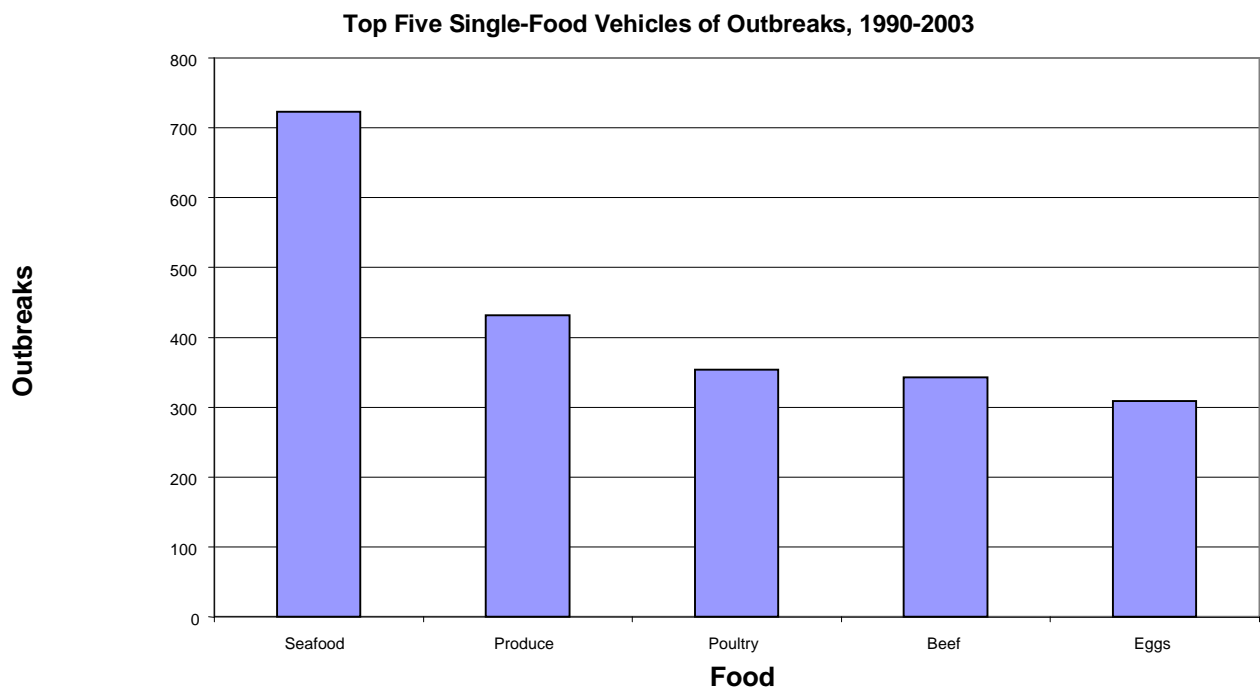


Figure 3



- **The top five food categories, not including multi-ingredient foods, linked to food-poisoning outbreaks were seafood, produce, eggs, beef, and poultry.** Seafood, with 723 outbreaks, made up 20 percent of total outbreaks. Produce, with 432 outbreaks, made up 12 percent; poultry, with 354 outbreaks, comprised 10 percent; beef, with 343 outbreaks, made up 10 percent, and eggs, with 309 outbreaks, comprised 9 percent. Those five sources were responsible for 61% of all outbreaks in CSPI's database.

