United States General Accounting Office

GAO

Testimony

Before the Subcommittee on Human Resources and Intergovernmental Relations, Committee on Government Reform and Oversight
House of Representatives

For Release
on Delivery
Expected at
10:00 a.m. EDT
Thursday
May 23, 1996

FOOD SAFETY

Reducing the Threat of Foodborne Illnesses

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GAO/T-RCED-96-185

Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to participate in this hearing on foodborne pathogens and their impact on public health. In previous reports and testimonies, we have discussed many aspects of food safety, including inspection and coordination activities and efforts to protect against unsafe chemical residues and microbiological hazards. Today, as you requested, we will focus on what is and is not known about the scope, severity, and cost of foodborne illnesses in the United States. We will also summarize our prior work on the structural problems that limit the federal government's ability to ensure food safety.

In summary, in our May 1996 report on foodborne illnesses,[1] we reported that existing data, although incomplete, indicate that foodborne illnesses are widespread and costly. Specifically, the best available data on foodborne illnesses demonstrate the following:

- Millions of illnesses and thousands of deaths in the United States each year can be traced to contaminated food. Moreover, the actual incidence may be much higher because public health experts believe that most cases are not reported. These experts also believe that the risk of foodborne illnesses has been increasing over the last 20 years.
- Foodborne illnesses generally cause temporary disorders of the digestive tract, but they can also lead to serious, long-term health consequences. Recent estimates of the cost of foodborne illnesses range from over $5 billion to over $22 billion annually. For example, the cost of medical treatment and lost productivity related to foodborne illnesses from seven of the most harmful bacteria ranged from $5.6 billion to $9.4 billion in 1993.

While providing useful indicators concerning the extent of foodborne illnesses, existing data have limitations. Public health and food safety experts believe that current data on foodborne illnesses do not provide a complete picture of the risk level and do not depict the sources of contamination and the populations most at risk in sufficient detail. More uniform and comprehensive data on the number and causes of foodborne illnesses could enable the development of more effective control strategies. While federal and state agencies have begun to collect such data in five areas across the country, federal officials expressed some concern about whether they would be able to continue funding this discretionary effort.

[1]Food Safety: Information on Foodborne Illnesses (GAO/RCED-96-96, May 8, 1996).

Providing more comprehensive data would help federal food safety officials develop better control strategies but would not address the structural problems with the food safety system. As we have previously reported,[2] the system evolved over many years in response to specific health threats and new technological developments, resulting in a patchwork of inconsistent approaches that weaken its effectiveness. Food products with similar risks are subject to different rules, limited inspection resources are not efficiently used, and agencies must engage in extensive and often unsuccessful coordination activities in an attempt to address food safety activities.

Background

The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services is the federal agency primarily responsible for monitoring the incidence of foodborne illness in the United States. In collaboration with state and local health departments and other federal agencies, CDC investigates outbreaks of foodborne illnesses and supports disease surveillance, research, prevention efforts, and training related to foodborne illnesses. CDC coordinates its activities concerning the safety of the food supply with the Food and Drug Administration (FDA), which is also in the Department of Health and Human Services. With respect to the safety of meat, poultry, and eggs, CDC coordinates with the Food Safety and Inspection Service (FSIS) in the U.S. Department of Agriculture (USDA).

CDC monitors individual cases of illness from harmful bacteria, viruses, chemicals, and parasites (hereafter referred to collectively as pathogens) that are known to be transmitted by foods, as well as foodborne outbreaks, through voluntary reports from state and local health departments, FDA, and FSIS. In practice, because CDC does not have the authority to require states to report data on foodborne illnesses, each state determines which diseases it will report to CDC. In addition, state laboratories voluntarily report the number of positive test results for several diseases that CDC has chosen to monitor. However, these reports do not identify the source of infection and are not limited to cases of foodborne illness. CDC also investigates a limited number of more severe or unusual outbreaks when state authorities request assistance.

At least 30 pathogens are associated with foodborne illnesses. For reporting purposes, CDC categorizes the causes of outbreaks of foodborne illnesses as bacterial, chemical, viral, parasitic, or unknown pathogens.

