



When Good Food Goes Bad:
Strengthening the US Response to Foodborne Disease Outbreaks

Center for Biosecurity of UPMC

Final Report – March 2013

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Executive Summary

Foodborne illness sickens or kills an extraordinary number of people each year. It also has great economic costs. Last year, an outbreak linked to contaminated cantaloupe in the United States sickened 146 and killed 30. In 2011, another outbreak in Germany that was eventually linked to contaminated sprouts, sickened more than 4,000 and caused at least 50 deaths. Foodborne disease outbreak response is a critical part of reducing the consequences of outbreaks that will occur in the future. If public health officials can more quickly recognize when a foodborne illness outbreak has occurred and identify the food causing the outbreak, lives can be saved and economic losses averted. The lessons learned from outbreak investigations can be used by industry and government to address the underlying causes of contamination that lead to illness, thus making food safer for everyone.

The Center for Biosecurity of UPMC produced this report to catalyze improvements in the country's ability to respond to large foodborne disease outbreaks. We analyzed the existing data and studies on foodborne illness outbreak response, identified emerging trends, and interviewed dozens of federal and state level officials and experts from industry, professional organizations, academia, and relevant international organizations. The report puts forth a series of recommendations to accelerate and strengthen responses to foodborne illness outbreaks in the US.

Findings

1. Foodborne illness outbreaks continue to impose enormous health and economic burdens in the US.

Foodborne diseases cause significant morbidity and mortality in the US, sickening more than 40 million people and causing 128,000 hospitalizations and 3,000 deaths each year.¹ Medical expenses combined with lost productivity from foodborne illness cost upwards of \$77 billion annually.² Compared to the significant health and economic tolls associated with foodborne illnesses, the level of resources devoted to preventing and responding to such outbreaks is quite small.



2. Effective surveillance for and rapid response to foodborne illness outbreaks are critical to overall preparedness.

In addition to helping to mitigate the consequences of accidental contamination of the food supply, effective surveillance and rapid response to foodborne disease outbreaks can help improve overall readiness for other public health emergencies. The same surveillance systems and public health investigation approaches used to conduct routine outbreak investigations will likely be the country's first response to deliberate contamination of the food supply. Therefore, maintaining state and local health departments' capacity to respond is a necessary component of preparedness for biological attacks.³

3. National surveillance programs have led to meaningful improvements in the detection of foodborne illness outbreaks and can drive improvements in food safety.

Foodborne disease surveillance programs such as the US Centers for Disease Control and Prevention's (CDC's) PulseNet, FoodCORE, and FoodNet have helped to improve response to foodborne illness outbreaks and food safety in general. Improved surveillance has led to the detection of many more foodborne illness outbreaks, including some that have involved just a handful of cases spread out among several states. Investigations in the past decade have resulted in the recall of hundreds of millions of pounds of contaminated products. More importantly, information obtained from outbreak investigations allows identification of previously unrecognized problems in the food supply, giving industry and regulators the information they need to implement changes to ensure safer food products.

4. Determining the source of foodborne illness outbreaks remains the top response challenge and will likely become harder as the complexity of the food supply increases.

Linking a known case of gastrointestinal illness to the ingestion of a specific contaminated food product continues to be a major challenge in responding to foodborne illness outbreaks. In nearly all outbreaks, public health agencies rely on interviews of individual case patients to determine what foods they may

have consumed around the estimated date of infection. Food histories are typically incomplete and insufficient to identify the source in time to make a difference. In addition, the complexity of the food system makes tracking down a single contaminated ingredient difficult.

5. Heterogeneity in states' capacities to detect and respond to outbreaks creates national vulnerabilities.

Local, regional, and state health departments have differing capabilities, budget priorities, and procedures. There is also a wide range in the speed and frequency with which states initiate foodborne illness outbreak investigations. States that are considered leaders in the field of foodborne illness outbreak response consistently commit to 3 response components: (1) they rapidly interview all patients reported to the health department as having been infected with a pathogen that is commonly associated with foodborne disease; (2) they pay for a courier services to transport specimens from clinical labs to public health laboratories for faster testing and analysis; and (3) they conduct strain-typing tests on all tracked organisms in the recommended time frame.

6. The increased adoption of culture-independent diagnostic testing by the clinical sector threatens to undermine early detection of foodborne illness outbreaks.

In recent years the advent of laboratory-based surveillance programs has greatly improved the speed and frequency with which foodborne illness outbreaks are detected in the US, but there are serious concerns about the viability of current surveillance approaches. This is because changing trends in clinical medicine have led to increased use of diagnostic tests that do not require isolation and culturing of pathogens. This change is causing a decline in the availability of clinical isolates on which PulseNet and other public health surveillance programs depend. Without clinical isolates, PulseNet will not function, and without PulseNet, our foodborne illness response efforts would be seriously degraded.

7. Tapping nontraditional data sources may help improve detection and response to outbreaks.

Persistent challenges in determining the source of foodborne illness outbreaks have prompted interest in new sources of data to aid in outbreak investigations. The most commonly cited example of this is health departments' growing use of data contained in shoppers' club cards. Other valuable nontraditional data may come from analysis of food distribution pathways, food consumption and marketing surveys, coordination with industry, and crowd-sourced information.

8. Better integration of existing surveillance programs is necessary to improve outbreak detection and response.

Improved access to existing foodborne illness outbreak information, such as that which exists at the CDC, the US Food and Drug Administration (FDA), and the US Department of Agriculture (USDA), is necessary to improve the speed and accuracy with which foodborne illness outbreaks are detected and their sources identified. Several high-profile outbreaks have led to a dedicated effort to improve communication and information sharing at the national level, but more integration of these systems is needed.

9. Federal funding cuts are expected to compromise the public health system's ability to respond to foodborne illness outbreaks.

Since 2005, there has been a net decline in the amount of federal funding available to support public health preparedness, while at the same time, state governments have drastically reduced their investments in public health.⁴ As a result, the capacity of state and local public health agencies to investigate and respond to foodborne illness outbreaks has been reduced. Federal support was cited as critical to enabling state and local practitioners to investigate foodborne illness outbreaks and identify leads. The consequence of planned cuts to state and local public health preparedness programs and of reduced funding for the key foodborne illness outbreak response systems we rely on across the country will be slower recognition of major foodborne disease outbreaks and the delayed ability—or even inability—to identify the contaminated foods that are responsible. Such an outcome threatens to exacerbate the economic consequences of the loss of consumer confidence in the food supply and to increase unnecessary severe illness and loss of life from foodborne illness.

10. The Food Safety Modernization Act has the potential to significantly improve the safety of the US food supply, but it will likely do little to improve public health response to foodborne illness outbreaks.

The Food Safety Modernization Act (FSMA) seeks to improve the safety of food produced or consumed in the United States by enhancing measures to prevent or detect food contamination closer to the source of production.⁵ If fully implemented and funded, FSMA will likely reduce the consumption of contaminated food, which should reduce the number of outbreaks. Congress should be commended for passing this food safety legislation,⁶ but there is still a need to strengthen systems for detecting and responding to foodborne illness outbreaks. First, implementation of FSMA has been slowed by delays in the rulemaking process and by lack of funding. Second, even if fully implemented, it is not likely that FSMA will protect the food supply sufficiently to reduce the need for robust outbreak surveillance and response systems. Third, although the law contains some requirements for improving foodborne disease

outbreak surveillance and response capacity at local, state, and federal levels, efforts on this front to date have been small and insufficient compared with what is needed. As a first priority, FSMA should be fully implemented and funded, including critical provisions to improve public health capacity, but measures beyond FSMA are also needed to address detection and response vulnerabilities highlighted elsewhere in this report.

Recommendations

1. The US government should fund the development of next-generation technologies that provide rapid diagnosis while preserving the capacity to identify and resolve large outbreaks.

Existing foodborne illness outbreak surveillance programs depend on testing pathogens that are isolated from cultures of clinical specimens. Increased use of diagnostic approaches that do not rely on culture-based approaches is reducing the number of isolates submitted to public health laboratories. Although a number of administrative patches to this problem have been suggested—for example, requiring that clinical laboratories perform additional culture-based testing on positive samples—many of these options are probably not feasible in the long term given efforts to reduce healthcare costs. A new technological solution is needed.

2. Congress should restore funding to state health departments.

Cuts to federal funding and declines in state budgets threaten to reverse critical improvements in detection and response to multistate foodborne illness outbreaks and to national preparedness for other public health emergencies. Increases in the complexity of the food system will require more, not less, intensive public health investigations. This will not happen with the coming budget reductions. To prevent the further erosion of the gains made since 2001, the US should restore funding for these programs to at least 2005 levels. This is a small but important investment relative to the substantial health and economic losses caused by foodborne illness outbreaks. Even small increases in funding for health departments for these programs (<\$1 million per state) could substantially increase the country's ability to respond to and resolve large foodborne illness outbreaks.

3. The US should develop a foodborne illness outbreak response network that taps the expertise and data that exist in the private sector.