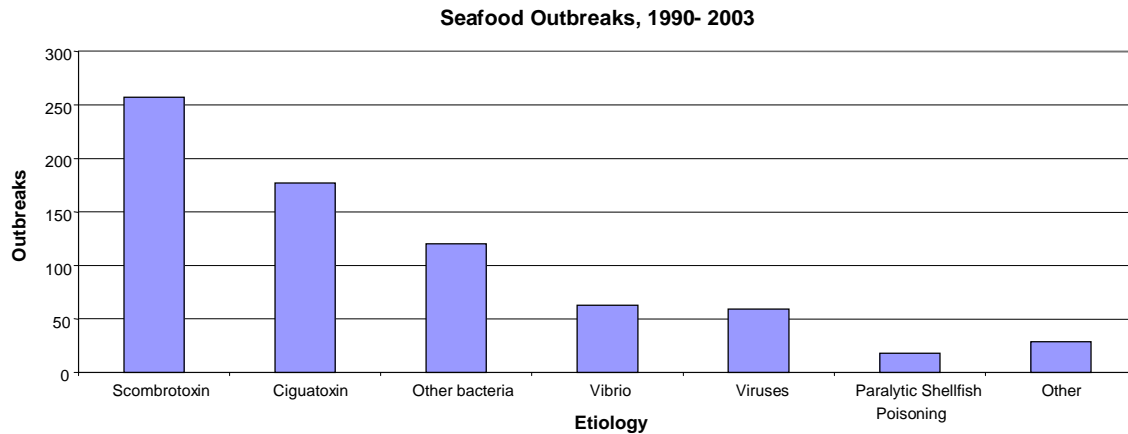
Figure 4



FDA-Regulated Foods

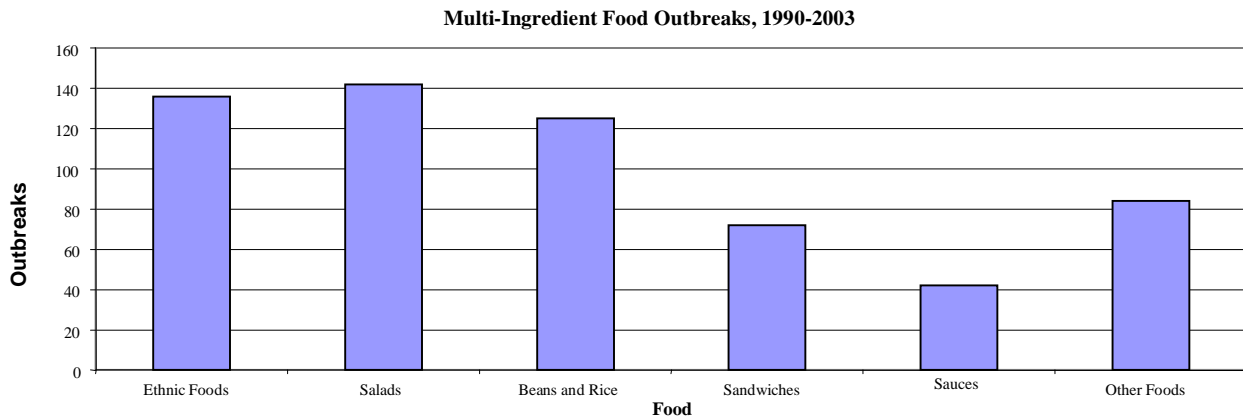
- 723 outbreaks with 8,071 cases were linked to seafood, including finfish, molluscan shellfish, other shellfish, and seafood dishes.** 463 outbreaks with 2,519 cases were linked to finfish, and 112 outbreaks with 2,956 cases were linked to molluscan shellfish, including oysters, clams, and mussels. Other seafood, such as crab and shrimp, were linked to 48 outbreaks with 653 cases. Seafood dishes were linked to 100 outbreaks with 1,943 cases. The seafood category had an average of 11 cases per outbreak. Hazards in seafood included scombrototoxin and ciguatoxin in finfish and *Vibrio* and Noroviruses in shellfish. The majority of seafood outbreaks were caused by natural toxins, rather than by bacteria or viruses.