[2]Food Safety and Quality: Uniform, Risk-Based Inspection System Needed to Ensure Safe Food Supply (GAO/RCED-92-152, June 26, 1992).

Although many people associate foodborne illnesses primarily with meat, poultry, eggs, and seafood products, many other foods—including milk, cheese, ice cream, orange and apple juices, cantaloupes, and vegetables—have also been involved in outbreaks during the last decade.

Bacterial pathogens are the most commonly identified cause of outbreaks of foodborne illnesses. Bacterial pathogens can be easily transmitted and can multiply rapidly in food, making them difficult to control. CDC has targeted four of them—E. coli O157:H7, Salmonella Enteritidis, Listeria monocytogenes, and Campylobacter jejuni—as being of greatest concern.

Foodborne Illnesses Are Believed to Be a Significant and Growing Problem

The existing data on foodborne illnesses have weaknesses and may not fully depict the extent of the problem. In particular, public health experts believe that the majority of cases of foodborne illness are not reported because the initial symptoms of most foodborne illnesses are not severe enough to warrant medical attention, the medical facility or state does not report such cases, or the illness is not recognized as foodborne. However, according to the best available estimates, based largely on CDC's data, millions of people become sick from contaminated food each year, and several thousand die. In addition, public health and food safety officials believe that the risk of foodborne illnesses is increasing for several reasons.

Between 6.5 million and 81 million cases of foodborne illness and as many as 9,100 related deaths occur each year, according to the estimates provided by several studies conducted over the past 10 years. The wide range in the estimated number of foodborne illnesses and related deaths is due primarily to the considerable uncertainty about the number of cases that are never reported to CDC. For example, CDC officials believe that many intestinal illnesses that are commonly referred to as the stomach flu are caused by foodborne pathogens. People do not usually associate these illnesses with food because the onset of symptoms occurs 2 or more days after the contaminated food was eaten.

Furthermore, most physicians and health professionals treat patients who have diarrhea without ever identifying the specific cause of the illness. In severe or persistent cases, a laboratory test may be ordered to identify the responsible pathogen.

Finally, physicians may not associate the symptoms they observe with a pathogen that they are required to report to the state or local health

authorities. For example, a CDC official cited a Nevada outbreak in which no illnesses from E. coli O157:H7 had been reported to health officials, despite a requirement that physicians report such cases to the state health department. Nevertheless, 58 illnesses from this outbreak were subsequently identified. In the absence of more complete reporting, researchers can only broadly estimate the number of illnesses and related deaths.

Food safety and public health officials believe that several factors are contributing to an increased risk of foodborne illnesses. First, the food supply is changing in ways that can promote foodborne illnesses. For example, as a result of modern animal husbandry techniques, such as crowding a large number of animals together, the pathogens that can cause foodborne illnesses in humans can spread throughout the herd. Also, because of broad distribution, contaminated food products can reach more people in more locations. Subsequent mishandling can further compound the problem. For example, leaving perishable food at room temperature increases the likelihood of bacterial growth and undercooking reduces the likelihood that bacteria will be killed. Knowledgeable experts believe that although illnesses and deaths often result from improper handling and preparation, the pathogens were, in many cases, already present at the processing stage.

Second, because of demographic changes, more people are at greater risk of contracting a foodborne illness. In particular, certain populations are at greater risk for these illnesses: people with suppressed immune systems, children in group settings like daycare, and the elderly.

Third, three of the four pathogens CDC considers the most important were unrecognized as causes of foodborne illness 20 years ago—Campylobacter, Listeria, and E. coli O157:H7.

Fourth, bacteria already recognized as sources of foodborne illnesses have found new modes of transmission. While many illnesses from E. coli O157:H7 occur from eating insufficiently cooked hamburger, these bacteria have also been found more recently in other foods, such as salami, raw milk, apple cider, and lettuce.

Fifth, some pathogens are far more resistant than expected to long-standing food-processing and storage techniques previously believed to provide some protection against the growth of bacteria. For example,

some bacterial pathogens (such as Yersinia and Listeria) can continue to grow in food under refrigeration.