The increasing complexity of food production and distribution requires greater information exchange among public health and industry officials during outbreaks than ever before to improve the speed and accuracy with which causes of outbreaks are identified. Most public health agencies rely on federal

agencies as their primary liaison with the private sector, but the resulting information is often insufficient for investigation and containment of foodborne illness outbreaks. State and local public health agencies need direct connections to the private sector.

4. Congress should adequately fund and agencies should fully implement FSMA, including provisions for strengthening surveillance and response to outbreaks.

Congress should adequately fund FSMA, and agencies should work quickly to fully implement this act. Although FDA and CDC have made significant progress in implementing FSMA provisions relating to outbreak response, full implementation has been unnecessarily slowed by funding shortages and belated rulemaking, leading to substantial delays. Congress should appropriate funds to meet FSMA's objectives to enhance disease surveillance by increasing coordination among local, state, and federal disease surveillance systems as well as by developing and implementing strategies for enhancing capacities at the state and local levels.

5. The US government should improve integration of existing foodborne illness surveillance efforts.

A first priority for improving surveillance for foodborne illness outbreaks should be to improve the integration of the food-related surveillance initiatives that exist across the federal government. There are many different, separate national surveillance systems that, if integrated, could provide a better understanding of the occurrence and possible causes of foodborne illness outbreaks. Federal agencies should digitally connect and automate the comparisons of data from the food, animal, and human health surveillance programs that are operated by CDC, FDA, and USDA, which may provide an earlier indication of a link between human and animal infections. At the very least, there should be a way to directly compare isolate patterns that are in animal and human health surveillance programs. CDC's PulseNet and USDA's VetNet programs should be linked and equipped to automate analysis of these 2 data streams for evidence of similarities that may indicate a common exposure.

The US government should also continue to work to improve public health officials' access to data from healthcare providers, which would expedite their response to foodborne illness outbreaks. In many places, reporting of foodborne diseases from the clinical sector continues to be incomplete or delayed. As the nation builds a national framework for electronic health records (EHRs), there is a great opportunity to develop critical connections between public health and healthcare to enable earlier detection of cases of gastrointestinal illness that may have been caused by consumption of contaminated food. In particular, EHR development efforts should focus on expediting disease reporting by clinical laboratories to public health agencies.



When Good Food Goes Bad: Strengthening the US Response to Foodborne Disease Outbreaks

Introduction

As evidenced by a number of recent large-scale high-profile outbreaks, foodborne illness continues to cause considerable morbidity, mortality, and adverse economic consequences in the United States and elsewhere. In 2011, the US experienced a deadly foodborne illness outbreak of listeriosis associated with cantaloupe that sickened 147 people and killed 33.⁷ Analysts anticipate that costs associated with that outbreak may exceed \$150 million.⁸ Also in 2011, Europe experienced one of the most deadly and costly outbreaks to date when a toxin-producing strain of *Escherichia coli* infected more than 4,000 people and killed dozens.⁹ In May 2012, health authorities in the US grappled with a large outbreak of *Salmonella* Bareilly and *Salmonella* Nchanga associated with a raw tuna product that infected 425 people in 28 states, leading to 55 hospitalizations.¹⁰

Despite recent efforts to improve the safety of the US food supply, foodborne illness outbreaks continue to occur at an alarming pace, posing threats to US health and the economy. Although most foodborne illnesses that occur in the US are not associated with recognized outbreaks, about 1,000 foodborne illness outbreaks are investigated and reported each year in the US. In 2011, the US Centers for Disease Control and Prevention's (CDC) foodborne illness outbreak response team investigated more than 200 multistate clusters of illness.¹¹ Since 2010, 44 proven multistate foodborne illness outbreaks have been identified among these clusters.¹² Public health investigations of these outbreaks resulted in 17 commercial food recalls,¹ one of which involved more than 36 million pounds of ground turkey that was thought to be contaminated with a multidrug-resistant strain of *Salmonella*.¹³ In the past 3 decades, nearly 20 infectious agents have been newly recognized as capable of being spread by the consumption of contaminated food.¹⁴

The Center for Biosecurity of UPMC sought to identify ways to improve US detection of and response to large-scale (ie, multistate) foodborne illness outbreaks. The Center contacted federal, state, and local



officials as well as industry representatives whose responsibilities center on foodborne illness outbreak detection and response. We interviewed them about their experiences with such events in an effort to understand their current response capabilities and to assess what policy solutions may enhance current capabilities. The Center was then able to: (1) document the current state of how public health departments recognize and respond to foodborne illness outbreaks; (2) identify strengths and weaknesses of the current approaches; and (3) make judgments regarding the ability of current surveillance systems to aid in the detection of foodborne illness outbreaks.

Methods

The Center reviewed reports of major foodborne disease outbreaks that have occurred in the past decade as well as US government policies and programs for preventing, detecting, and responding to multistate foodborne disease outbreaks. We performed a comprehensive review of the published literature and key US government documents. The Center conducted a series of discussions with more than 40 US and international experts from 25 organizations in the fields of foodborne disease epidemiology and infectious disease outbreak management. Their organizations included the White House, CDC, FDA, USDA, and state and local health departments, as well as private industry, academia, and non-governmental organizations (see Appendix A).

This article presents the Center's analysis of the science, policy, and public health programs that bear on these issues and provides our recommendations for strengthening US response to foodborne illness outbreaks. All of our discussions with key informants were held on a not-for-attribution basis. The views of the participants appear in italics throughout this report but are not attributed to specific individuals. The Center did not attempt to achieve consensus in its discussion with experts. The recommendations are from the authors and do not necessarily reflect the views of those interviewed.

Findings

Current federal initiatives to prevent foodborne disease outbreaks have focused largely on prevention efforts. These initiatives work to make food safer to eat through food safety laws, standards, and preventive measures taken at food production and service facilities as well as through food inspections. These efforts have been vitally important, but the Center's findings focused on the systems used for detection of and response to foodborne illness outbreaks that occur when such preventive efforts have failed. Recognizing when outbreaks occur, moving swiftly to respond, and obtaining information to improve prevention of future outbreaks are critical parts of maintaining a safe food supply.

1. Foodborne illness outbreaks continue to impose enormous health and economic burdens in the US.

Foodborne diseases continue to cause significant morbidity and mortality in the US each year. Recent estimates from CDC suggest that annually more than 40 million people in the US—approximately 1 in 6 Americans—become sick from contaminated food.¹⁵ These illnesses result in 128,000 hospitalizations and 3,000 deaths annually.¹ Long-term follow-up studies suggest that those who survive a bout of foodborne illness may experience prolonged complications, including increased probability of suffering from chronic medical conditions such as arthritis, kidney disease (including dialysis for those who develop kidney failure), heart disease, and others.¹⁶

Despite recent efforts to improve the safety of the US food supply, foodborne illness outbreaks continue to occur at an alarming pace. Each year approximately 1,000 outbreaks are reported and investigated, many of which affect multiple states at the same time. In 2008 (the most recent year for which data are available), of the 1,043 outbreaks that were investigated, health officials identified 23,152 cases of illness, 1,276 hospitalizations, and 22 related deaths.¹⁷

Although reported outbreak numbers are significant, for a variety of reasons, official reports underrepresent the magnitude of the occurrence of foodborne illness in this country. Outbreaks can be recognized by public health authorities only if all of the following conditions are met: (1) people with foodborne disease seek medical attention; (2) clinical providers request laboratory tests to confirm the cause of patients' illness; (3) positive laboratory results are reported to public health authorities for follow-up testing; and (4) public health authorities have enough resources to initiate an investigation and can reach patients for an epidemiologic interview. Unfortunately, the number of instances in which all 4 conditions have been met is small compared to the number of estimated foodborne diseases that occur each year. Although US capacity to detect foodborne disease outbreaks has been strengthened over time,

more needs to be done to ensure that outbreaks are detected and managed quickly and correctly in order to reduce the vast numbers of illnesses and deaths that occur as a result of foodborne diseases each year.

The continual occurrence of foodborne diseases carries a great cost. A recent analysis estimated that the medical expenses combined with the lost productivity from functional disability due to foodborne illness cost the US more than \$77 billion annually, with an average cost per case of \$1,626.² In the case of *E. coli* O157, the average cost per case for a patient who dies of hemolytic uremic syndrome is estimated at \$6.2 million.¹⁸ Some analysts estimate that the healthcare costs associated with the provision of short- and long-term follow-up care to those affected by the 2011 *E. coli* O104:H4 outbreak in Germany may approach \$3 billion.¹⁹

Figure 1

Foodborne Outbreaks By the Numbers

✓ \$77 billion	Annual cost of foodborne illness in the US*
✓ \$1,626	Average cost per case of foodborne illness*
✓ \$1 billion	Lost peanut sales resulting from 2008 salmonellosis outbreak [†]
✓ \$1,508 billion	Total US food sales in 2011 [§]
✓ \$27.1 million	Enacted FY2012 budget for the CDC food safety program
✓ \$280 million	Average annual authorizations in FSMA [¶]

*Scharff RL. Economic burden from health losses due to foodborne illness in the United States. *J Food Prot.* 2012 Jan;75(1):123-131.