Figure 5



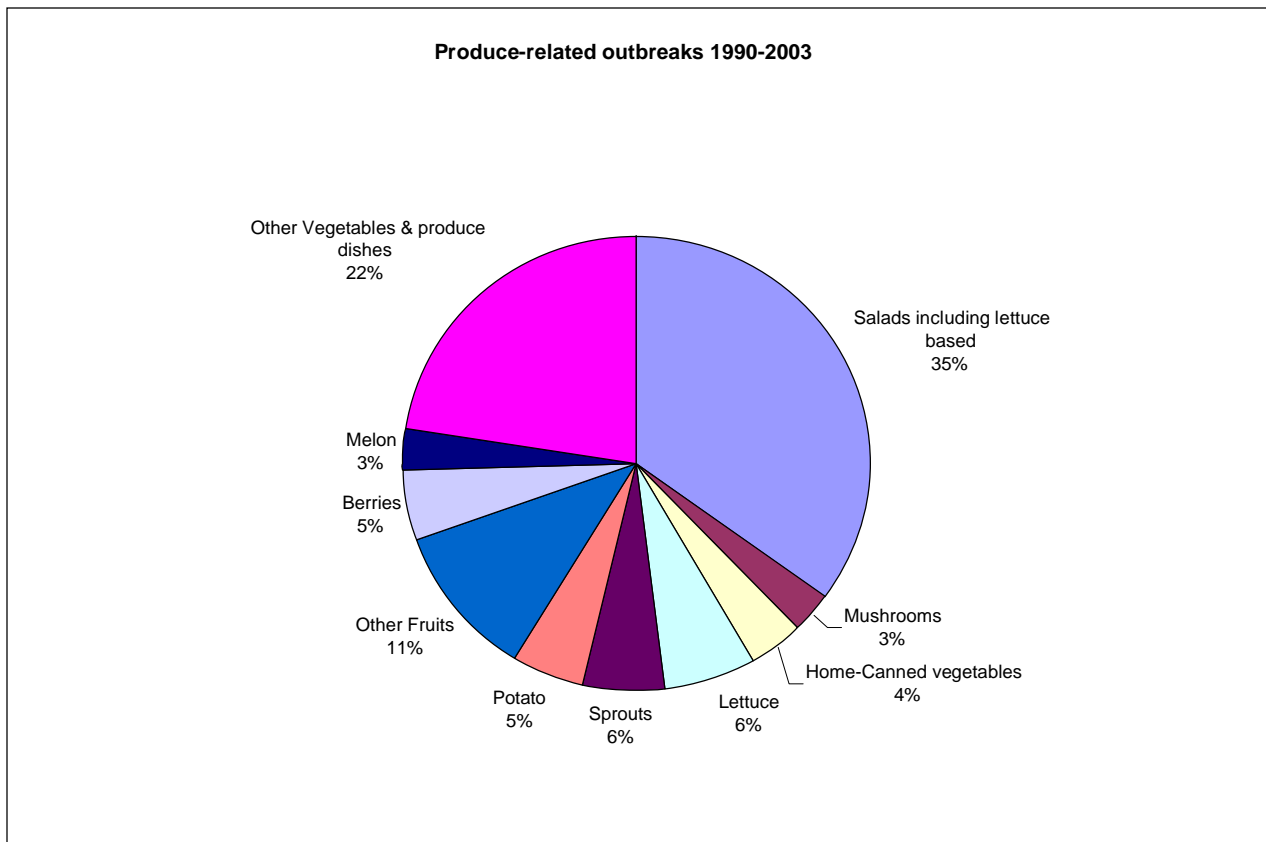
- 601 outbreaks with 18,006 cases were linked to multi-ingredient foods.** Of those foods, 142 outbreaks with 6,513 cases were linked to salads. Contaminated multi-ingredient ethnic foods, such as Italian, Mexican, and Chinese, caused 136 outbreaks with 2,597 cases. 125 outbreaks with 3,371 cases were linked to rice, beans, stuffing, and pasta dishes, and 72 outbreaks with 2,146 cases were linked to sandwiches. Contaminated sauces, dressings, and oils caused 42 outbreaks with 1,547 cases, and 84 outbreaks with 1,832 cases were linked to such other foods as soups, puddings, and dips. The multi-ingredient-food category had an average of 30 cases per outbreak. *Salmonella* and Noroviruses were the most common hazards in the multi-ingredient food category.