Finally, according to CDC officials, virulent strains of well-known bacteria have continued to emerge. For example, one such pathogen, E. coli O104:H21, is another potentially deadly strain of E. coli. In 1994, CDC found this new strain in milk from a Montana dairy.

Foodborne Illnesses Can Be Debilitating and Costly

While foodborne illnesses are often temporary, they can also result in more serious illnesses requiring hospitalization, long-term disability, and death. Although the overall cost of foodborne illnesses is not known, two recent USDA estimates place some of the costs in the range of $5.6 billion to more than $22 billion per year. The first estimate, covering only the portion related to the medical costs and productivity losses of seven specific pathogens, places the costs in the range of $5.6 billion to $9.4 billion. The second, covering only the value of avoiding deaths from five specific pathogens, places the costs in the range of $6.6 billion to $22 billion.

Although often mild, foodborne illnesses can lead to more serious illnesses and death. For example, in a small percentage of cases, foodborne infections can spread through the bloodstream to other organs, resulting in serious long-term disability or death. Serious complications can also result when diarrhetic infections resulting from foodborne pathogens act as a triggering mechanism in susceptible individuals, causing an illness such as reactive arthritis to flare up. In other cases, no immediate symptoms may appear, but serious consequences may eventually develop. The likelihood of serious complications is unknown, but some experts estimate that about 2 to 3 percent of all cases of foodborne illness lead to serious consequences. For example:

- E. coli O157:H7 can cause kidney failure in young children and infants and is most commonly transmitted to humans through the consumption of undercooked ground beef. The largest reported outbreak in North America occurred in 1993 and affected over 700 people, including many children who ate undercooked hamburgers at a fast food restaurant chain. Fifty-five patients, including four children who died, developed a severe disease, Hemolytic Uremic Syndrome, which is characterized by kidney failure.
- Salmonella can lead to reactive arthritis, serious infections, and deaths. In recent years, outbreaks have been caused by the consumption of many

different foods of animal origin, including beef, poultry, eggs, milk and dairy products, and pork. The largest outbreak, occurring in the Chicago area in 1985, involved over 16,000 laboratory-confirmed cases and an estimated 200,000 total cases. Some of these cases resulted in reactive arthritis. For example, one institution that treated 565 patients from this outbreak confirmed that 13 patients had developed reactive arthritis after consuming contaminated milk. In addition, 14 deaths may have been associated with this outbreak.

- Listeria can cause meningitis and stillbirths and is fatal in 20 to 40 percent of cases. All foods may contain these bacteria, particularly poultry and dairy products. Illnesses from this pathogen occur mostly in single cases rather than in outbreaks. The largest outbreak in North America occurred in 1985 in Los Angeles, largely in pregnant women and their fetuses. More than 140 cases of illness were reported, including at least 13 cases of meningitis. At least 48 deaths, including 20 stillbirths or miscarriages, were attributed to the outbreak. Soft cheese produced in a contaminated factory was confirmed as the source.
- Campylobacter may be the most common precipitating factor for Guillain-Barre syndrome, which is now one of the leading causes of paralysis from disease in the United States. Campylobacter infections occur in all age groups, with the greatest incidence in children under 1 year of age. The vast majority of cases occur individually, primarily from poultry, not during outbreaks. Researchers estimate that 4,250 cases of Guillain-Barre syndrome occur each year and that about 425 to 1,275 of these cases are preceded by Campylobacter infections.

While the overall annual cost of foodborne illnesses is unknown, the studies we reviewed estimate that it is in the billions of dollars. The range of estimates among the studies is wide, however, principally because of uncertainty about the number of cases of foodborne illness and related deaths. Other differences stem from the differences in the analytical approach used to prepare the estimate. Some economists attempt to estimate the costs related to medical treatment and lost wages (the cost-of-illness method); others attempt to estimate the value of reducing the incidence of illness or loss of life (the willingness-to-pay method). Two recent estimates demonstrate these differences in analytical approach.