[†]Peanut industry: Recall price tag \$1 billion. msnbc.com. Available at: http://www.msnbc.msn.com/id/29634279/ns/business-going_green/t/peanut-industry-recall-price-tag-billion/. Accessed February 9, 2013.

[§]U.S. food industry overview. Plunkett Research, Ltd. 2012. <http://www.plunkettresearch.com/food-beverage-grocery-market-research/industry-statistics>. Accessed December 13, 2012.

^{||}Centers for Disease Control and Prevention. *FY 2013: Justification of Estimates for Appropriations Committees.* 2012. http://www.cdc.gov/fmo/topic/Budget%20Information/appropriations_budget_form_pdf/FY2013_CDC_CJ_Final.pdf. Accessed December 12, 2012.

[¶]FDA Food Safety Modernization Act, Pub. L. 111-353, 124 Stat. 3885, § 205.

Foodborne illness outbreaks have caused significant economic damage to the food industry in a variety of ways. First, in today's highly distributed, complex food supply, contamination of a single ingredient at a single plant can affect the safety of multiple companies' products at once. A 2008 salmonellosis outbreak associated with processed peanut products caused an estimated \$1 billion in lost peanut sales alone and forced a peanut product company into bankruptcy.²⁰⁻²² Second, persistent difficulties in determining the source of outbreaks have affected the bottom lines of companies whose products are not found to be contaminated. During the first few weeks of the 2011 *E. coli* outbreak in Germany, cucumbers from Spain were erroneously thought to be the outbreak vehicle, costing cucumber growers \$200 million per week.²³ Third, outbreaks can lead to reduced consumer confidence in the safety and integrity of food, which can reduce demand and sales. Although a 2011 outbreak of listeriosis was likely to have been caused by a single cantaloupe producer in a limited area, the entire cantaloupe industry was affected: the price of cantaloupes dropped 33.6% nationwide as consumer fear drove down demand.²⁴

Mitigating the effects of foodborne illness outbreaks is critical to US interests. The industries that produce the food that Americans eat have a large stake in the national economy. Food sales in US account for 10% of GDP.²⁵ The agriculture sector alone represents a \$300 billion industry and accounts for 1 in 12 jobs.²⁵ Loss of consumer confidence in the foods produced by these industries can lead to declines in revenue that can last long after an outbreak is over. Following a hepatitis outbreak associated with contaminated green onions, some growers reported a decrease in sales lasting up to 4 months.²⁰

Ironically, the more outbreaks we find, the safer our foods become. In the long run, outbreak investigations help the economy by identifying gaps in our systems and driving compliance with safe practices.

Compared with the \$77 billion in annual health and economic tolls associated with foodborne illnesses, the resources devoted to responding to such outbreaks are considerably less. Food safety initiatives in the FDA and the USDA Food Safety Inspection Service (FSIS) are both funded at slightly more than \$1 billion, but most of that funding is dedicated to prevention, with funding for foodborne disease outbreak response constituting a very small portion of that budget.^{26,27} Other key foodborne illness outbreak response programs receive relatively limited funding. The FoodNet Program receives approximately \$5 million, PulseNet approximately \$4 million, OutbreakNet approximately \$3 million, and FoodCORE approximately \$2 million.²⁸ Overall, the CDC Food Safety Program enacted budget for FY2012 is \$27.113 million.²⁹

Maintaining effective foodborne illness outbreak surveillance and response to foodborne disease programs has clear advantages. A cost-benefit analysis found that PulseNet, a program highlighted by project participants as a key resource for identifying and stopping outbreaks early and quickly, has to

Figure 2

Notable Foodborne Illness Outbreak Response Programs

PulseNet: A national network of public health agency laboratories, local health departments, state public health departments, and federal agencies, including CDC, USDA/FSIS, and FDA. Network participants perform Pulse Field Gel Electrophoresis (PFGE) subtyping and create a “fingerprint” of a foodborne illness outbreak – causing bacteria and share these results with the network, allowing users to identify outbreaks and connections early. By obtaining highly specific genetic information, PulseNet is able to link related individual cases of foodborne illness that occur in different states. This has led to the earlier and more sensitive detection of multistate outbreaks and has earned PulseNet praise from its users as being one of the most important biosurveillance systems in the country.³¹

FoodCORE (Foodborne Diseases Centers for Outbreak Response Enhancement): A pilot project funded by CDC and USDA/FSIS to provide funding to specific sites around the country to assess faster and better methods that state and local health departments can use to detect, investigate, respond to, and control multistate outbreaks of foodborne diseases. Currently, there are 7 FoodCORE sites. FoodCORE participants have used additional funding received by this pilot program to bolster local capacity. For example, one site hired public health students to increase the number and improve the timeliness of case patient interviews that the health department is able to conduct.

FoodNet (Foodborne Disease Active Surveillance Network): A network operated in collaboration with the 50 state health departments, USDA/FSIS, and FDA that conducts surveillance for foodborne illness-causing organisms through enhanced

surveillance; surveys of laboratories, physicians, and the general population; and population-based epidemiologic studies. The analyses that FoodNet participants have conducted have yielded important information about new foodborne pathogens and food vehicles. For example, FoodNet helped to identify that cut cantaloupe could serve as a potential vehicle for listeriosis. This knowledge proved helpful during the recent large-scale cantaloupe outbreak, as cantaloupe had already been added to the questionnaires that health departments use during outbreak investigations.

NARMS (National Antimicrobial Resistance Monitoring System): A collaboration among CDC, FDA’s Center for Veterinary Medicine, and USDA’s Agricultural Research Service that monitors the development of antibiotic resistance in enteric bacteria. Participating health departments forward portions of isolates received at their laboratories to CDC, where they are tested for susceptibility to 17 antibiotic compounds. These data are compared to isolates obtained from food animals and retail meats.

VetNet: Modeled after PulseNet, VetNet was established in 2003 to provide molecular subtyping of pathogens isolated from animals that have the potential for zoonotic transmission. Maintained by USDA, VetNet subtypes zoonotic pathogens submitted to the animal arm of the NARMS, compares USDA VetNet and PulseNet PFGE patterns, and uses the comparative data for surveillance and investigation of foodborne illness outbreaks. Compared with PulseNet, which analyzes data associated with 7 different foodborne disease-causing bacteria, VetNet monitors 2: nontyphoidal *Salmonella* serotypes and *Campylobacter*.

prevent just 5 cases of *E. coli* O157:H7 each year for the cost savings associated with medical expenditures, lost productivity, and lifetime earnings losses averted to outweigh the funding amount provided for the program.³⁰

2. Effective surveillance for and rapid response to foodborne illness outbreaks are critical to overall preparedness.

In 2010, US officials confirmed the existence of credible threats that affiliates of Al-Qaeda were planning to wage multiple simultaneous attacks on the United States by poisoning salad bars and buffets at hotels and restaurants over a single weekend.³² News outlets reported that the plot involved ricin and cyanide. US officials cautioned that even small amounts of these chemicals in food could cause serious harm.

*You can't take yourself out of the food system. You don't have to get on a train or a plane, but you do have to eat. You are always a target.*³³

Initially, it will be very difficult to distinguish deliberate contamination of the food supply from a naturally occurring outbreak. In 1984, a religious group in The Dalles, Oregon, intentionally contaminated salad bars with *Salmonella* to sicken people and thus interfere with upcoming local elections.³⁴ Before the criminal investigation revealed that contamination had been deliberate, a public health investigation had concluded that the outbreak was likely caused by poor hygiene among food handlers.^{35,36}

We may be blindsided by an intentional food-based attack on this nation sometime soon.

*Al-Qaeda blogs posted commentary about using *E. coli* as a weapon.*

The continued threat of deliberate contamination of food supplies highlights the importance of strong systems for rapid detection of and response to foodborne illness outbreaks. Since a deliberate contamination of the food supply is likely to resemble a natural outbreak at the start, initial responsibility for responding to deliberate contamination events will fall to state and local health departments.³⁷ The same surveillance systems and public health investigation approaches used to conduct routine outbreak investigations will likely be the country's first response to deliberate contamination of the food supply.³

Foodborne illness outbreaks are a monthly exercise in surveillance and attribution.

Routine ongoing efforts to respond to foodborne illness outbreaks in the US help to identify historical trends and risk factors for infection that enable public health officials to detect subsequent outbreaks earlier and limit their impact. If health departments cannot maintain core competencies in surveillance and response to foodborne disease outbreaks, it is not likely that they will be able to respond adequately to deliberate foodborne contamination events or other types of public emergencies.⁹

*If we want the capacity to respond to the intentional events,
we need to focus on the everyday assets.*

When an event occurs, you respond with the systems you use daily.