Figure 6



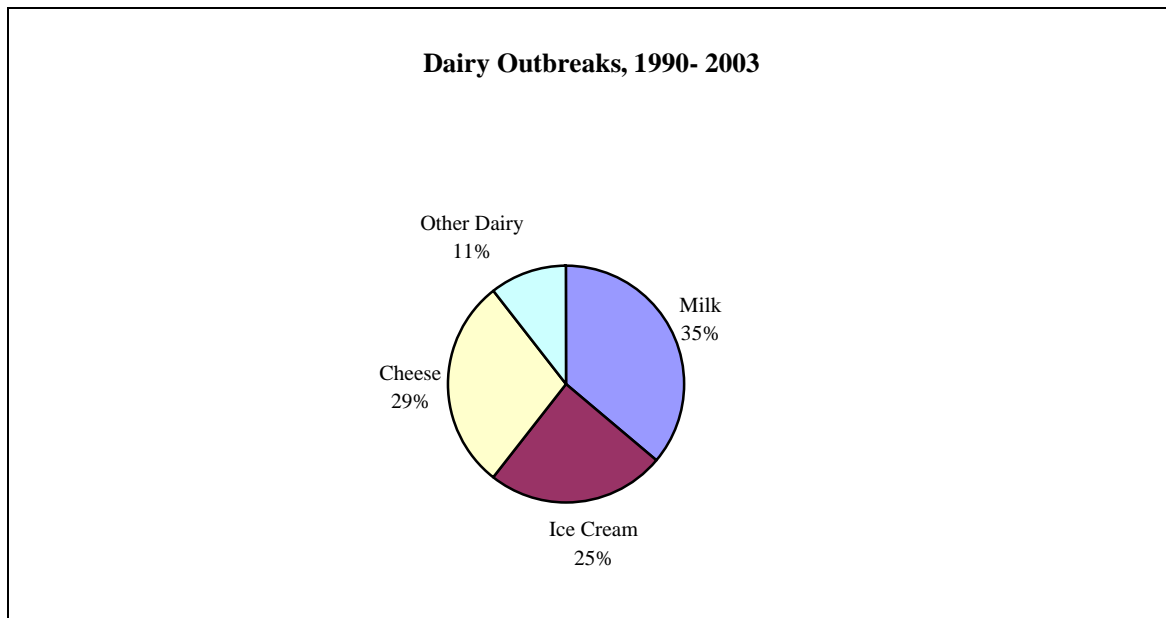
- 432 outbreaks with 25,823 cases were linked to produce and produce dishes.** Vegetables were linked to 161 outbreaks with 8,858 cases, while fruits were the vehicle in 82 outbreaks with 9,066 cases. Of the 82 outbreaks caused by fruit, 22 were due to berries and 13 were due to melon. Produce dishes were linked to 189 outbreaks with 7,899 cases. The produce category had an average of 60 cases per outbreak. In produce, *Salmonella*, Noroviruses, and *E. coli* were the most common hazards.

Figure 7



- 309 outbreaks with 10,750 cases were linked to eggs and egg dishes.** Egg-based dishes such as French toast, omelets, and egg salad, were linked to 249 outbreaks with 8,837 cases, and eggs themselves were linked to 60 outbreaks with 1,913 cases. The egg food group had an average of 35 cases per outbreak. In eggs and egg dishes, *Salmonella* Enteritidis was the most common hazard, causing 88 percent of outbreaks.
- 122 outbreaks with 4,795 cases were linked to dairy products, including cheese, pasteurized and raw milk, and ice cream.** Milk was the vehicle in 44 outbreaks with 1,032 cases, cheese in 35 outbreaks with 1,564 cases, and ice cream in 30 outbreaks with 1,525 cases. The dairy-products category had an average of 38 cases per outbreak. In dairy foods, *Salmonella* and *Campylobacter* were the most common hazards.