In the first, USDA's Economic Research Service (ERS) used the cost-of-illness approach to estimate that the 1993 medical costs and losses in productivity resulting from seven major foodborne pathogens ranged between $5.6 billion and $9.4 billion. Of these costs, $2.3 billion to $4.3 billion were the estimated medical costs for the treatment of acute

and chronic illnesses, and $3.3 billion to $5.1 billion were the productivity losses from the long-term effects of foodborne illnesses.

CDC, FDA, and ERS economists stated that these estimates may be low for several reasons. First, the cost-of-illness approach generates low values for reducing health risks to children and the elderly because these groups have low earnings and hence low productivity losses. Second, this approach does not recognize the value that individuals may place on (and pay for) feeling healthy, avoiding pain, or using their free time. In addition, not all of the 30 pathogens associated with foodborne illnesses were included.

In the second analysis, ERS used the willingness-to-pay method to estimate the value of preventing deaths for five of the seven major pathogens (included in the first analysis) at $6.6 billion to $22 billion in 1992. The estimate's range reflected the range in the estimated number of deaths, 1,646 to 3,144, and the range in the estimated value of preventing a death, $4 million to $7 million. Although these estimated values were higher than those resulting from the first approach, they may have also understated the economic cost of foodborne illnesses because they did not include an estimate of the value of preventing nonfatal illnesses and included only five of the seven major pathogens examined in the first analysis.

Better Data Could Lead to More Effective Control Strategies

The federal food safety system has evolved over the years as changes were made to address specific health threats and respond to new technological developments. Often such changes occurred in reaction to a major outbreak of foodborne illness when consumers, industry, regulatory agencies, and the Congress agreed that actions needed to be taken. The system has been slow to respond to changing health risks, for a variety of reasons, including a lack of comprehensive data on the levels of risk and the sources of contamination.

While current data indicate that the risk of foodborne illnesses is significant, public health and food safety officials believe that these data do not identify the level of risk, the sources of contamination, and the populations most at risk in sufficient detail. According to these experts, the current voluntary reporting system does not provide sufficient data on the prevalence and sources of foodborne illnesses. There are no specific national requirements for reporting on foodborne pathogens. According to CDC, states do not (1) report on all pathogens of concern, (2) usually

identify whether food was the source of the illness, or (3) identify many of the outbreaks or individual cases of foodborne illness that occur.

Consequently, according to CDC, FDA, and FSIS, public health officials cannot precisely determine the level of risk from known pathogens or be certain that they can detect the existence and spread of new pathogens in a timely manner. They also cannot identify all factors that put the public at risk or all types of food or situations in which microbial contamination is likely to occur. Finally, without better data, regulators cannot assess the effectiveness of their efforts to control the level of pathogens in food.

More uniform and comprehensive data on the number and causes of foodborne illnesses could form the basis of more effective control strategies. A better system for monitoring the extent of foodborne illnesses would actively seek out specific cases and would include outreach to physicians and clinical laboratories. CDC demonstrated the effectiveness of such an outreach effort when it conducted a long-term study, initiated in 1986, to determine the number of cases of illness caused by Listeria. This study showed that a lower rate of illness caused by Listeria occurred between 1989 and 1993 during the implementation of food safety programs designed to reduce the prevalence of Listeria in food.

In July 1995, CDC, FDA, and FSIS began a comprehensive effort to track the major bacterial pathogens that cause foodborne illnesses. These agencies are collaborating with the state health departments in five areas across the country to better determine the incidence of infection with Salmonella, E. coli O157:H7, and other foodborne bacteria and to identify the sources of diarrheal illness from Salmonella and E. coli O157:H7.[3] Initially, FDA provided $378,000 and FSIS provided $500,000 through CDC to the five locations for 6 months. For fiscal year 1996, FSIS is providing $1 million and FDA is providing $300,000. CDC provides overall management and coordination and facilitates the development of technical expertise at the sites through its established relationships with the state health departments.

CDC and the five sites will use the information to identify emerging foodborne pathogens and monitor the incidence of foodborne illness. FSIS will use the data to evaluate the effectiveness of new food safety programs and regulations to reduce foodborne pathogens in meat and poultry and

[3]The areas are (1) the greater metropolitan area of Atlanta, (2) an area that is comprised of two northern California counties, (3) an area that is comprised of two Connecticut counties, (4) the state of Minnesota, and (5) the state of Oregon.

assist in future program development. FDA will use the data to evaluate its efforts to reduce foodborne pathogens in seafood, dairy products, fruit, and vegetables.