3. National surveillance programs have led to meaningful improvements in the detection of foodborne illness outbreaks and can drive improvements in food safety.

Historically, detection of foodborne disease outbreaks was slow and largely limited to large or geographically-focused outbreaks. For example, in 1994, an outbreak of *E. coli* O157:H7 associated with Jack in the Box hamburgers caused illness and death for more than a month before it was detected.³⁸ Once health authorities recognized that an outbreak was occurring, it took another 6 months to identify the subtype of the bacteria responsible for the infections.³⁹

PulseNet changed this. It employs DNA-fingerprinting techniques to link cases of infection from the same outbreak. Currently, there are 87 laboratories in the PulseNet network, with at least 1 in every state.⁴⁰ In addition, a companion surveillance program, FoodNet, conducts in 10 states (covering 15% of the US population) detailed surveillance for specific pathogens that are associated with foodborne diseases.⁴¹ Data from this program are used to better understand changes in the incidence and trends of foodborne illness and to inform future foodborne disease outbreak investigations. For example, investigations conducted during a 2010 outbreak of *Salmonella enteritidis* related to eggs led to voluntary Egg Quality Assurance Programs and, ultimately, to development of the 2010 Egg Safety Rules.¹

Such programs have helped to improve response to foodborne illness outbreaks.⁴² The adoption of PulseNet across the country has led to detection of many more foodborne illness outbreaks than occurred in the years prior to its existence, including those that have involved just a handful of cases spread out among several states. Information from outbreak investigations helped to identify previously unrecognized foodborne pathogens and foodstuffs that serve as vehicles of contamination. For example, FoodNet investigations of risk factors for illness helped establish cut cantaloupe as a previously unrecognized vehicle for listeria contamination. Upon learning this, public health authorities added pre-cut cantaloupe to questionnaires used routinely all over the country to interview patients with listeriosis. Having this category of consumed food on the case interview questionnaire is credited with rapid detection of the 2011 multistate outbreak of listeriosis and to the quick identification of cantaloupe as a potential cause of the outbreak.

The cantaloupe outbreak was a FoodNet success. We had previously identified cantaloupe as a risk for listeria exposure through FoodNet-funded investigations, so when the outbreak occurred, we had a good idea which foods to follow up on during patient interviews.

4. Determining the source of foodborne illness outbreaks remains the top response challenge and will likely become harder as the complexity of the food supply increases.

Identifying the specific agent (ie, virus, bacteria, or chemical contaminant) and contaminated food source that are responsible for observed outbreaks continues to be a significant national challenge. Between 1999 and 2008, 55% to 65% of all foodborne illness outbreaks were unsolved, meaning that the food vehicle and/or the causative pathogen were not known.⁴³ We can improve those odds by building capacity at state and local health departments to conduct more robust epidemiologic and environmental investigations more quickly after outbreaks are detected.

*I am involved in roughly 200 foodborne outbreak investigations a year.
At most, 80 of those will have enough information to identify the source.*

Part of the difficulty in isolating the source of a foodborne illness outbreak lies in the vastness and diversity of the US food supply, which is becoming increasingly more complex and distributed. Food accounts for one of the largest manufacturing sectors in the US, where, in 2006, there were 28,000 food manufacturing establishments.⁴⁴ Most are small: 89% employ fewer than 100 workers. The US also imports a considerable quantity of foods each year: Imported foods account for 16% of all food consumed in the US.⁴⁵ For some foods, imports make up a much higher percentage of food consumed—for example, 85% of seafood and 60% of produce consumed in the US originates abroad. More than 130,000 entities have registered with the FDA to import food products into the US.⁴⁶ As a result of this increasing number of entities involved in the production and distribution of food, the challenge of determining the source of foodborne illness outbreaks will likely become more difficult with time.

Delays or inaccuracies in identifying the agent or contaminated food source of an outbreak can exacerbate the health and economic consequences of such events. In 2008, peanut products contaminated with *Salmonella* Typhimurium caused a nationwide outbreak leading to 714 identified cases in 46 states, with 166 hospitalizations and 9 deaths. Although laboratory testing linked the cases to a common strain of *Salmonella*, epidemiologists were unable to identify the food vehicle for nearly 2 months. It was only after tracing back to a peanut processing plant that produced roasted peanuts, peanut meal, and peanut paste that a common food ingredient link was revealed. Because of the widespread distribution of the various peanut products from the plant, the recall of contaminated product was the largest in US history. It involved 361 companies and 3,913 different products that used the contaminated peanut ingredient.⁴⁷

In nearly all outbreaks, public health agencies interview individual case patients to determine what foods they may have consumed around the estimated date of infection that may have caused illness. Public health officials aggregate food history data from all case patients in an outbreak and search for

Case Study

Salmonella in Shell Eggs, 2010

From May 1 to September 14, 2010, more than 2,500 people in 10 states became ill from *Salmonella* Enteritidis (SE).^{*} Thanks to persistent investigative work by state and local health departments in California—including public health nurses using the crowd-sourcing restaurant review website Yelp—CDC and FDA were able to link approximately 1,600 illnesses to the consumption of shell eggs produced by Quality Egg, LLC, (operating as Wright County Egg) or Hillandale Farms of Iowa, Inc.[†] Laboratory tests conducted by the FDA with samples from the egg facilities confirmed the presence of the same SE strain detected via CDC's PulseNet in the water used to wash eggs as well as various other surfaces around the farm.[§] The scale and complexity of the recall was staggering. Hillandale Farms distributed more than 150 million eggs in 14 states. Quality Egg had distributed 380 million eggs in 22 states and Mexico. In total, 13 egg brand names were involved in the recall. The outbreak led to a nationwide recall of more than 500 million eggs, as well as public concern regarding the sanitary conditions at the egg production facilities and outrage at the current regulatory system for food safety.^{||}

The outbreak reignited the debate about food safety modernization and the fragmented regulatory system. Inspection documents from mid-May 2010 indicated that the USDA knew of substandard conditions at the Quality Egg, LLC, and Hillandale facilities before the outbreak but did not inform the FDA of their findings, noting that food safety infractions were outside their inspection jurisdiction.[¶]

The confusion regarding regulatory responsibility led to public outrage that the Salmonella outbreak could have been averted if not for major legislative and regulatory failures.[#]

^{*}Investigation update: multistate outbreak of human Salmonella enteritidis infections associated with shell eggs. Centers for Disease Control and Prevention website. Updated December 2, 2010. <http://www.cdc.gov/salmonella/enteritidis/>. Accessed December 12, 2012.

[†]Young A. Food-safety experts: finding an outbreak's source not easy. *USA Today*. August 26, 2010. http://www.usatoday.com/yourlife/food/safety/2010-08-26-eggside26_ST_N.htm. Accessed December 12, 2012.

[§]Frequently asked questions and answers: FDA's investigation into the Salmonella enteritidis outbreak involving the recall of shell eggs. U.S. Food and Drug Administration website. Updated August 27, 2010. <http://www.fda.gov/Food/NewsEvents/WhatsNewinFood/ucm223723.htm>. Accessed December 12, 2012.

^{||}Wollner S. The 2010 outbreak of Salmonella in eggs. *Biosecur Bioterror*. 2010;8(4):295-303.

[¶]Hobson K. USDA graders saw bugs and trash at egg producer; didn't tell FDA. *Wall Street Journal*. September 10, 2010. <http://blogs.wsj.com/health/2010/09/10/usda-graders-saw-bugs-and-trash-at-egg-producer-didnt-tell-fda/>. Accessed December 12, 2012.

[#]Shiner M. Senate stall to blame for slow egg recall? *Politico*. August 24, 2010. <http://www.politico.com/news/stories/0810/41391.html>. Accessed December 12, 2012.

commonality among all the cases. This “hypothesis generating and testing” process may then proceed in different ways. In some situations, epidemiologists conduct case control studies—that is, they compare the food histories of sick people (cases) to groups of people who did not get sick (control) to determine what the sick people may have consumed that is different from those who did not get sick. Although case control studies have long been standard practice in public health investigations, they are becoming increasingly more difficult to do because of the time and resources it takes to do them and the difficulties in reaching an appropriate control population by telephone as landline coverage decreases.

An alternative approach for hypothesis generating and testing that is increasingly being used by health departments to help identify the cause of outbreaks is to compare patients’ food histories to statewide or national food consumption surveys. With this approach, health departments extensively interview cases for possible exposures, as they do for case control studies, but instead of interviewing controls they look for types of food consumed by cases in quantities that exceed those of the survey population. In 2006–07, CDC conducted a national food history survey to establish general eating habits against which cases’ food histories can be compared.⁴⁸ Many of the public health departments we spoke with rely heavily on such surveys. The survey is now several years old, and there is concern that general food consumption patterns may have changed since the survey was completed, but health officials acknowledge that it is difficult and resource-intensive to conduct national surveys of this sort.