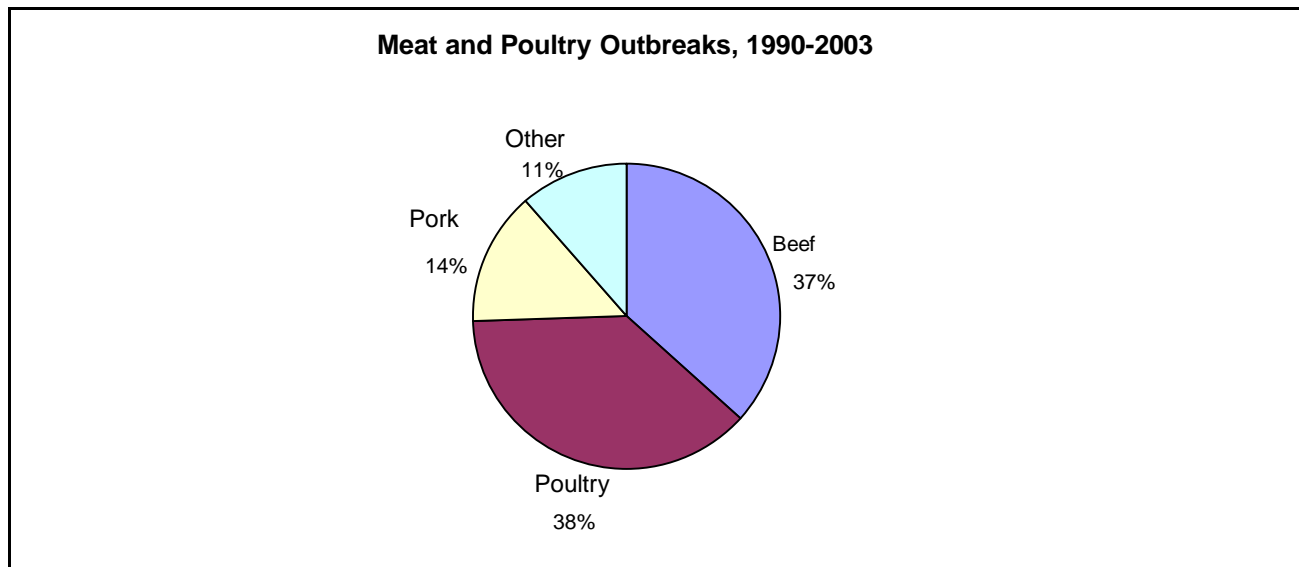
Figure 8



- **91 outbreaks with 2,782 cases were linked to breads and other bakery items.** 23 outbreaks with 809 cases were linked to breads, while 68 outbreaks with 1,973 cases were linked to other bakery items, such as cake, pie, and cheesecake. The bread and bakery category had an average of 31 cases per outbreak. *Salmonella* and Noroviruses were the most common hazards in bread and bakery items.
- **53 outbreaks with 2,035 cases were linked to beverages.** 20 outbreaks with 1,158 cases were linked to juice, and 33 outbreaks with 877 cases were linked to other beverages such as soda, punch, coffee, tea, and beer. The beverage category had an average of 39 cases per outbreak. Contamination from chemicals, *Salmonella*, and *E. coli* O157:H7 were the most common hazards in beverages.
- **22 outbreaks with 156 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, the parasite *Trichinella* was the most common hazard.

