

# Food Safety: Status of Foodborne Illness in the U.S.

GAO-25-107606

Q&amp;A Report to Congressional Addressees

February 3, 2025

## Why This Matters

Although the U.S. food supply is generally considered safe, tens of millions of Americans get sick from foodborne illness every year, and some die, according to estimates from the Department of Health and Human Services' (HHS) Centers for Disease Control and Prevention (CDC). In addition, according to CDC data, over 9,000 foodborne illness outbreaks were reported between 2011 and 2022 across all 50 states. Foodborne illness has widespread economic consequences, costing Americans an estimated \$75 billion (in 2023 dollars) annually in medical care, lost productivity, and premature deaths, including those associated with secondary chronic illnesses and conditions that develop after the initial illness, according to a study by researchers from U.S. Department of Agriculture's (USDA) Economic Research Service and collaborators.

At least 30 federal laws govern the safety and quality of the U.S. food supply, both domestic and imported. Collectively, 15 federal agencies administer these laws, including CDC, USDA's Food Safety and Inspection Service (FSIS), and HHS's Food and Drug Administration (FDA). The federal food safety oversight system is supplemented by states, localities, Tribes, and territories, which may have their own laws and agencies to address the safety and quality of food.

Foodborne pathogens can be transmitted through multiple types of food and, therefore, can affect both FDA- and FSIS-regulated foods. For example, in 2024, two *Salmonella* outbreaks—one attributed to cucumbers, an FDA-regulated food, and one attributed to charcuterie meats, an FSIS-regulated food—collectively caused 650 confirmed illnesses and about 180 hospitalizations.

We have long reported that the fragmented nature of the federal food safety oversight system causes inconsistent oversight, ineffective coordination, and inefficient use of resources. Since 2007, we have identified federal oversight of food safety as a high-risk issue and made several recommendations and matters for congressional consideration. In 2017, we called for the Executive Office of the President to develop and implement a national strategy for overseeing food safety. As of January 2025, there were no plans to create a national strategy, according to officials from the Office of Management and Budget.

We prepared this report at the initiative of the Comptroller General to assist Congress with its oversight of CDC, FDA, and FSIS's roles in reducing foodborne illness. This report describes foodborne illness and how foods get contaminated, what is known about the magnitude of foodborne illness and associated foods, and federal goals associated with identifying and reducing foodborne illness.

## Key Takeaways

- Foodborne illness in the U.S. is a serious and continuing problem. A forthcoming 2025 CDC study estimates that six pathogens—including *Salmonella*, *Listeria monocytogenes*, *Campylobacter*, *Clostridium perfringens*, Shiga toxin-producing *Escherichia coli* (STEC), and norovirus — cause about 10 million cases of foodborne illnesses annually in the U.S.

These illnesses result in about 53,300 hospitalizations and over 900 deaths each year. Prior CDC estimates from 2011, which included a broader range of pathogens, indicate that over 3,000 people die and 128,000 are hospitalized each year due to foodborne illness.

- The precise magnitude of foodborne illness in the U.S. is unknown. According to CDC, only a small proportion of all foodborne illnesses are diagnosed and reported to public health authorities. For example, CDC has estimated that foodborne *Salmonella* causes 29 illnesses for each case that is detected through laboratory testing. A foodborne illness case may go undiagnosed if, for example, a sick person does not seek medical treatment. Additionally, CDC largely relies on public health authorities across the country to voluntarily report cases of foodborne illness in their jurisdictions, but some possible cases of foodborne illness may not be reported for various reasons. For example, according to CDC officials, some cases of foodborne illness may not be investigated or reported because of resource limitations at the state or local level.
- CDC, FDA, and FSIS have taken some steps to develop agency-specific and joint goals related to reducing foodborne illness. However, the most recently available data show that FDA and FSIS have not met their goals to reduce foodborne illness—in one case, by a wide margin. In addition, the Healthy People 2030 initiative sets joint-agency performance metrics to reduce foodborne illness through a working group that includes CDC, FDA, and FSIS officials. However, the working group has reported limited progress towards meeting these performance measures. For example, six metrics aimed at reducing foodborne illness outbreaks are still under development and do not have defined baseline data to identify targets and measure progress about 5 years into the 10-year Healthy People cycle.
- We previously reported on the need for a national strategy to guide federal efforts to address ongoing fragmentation and improve the federal food safety oversight system. This strategy could address our other previous matters for congressional consideration about a government-wide performance plan and sustained leadership for federal food safety. We maintain that such a strategy could create an opportunity to further strengthen federal oversight of the nation's food supply and reduce the economic and public health effects of foodborne illness.

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## What is foodborne illness?

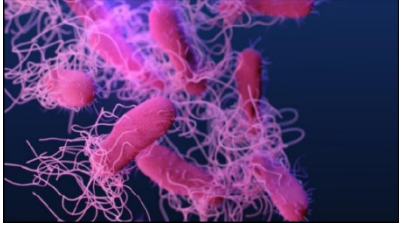


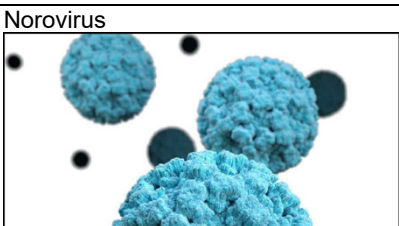

Foodborne illness occurs when a person becomes sick after consuming contaminated food, which can include produce, meat, poultry, seafood, dairy, or processed products. A number of pathogens, or harmful organisms, can be transmitted through food and cause foodborne illness. These illnesses can result in various symptoms and long-term effects. Cases of foodborne illness can occur sporadically in individuals or can become outbreaks, which CDC defines as two or more cases of illness linked to consumption of the same contaminated food. A public health investigation must link an outbreak to consumption of a food for CDC to consider it a foodborne illness outbreak. According to CDC, while foodborne illness outbreaks are common, about 95 percent of foodborne illnesses occur as sporadic (nonoutbreak) cases.

## Pathogens

According to CDC, common pathogens that cause foodborne illness, hospitalizations, and deaths include *Salmonella*, *Listeria monocytogenes*, and *Campylobacter*.<sup>1</sup> Such pathogens can contaminate all types of foods, including

meat, vegetables, and dairy. Table 1 describes the illnesses and symptoms that five of these foodborne pathogens can cause.

**Table 1: Examples of Pathogens and Associated Foodborne Illnesses and Symptoms**

<p><i>Salmonella</i></p> 	<p><i>Salmonella</i> are bacteria that can make people sick with an illness called salmonellosis. <i>Salmonella</i> live in the intestines of people and animals. People can get infected with <i>Salmonella</i> in many ways, including by eating contaminated food, according to CDC.</p> <p>Symptoms include watery diarrhea that may contain blood or mucus, stomach cramps, headache, nausea, vomiting, and loss of appetite. Symptoms usually start 6 hours to 6 days after infection and usually last 4 to 7 days.</p> <p><i>Salmonella</i> infection can sometimes spread to urine, blood, bones, joints, the brain, or other internal organs, causing infections outside of the intestines that can have long-lasting effects.</p>
<p><i>Listeria</i></p> 	<p><i>Listeria</i> are bacteria that can contaminate many foods and cause an infection called listeriosis. Listeriosis can cause intestinal illness and develop to invasive illness (meaning bacteria have spread beyond the intestines), according to CDC.</p> <p><i>Listeria</i> are most likely to harm pregnant people, newborns, older adults, and people with weakened immune systems. Symptoms of listeriosis typically include fever and flu-like symptoms. However, symptoms and effects can be more severe for some populations. For example, listeriosis during pregnancy can lead to miscarriage, stillbirth, premature delivery, or life-threatening infection of the newborn.</p>
<p><i>Campylobacter</i></p> 	<p><i>Campylobacter</i> are bacteria that can make people ill with diarrhea, causing the illness campylobacteriosis.</p> <p><i>Campylobacter</i> can live in the intestines, liver, and other organs of animals. It takes very few <i>Campylobacter</i> to make someone sick. For example, a single drop of juice from raw chicken can contain enough <i>Campylobacter</i> to cause an infection, according to CDC.</p> <p>Symptoms of <i>Campylobacter</i> infection include diarrhea that can be bloody, fever, and stomach cramps that usually start 2 to 5 days after consumption and end within 7 days. However, <i>Campylobacter</i> infection can lead to other health problems, including irritable bowel syndrome, arthritis, and nerve damage.</p>
<p>Norovirus</p> 	<p>Norovirus is a contagious virus that can make people ill with vomiting and diarrhea, causing acute gastroenteritis. Norovirus spreads very easily and is commonly caused by contact with someone with norovirus or consuming contaminated food or water.</p> <p>Symptoms of norovirus include diarrhea, vomiting, nausea, stomach pain, fever, headache, and body aches. A person usually develops symptoms 12 to 48 hours after exposure to norovirus. Most people get better within 1 to 3 days, but they can still spread the virus for a few days afterwards. Children and people with weakened immune systems are more likely to develop severe infections from norovirus.</p>
<p>Shiga toxin-producing <i>E. coli</i> (STEC)</p> 	<p>STEC is a type of <i>Escherichia coli</i> (<i>E. coli</i>) bacteria that can make people ill with diarrhea, causing STEC infection. STEC infections are commonly caused by consuming contaminated food, especially leafy greens; unsafe water; or coming into contact with animals, animal feces, or feces from an infected person.</p> <p>Symptoms of STEC infection include bloody diarrhea, severe stomach cramps, and vomiting. STEC infections are most likely to harm children and the elderly and can lead to hemolytic uremic syndrome, which can cause kidney failure, permanent health problems, and even death.</p>

Source: GAO summary of Centers for Disease Control and Prevention (CDC) information and CDC images. | GAO-25-107606.