Better integration of epidemiologic and environmental health investigations and expanded efforts to test suspect products may also help in determining the source of outbreaks. In most outbreaks, microbiological evidence will never be obtained from a suspect food. In some cases, earlier and more frequent testing of suspect food products may lead to earlier isolation of a pathogen. Some jurisdictions are better than others in engaging sanitarians to test suspect foods. A 2011 study conducted by the Council of State and Territorial Epidemiologists (CSTE) found that the majority of states collected food samples for fewer than half of foodborne illness outbreaks.⁴⁹ The nation should work to ensure that all jurisdictions have sufficient capacity to conduct appropriate and timely testing of suspect foods and to fully integrate the results of such environmental testing efforts into ongoing epidemiologic investigations.

Case Study

“Peanut Product” Salmonella Outbreak, 2008

The 2008 case of *Salmonella* Typhimurium in peanut products highlights the challenge of product trace back in an increasingly complex food production and distribution system. Contaminated peanut butter and peanut products caused a nationwide outbreak, leading to 714 identified cases in 46 states with 166 hospitalizations and 9 deaths.* Laboratory investigations linked the cases to a common strain of *Salmonella*. But for 2 months, epidemiologists were unable to generate a comprehensive hypothesis for the vehicle agent because the trace back revealed that some patients had consumed the suspected peanut butter brand, but others had not. It was only after tracing back further to a peanut processing plant, which produced roasted peanuts, peanut meal, and peanut paste, that a common food ingredient link was revealed.† Because of the widespread distribution of the various peanut products from the plant, the recall of contaminated products was the largest in US history. It involved 361 companies and 3,913 different products that used the contaminated peanut ingredient.§ The outbreak cost an estimated \$1 billion in lost peanut sales alone and forced the peanut product company into bankruptcy.||

After the peanut outbreak, every peanut butter producer was looking at their production methods. The entire industry is safer because of the trace back work.

*February 24, 2009 - Investigation Update: Outbreak of Salmonella Typhimurium Infections, 2008–2009. CDC. Available at: <http://www.cdc.gov/salmonella/typhimurium/update.html>. Accessed February 8, 2013.

†Salmonella Outbreak Leads To Peanut Butter Recall: NPR. NPR.org. Available at: <http://www.npr.org/templates/story/story.php?storyId=99341551>. Accessed February 8, 2013.

§2009 Peanut Butter Outbreak: Three Years On, Still No Resolution for Some. Food Safety News. Available at <http://www.foodsafetynews.com/2012/04/2009-peanut-butter-outbreak-three-years-on-still-no-resolution-for-some>. Accessed February 8, 2013.

||Peanut industry: Recall price tag \$1 billion. msnbc.com. Available at: http://www.msnbc.msn.com/id/29634279/ns/business-going_green/t/peanut-industry-recall-price-tag-billion/. Accessed February 9, 2013.

5. Heterogeneity in states’ capacities to detect and respond to outbreaks creates national vulnerabilities.

Local, regional, and state health departments have differing capabilities, budget priorities, and procedures. There is also a wide range in the speed and frequency with which states initiate foodborne illness outbreak investigations. A 10-year perspective on foodborne disease outbreak data showed extremes in state-to-state variability in outbreak reporting, noting that those states reporting the lowest number of outbreaks were more than likely failing to identify outbreaks rather than simply having few to report.⁵⁰ Most outbreaks are disproportionately detected and solved by a handful of states.¹⁷

States that are considered leaders in the field of foodborne illness outbreak detection and response have some characteristics in common: (1) they rapidly interview all patients reported to the health department as having been infected with a pathogen that is commonly associated with foodborne disease; (2) they pay for a courier services to transport specimens from clinical labs to public health laboratories for faster testing and analysis; and (3) they conduct strain-typing tests on all tracked organisms in the recommended time frame. These practices are resource-intensive, and most states lack the resources to do this. Many states do not have enough staff to interview sick people unless they have been identified as part of a recognized outbreak. Most states do not pay for expedited transport of specimens from clinical laboratories but rather expect clinical labs to cover the costs of specimen transport. As a result, clinical laboratories in most states may wait until they have a batch of specimens before they send them to state public health labs.

We can't change people's healthcare-seeking behavior, but we can change the 3- to 4-week delay in subtyping clinical isolates.

Private labs often take excessive time to submit specimens or isolates to state labs.

Increasing the speed and frequency with which states interview case patients and test specimens from clinical laboratories would improve the detection of foodborne illness outbreaks. Delayed testing and interviewing of patients reduces the likelihood that outbreaks will be detected at their earliest stages before many others have become ill and reduces the likelihood that cases will be remember what they ate prior to becoming sick. In many states, resource constraints force public health laboratories to batch test or cut back on the types of bacteria they include in their surveillance programs.

Some states are not able to test all cases of E. coli or Salmonella. It's a cost issue.

When you have a case in [State A], you are happy because you know that the interview has been done and you'll have good information. This is not the case in many states.

Differences in the way states interview case patients is a factor in slowing response to multistate outbreaks. While lab-based surveillance for foodborne illness has become increasingly standardized, not all state and local health departments use similar approaches to interviewing. Health departments across the country use different questionnaires to interview the sick, which can lead to collection of data that are hard to compare from state to state during a multistate outbreak. Although these forms are often developed to suit the needs of the local health department, adopting standardized forms would help with local investigation and hypothesis generation during multistate outbreaks.

6. The increased adoption of culture-independent diagnostic testing by the clinical sector threatens to undermine early detection of foodborne illness outbreaks.

Although the advent of laboratory-based surveillance programs has greatly improved the speed and frequency with which foodborne illness outbreaks are detected in the US, there are increasing concerns about the long-term viability of current surveillance approaches. Changing trends in the practice of clinical medicine have led to increased use of diagnostic tests that do not require pathogen isolation and culturing. This change has consequences for public health: it is causing a decline in the availability of clinical isolates on which public health surveillance programs like PulseNet depend.

The rapid tests don't have any material that can be readily cultured. The whole PulseNet system depends on cultures. If we don't get any isolates, we are dead in the water.

Culture-independent diagnostic tests offer a number of advantages that make them attractive to the clinical sector: (1) they often yield results faster than culture; (2) for some diseases, they may provide additional, clinically relevant information (eg, for *E. coli* infection, rapid tests can determine whether infection is Shiga toxin-producing or not, an indication of how severe infection may be); and (3) they may be less invasive (eg, culture-independent tests for gonorrhea require a urine sample, whereas culture-based tests for this disease require a urethral swab). Despite these advantages, there are a number of concerns about the increased reliance on culture-independent tests. Pathogen isolation via culture is a necessary first step for evaluation of a pathogen by existing public health foodborne surveillance systems, most notably PulseNet. Thus, exclusive pursuit of these new culture-independent diagnostic tests, if not coupled with pathogen isolation, is incompatible with our major existing surveillance systems. Additionally, the performance characteristics (eg, sensitivity and specificity) of culture-independent tests may differ from culture-based approaches, which can further complicate efforts to conduct surveillance for these pathogens.

The rapid tests [for foodborne pathogens that are in use in the clinical sector] have questionable sensitivity and specificity, so we could be on the verge of a real nightmare.

The incompatibility of culture-independent diagnostic testing with existing public health foodborne surveillance approaches has emerged as one of the top issues in foodborne illness outbreak response. Many health departments are already seeing a reduction in submissions of isolates to PulseNet that correlate with the increasing use of rapid tests to diagnose these diseases. In one survey conducted by a state public health department, nearly 16% of clinical laboratories reported using only non-culture-based approaches to test for infection with *Campylobacter*.⁵¹ Should these trends continue, it would significantly reduce the availability of clinical isolates available for testing as part of the PulseNet program. This could compromise both the detection of foodborne illness outbreaks and continued progress in understanding

factors important for transmission of foodborne illness. The 2011 *E. coli* outbreak in Germany illustrates the serious public health consequences of not having a laboratory-based public health surveillance program for rapid and detection foodborne illness outbreaks.

Germany does not have a PulseNet system, so it takes an immense or highly focused event for anything to rise above the noise. This is where we were in 1993 before PulseNet was developed in the US.

[Without PulseNet] That's where Germany is and that's where we will be: Shiga toxin bacteria outbreaks will be rarely detected and horrific when they are.

Project participants made several suggestions regarding what could be done to preserve current surveillance capacities. One was that those clinical laboratories that no longer perform culture-based analytic methods could be asked to preserve and send whole clinical specimens to public health laboratories. This would essentially shift the responsibility for isolating and growing organisms from clinical specimens—steps that were previously performed by most clinical laboratories—to public health laboratories. However, there would be significant limitations to this approach. First, public health laboratories, which are already struggling under budget cuts and staff shortages, may not have the capacity to perform this additional analytic work, and overall fewer isolates would undergo the additional analyses required to be entered into PulseNet. Second, specimens collected for some types of culture-independent testing may be incompatible with culture-based approaches, and so data from these patients would likely not be captured by PulseNet, unless additional tests were ordered.