USDA-Regulated Foods

Figure 9

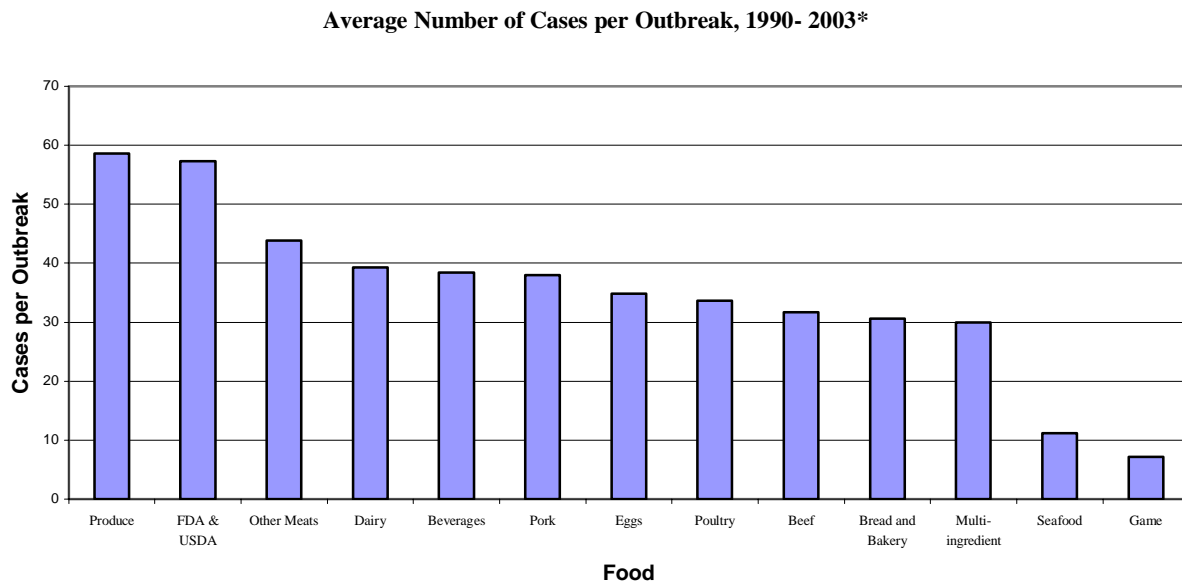


- **354 outbreaks with 11,894 cases were linked to poultry.** Chicken was linked to 132 outbreaks with 2,801 cases, while turkey was the vehicle in 69 other outbreaks with 4,162 cases. Five outbreaks with 104 cases were linked to other kinds of poultry, such as duck, game hen, and goose. Poultry dishes were linked to 148 outbreaks with 4,827 cases. The poultry category had an average of 34 cases per outbreak. The most significant hazards in the poultry category were *Salmonella* spp., *Clostridium perfringens*, and *Staphylococcus aureus*.
- **343 outbreaks with 10,872 cases were linked to beef.** 124 outbreaks with 2,615 cases were linked to ground beef, and 128 outbreaks with 5,552 cases were linked to other types of beef such as roast beef, veal, and beef jerky. Beef dishes such as casseroles, gravies, and stews were linked to 91 outbreaks with 2,705 cases. The beef category had an average of 32 cases per outbreak. In beef products, the most common hazards were *E. coli* O157:H7, *Clostridium perfringens*, and *Salmonella*.
- **132 outbreaks with 5,009 cases were linked to pork.** Ham was the vehicle in 38 outbreaks with 1,829 cases. Other types of pork were linked to 77 outbreaks, which accounted for 2,541 cases. Pork dishes accounted for 17 outbreaks with 639 illnesses. The pork category had an average of 38 cases per outbreak. The most common hazard was *Staphylococcus aureus*.
- **106 outbreaks with 4,652 cases were linked to other meats.** Of these, 35 outbreaks with 619 cases were attributed to hot dogs and such other ready-to-eat luncheon meats as bologna and salami. 26 outbreaks with 2,030 cases were linked to other meats, such as lamb, goat, and sausage. Meat dishes were linked to 45 outbreaks with 2,003 cases. The other-meats group had an average of 44 cases per outbreak. *Clostridium perfringens* was the most common hazard in the other-meat category.

Foods Regulated by Both FDA and USDA

- **241 outbreaks with 13,825 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 57 cases per outbreak. In foods regulated by both the FDA and USDA, *Salmonella* was the most common hazard.

Figure 10



* This graph shows the average size of each outbreak in a product category. For example, produce outbreaks tend to be larger, with 60 individual cases per outbreak. While seafood is the most frequent cause of foodborne-illness outbreaks in the U.S., the average size of each outbreak is significantly smaller, at 11 cases per outbreak. The remaining food categories cause an average number of illnesses in the range of 30 to 50 cases per outbreak.

RECOMMENDATIONS

With the continuing occurrence of foodborne illnesses and more recent concerns about bioterrorism, 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 food-poisoning outbreaks would allow policymakers and the food industry 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 on-line 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.¹⁴ In the last four years, the CDC has published new outbreak information on its website, including new line listings for 2001 and an *E. coli* O157 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.¹⁵
- 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 food-poisoning 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 National Academy of Sciences (NAS) report on food safety called for the consolidation of food-safety responsibility under a single statute, with a single budget and single leader. The NAS report concluded that the “current fragmented regulatory structure is not well equipped to meet the current challenges.”¹⁶ In October 2001, the General Accounting Office reported that:

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.¹⁷

Tom Ridge, Director of Homeland Security, raised questions about the current regulatory system:

We need to see whether the system that has developed over the last few decades is the one we need in the future . . . whether or not we need multiple agencies dealing with food-safety responsibilities.¹⁸

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 Administration (FSA). 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-related 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 a several-year period, 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.¹⁹
- *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 food poisoning 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: Outbreak Database
Summary of Outbreaks and Cases 1990-2003**

FDA

Category	Food	Outbreaks	Cases	Category	Food	Outbreaks	Cases
Seafood	Finfish	463	2,519	Dairy	Milk	44	1,032
	Molluscan				Cheese	35	1,564
	Shellfish	112	2,956		Ice Cream	30	1,525
	Other Seafood	48	653		Other Dairy	13	674
	Seafood Dishes	100	1,943		Total	122	4,795
Total		723	8,071				
Eggs	Eggs	60	1,913	Breads and Bakery	Breads	23	809
	Egg Dishes	249	8,837		Bakery	68	1,973
	Total	309	10,750		Total	91	2,782
Produce	Fruits	82	9,066	Multi-Ingredient	Ethnic Foods	136	2,597
	Vegetables	161	8,858		Salads	142	6,513
	Produce Dishes	189	7,899		Rice/Beans	125	3,371
	Total	432	25,823		Sandwiches	72	2,146
Beverages	Juices	20	1,158		Sauces	42	1,547
	Other Bev.	33	877		Other Foods	84	1,832
	Total	53	2,035		Total	601	18,006
				Game	Total	22	156
Total Outbreaks		2353	Total Cases	72418			