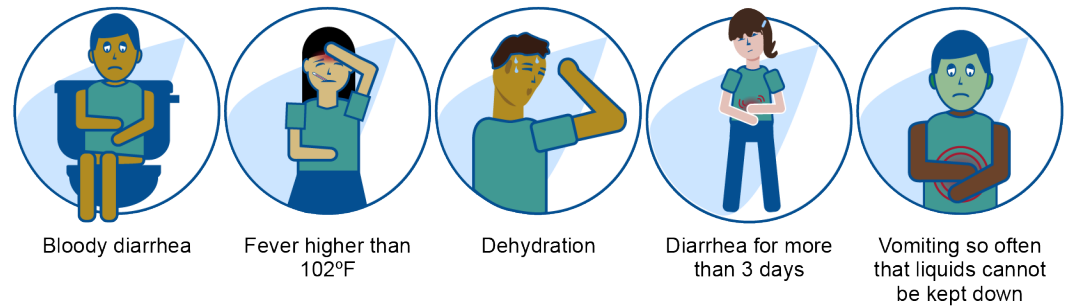
Note: We selected these five foodborne pathogens and associated illnesses to describe because of their relevance to other areas of this report, including foodborne illness estimates, food source attribution estimates, and both individual agency goals and Healthy People 2030 goals. Other pathogens, such as *Clostridium perfringens* and *Cronobacter*, can also cause foodborne illness.

### Symptoms and long-term effects

Foodborne illnesses cause a wide range of mild to severe symptoms, which can occur within hours to days or weeks after someone consumes contaminated food. Most foodborne illnesses are enteric illnesses that affect the stomach and intestines. Such gastrointestinal illnesses are characterized by symptoms such as diarrhea, stomach pain or cramps, nausea, vomiting, or fever (see fig. 1).

While many cases are mild and can be treated at home, cases with severe symptoms can require medical care or hospitalization.

**Figure 1: Examples of Symptoms of Severe Food Poisoning**



Sources: GAO summary of Centers for Disease Control and Prevention information and GAO (icons). | GAO 25-107606

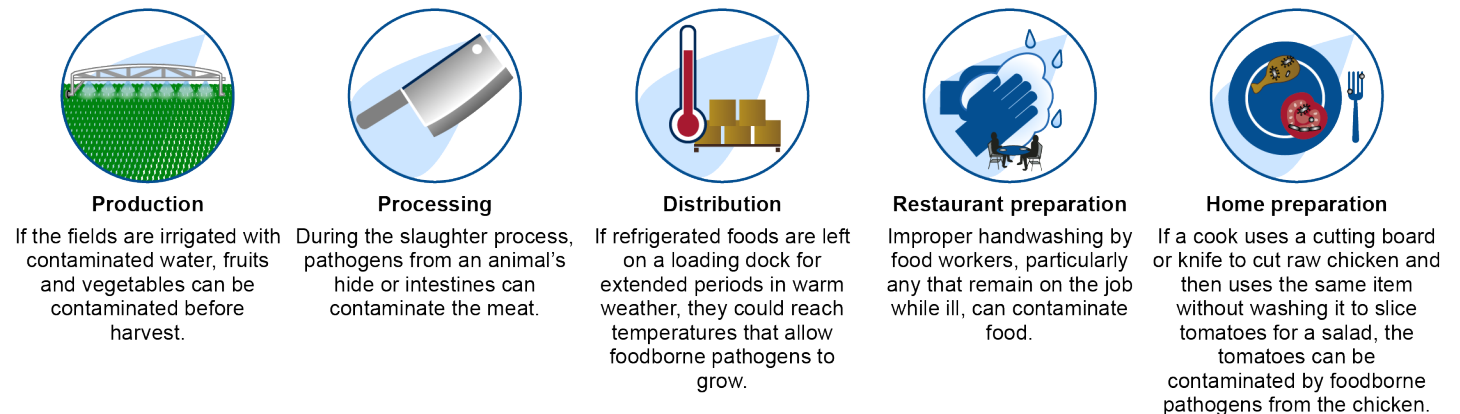
Some foodborne illnesses can result in long-term health complications or even death. According to CDC, complications from a foodborne illness may last for months or indefinitely. Foodborne illness can also lead to more serious diseases, such as meningitis, kidney damage, or hemolytic uremic syndrome, which can lead to kidney failure and brain and nerve damage, according to CDC.

Foodborne illnesses can be especially dangerous for vulnerable populations, such as the elderly, young children, pregnant people, and those with weakened immune systems. For example, in 2022, a company recalled powdered infant formula after FDA received information about three cases of *Cronobacter* illness or death in infants who consumed powdered infant formula manufactured at the same facility.<sup>2</sup> FDA conducted an onsite inspection at the facility, found unsanitary conditions, and subsequently warned consumers not to use certain products manufactured at that facility. According to CDC, *Cronobacter* can cause bloodstream and central nervous system infections, such as sepsis and meningitis. *Cronobacter* infection in infants can cause deaths or complications such as brain abscesses, developmental delays, and motor impairments. The 2022 *Cronobacter* investigation identified four cases of illness, including two deaths, according to FDA.

## How do foods get contaminated?

According to CDC, any foods can be contaminated at various stages in the food production chain, as figure 2 shows.

**Figure 2: Food Production Chain and Examples of Sources of Contamination**



Source: GAO analysis of Centers for Disease Control and Prevention information; GAO (icons). | GAO-25-107606



Foods attributed to foodborne illness outbreaks have been contaminated at various stages, including the following:

- **Production.** In 2018, an *E. coli* outbreak was attributed to romaine lettuce that was most likely contaminated by an on-farm water reservoir that tested positive for the same strain of *E. coli* as the outbreak.<sup>3</sup> According to CDC, 62 reported illnesses, 25 hospitalizations, and two cases of hemolytic uremic syndrome were associated with this outbreak.
- **Processing.** In 2024, a *Salmonella* outbreak was linked to ready-to-eat meat charcuterie products, leading to a nationwide recall. FSIS determined that the recalled product might have been underprocessed. According to FSIS, during production of ready-to-eat products, underprocessing can occur when established processing parameters, such as drying or cooking times and temperatures, are not met or are not sufficient to eliminate all pathogens that may be present. According to CDC, 104 reported illnesses and 27 hospitalizations were associated with this outbreak.
- **Restaurant preparation.** In 2022, a norovirus outbreak was linked to consumption of salad in an Illinois restaurant. Contamination of the salads and salad dressing occurred throughout the preparation process, including the storing of ingredients and the illness of the individual who prepared the food. According to a CDC report, the outbreak investigation identified 317 norovirus infections among those who dined at the restaurant during the investigation time frame.<sup>4</sup>

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## What are the roles of federal agencies related to foodborne illness?

CDC, FDA, and FSIS are the primary federal agencies with roles related to foodborne illness, which is an important public health issue. However, state and local public health agencies are also responsible for identifying, investigating, and responding to foodborne illness and outbreaks in their jurisdictions, and a network of more than 3,000 public health departments across the nation carry out these activities.<sup>5</sup>

### Public health

CDC serves as the lead federal agency for addressing public health and is responsible for the prevention and control of a wide range of infectious diseases, including foodborne illnesses. The Public Health Service Act authorizes CDC to identify and monitor foodborne diseases and to investigate foodborne illness outbreaks in coordination with state and local health agencies.<sup>6</sup> CDC can assist with outbreak investigations if invited by the state and can lead investigations into multistate outbreaks.

### Food safety

The safety and quality of the U.S. food supply are governed by at least 30 federal laws collectively administered by 15 federal agencies—most notably FDA and FSIS.<sup>7</sup> Federal oversight of the U.S. food supply includes imported foods which, according to FDA, account for about 15 percent of the nation's overall food supply and a much higher percentage for specific foods. For example, over 90 percent of seafood consumed in the U.S. is imported, according to FDA. The federal food safety oversight system is supplemented by states, localities, Tribes, and territories, which may have their own laws and agencies to address the safety and quality of food.

- **FDA.** In general, FDA oversees the safety of virtually all domestic and imported food products except those regulated by FSIS. FDA-regulated foods account for nearly 80 percent of the nation's food supply and include fruits,

vegetables, processed foods, dairy products, and most seafood. FDA is responsible for routine surveillance inspections at about 75,000 domestic food facilities and about 125,000 foreign food facilities.<sup>8</sup> As of July 2024, FDA had a total of 432 investigators who conduct both domestic and foreign inspections of food facilities, according to FDA officials. FDA also contracts with states and Puerto Rico to conduct food safety inspections on behalf of the agency.<sup>9</sup>

FDA's authority requires a risk-based approach, in which FDA must prioritize facility inspections using various risk factors, including the level of risk associated with a food product.<sup>10</sup> For domestic food facility inspections, FDA is to conduct inspections at least once every 3 years at high-risk facilities and at least once every 5 years at non-high-risk facilities.<sup>11</sup> For foreign food facility inspections, FDA has an annual target of 19,200 facility inspections.<sup>12</sup> In January 2025, we found that between fiscal year 2018 and fiscal year 2023, FDA did not meet its mandated targets for conducting domestic inspections and conducted far fewer foreign inspections than its annual target.<sup>13</sup> For example, according to FDA data, between 2018 and 2023 the agency conducted an average of 917 foreign food safety inspections each year—about 5 percent of its target. We recommended that FDA take steps to determine the appropriate workforce size to meet foreign inspection goals, among other things.