Some participants suggested that clinical laboratories should be required, through either changes in state reporting or reimbursement requirements, to use culture-based methods to confirm any positive test results obtained from culture-independent testing and to submit isolates to a public health laboratory for PFGE analysis. However, others noted that additional testing mandated in this manner may not be covered by insurance companies. Therefore, additional funding sources would be necessary.

Private labs don't have an incentive to submit specimens after they have met their patient management requirements.

When a dipstick is positive, there needs to be a reflexive culturing of those tests.

If Medicare, Medicaid, or insurance companies will reimburse for the reflexive culture test, it is a possibility that will make it happen. If they don't, we'll be in trouble.

Others suggested that FDA should consider the impact that culture-independent diagnostics will have on existing public health surveillance. Some went so far as to suggest that FDA should not grant clearance to any diagnostic test that will undermine public health surveillance, citing reports of low sensitivity

and specificity associated with some tests that are currently in use as justification for this stance. Other participants suggested that FDA could effectively compel laboratories to conduct culture-based testing by including in the packaging inserts that accompany commercial diagnostic tests directive guidance that positive test results should be followed up with culture.

The longer-term solution to the current threats to foodborne illness surveillance systems posed by culture-independent diagnostics is to develop new scientific approaches to surveillance for foodborne illness. There is no widely available alternative technology that provides the same specificity as that provided by PulseNet. In the meantime, genetic sequencing may play an increasing role in foodborne illness outbreaks and other infectious diseases.⁵² Within weeks after officials in Germany reported that a deadly *E. coli* O104 outbreak was occurring, a team of scientists from Germany and China announced that they had sequenced the entire genome of the outbreak strain—a feat that took them 3 days.⁵³ The genetic sequence provided insights into why the virus may have caused more severe symptoms than is typical for *E. coli* O104: The outbreak strain appeared to have acquired several genes that could make it more pathogenic.⁵⁴ The sequence also revealed that the outbreak strain was similar to those seen elsewhere, including a bacterium that was isolated from Central Africa in the late-1990s.⁵⁵ The ability to link pathogens to those isolated elsewhere may provide clues about how the strain came to infect people in Germany—a discovery that could be useful in determining the source of the outbreak.

There may be a high-tech solution to this by . . . going directly to sequencing strains at the bedside. Even that will present some challenges because there will be so much variation between strains, some of which will be irrelevant to identifying outbreak strains. Overall, having a sequence would be great.

However, like the methods used by PulseNet, genome sequencing currently requires isolates, and therefore cannot directly solve the problem of culture-independent diagnostics. Alternative approaches, such as targeted sequencing, metagenomics, or single-cell isolation sequencing, would be necessary for this new technology to be applied directly to specimens. Thus, even though genetic sequencing is becoming more rapid and less expensive, genomic-based approaches will require much more development before they are routinely used and can be applied to a national surveillance program.

7. Tapping nontraditional data sources may help improve detection and response to outbreaks.

Persistent challenges in determining the source of foodborne illness outbreaks have prompted interest in new sources of data to aid in outbreak investigations. Public health officials are increasingly relying on more than just epidemiologic data to solve foodborne disease outbreaks.

The most commonly cited example of the use of new data sources is health departments' increasing reliance on data contained in shoppers' club cards. Information in these cards can help to identify with greater precision the products that consumers purchased in a given time frame. Health departments noted that such data can be valuable, as people often incorrectly remember which foods they purchased and consumed. With access to shopping histories, public health departments have been able to more accurately identify food items that cases have in common.

*The shoppers' cards are huge. People's memories are flawed.
We are starting to routinely retrieve shopping data.*

While use of shoppers' club cards during outbreaks has become more common, there are barriers that prevent greater use of this resource. First, some populations, such as those living in large cities, do not shop at food purveyors that employ shoppers' club cards. Second, health departments report mixed success in accessing shoppers' club data during outbreaks. Most stores are willing to share customer data with public health departments during outbreak investigations, but occasionally store managers may be reluctant to share this information because of concerns about customer privacy. It would be helpful to have well-established agreements in place in advance of an outbreak to avoid having to negotiate data-sharing agreements with individual food purveyors during each outbreak. CDC or another federal agency could negotiate with the corporate headquarters of larger supermarket chains a national data sharing agreement that would allow states to quickly retrieve shoppers' club data during outbreaks.

Analysis of food distribution pathways is also becoming an increasingly important means of explaining observed patterns of illness.⁵⁶ Following weeks of delay in tracking down the source of the 2011 *E. coli* outbreak in Europe, shipping manifests and inventory data were used to identify contaminated sprouts as the likely true source of the outbreak, not cucumbers from Spain as authorities had initially concluded.⁵⁷⁻⁵⁹ Had US officials known during the 2008 *Salmonella* outbreak that it was too early in the season for tomatoes grown in Florida to have been shipped to areas where illnesses were occurring, they may have been less likely to misattribute Florida-grown tomatoes as the cause of the 2008 *Salmonella* outbreak. Such events suggest that food production and shipping data may be critical to public health investigations, and improved access to these data sources are needed to facilitate response and to prevent unnecessary losses to industry.

Commercial food product marketing surveys is another type of data that may aid in foodborne illness investigations. Food marketing firms make it their business to understand food consumption preferences in geographic locations in order to predict which ingredients or foods will be likely to sell. This data may aid in the hypothesis generating phase of outbreak investigations, much in the same way that data from the National Food History Survey is currently being used. Food marketing data are more geographically

targeted and up to date and, therefore, more useful to public health investigations than government-sponsored food consumption surveys.

Nearly all participants in this project hoped to improve direct communication and information exchange between public health agencies and private industry. While some public health practitioners have developed their own relationships with food processors, purveyors, and distributors in their state and have drawn on these relationships during outbreaks, most do not have these relationships.

If you have a cooperative industry person during an outbreak, it can be invaluable.

Some suggested that a nongovernmental organization or network could play an important role in improving the exchange of information between public health departments and private industry during outbreaks and would be valuable for improving the response to outbreaks—particularly for helping to more quickly and accurately determine the source of an outbreak after it is detected. A liaison between public health agencies and the private sector could help review outbreak data and consult with private sector experts to suggest potential food sources or production practices that may explain observed patterns of illnesses. Although there are likely legal and liability concerns that may limit the amount of information that private companies are willing to share with regulators, public health departments, and members of the public, a nongovernmental entity without regulatory authority could facilitate information exchange during outbreaks.

We have to formalize interactions between public health and industry to ensure that it's a common part of practice.

We have to deputize people in industry who are committed to and responsible for working with public health. And we have to have agreements in place to ensure the confidentiality of information.

There is also a rising interest in augmenting traditional public health investigations through the use of crowd-sourcing and other participatory epidemiologic techniques. Interest in these approaches is driven largely by the fact that public health agencies have limited resources to conduct interviews of cases during a foodborne illness outbreak. There is also some thought that crowd-sourced disease reporting may provide an earlier indication of potential outbreaks than is currently possible with today's clinician-dependent surveillance approaches. Typically, interviews are conducted by phone, which can be time-consuming. To address this, some health departments have explored the use of web-based questionnaires that enable patients to submit information on their own regarding their particular symptoms and the foods they consumed before becoming ill. Some researchers are investigating whether social media streams can be analyzed to detect clusters of reported illnesses that may be food related. Others are

looking into web-based systems that enable members of the public to report if they are experiencing symptoms that may be consistent with foodborne illness. Such crowd-sourcing approaches need to be validated, and it is too early to tell whether or how they may be used to augment current practice.

Crowd-sourcing also played a role in the response to the 2011 *E. coli* O104:H4 outbreak in Germany. After a team of scientists from Germany and China sequenced the outbreak strain, they released sequence data into the public domain.⁵⁵ Within 24 hours, volunteer bioinformaticians on 4 continents had assembled the entire genome, and a day later they assigned the genome to an existing sequence type.

8. Better integration of existing surveillance programs is necessary to improve outbreak detection and response.

Improved access to existing foodborne illness outbreak information that exists across government agencies is necessary to improve the speed and accuracy with which foodborne outbreaks are detected and their sources identified. Several high-profile outbreaks have led to a dedicated effort to improve communication and information sharing at the national level. CDC, FDA, and USDA now assign permanent liaisons and detail staff to work on an ongoing basis with partner agencies. Participation of multiple federal agencies on outbreak response calls has also helped to improve information exchange. While these efforts are steps in the right direction, there are additional areas where enhanced coordination is necessary to improve outbreak response.

The first area is improved integration of the disease surveillance data that are collected and maintained by state and local health departments. The “silo-ing” of laboratory and epidemiology data that exists at many health departments contributes to delays in analysis and synthesis of information gathered during outbreaks. Increased adoption of electronic laboratory reporting and EHRs would greatly increase the speed and accuracy with which health departments are capable of analyzing outbreak data.

Electronic laboratory reporting would be a major help. Right now on the lab side, we hand-enter data into computers, and it really slows the process down.

Labs report data, but they often contain no information on the patient.