The agencies believe that this effort should be a permanent part of a sound public health system. According to CDC, FDA, and FSIS officials, such projects must collect data over a number of years to identify national trends and evaluate the effectiveness of strategies to control pathogens in food. Funding was decreased (on an annualized basis) for this project in 1996, and these officials are concerned about the continuing availability of funding, in this era of budget constraints, to conduct this discretionary effort over the longer term.

Structural Problems Limit the Federal Government's Ability to Ensure Food Safety

While providing more comprehensive data would help federal food safety officials develop better control strategies, it would not address the structural problems that adversely affect the federal food safety system. As we previously testified to this Committee, the current system was not developed under any rational plan but evolved over many years to address specific health threats from particular food products and has not responded to changing health risks.[4] As a result, the food safety system is a patchwork of inconsistent approaches that weaken its effectiveness. For example, as we reported in June 1992, food products posing the same risk are subject to different rules, limited inspection resources are inefficiently used, and agencies must engage in extensive and often unsuccessful coordination activities in an attempt to address food safety issues.

While federal agencies have made progress in moving towards a scientific, risk-based inspection system, foods posing similar health risks, such as seafood, meat, and poultry, are still treated differently because of underlying differences in regulatory approach. For example, FDA's hazard analysis critical control point (HACCP) requirement for seafood processors differs from FSIS' proposed HACCP program for meat and poultry processors.[5] Under FSIS' proposal, meat and poultry plants would be required to conduct microbiological tests to verify the overall effectiveness of their critical controls and processing systems.[6] In

[4]Food Safety: A Unified, Risk-Based Food Safety System Needed, (GAO/T-RCED-94-223, May 25, 1994).

[5]Food Safety: New Initiatives Would Fundamentally Alter the Existing System (GAO/RCED-96-81, Mar. 27, 1996).

[6]Meat and Poultry Inspection: Impact of USDA's Food Safety Proposal on State Agencies and Small Plants (GAO/RCED-95-228, June 30, 1995) and Analysis of HACCP Costs and Benefits (GAO/RCED-96-62R, Feb. 29, 1996).

comparison, FDA's HACCP program for seafood products has no testing requirement. Furthermore, because the frequency of inspection is based on the agencies' regulatory approach, some foods may be receiving too much attention, while other foods may not be receiving enough. FSIS will conduct oversight of industries that use HACCP programs on a daily basis and will continue to inspect every meat and poultry carcass. Conversely, FDA will inspect seafood plants about once every 2 years and will only inspect other food plants under its jurisdiction an average of about once every 8 years. As we stated in our June 1992 report, such widely differing inspection frequencies for products posing similar risk is an inefficient use of limited federal inspection resources.

Moreover, federal agencies are often slow to address emerging food safety concerns because of fragmented jurisdictions and responsibilities. For example, in April 1992, we reported that jurisdictional questions, disagreement about corrective actions, and poor coordination between FDA and USDA had hindered the federal government's efforts to control Salmonella in eggs for over 5 years.[7] At that time, we stated that the continuing nature of such problems indicated that the food safety structure—with federal agencies having split and concurrent jurisdictions—had a systemic problem. The system's fragmented structure limited the government's ability to deal effectively with a major outbreak of foodborne disease, especially when such an outbreak required joint agency action.

Today, federal agencies are concerned with the potential impact on public health posed by Bovine Spongiform Encephalopathy (the so-called mad cow disease), which was the subject of your May 10, 1996, hearing. Because there is still no single, uniform food safety system, jurisdiction remains split between agencies. Ironically, FSIS is responsible for the safety of meat products sold to the public, but is not responsible for preventing cattle from being given feeds that could endanger public health. FDA is responsible.

Mr. Chairman, this concludes my prepared remarks, we would be happy to respond to any questions you may have.

[7]Food Safety and Quality: Salmonella Control Efforts Show Need for More Coordination, (GAO/RCED-92-69, Apr. 21, 1992).

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