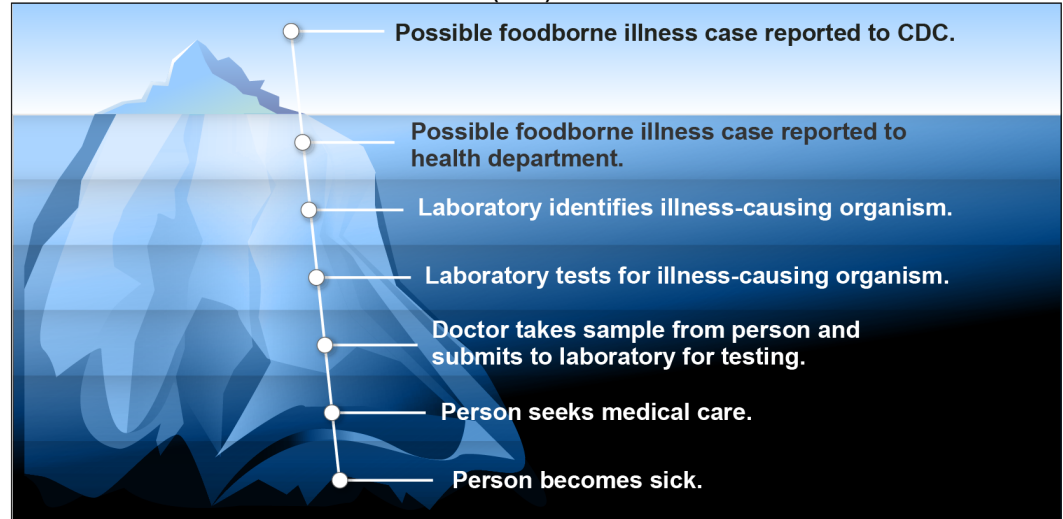
- **FSIS.** FSIS oversees the safety of meat (including fish of the order Siluriformes), poultry, and egg products.<sup>14</sup> According to FSIS officials, the agency conducts inspection activities at approximately 7,100 federally regulated meat, poultry, and egg product establishments. These activities include carcass-by-carcass inspections at all meat and poultry slaughter establishments (about 1,300 establishments). At facilities that process meat, poultry, and egg products, FSIS conducts establishment inspections at least once per production shift, following the agency's longstanding interpretation of its statutes requiring it to do so. FSIS also may maintain a constant presence, depending on the type of facility. As of August 2023, FSIS had about 6,500 inspection personnel nationwide. When a state imposes and enforces requirements that are "at least equal to" federal requirements, FSIS can cooperate with the state to develop and administer an inspection program with respect to meat and poultry plants that operate solely for distribution within that state, according to FSIS officials.

FSIS sets standards for the reduction of certain pathogens known to cause foodborne illness in certain meat (beef and pork) and poultry (chicken and turkey) products, among other products. These pathogen reduction performance standards (pathogen standards) apply at federally regulated processing and slaughter plants that produce meat and poultry products sold for human consumption. In January 2025, we found that FSIS had not updated or developed some pathogen standards, such as standards for *Campylobacter*, since 2018 or earlier.<sup>15</sup> FSIS has instead focused its resources on a framework of standards for *Salmonella* in raw poultry. We found the agency needs to better understand the trade-offs of solely focusing on this framework to avoid gaps in overall pathogen oversight. We recommended that FSIS develop a prioritization plan for additional policies needed to reduce pathogens in foods and that it review the public health effects of delaying proposed standards to reduce pathogens, among other things.

## How does CDC identify cases of foodborne illness in the U.S.?

CDC identifies cases of foodborne illness through voluntary reporting from public health authorities across the country and through the Foodborne Diseases Active Surveillance Network (FoodNet), which we discuss below. However, many steps generally occur before a case of foodborne illness becomes visible to CDC, as figure 3 shows.

**Figure 3: Steps That Generally Occur Before a Possible Case of Foodborne Illness Becomes Visible to the Centers for Disease Control and Prevention (CDC)**



Source: GAO analysis of Centers for Disease Control and Prevention information. | GAO 25-107606

### Reporting from public health authorities

CDC identifies foodborne illnesses and outbreaks through voluntary reporting from state and local public health authorities. States and localities are not required to report foodborne illnesses or outbreaks to CDC, and CDC does not have the authority to mandate such reporting. However, CDC and the Council of State and Territorial Epidemiologists have established a list of priority diseases and conditions that they recommend states require be reported to public health officials in their jurisdictions and, ultimately, to CDC. This list includes illnesses commonly caused by foodborne pathogens such as *Salmonella*, *Listeria monocytogenes*, and STEC.

While reporting is voluntary, CDC officials we spoke with said that they believe states are generally reporting the information they have on foodborne illnesses and outbreaks. Public health authorities can report information on foodborne illness cases or outbreaks to CDC through various reporting systems, including the National Notifiable Diseases Surveillance System and the National Outbreak Reporting System.

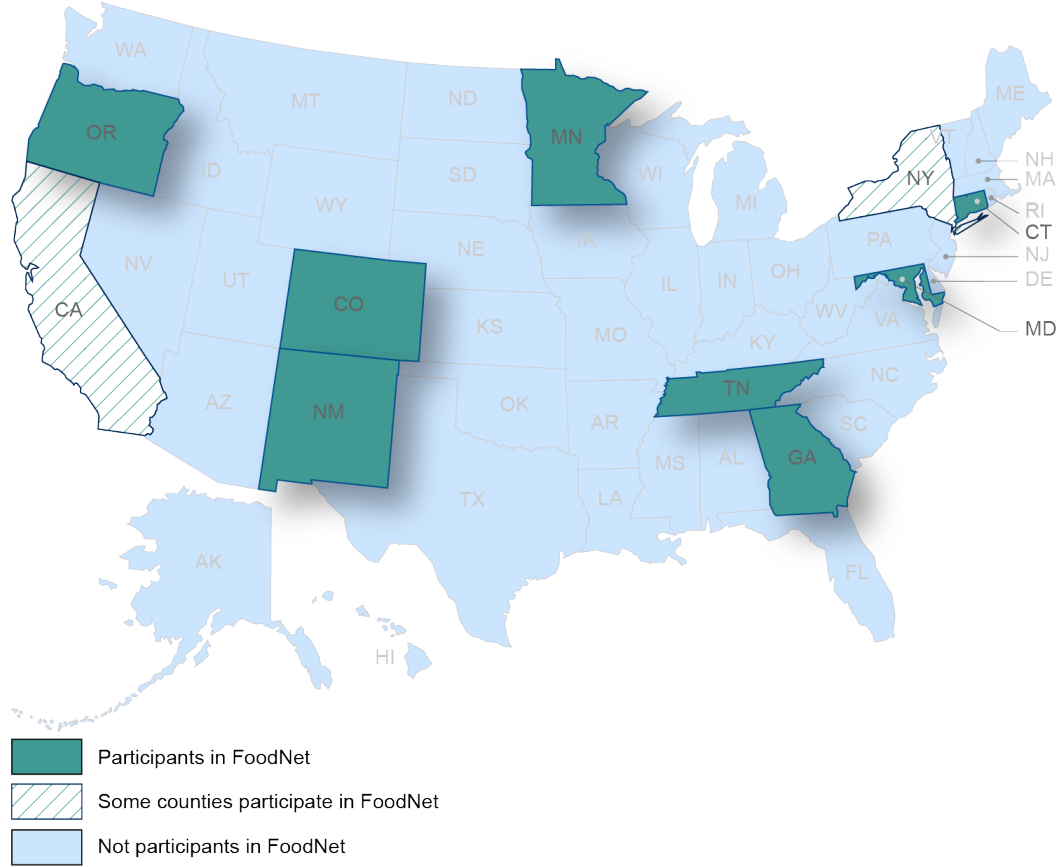
**National Notifiable Diseases Surveillance System.** The system collects case reports on about 120 diseases and conditions of public interest, including illnesses commonly caused by foodborne pathogens. CDC annually updates this list in partnership with the Council for State and Territorial Epidemiologists.

**National Outbreak Reporting System.** The system collects information on gastrointestinal disease outbreaks caused by bacterial, viral, parasitic, chemical, toxin, and unknown agents, as well as foodborne and waterborne outbreaks of nongastrointestinal disease and certain fungal disease outbreaks. Public health authorities can report information such as the date and location of the outbreak, the number of people who became ill and their symptoms, the pathogen that caused the outbreak, and the likely or known food source.

### Foodborne Diseases Active Surveillance Network

CDC also identifies foodborne illnesses through FoodNet. Established in 1995, FoodNet is an active surveillance collaboration among CDC, FDA, FSIS, and 10 state health departments (see fig. 4). FoodNet represents about 16 percent of the U.S. population, according to CDC.<sup>16</sup> As of January 2025, FoodNet was conducting surveillance on eight pathogens commonly associated with foodborne illness.<sup>17</sup>

**Figure 4: States That Participate in the Foodborne Diseases Active Surveillance Network (FoodNet), as of January 2025**



Sources: Centers for Disease Control and Prevention; Map Resources (map). | GAO-25-107606

As part of an active surveillance network, state public health officials at each FoodNet site routinely communicate with more than 700 clinical laboratories in the surveillance area to ensure all infections are reported. FoodNet also conducts periodic population surveys, according to CDC, to more precisely estimate how often people in the surveillance area get acute diarrheal illness, how often they seek care for these illnesses, and the frequency of exposures linked to diarrheal illness. According to CDC officials, FoodNet is considered the “gold standard” for collecting foodborne illness data. CDC officials said there are no immediate plans to expand FoodNet to other areas of the country because of funding availability.