New tools that can integrate data coming from different sources are necessary to improve management of data that states submit during multistate outbreaks. Participants noted that outbreak data management still requires a fair amount of manual data entry and e-mailing of separate files. New data management tools would help to more quickly and accurately aggregate and analyze data that are collected by states and shared at the national level during multistate outbreaks.

Our lab database does not directly interface with our epi database. If we had better technology in the lab, it could be easier. We could really use some programmers.

*We're sending out Excel spreadsheets for states to manually enter their information.
It's not efficient.*

Sending around Excel spreadsheets continues to be state of the art.

Improved integration of animal and human health surveillance data maintained by separate federal agencies is also needed to improve detection and determine the source of foodborne illness outbreaks. Identifying matches between isolates from humans and isolates from animals may provide earlier indication of potential transmission and may aid in efforts to determine the source of outbreaks after they have been detected. While it is encouraging that some isolates from FDA and USDA are directly entered into PulseNet, not all agricultural, food, and human surveillance systems are directly linked. For example, PulseNet is not interoperable with a similar laboratory-based surveillance system in the agricultural sector, VetNet. Although analysts at the federal level may access the databases of both surveillance systems, the data contained in each are not linked. To enhance analysis of both animal and human health isolates, it would be helpful to electronically combine data contained in these surveillance systems for easy linking of matching isolates. Furthermore, federal officials should find ways of sharing VetNet data with state and local public health departments without violating confidentiality agreements with agricultural producers.

Ongoing [isolate] pattern sharing between public health and agriculture should be the norm.

State and local officials want the federal government to share more detailed information on food recalls and testing data; what they receive from the federal government is not sufficient to aid in their efforts to investigate and contain outbreaks.

We frequently get food recall notices from the FDA that state there have been no reported human cases as a result of the recall. But how do they know that?

We can't tell that unless we get information about the isolate patterns.

We need that information to be able to tell if people in our state were infected as a result of eating the food that is now being recalled.

FDA considers its information proprietary and unsharable, so while they ask states and locals for data, they are unable to reciprocate and end up doing their own thing.

Although the speed with which public health officials detected the outbreak and identified the causative agent of the 2012 listeriosis outbreak has been heralded as a public health victory, state and local health officials' efforts to identify the contaminated produce in stores were slowed by insufficient product-tracing information. After health authorities isolated all 4 outbreak strains of *Listeria monocytogenes* in whole and cut cantaloupe samples from patients' homes and from samples of Jensen Farms' cantaloupe

Case Study

“Peppered Salami” Salmonella Outbreak, 2009-10

In late summer of 2009, PulseNet detected a multistate cluster of *Salmonella* Montevideo infections. The cases were geographically dispersed, and the age and sex distributions were characteristic of reported *Salmonella*. CDC began a multistate investigation in November 2009 after PulseNet detected an increase in the number of isolates. The investigation revealed 272 illnesses across 44 states and Washington, DC, resulting from consumption of ready-to-eat Italian meats containing *Salmonella* Montevideo. The outbreak investigation was conducted by the FDA, CDC, USDA-FSIS, and numerous state health departments, including those in Rhode Island and Minnesota.*

Rhode Island-based Daniele, Inc., voluntarily recalled more than 1.4 million pounds of ready-to-eat salami products after *Salmonella* was associated with its products, which are regulated by USDA.† Simultaneously, FDA investigated the supply chain of black and red pepper supplied to Daniele, Inc., for seasoning.§ Ultimately, a multiagency investigation conducted by USDA-FSIS, FDA, and the Rhode Island Department of Health revealed that contamination had originated from black and red pepper used to season salami. Notably, USDA-FSIS used data generated by shopper loyalty cards to trace back ingredients, enabling FDA to identify sources of the black and red pepper used to produce the contaminated products.*

This outbreak illustrates the fragmented food safety regulatory structure and the importance of the USDA and FDA working together to investigate foodborne illness outbreaks.

For a couple of years now, because of their sheer complexity, it seems like outbreaks have required FDA, USDA, CDC synergistic involvement. For example, pepper-coated salami represented a contaminated product that was regulated by both agencies.

*Centers for Disease Control and Prevention. Salmonella Montevideo infections associated with salami products made with contaminated imported black and red pepper—United States, July 2009–April 2010. *MMWR Morb Mortal Wkly Rep.* 2010 Dec 24;59(50):1647-1650.

†Flynn D. Red pepper suspected in Salmonella outbreak. *Food Safety News.* February 18, 2010. <http://www.food-safetynews.com/2010/02/red-pepper-suspecte-in-salmonella-outbreak/>. Accessed December 12, 2012.

§Red & black pepper spice recalls linked to the Salmonella Montevideo outbreak investigation. U.S. Food and Drug Administration website. Updated March 30, 2010. <http://www.fda.gov/Food/NewsEvents/WhatsNewinFood/ucm206052.htm>. Accessed December 12, 2012.

collected from grocery stores and the farm, the company voluntarily recalled its product. FDA promptly issued notice of Jensen Farms' recall, noting that cantaloupes had been shipped to stores in 17 states. Several participants expressed dismay that product and recall information provided by federal agencies during the listeria outbreak did not provide sufficient detail to take action at the state level to assure the protection of the public's health. They noted that it would have been more helpful to know which of the thousands of grocery stores in each of their states had received shipments of cantaloupes that were included in the recall.

It is hard on industry when you can't be specific about what label of produce to avoid. But public health can't wait for specifics because people will be dying—this information needs to be available sooner.

9. Federal funding cuts are expected to compromise the public health system's ability to respond to foodborne illness outbreaks.

Since 2005, there has been a net decline in the amount of federal funding available to support public health preparedness, while at the same time state governments have drastically reduced their investment in public health.⁴ As a result, the capacity of state and local public health agencies to investigate and respond to foodborne illness outbreaks has been reduced and will continue to be reduced as trained workers leave the workforce and are not replaced. Many states lack adequate funding for public health, and the percentage of solved outbreaks has declined from a high of 44% in 2001 to 34% in 2007.⁵⁰

The biggest thing that comes up for us is the public health infrastructure. If there are folks out there doing the follow-up interviews and gathering epi data, then things go well. If that isn't done well, we aren't able to do our job. That well-trained workforce and infrastructure seems to be eroding more and more.

State public health departments reported that more than 300 additional full-time epidemiologists are needed to ensure that foodborne disease programs have adequate capacity at the state, regional, and local levels.⁶⁰ According to CDC, nearly a quarter of states were unable to meet federal benchmarks for reporting *E. coli* test results to the national lab surveillance system (PulseNet) because of decreased operating budgets and capacities at public health departments.⁶¹

No matter what we're doing on the federal level, I can't get over the bump that we're entirely dependent on the states and locals, and if they lose funding it would be disastrous.

State and local public health workers depend heavily on federal monies to work effectively and are in large part funded or subsidized by federal funding. A participant from one state health department said that only 3 out of 55 health department personnel had state funding. Federal support is a critical element

for state and local practitioners who do the bulk of the initial investigational work (eg, interviewing) that provides the initial leads in identifying an outbreak, whether it is local or multistate.

States have completely eliminated all of their funding for public health.

We rely exclusively on federal funds.

As funding declines, states must cut down on foodborne illness outbreak response protocols. Budget cuts also jeopardize the number of laboratory tests that can be performed. Surveillance for different disease-causing pathogens has already declined due to current funding cuts, and more are expected. Together, these reductions in capacity erode the response framework for foodborne illness outbreaks.

States are beginning to cut protocols out left and right because funding is declining.

The enormous potential budget cuts coming down the road will jeopardize the amount of tests performed through PulseNet.

One important consequence of reduced funding is the real reduction in trained staff that has already occurred and will continue given current budget conditions. One state recently lost 13 positions in its lab. In a recent CSTE survey, 29 states reported that a lack of sufficient numbers of foodborne safety staff members had created a barrier to investigating foodborne illness outbreaks, 20 states note an inability to pay overtime, and 12 cited a lack of adequate epidemiology experts.⁴⁹

An inability to hire or retain competent staff will likely affect more than just foodborne illness outbreak response. It also threatens to undermine the capacity to respond to any complex public health emergency, including deliberate foodborne contamination. It will take a fair amount of skill and experience to respond effectively to any major outbreak, whether natural or deliberate. As public health funding continues to contract, it is expected to lead to a loss of staff members who have these necessary skills and experience. Even modest increases in funding could lead to significant improvements in the current capacity to detect and respond to foodborne illness outbreaks. States that have received additional funding possess many response capabilities that would not normally have been possible without this funding. For example, the FoodCORE pilot program has provided select local jurisdictions with additional funds to augment current capacity to respond to foodborne illness outbreaks. However, sites that received such funding were able to increase interview rates from 7% to 8% of all salmonella cases to 80% to 86%. Another site was able to increase PFGE testing from 40% of clinical specimens received by the public health laboratory to nearly 100%. Other recipients have used FoodCORE funding to pay for courier service to expedite the shipment of clinical isolates from health clinics to the public health laboratory. Special funding has also enabled health departments to conduct specialized studies to better understand factors governing the localized transmission of foodborne infection. While states

receiving monies from special grant programs were capable of making significant strides in outbreak investigation, the actual level of funding provided was moderate: Most sites received approximately a few hundred thousand dollars.