USDA

Category	Food	Outbreaks	Cases	Category	Food	Outbreaks	Cases
Beef	Ground Beef	124	2,615	Pork	Ham	38	1,829
	Other Beef	128	5,552		Other Pork	77	2,541
	Beef Dishes	91	2,705		Pork Dishes	17	639
	Total	343	1,0872		Total	132	5,009
Poultry	Chicken	132	2,801	Other Meats	Luncheon	35	619
	Turkey	69	4,162		Other Meats	26	2,030
	Other Poultry	5	104		Meat Dishes	45	2,003
	Poultry Dishes	148	4,827		Total	106	4,652
	Total	354	11,894				
Total Outbreaks		935	Total Cases	32,427			

Both FDA and USDA

Total Outbreaks		241	Total Cases	13,825			
Grand Total							
Total Outbreaks		3529	Total Cases	118,670			

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). Morton Satin, *Food Alert! The Ultimate Sourcebook for Food Safety* 16-17 (1999).

² Paul S. Mead, et. al. *Food-Related Illness and Death in the United States*, 5 Morbidity and Mortality Weekly Report 607-625 (Sept.-Oct. 1999). Foodborne illnesses and deaths are caused by viruses, prions, bacteria, parasites, toxins, and metals that contaminate foods.

³ General Accounting Office, *Food Safety: Overview of Federal and State Expenditures* 2-3 (2001) [hereinafter *GAO Food Safety Expenditures*]; U.S. Department of Agriculture, Office of Budget Program and Analysis, USDA FY 2004 Budget Summary, available at <<http://www.usda.gov/agency/obpa/Budget-Summary/2004/master2004.pdf>>; Food and Drug Administration, FY2004 Justification of Estimates or Appropriations Committees, available at <<http://www.fda.gov/oc/oms/ofm/budget/2004/1Foods.htm>>.

⁴ This estimate is based on the new resources the FDA received in the FY2002 bioterrorism supplemental appropriations. Hearing on FY 2003 Food and Drug Administration Appropriations Before the Subcommittee on Agriculture, Rural Development, FDA and Related Agencies of the House Committee on Appropriations (written responses of Lester M. Crawford, Deputy Commissioner).

⁵ *GAO Food Safety Expenditures*, at 12, 16.

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 National Academy of Sciences Institute of Medicine, *Seafood Safety* 88 (1991).

⁸ 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.

⁹ 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>>

¹⁰ Recently, in July 2002, there was a 19 million pound recall and at least 38 illnesses due to *E. coli* O157:H7 in ground beef.

¹¹ A foodborne disease outbreak is defined as an incident in which two or more people experienced a similar illness after ingestion of a common food. 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.

¹² The CDC’s U.S. Foodborne Illness Outbreaks, 1990-2001 contained about 5,000 outbreaks with unknown etiology or vehicles that were not included in CSPI’s database. (Outbreaks were included in CSPI’s database if a suspected vehicle was identified.)

¹³ In 2001, CSPI's entire database was screened for repeated entries. An entry was considered to be a duplicate if it could, with certainty, be identified as a repeat entry. During this review, approximately 80 outbreaks found to be duplicates were removed from the database. That analysis also revealed duplicates in the CDC lists, which were acknowledged by the CDC in a conference call with Dr. Paul Mead on May 1, 2002

¹⁴ 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.

¹⁵ CSPI obtained the older, unpublished version of the 1990-1997 line listings by submitting a Freedom of Information (FOIA) request to the CDC.

¹⁶ National Academy of Sciences, Institute of Medicine, *Ensuring Safe Food From Production to Consumption* 12 (1998).

¹⁷ 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.

¹⁸ Speech by Tom Ridge, Director of Homeland Security, at the National Food Processors Association meeting, March 12, 2002.

¹⁹ Although food-poisoning 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.