### What challenges does CDC face with identifying cases of foodborne illness?

According to CDC officials and documents, identifying cases of foodborne illness can be challenging for CDC if a sick person is not diagnosed (underdiagnosis) or a possible case of foodborne illness is not reported to state or local public health authorities or CDC (underreporting).

- **Underdiagnosis.** A possible case of foodborne illness may not be diagnosed for various reasons. For example, a sick person may not believe their symptoms are severe enough to warrant medical attention, or they may not have access to medical care. Additionally, a laboratory may not be able to



detect the illness-causing pathogen. According to CDC, only a small proportion of all foodborne illnesses are detected through laboratory testing and reported to state and local public health authorities, as figure 3 shows. For example, CDC estimates that 29 illnesses caused by foodborne *Salmonella* occur for each single case that is detected through laboratory testing.

- **Underreporting.** A possible case of foodborne illness may not be reported to state or local public health authorities or CDC for various reasons. For example, according to CDC, some cases of foodborne illness may not be investigated or reported due to resource limitations at the state or local level. A 2022 study of foodborne outbreaks that states reported to CDC found that the number and types of foodborne outbreaks reported varied across states. Among other things, the study found that states that received more per capita funding from CDC's Epidemiology and Laboratory Capacity Program to detect, respond to, control, and prevent infectious diseases reported greater numbers of outbreaks to CDC. The study did not, however, enable identification of a causal connection between increased funding and increased reporting or account for any additional sources of funding that might be available to states for related purposes in this analysis.<sup>18</sup>

Additionally, states establish their own legal requirements for diseases and conditions that must be reported to public health authorities within their jurisdictions. Some foodborne illness cases may not be reported to CDC if the state does not require reporting of the illness. For example, CDC officials said that many states do not require reporting of *Cronobacter* infections within their jurisdictions. In 2024, *Cronobacter* infections were added to the list of diseases and conditions that CDC recommends states require be reported. CDC officials said it can take time for states to add a new disease to their reporting requirements.

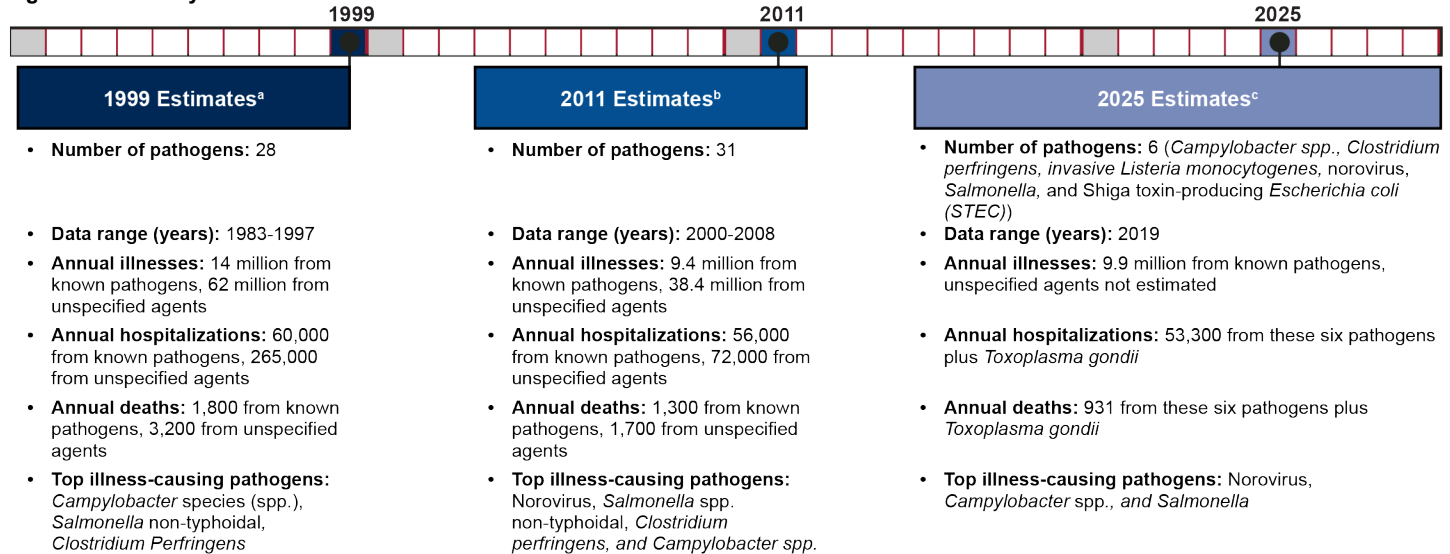
Even if a possible case of foodborne illness is diagnosed and reported to public health authorities, public health authorities would generally need to conduct an epidemiological investigation to identify the likely food source and any additional cases that may be connected. This can be challenging for various reasons. For example, the sick person may be unwilling to participate in an investigation. Additionally, CDC officials said that parasitic foodborne illnesses, such as cyclosporiasis, often have a lag time before the parasite is detected. This lag time can make it difficult to connect the illness to a food source if the contaminated food has a short shelf life and is no longer available to be tested.

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## What is the full magnitude of foodborne illness in the U.S.?

The precise magnitude of foodborne illness in the U.S. is unknown due to underdiagnosis and underreporting. Since 1999, CDC has conducted three studies, about 10 years apart, that evaluated the magnitude of foodborne illness in the U.S. These studies included estimates of annual illnesses, hospitalizations, and deaths from certain foodborne pathogens (see fig. 5). According to CDC officials, they employed different scopes and methodologies for each study, so the estimates cannot be directly compared or used to measure changes in the incidence of foodborne illness over time.

**Figure 5: Summary of Foodborne Illness Estimate Studies from the Centers for Disease Control and Prevention**



**Note: Due to changes in methodology between reports, these estimates cannot be directly compared or used to measure an increase or decrease in foodborne illness over time.**

Source: GAO summary of Centers for Disease Control and Prevention (CDC) information. | GAO-25-107606

<sup>a</sup>Paul S. Mead, et al., “Food-Related Illness and Death in the United States,” Centers for Disease Control and Prevention, *Emerging Infectious Diseases*, vol. 5, no. 5 (Atlanta, GA.: October 1999).

<sup>b</sup>Elaine Scallan, et al., “Foodborne Illness Acquired in the United States—Major Pathogens,” *Emerging Infectious Diseases*, vol. 17, no. 1 (January 2011); and Elaine Scallan, et al., “Foodborne Illness Acquired in the United States—Unspecified Agents,” *Emerging Infectious Diseases*, vol. 17, no. 1 (January 2011). Estimates are of domestically acquired foodborne illnesses, meaning these illnesses were transmitted only in the U.S.

<sup>c</sup>As of November 2024, the most recent 2025 CDC estimates report was not publicly available. Summary information shown in the figure and noted below are attributed to CDC officials.

Notes: For the 2011 and 2025 estimates, CDC provides 90 percent credible interval (CrI) estimates, the interval for which there is 90 percent probability that the true (unknown) estimate lies, given the evidence provided by the observed data. For 2011 CrIs for known pathogens, these intervals are, for illnesses, 6.6 million to 12.8 million; hospitalizations, 39,000 to 76,000; and deaths, 700 to 2,268. For 2025 CrIs for known pathogens, these intervals are, for illnesses, 5.9 million to 15.4 million; hospitalizations, 36,000 to 75,000; and deaths, 530 to 1,460. See 2011 source for CrI for unspecified agents, which represent cases of gastrointestinal illnesses that were likely to have been caused by foodborne pathogens, but for which CDC did not have sufficient data to link the illness to a specific pathogen. No measures of uncertainty were provided for the 1999 estimates.

The scope of the 1999, 2011, and 2025 CDC studies varied in that they evaluated foodborne illness for different numbers of pathogens. For example, according to CDC officials, CDC’s forthcoming 2025 estimate report does not include estimates for unspecified agents, which were included as part of the 1999 and 2011 estimates. According to CDC, estimates of unspecified agents represent cases of gastrointestinal illnesses that were likely to have been caused by foodborne pathogens, but could not be definitively classified as such for various reasons. For example, CDC may not have had sufficient data to link the illness to a specific pathogen.<sup>19</sup> Officials said that for the 2025 study, CDC focused on updating the disease burden estimates for priority pathogens and considers these estimates to be more valuable to food safety regulators than estimates for unspecified agents.

CDC also updated its methodology with each subsequent estimate to reflect recent data and improved statistical approaches. These updates included using different data sources and base years, according to CDC officials. To develop foodborne illness estimates for its 2011 study, CDC used reported case data from FoodNet, outbreak data, population surveys, and laboratory surveys to develop multipliers that account for underdiagnosis and underreporting of the pathogens included in the study.

According to CDC, these periodic estimates provide the most accurate picture of the magnitude of foodborne illnesses in the U.S. for the pathogens responsible for the most illnesses at the time of the study. CDC and federal, state, and local partners use these estimates to help set public health goals, allocate resources, and measure the economic impacts of disease.

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**What foods have been associated with foodborne illness and what are the challenges in identifying them?**

According to the most recent Interagency Food Safety Analytics Collaboration (IFSAC) report, which uses outbreak data from 1998 through 2022,

- Foodborne *Salmonella* illnesses were most attributed to chicken, an FSIS-regulated product;
- Foodborne *E. coli* O157 illnesses were most attributed to the vegetable row crop category, an FDA-regulated food category that includes lettuce, broccoli, and celeries, among others; and
- Foodborne *Listeria monocytogenes* illnesses were most attributed to dairy, an FDA-regulated food category.<sup>20</sup>

Determining the sources of foodborne illness is an important part of identifying opportunities to improve food safety. CDC defines foodborne illness source attribution as the process of estimating the most common food categories responsible for illnesses caused by specific pathogens.

Similar to understanding the full magnitude of foodborne illness, attributing specific foods to individual cases of suspected foodborne illness poses a challenge. According to CDC, it is often difficult for people to accurately remember what they ate that may have made them sick. As a result, single cases of presumptive foodborne illnesses reported to a health department often do not have an attributed source, making reported outbreak investigation data a better source for estimating food attribution.

When multiple people become ill from a single food source, as happens with an outbreak, investigators can more easily link the illness to the responsible food, according to CDC and IFSAC officials. However, not all outbreaks are identified or reported to public health officials, as discussed above. Even when they are, the precise food source may not be known (e.g., a food product is linked to the cases, but not the specific ingredient that made people sick).

To address the challenges in determining foods associated with illness, CDC, FDA, and FSIS formed IFSAC in 2011 to focus on improving the estimates of food source attribution. The agencies use outbreak data to produce annual reports with source attribution estimates of the foods associated with foodborne illnesses, including *Salmonella*, *E. coli* O157, and *Listeria monocytogenes*. IFSAC produces estimates for these three pathogens because of the frequency and severity of illness they cause.<sup>21</sup> According to IFSAC officials, estimates of these pathogens are also useful because industry and food regulatory agencies can take targeted actions to reduce illnesses that these pathogens cause.

IFSAC's most recent food source attribution estimate report was published in 2024. Estimates are based on outbreak data from 1998 to 2022, with the most recent 5 years of data (2018–2022) weighted more heavily in the estimation models. Figure 6 shows the most common food categories associated with foodborne illness for three key pathogens, arranged by which agency regulates that food category. For example, FDA-regulated vegetable row crops account for an estimated 64 percent of foodborne *E. coli* O157 illnesses.

**Figure 6: Food Categories Most Commonly Associated with Foodborne Illness Caused by Three Pathogens, by Regulatory Agency Responsible for the Food Category, Based on Outbreak Data from 1998–2022**

Salmonella		Escherichia coli O157		Listeria monocytogenes	
FDA	FSIS	FDA	FSIS	FDA	FSIS
	20% Chicken	64% Vegetable row crops		37% Dairy	
15% Fruit			21% Beef	23% Vegetable row crops	
12% Seeded vegetables		3% Dairy		17% Fruit	
	12% Pork		3% Pork	9% Other produce	
9% Other produce		2% Fruit			5% Pork

**Agency responsible for regulating food category**

FDA – Food and Drug Administration  
 FSIS – U.S. Department of Agriculture Food Safety and Inspection Service

Sources: GAO analysis of Interagency Food Safety Analytics Collaboration (IFSAC) data; gheatza/stock.adobe.com and GAO (icons). | GAO-25-107606

Notes: The percentages represent the point estimates of attribution percentage of the food category for each pathogen. For the estimates of attribution percentage, IFSAC provides 90 percent credible intervals. For example, the 90 percent credible interval for chicken causing foodborne *Salmonella* illnesses is 15.4 to 24.7 percent. The credibility intervals overlap for the *Salmonella* and *Listeria monocytogenes* categories with the highest attribution percentages, indicating no statistically significant difference among them. For *E. coli*, vegetable row crops and beef had significantly higher estimated attribution percentages than all other categories. Estimates may be subject to bias because only 34 percent of the 3,996 outbreaks reported from 1998 to 2022 are analyzed, due to the inability to assign some reported outbreaks to a single food category, and estimates for pathogens with fewer outbreaks are disproportionately influenced by outbreaks with the most illnesses. Estimates are based only on outbreak data, which may have limitations when used in assessing foods associated with sporadic illness. The results are based on 1,010 outbreaks caused or suspected to be caused by *Salmonella*; 281 by *E. coli* O157; and 64 by *Listeria monocytogenes*. IFSAC uses a food categorization scheme to simplify food into 17 different categories that closely align with U.S. food regulatory agencies' classification needs.

Recent outbreaks illustrate the continuing links between these food categories and illness.

- **Chicken and *Salmonella*.** In 2018, an outbreak of *Salmonella* in chicken products was associated with 129 reported illnesses, 25 hospitalizations, and one death across 32 states. FSIS and CDC investigated this outbreak and identified *Salmonella* in samples taken from raw chicken pet food, raw chicken products, and live chickens. This suggested that the outbreak was linked to multiple chicken products spread throughout the industry, according to FSIS. According to CDC, chicken can cause foodborne illness when undercooked, because it can be contaminated with *Salmonella*, among other harmful pathogens. Improper handling of raw chicken can also lead to illness because pathogens in the raw chicken can contaminate other foods or surfaces.
- **Vegetable row crops and *E. coli*.** In 2018, an outbreak of *E. coli* in romaine lettuce affected consumers across 36 states and was associated with 210 reported illnesses, 96 hospitalizations, 27 cases of hemolytic uremic syndrome, and five deaths, according to FDA. The outbreak investigation found a strain of *E. coli* in three samples of water from an irrigation canal that was closely related to the strain of *E. coli* that made people sick. The investigation concluded that water from the irrigation canal most likely led to contamination of the romaine lettuce; however, other sources or means of contamination could not be ruled out.<sup>22</sup> A large, concentrated animal feeding operation was located near the canal, but no obvious route of contamination from this facility to the canal was identified.
- **Dairy and *Listeria monocytogenes*.** In 2024, FDA and CDC investigated an outbreak of *Listeria monocytogenes* (clinical illnesses ranged from 2014 to 2023) in queso fresco and cotija cheese that resulted in 26 identified illnesses, 23 hospitalizations, and two deaths across 11 states. This outbreak

resulted in a pregnancy loss and two newborns with *Listeria monocytogenes* infections. When investigating this outbreak, FDA found that the cheese manufacturer was not in compliance with the Federal Food, Drug, and Cosmetic Act and implementing regulations. The firm was prohibited from manufacturing certain food products until it complies with federal regulations. According to CDC, *Listeria* is often found in dairy such as soft cheeses. Soft cheeses have high moisture and low acidity, conditions that support the growth of *Listeria*.

**What are CDC, FDA, and FSIS foodborne illness reduction goals and reported progress?**

CDC, FDA, and FSIS have individual agency strategic goals and performance goals related to reducing foodborne illness, based on each agency's role in federal food safety. For example, CDC has goals and measures aimed at improving its capacity to further identify foodborne pathogens through laboratory testing. FDA and FSIS have goals and measures aimed at reducing infections caused by pathogens such as STEC, *Listeria monocytogenes*, and *Salmonella*, which are found in the foods each agency regulates. Each agency defines performance measures in its respective budget justifications that set measurable targets towards achieving the agency's strategic goal related to reducing foodborne illness. The agencies report progress towards their performance goals in their annual budget justifications to Congress or their annual performance reports.

The most recent progress reports show that overall, annual targets for most performance measures were not met. Of note, FSIS and FDA have not met their goals to reduce infections caused by key pathogens found in foods that each agency regulates—in one case, by a wide margin—as table 3 shows.

**Table 3: CDC, FDA, and FSIS Summary of Strategic Goals, Performance Goals, and Reported Progress Related to Reducing Foodborne Illness**

Agency	Foodborne illness-related strategic goal or objective	Performance goals	Performance goal annual target	Desired direction	Most recently reported result	Performance goals status
CDC	Protect Americans from infectious diseases – foodborne illness	Increase the epidemiologic capacity of the Epidemiology and Laboratory Capacity Program Section F1 recipients for <i>Salmonella</i> , <i>Listeria</i> , and Shiga toxin-producing <i>E. coli</i> (STEC), surveillance and outbreak investigations.	85 percent	Increase	61 percent	Target not met
		Percentage of isolates of priority PulseNet pathogens ( <i>Salmonella</i> , STEC, and <i>Listeria monocytogenes</i> ) sequenced and uploaded to the PulseNet National Database.	80 percent	Increase	84 percent	Target exceeded
		Increase the percentage of cases with positive culture-independent diagnostic tests for STEC and culture isolation attempted or specimen metagenomics obtained.	90 percent	Increase	83 percent	Target not met
FDA	Food safety: Protect America's consumers and animals from foreseeable hazards	Foodborne illness - Reduce the incidence of laboratory-diagnosed, domestically acquired STEC infections in humans.	4.3 cases out of 100,000	Decrease	4.6 cases out of 100,000	Target not met
		Foodborne illness - Reduce the incidence of laboratory-diagnosed, domestically acquired <i>Listeria monocytogenes</i> infections in humans.	0.25 cases out of 100,000	Decrease	0.26 cases out of 100,000	Target not met
		Foodborne illness - Reduce the incidence of laboratory-diagnosed, domestically acquired <i>Salmonella</i> infections in humans.	14.0 cases out of 100,000	Decrease	14.5 cases out of 100,000	Target not met
FSIS	Prevent foodborne illness and protect public health	Percent reduction in the proportion of poultry samples with <i>Salmonella</i> serotypes commonly associated with human illness.	4 percent reduction	Decrease	22 percent increase	Target not met

Legend:  
 CDC = Centers for Disease Control and Prevention



Each agency also reports additional details on progress towards performance goals and reasons for reaching or not reaching targets. For example, CDC acknowledged that a lack of staffing capacity at state and local health departments affects its ability to meet its target to increase the epidemiologic capacity of the Epidemiology and Laboratory Capacity Program. This program provides flexible funding to the nation's health departments to detect, prevent, and respond to infectious disease outbreaks. CDC reported that state and local health departments are experiencing high turnover and difficulty hiring, which affects their ability to conduct interviews during outbreak investigations.

Similarly, FDA and FSIS reported challenges in meeting performance goals. FDA reported that prevention activities from the COVID-19 pandemic likely contributed to an unprecedented decrease in foodborne illness infections in calendar year 2020; however, in 2022, infection rates rose to prepandemic levels. FDA officials said that continued surveillance might improve the understanding of how the pandemic affected foodborne illness, leading to improvements in infection reduction strategies moving forward.

In addition, FSIS is addressing its *Salmonella* performance measure with plans to respond to comments on its proposed *Salmonella* framework and develop the final rule as soon as possible, according to agency officials. The framework is designed to more effectively reduce *Salmonella* contamination and illnesses associated with raw poultry products.<sup>23</sup> According to FSIS officials, if this proposed framework rule becomes final, it will help prevent certain contaminated products from entering the market. The rule will also clarify current requirements that all poultry slaughter establishments develop, implement, and maintain written procedures to prevent contamination.

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## What progress towards achieving Healthy People 2030 objectives has been reported?

Limited progress has been made towards achieving the Healthy People 2030 objectives related to reducing foodborne illness. In addition, six objectives related to reducing outbreaks remain under development about 5 years into the 10-year performance cycle. The Healthy People initiative, which began in 1979, identifies public health priorities with 10-year, measurable public health objectives. The latest iteration, Healthy People 2030, identifies specific objectives related to the goal of reducing foodborne illness. These objectives were developed by a working group comprised of officials from CDC, FDA, FSIS, and other agencies with expertise in food safety.

To develop the specific objectives and performance goals, working group representatives worked with their respective agencies to develop scientifically based objectives with reasonable targets, according to working group officials from CDC, FDA, and FSIS. According to these officials, when setting performance goals for objectives, representatives also consider whether the agency has a plan in place, or future plans to be implemented during the Healthy People cycle, to help the agency reach the target.

For example, FDA's 2021 Foodborne Outbreak Response Improvement Plan includes strategies to help limit outbreaks attributed to FDA-regulated foods, in turn helping to reduce foodborne illnesses and outbreaks. In addition, FSIS is working on its proposed *Salmonella* framework, with the goal of keeping contaminated poultry from entering commerce, ultimately reducing *Salmonella* illnesses and outbreaks. However, as we noted above, FDA and FSIS have not reached their agency goals as of the most recently reported progress.

As table 4 shows, the latest reported progress on incidence and outbreak-related strategic objectives shows some limited progress towards the objectives. For

example, while improvements have been made in reducing *Listeria* and *Salmonella* infections, *Campylobacter* and STEC infections have seen little to no detectable change. In addition, several objectives still do not have the baseline data necessary to evaluate progress.

**Table 4: Healthy People 2030 Strategic Objectives Related to Reducing Foodborne Illness Infections and Outbreaks**

Healthy People 2030 strategic objective	Federal agencies involved	Baseline data	2030 target	Most recently reported result, as of December 2024	Status, as reported by Healthy People 2030
Reduce the incidence of laboratory-diagnosed, domestically acquired <sup>a</sup>					
<i>Listeria monocytogenes</i> infections	CDC, FDA, FSIS	0.27 laboratory-diagnosed per 100,000 population	0.22 laboratory-diagnosed per 100,000 population	0.26 per 100,000	Improving
<i>Salmonella</i> infections	CDC, FDA, FSIS	15.3 laboratory-diagnosed per 100,000 population	11.5 laboratory-diagnosed per 100,000 population	14.4 per 100,000	Improving
<i>Campylobacter</i> infections	CDC, FDA, FSIS	16.2 laboratory-diagnosed per 100,000 population	10.9 laboratory-diagnosed per 100,000 population	17.2 per 100,000	Little or no detectable change
Shiga toxin-producing <i>Escherichia coli</i> (STEC) infections	CDC, FDA, FSIS	4.6 laboratory-diagnosed per 100,000 population	3.7 laboratory-diagnosed per 100,000 population	4.6 per 100,000	Little or no detectable change
Reduce outbreaks of STEC, <i>Campylobacter</i> , <i>Listeria</i> , and <i>Salmonella</i> infections linked to <sup>b</sup>					
beef		Under development			No reported results
dairy		Under development			No reported results
fruits and nuts		Under development			No reported results
leafy greens		Under development			No reported results
poultry		Under development			No reported results
Reduce number of norovirus outbreaks		Under development			No reported results

Legend:

CDC = Centers for Disease Control and Prevention  
 FDA = Food and Drug Administration  
 FSIS = Food Safety and Inspection Service

Source: GAO analysis of Healthy People 2030 information. | GAO-25-107606.

Note: According to Healthy People 2030, objectives under development include high-priority public health issues that have evidence-based interventions to address them, but the objective does not yet have reliable baseline data.

<sup>a</sup>The Healthy People 2030 targets for reducing incidences of laboratory-diagnosed, domestically acquired *Listeria monocytogenes*, *Salmonella*, and STEC infections differ and call for a greater reduction in incidences than individual agency targets. The Healthy People 2030 targets are 10-year targets and individual agency targets are annual targets. There were no CDC, FDA, or FSIS individual agency goals for reducing *Campylobacter* infections in the most recent agency updates.

<sup>b</sup>The strategic objectives under development do not have baseline data defined to measure progress or targets; therefore, we could not identify which federal agencies might be involved in achieving those objectives.

According to agency officials, the use of advanced testing methods to detect foodborne pathogens may cause an increased incidence rate in the data, making progress towards goals more challenging to measure. For example, officials said the absence of progress towards reduction in *Campylobacter* and STEC cases could be attributed to the use of advanced testing methods, which has resulted in the diagnosis of foodborne illnesses that previously would have gone undetected, rather than an increase in actual incidence.

Nevertheless, objectives related to reducing outbreaks of *Campylobacter*, STEC, *Listeria*, and *Salmonella* infections linked to beef, dairy, fruits and nuts, leafy greens, and poultry, and outbreaks of norovirus are still under development. According to the Healthy People 2030 website, objectives in a “developmental” status include high-priority public health issues that have evidence-based

interventions to address them, but do not yet have reliable baseline data. CDC, FDA, and FSIS officials in the working group said that several factors affect the group's ability to identify reliable data; these factors include volatility in outbreak data and capacity challenges at state and local health departments.

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### What key recommendations have we made to improve federal oversight of food safety?

Since we added food safety to our High Risk List in 2007, we have made numerous recommendations to address fragmentation, enhance collaboration, and identify capacity needs among agencies with food safety responsibilities.<sup>24</sup> As of January 2025, six recommendations and five matters for congressional consideration that we consider significant for removing federal oversight of food safety from the High Risk List remain unaddressed.

Most significantly, in January 2017, we recommended that the Executive Office of the President, in consultation with relevant federal agencies and stakeholders, develop a national strategy to guide the nation's efforts to improve the federal food safety oversight system.<sup>25</sup> A national strategy could establish sustained high-level leadership across food safety agencies over time; identify resource requirements across agencies to achieve crosscutting goals, such as the aforementioned pathogen and foodborne illness reduction goals; and monitor progress in meeting these goals, among other things. In addition, a national strategy with these elements could address our previous matters for congressional consideration on the need for a government-wide performance plan for food safety and sustained leadership across federal food safety agencies.<sup>26</sup> As of January 2025, there were no plans to create a national strategy, according to officials from the Office of Management and Budget.

As previously stated, foodborne illness continues to be a serious and costly problem, annually affecting tens of millions of Americans and costing billions of dollars. This is further exacerbated by changes in the U.S. food supply, such as increases in food imports within the last decade and emerging foods such as cell-cultured meat, that place further pressure on federal oversight of food safety.<sup>27</sup> We maintain that the development and implementation of a national strategy for food safety creates an opportunity to further strengthen the oversight of the nation's food supply, in turn reducing the economic and public health impacts of foodborne illness.

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### Agency Comments

We provided a draft of this report to HHS and USDA for review and comment. HHS and USDA provided technical comments, which we incorporated as appropriate. Additionally, in USDA's comments, reproduced in appendix I, it generally agreed with our findings and provided additional context regarding its pathogen standards.

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### How GAO Did This Study

To describe foodborne illness and how foods get contaminated, we reviewed CDC information on foodborne illness, including different pathogens, symptoms, and long-term effects of foodborne illness. We selected five foodborne pathogens and associated illnesses to review in greater detail, including illness description, symptoms, and long-term effects. We selected these pathogens based on the availability of recent estimates of foodborne illness, available estimates of food source attribution, and identification of the pathogen in agency goals associated with foodborne illness. To describe how foods get contaminated, we reviewed our prior work on foodborne illness outbreaks and reviewed CDC information on food contamination. We reviewed and summarized selected outbreak reports, ranging from 2018 to 2024, from CDC, FDA, and FSIS to describe recent outbreaks that corresponded with various stages of the food production chain.

To describe the roles federal agencies have in identifying cases of foodborne illness, we reviewed agency documentation, policies, and directives related to roles and response to foodborne illness and outbreaks. We also conducted site visits to FDA's Atlanta Human and Animal Food Laboratory, FSIS's Eastern Laboratory, and CDC laboratory facilities to observe how these laboratories analyze samples, among other things. We also interviewed officials from the CDC's National Center for Emerging and Zoonotic Infectious Diseases to better understand CDC's foodborne illness surveillance systems, including the information CDC collects, the reporting parties, and limitations of the surveillance systems. To understand each agency's role, we interviewed FDA and FSIS officials with responsibilities for identifying and investigating foodborne illnesses and outbreaks and reporting that information to CDC. In addition, we interviewed the Council of State and Territorial Epidemiologists to better understand the roles of state and local parties in identifying, investigating, and responding to foodborne illness and outbreaks.

To describe what is known about the magnitude of foodborne illness and foods associated with illness, we reviewed CDC estimate reports from 1999 and 2011 and the latest IFSAC source attribution estimate report, released in December 2024. We identified the methodology, data sources, and limitations with each study, and determined how to accurately summarize findings and caveat limitations for our reporting purposes. We also interviewed CDC officials to collect further information on the 1999, 2011, and 2025 estimate reports, and IFSAC working group officials for further information about the IFSAC source attribution estimate reports. To summarize outbreak examples, we reviewed and summarized outbreak reports from CDC, FDA, and FSIS and chose recent examples associated with IFSAC food categories.

To summarize agency goals related to reducing foodborne illness, we reviewed agency documents, including the most current strategic plans or annual progress reports, and the fiscal year 2025 budget justifications that described related goals, objectives and performance measures, progress towards goals, and challenges. We interviewed CDC, FDA, and FSIS officials to identify agency-specific goals and how they measure and report progress towards goals. We also reviewed the Healthy People 2030 website and interviewed working group officials from CDC, FDA, and FSIS to further understand the process for identifying and measuring progress towards foodborne illness objectives.

We conducted this performance audit from May 2024 to February 2025 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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## List of Addressees

The Honorable John Boozman  
Chair  
The Honorable Amy Klobuchar  
Ranking Member  
Committee on Agriculture, Nutrition, and Forestry  
United States Senate

The Honorable Bill Cassidy, M.D.  
Chair  
The Honorable Bernard Sanders  
Ranking Member  
Committee on Health, Education, Labor and Pensions  
United States Senate

We are also sending copies of this report to the appropriate congressional committees, the Secretaries of Agriculture and Health and Human Services, and other interested parties. In addition, the report is available at no charge on the GAO website at <https://www.gao.gov>.





DEPUTY UNDER SECRETARY FOR FOOD SAFETY  
WASHINGTON, D.C.  
20250-0121

January 17, 2025

Steve D. Morris  
Director  
Natural Resources and Environment  
United States Government Accountability Office  
441 G Street, N.W.  
Washington, DC

Dear Mr. Morris,

The U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) appreciates the opportunity to review the U.S. Government Accountability Office (GAO) draft report entitled "*Status of Foodborne Illness in the U.S.*" (GAO-25-107606). We offer the following general and specific comments to the draft report, as outlined below.

FSIS generally agrees with the findings in the GAO draft report. We do want to emphasize the collaborative and cooperative efforts of FSIS with the U.S. Food and Drug Administration, the U.S. Centers for Disease Control and Prevention, and other public health partners to address and decrease foodborne illness in the United States. FSIS oversees the safety of meat (including Siluriformes fish), poultry and egg products. The agency conducts inspection activities at approximately 7,100 federally regulated meat, poultry, and egg product establishments. These activities include carcass-by-carcass inspections at all meat and poultry slaughter establishments, approximately 1,300 establishments in total.

FSIS ensures food safety through the authorities of the Federal Meat Inspection Act, the Poultry Products Inspection Act, the Egg Products Inspection Act, and humane animal handling through the Humane Methods of Slaughter Act.

FSIS would like to provide additional context regarding the discussion in the report on page 6 under Food Safety. FSIS has established *Salmonella* and *Campylobacter* standards for raw product. FSIS also tests ready-to-eat (RTE) product for *Listeria monocytogenes* and *Salmonella*. If FSIS or public health partners find evidence of *Listeria monocytogenes* or *Salmonella* in RTE products, the product is considered adulterated and cannot enter commerce, or it is subject to recall action to remove it from commerce. Similarly, FSIS tests certain raw beef products for adulterant Shiga toxin-producing *Escherichia coli* (STEC). Again, if FSIS or other public health partners confirm its presence in these products, the product is considered adulterated.

Steve D. Morris  
Page 2

The report indicates: "...we found that FSIS had not updated or developed some pathogen standards... (and) has instead focused its resources on a framework of standards for *Salmonella* in raw poultry." GAO suggested that "FSIS develop a prioritization plan for additional policies needed to reduce pathogens found in foods..." Historically, FSIS has relied on pathogen reduction performance standards as one way to assess process control (i.e., that an establishment is producing safe food) at establishments that prepare meat and poultry products. FSIS also collects routine samples at establishments subject to applicable performance standards to verify the effectiveness of the establishment's food safety system as well as for other regulatory purposes. These samples are used to assess and categorize each establishment's performance compared to the standard.

FSIS data have demonstrated that there have been consistent reductions in the occurrence of *Salmonella* in poultry products over the years; however, these reductions have not correlated with a reduction in illnesses attributable to *Salmonella* in poultry. More than 1 million consumer illnesses due to *Salmonella* occur annually, with nearly a quarter of those illnesses attributed to consumption of chicken and turkey. For this reason, FSIS determined it was time to reconsider our approach to *Salmonella* in poultry, adopting this effort as a top priority in 2021. As part of this effort, in April 2024, FSIS announced a [final determination](#) to declare *Salmonella* an adulterant in raw breaded stuffed chicken products when they exceed a specific threshold (1 colony forming unit (CFU) per gram or higher) for *Salmonella* contamination. That determination will go into effect a year after its publication (May 2025). To build on this action, in July 2024, FSIS announced a [comprehensive proposed rule and determination](#) to more effectively reduce *Salmonella* contamination and illnesses associated with raw poultry products. The proposal includes final product standards to prevent raw chicken carcasses, chicken parts, ground chicken and ground turkey products that contain any type of *Salmonella* at or above 10 CFU per gram/ml and any detectable level of at least one of the *Salmonella* serotypes of public health significance from entering commerce. Both policy announcements involved extensive collaboration and engagement with stakeholders and rigorous scientific evaluation.

In addition, following *Listeria monocytogenes*-related recalls and illness outbreaks that occurred in 2024 and were associated with FSIS-regulated product, in December 2024, the agency [announced several measures](#) it is taking to strengthen its oversight of RTE establishments to protect the public from this pathogen. FSIS is continuing to work on its long-term vision to modernize the agency's regulatory approach to *Listeria monocytogenes*, which includes leveraging the expertise of the National Advisory Committee on Microbiological Criteria for Foods.

FSIS is committed to constantly reviewing and improving our policies and processes to protect the public from foodborne illness.

Thank you again for the opportunity to review and respond to the GAO draft report. Technical comments were submitted under a separate cover.

Sincerely,



Sandra Eskin  
Deputy Under Secretary  
Office of Food Safety

## GAO Contact Information

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## Endnotes

<sup>1</sup>While foodborne illnesses can also be caused by chemical and physical agents, this report focuses on biological agents.

<sup>2</sup>According to FDA officials, although reports indicated that ill patients consumed powdered infant formula produced at the same facility, clinical and product samples did not match the environmental samples. Specifically, CDC tested clinical samples and found that the strain was not a genetic match to the multiple strains found in the environmental samples or to any other clinical isolates in the National Center for Biotechnology Informatics database. Additionally, FDA analyzed the product samples it collected for *Cronobacter* and found them to be negative, according to FDA officials.

<sup>3</sup>While FDA's investigation found no evidence to indicate that this farm was the sole source of the outbreak, the outbreak strain was not detected in any other samples collected during this investigation. See FDA's [investigation summary](#): Food and Drug Administration, "Investigation Summary: Factors Potentially Contributing to the Contamination of Romaine Lettuce Implicated in the Fall 2018 Multi-State Outbreak of *E. coli* O157:H7" (Feb. 13, 2019).

<sup>4</sup>M.N. Hanley, S.M. Altman, A. Phillips, "Notes from the Field: Outbreak of Norovirus Linked to a Food Establishment — Illinois, November 2022," *Morbidity and Mortality Weekly Report*, vol. 72, no. 33 (Atlanta, GA: August 2023).

<sup>5</sup>For the purposes of this report, we focus primarily on state and local public health departments, but territorial public health departments may also conduct such activities. Tribes are not included in this report. Tribes conduct their own foodborne illness surveillance, investigations, and response activities, but nontribal entities—such as the Indian Health Service and state or local health agencies—may become involved at a Tribe's request.

<sup>6</sup>See 42 U.S.C. § 264(a).

<sup>7</sup>Other federal agencies also have responsibilities for food safety. For example, the National Marine Fisheries Service provides voluntary fee-for-service examinations of seafood for safety and quality. The Environmental Protection Agency regulates the use of certain chemicals and substances, as well as pesticides. U.S. Customs and Border Protection inspects imported food products, plants, and live animals for compliance with U.S. law and regulations.

<sup>8</sup>The approximate total of 75,000 domestic facilities represents FDA's domestic inventory at the end of fiscal year 2023, according to FDA data. The approximate total of 125,000 foreign facilities represents FDA's foreign inventory as of March 2023, according to FDA documentation.

<sup>9</sup>From fiscal year 2018 through fiscal year 2023, states conducted about one-third of routine surveillance food safety inspections on behalf of FDA, according to agency data.

<sup>10</sup>The Food Safety Modernization Act requires FDA to identify the risk level of domestic facilities that manufacture, process, pack, and store food and to conduct inspections according to the facilities' known safety risks. Pub. L. No. 111-353, tit. II, § 201, 124 Stat. 3885, 3923 (2011) (codified at 21 U.S.C § 350j(a)). The act also establishes factors for FDA to use in identifying high-risk facilities, including known safety risks of the food produced, a facility's compliance history, and the rigor and effectiveness of a facility's hazard analysis and risk-based preventive controls. Pub. L. No. 111-353 § 201 (codified at 21 U.S.C § 350j(a)(1)). Unlike domestic facilities, FDA does not explicitly categorize individual foreign food facilities as high-risk or non-high-risk. Pub. L. No. 111-353, § 201 (codified at 21 U.S.C § 350j(a)(2)). However, according to FDA officials, the agency uses a risk-based approach to prioritize inspections at facilities determined to have a higher risk profile. In determining a foreign facility's risk profile, FDA considers the type of food produced and the facility's compliance history. For example, if a facility's products have been denied entry into the United States, FDA may identify the facility as having a higher risk profile. In addition, the Food and Drug Omnibus Reform Act of 2022 mandates inspections of the facilities of each manufacturer of an infant formula required to be registered at an annual frequency and in accordance with a risk-based approach. Pub. L. No. 117-328, div. FF, tit. III, subtit. D, § 3401(i)(3), 136 Stat. 4459, 5843.

<sup>11</sup>The FDA Food Safety Modernization Act required FDA to increase the frequency of inspection of all facilities. Pub. L. No. 111-353, tit. II, § 201, 124 Stat. 3885, 3924 (2011) (codified at 21 U.S.C. § 350j(a)(2)(B), (C), (D)). The statute defines "facility" as a domestic or foreign facility that is required to register under 21 U.S.C. § 350d, which encompasses any facility engaged in manufacturing,

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processing, packing, or holding food for consumption in the United States. Pub. L. No. 111-353, § 201 (codified at 21 U.S.C. § 350j(e)); 21 U.S.C. § 350d. Under 21 U.S.C. § 350d(c)(3), foreign facilities are required to register only when food from the facility is exported to the United States without further processing or packaging outside the United States. The Food Safety Modernization Act directed FDA to inspect each domestic high-risk facility at least once during the 5-year period following January 4, 2011, and each domestic non-high-risk facility at least once during the 7-year period following January 4, 2011. Pub. L. No. 111-353, § 201 (codified at 21 U.S.C. § 350j(a)(2)(B)(i), (C)(i)). Once the initial cycle was completed, the act required FDA to inspect domestic high-risk facilities at least once every 3 years and domestic non-high-risk facilities at least once every 5 years. Pub. L. No. 111-353, § 201 (codified at 21 U.S.C. § 350j(a)(2)(B)(ii), (C)(ii)).

<sup>12</sup>The Food Safety Modernization Act directed FDA to inspect at least 600 foreign facilities in the 1-year period beginning on January 4, 2011. Pub. L. No. 111-353, tit. II, § 201, 124 Stat. 3885, 3924 (2011) (codified at 21 U.S.C. § 350j(a)(2)(D)(i)). For each of the 5 years following this 1-year period, the act directed FDA to inspect at least twice the number of facilities it had inspected during the previous year. Pub. L. No. 111-353, § 201 (codified at 21 U.S.C. § 350j(a)(2)(D)(ii)). In our 2015 report, we described two scenarios in which FDA responds to the act's requirements for conducting foreign inspections. The first scenario had FDA inspecting twice the actual number of foreign food facilities inspected the previous year, starting with the actual number of FDA inspections conducted in 2011. The second scenario had FDA inspecting 600 food facilities in 2011—the statutory minimum—and then doubling that number in each of the 5 following years. FDA has interpreted the Food Safety Modernization Act to impose an inspection target of 19,200 foreign facilities in 2016 and beyond. GAO, *Food Safety: Additional Actions Needed to Help FDA's Foreign Offices Ensure Safety of Imported Food*, [GAO-15-183](#) (Washington, D.C.: Jan. 30, 2015).

<sup>13</sup>GAO, *Food Safety: FDA Should Strengthen Inspection Efforts to Protect the U.S. Food Supply*, [GAO-25-107571](#) (Washington, D.C.: Jan. 8, 2025). We have also previously reported on challenges FDA faces with meeting food facility inspection targets. In 2015, we recommended that FDA conduct an analysis to determine the annual number of foreign inspections sufficient to ensure the safety of imported food. We also stated that if the number FDA identified was different from the annual target of 19,200 foreign inspections, FDA should report the results to Congress and recommend appropriate legislative changes. See [GAO-15-183](#). We have highlighted this recommendation as a priority for FDA on an annual basis since 2017 because we believe implementing it will help the agency improve its operations and make progress in addressing a long-standing high-risk issue area—improving federal oversight of food safety. GAO, *Priority Open Recommendations: Department of Health and Human Services*, [GAO-24-107257](#) (Washington, D.C.: May 28, 2024). Priority recommendations are those that GAO believes warrant priority attention from heads of key departments or agencies. They are highlighted because, upon implementation, they may significantly improve government operations, for example, by realizing large dollar savings; eliminating mismanagement, fraud, and abuse; or making progress toward addressing a high-risk or duplication issue. As of January 2025, this recommendation remained open.

<sup>14</sup>Federal Meat Inspection Act, 21 U.S.C. §§ 601-683 and Poultry Products Inspection Act, 21 U.S.C. §§ 451-472. In addition to meat and poultry products, FSIS is responsible for ensuring the safety of processed egg products under the Egg Products Inspection Act, 21 U.S.C. §§ 1031-1056, and fish of the order *Siluriformes* (e.g., catfish) under the Agricultural Act of 2014, Pub. L. No. 113-79, tit. I, subtit. B, § 12106(a), 128 Stat. 649, 980-81 (2014).

<sup>15</sup>GAO, *Food Safety: USDA Should Take Additional Actions to Strengthen Oversight of Meat and Poultry*, [GAO-25-107613](#) (Washington, D.C.: Jan. 22, 2025).

<sup>16</sup>FoodNet sites are located in Colorado, Connecticut, Georgia, Maryland, Minnesota, New Mexico, Oregon, and Tennessee, as well as certain counties in California and New York.

<sup>17</sup>FoodNet monitors the following eight pathogens: *Campylobacter*, *Cyclospora*, *Listeria*, *Salmonella*, Shiga toxin-producing *E. coli*, *Shigella*, *Vibrio*, and *Yersinia*.

<sup>18</sup>Alice E. White, Alexandra R. Tillman, Craig Hedberg, Beau B. Bruce, Michael Batz, Scott A. Seys, Daniel Dewey-Mattia, Michael C. Bazaco, Elaine Scallan Walter, "Foodborne Illness Outbreaks Reported to National Surveillance, United States, 2009-2018," *Emerging Infectious Diseases*, vol. 28, no. 6 (June 2022).

<sup>19</sup>According to CDC, unspecified agents fall into four general categories, including 1) agents with insufficient data to estimate agent-specific burden, 2) known agents not yet recognized as causing

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foodborne illness, 3) microbes, chemicals, or other substances known to be in food whose pathogenicity is unproven, and 4) agents not yet described.

<sup>20</sup>Estimates are derived from 48,375 illnesses linked to 1,355 foodborne disease outbreaks. Data from the last 5 years, between 2018 and 2022, are more heavily weighted in the estimation method; data from previous years, between 1998 and 2017, are given exponentially less weight.

<sup>21</sup>Prior to IFSAC's 2022 estimate report, IFSAC included *Campylobacter* in the annual food attribution estimates. However, according to IFSAC, *Campylobacter* is not presented in the 2022 report because evidence suggests the sources of *Campylobacter* outbreaks likely differ considerably from the sources of non-outbreak-associated illnesses. According to IFSAC's 2022 report, the group is exploring alternative approaches for estimating the sources of *Campylobacter* illnesses.

<sup>22</sup>This irrigation canal delivers water to farms in the local area, including several identified in the investigation as having potentially shipped romaine lettuce contaminated with the outbreak strain. No other environmental samples collected in the region yielded the outbreak strain of *E. coli* O157:H7. FDA cannot rule out other sources or means of romaine lettuce contamination that were not identified during the Environmental Assessment investigation. See [FDA environmental assessment](#): Food and Drug Administration, "Environmental Assessment of Factors Potentially Contributing to the Contamination of Romaine Lettuce Implicated in a Multi-State Outbreak of *E. coli* O157:H7" (Nov. 1, 2018).

<sup>23</sup>*Salmonella Framework for Raw Poultry Products*, 89 Fed. Reg. 64678, 64684 (Aug. 7, 2024).

<sup>24</sup>GAO, *High-Risk Series: Efforts Made to Achieve Progress Need to Be Maintained and Expanded to Fully Address All Areas*, [GAO-23-106203](#) (Washington, D.C.: Apr. 20, 2023).

<sup>25</sup>GAO, *Food Safety: A National Strategy Is Needed to Address Fragmentation in Federal Oversight*, [GAO-17-74](#) (Washington, D.C.: Jan. 13, 2017).

<sup>26</sup>GAO, *Federal Food Safety Oversight: Additional Actions Needed to Improve Planning and Collaboration*, [GAO-15-180](#) (Washington, D.C.: Dec. 18, 2014).

<sup>27</sup>We previously reported on the increase of imported food and cell-cultured meats. See [GAO-15-183](#) and GAO, *Food Safety: FDA and USDA Could Strengthen Existing Efforts to Prepare for Oversight of Cell-Cultured Meat*, [GAO-20-325](#) (Washington, D.C.: Apr. 7, 2020).