10. The Food Safety Modernization Act (FSMA) has the potential to significantly improve the safety of the US food supply, but it will likely do little to improve public health response to foodborne illness outbreaks.

Enacted in early 2011, the FSMA represents the most significant change to US food safety laws since the passage of the Federal Food, Drug and Cosmetic Act in 1938. FSMA aims to shift the focus of federal food safety regulations from response to deadly outbreaks to prevention.⁵⁵ If properly funded and implemented, FSMA is expected to address a number of vulnerabilities in today's food supply chain. It will give the FDA new enforcement authorities designed to achieve higher rates of compliance with prevention- and risk-based food safety standards applied across the food supply. By reducing the amount of contaminated food in the supply chain, FSMA should in turn reduce the number of disease outbreaks that occur.

FSMA makes many advances that are essential to improved food safety, including granting FDA mandatory recall authority and greater authority to ensure that imported foods meet US safety standards (see Appendix B for a description of FSMA). With respect to response, the law makes important strides toward improving surveillance by providing a framework for increasing outbreak detection and reporting.

Historically, local and state public health officials have been tasked with tracking and investigating foodborne illness outbreaks and reporting them to the CDC, although an analysis of states' reporting of outbreaks to CDC over a 10-year period, from 1997 to 2007, revealed major variability among the states, with 14 states receiving an "F" grade on reporting outbreaks of foodborne illness.⁵⁰ FSMA provides a framework for improving the state-based reporting system by authorizing \$24 million per year to assist in surveillance activities at the state level by coordinating federal, state, and local disease reporting. The federal surveillance system established by FSMA could include coordinating and integrating federal, state, and local surveillance systems; improving the sharing of information; increasing public access to aggregate surveillance data; and expanding system capacity.

The law also contains some requirements for improving foodborne disease outbreak surveillance and response capacity at local, state, and federal levels. For example, the law instructs the Secretary of the US Department of Health and Human Services (HHS), acting through the Director of CDC, to enhance foodborne illness surveillance systems through better coordination with the states, more rapid sharing of information, and improvement in food attribution in the reporting of outbreaks.⁶²

FSMA also aims to increase local health departments' capacity by instructing the secretary of HHS to develop and implement strategies for enhancing food safety capacities at the state and local levels to accelerate surveillance and outbreak investigations and share information more rapidly with industry, healthcare providers, and the public.⁶² Lastly, recognizing the importance of involving the private sector in surveillance, FSMA also requires that CDC establish a working group composed of public- and private-sector experts and stakeholders, which will gather annually and issue recommendations for the improvement of foodborne disease outbreak surveillance systems.⁶²

Regarding FSMA—the devil is in the details, so it really depends on how FDA implements it.

Congress should be applauded for passing long-needed comprehensive food safety legislation, but there is still a need to strengthen systems for detecting and responding to foodborne illness outbreaks. First, implementation of FSMA has been encumbered by substantial funding shortages.⁶ Implementation of the landmark legislation is very much dependent on discretionary appropriations from Congress, and many have questioned whether the \$1.4 billion over 5 years required for implementation, including \$24 million per year to enhance foodborne illness surveillance, is available in the current budgetary climate.⁶³ Although President Obama signed FSMA into law on January 4, 2011, provisions relating to foodborne illness surveillance and outbreak response have not been fully implemented. Implementation of the responsibilities assigned to CDC remains subject to findings of an ongoing agency review of current programs and gaps.⁶⁴ Second, even if fully implemented, FSMA, which is largely focused on securing the quality of the food supply, contains only a few legislative provisions aimed at improving the capacity to detect and respond to foodborne illness outbreaks. Third, although the law contains some requirements for improving foodborne disease outbreak surveillance and response capacity at local, state, and federal levels, FSMA does not address many of the other shortcomings in current response capacity that this report has discussed and that will need to be remedied to ensure that outbreaks are detected and resolved.

Therefore, while it is important that FSMA be fully funded and implemented, additional efforts will be needed to improve the systems for responding to and containing foodborne illness outbreaks when they do occur.

*FSMA is a hugely unfunded federal mandate. The concepts are all great;
it's how in the world are you going to make that work?*



Recommendations

1. **The US government should fund development of next-generation technologies that provide rapid diagnosis while preserving the capacity to identify and resolve large outbreaks.**

By far the biggest threat facing efforts to confront foodborne diseases is the change in diagnostic practice in the clinical sector that is reducing the submission of isolates to public health surveillance programs. The development of national programs for surveillance of foodborne illness has dramatically improved the frequency and speed with which foodborne disease outbreaks are detected and has helped to drive improvements in food safety. However, currently existing surveillance programs depend entirely on testing pathogens that are isolated from cultures of clinical specimens. Increased uptake of diagnostic approaches that do not rely on culture-based approaches is already reducing the number of isolates submitted to public health laboratories.

Although a number of administrative patches to this problem have been suggested — for example, requiring that clinical laboratories perform additional culture-based testing on positive samples — many of these options do not seem feasible in the long term given today's interest in streamlining healthcare procedures to cut costs. A new technological solution is needed.

If PulseNet is no longer able to operate because of the loss of cultures, there are no diagnostic technologies currently available that will provide the specificity of information needed to quickly link individual cases of foodborne illness that are spread across multiple states. Although genomic-based approaches look promising, more planning is needed before these technologies can enter routine use at public health laboratories. It is also not clear whether genomic sequencing will provide enough information to determine important clinical attributes of a foodborne pathogen, such as its susceptibility to antibiotics.

The threat of culture-independent diagnostics is not limited to surveillance for foodborne illness. Previous analyses conducted by the Center suggests that culture-based approaches are also essential to US international biosurveillance goals.^{65,66} Without a suitable alternative to culture, multiple surveillance

programs would be in jeopardy. Priority in allocating research funding should be given to developing rapid diagnostic tools that can provide clinically relevant information and support public health surveillance efforts. Developing next-generation diagnostic technologies that can replace PFGE and other culture-based technologies that are the backbone of public health surveillance is a national imperative and would help to fulfill the goals articulated in the Obama administration's National Strategy for Countering Biological Threats.⁶⁷

2. Congress should restore funding to state and local health departments.

A rollback of federal funding and declines in state budgets threaten to reverse critical improvements in detection and response to multistate foodborne outbreaks and national preparedness for other public health emergencies. Increases in the complexity of the food system will require more intensive public health investigations, which cannot be undertaken given current resource allocations. Annual federal grant support for state and local public health activities that are critical for national preparedness has decreased significantly since 2005. Federal support for public health preparedness decreased by nearly a third between 2005 and 2012.⁶⁸

To prevent further erosion of the gains we have made since 2001, the US should restore funding for these programs to at least their 2005 levels. This would be a small but important investment relative to the substantial health and economic losses that can occur when foodborne illness outbreaks are not detected and contained in a timely manner because public health programs have been cut. Even small increases in funding for health departments can make a big difference. As evidenced by the FoodCORE pilot program, even a few extra hundred thousand dollars per health department can lead to meaningful improvements in existing capacities.

3. The US should develop a foodborne illness outbreak response network that taps the expertise and data that exist in the private sector.

Experience with recent outbreaks has demonstrated that epidemiologic information alone is not sufficient for detecting and determining the source of outbreaks. The increasing complexity of food production and distribution necessitates greater information exchange among public health agencies and private industries during outbreaks in order to improve the speed and accuracy with which causes of outbreaks are identified. Although most public health agencies rely on federal agencies as their primary liaison with the private sector, the information they receive from private industry via the federal government is often inadequate to the task of investigating and containing outbreaks. Most often, this is because of privacy agreements between regulators and industry.

There do not seem to be sufficient means for public health officials to converse with food industry experts during outbreaks. Existing mechanisms are largely tied to regulatory agencies, which have difficulty sharing information they obtain for fear of divulging companies' proprietary information or revealing information that will later be used in a regulatory action. An external organization, perhaps one convened by a nongovernment entity, may be better suited to broker conversations between public health agencies and private industry during an emergency.

Private industry has a vested interest in participating in these networks. Rapidly and accurately determining the source of an outbreak helps in implementing targeted control measures and minimizing damage from loss of consumer confidence. In the absence of specific information about which foods are affected, public health officials will continue to issue broad warnings about food safety in the interest of protecting the public's health. This can exacerbate the economic damages of an outbreak and affect companies and industries that are not directly involved in the outbreak.

4. Congress should adequately fund and agencies should fully implement FSMA, including provisions for strengthening surveillance and response to disease outbreaks.

While a fully implemented and adequately funded FSMA has the potential to significantly improve prevention of foodborne disease, the legislation does not fully address all aspects of food safety. Implementation of FSMA, though seemingly stalled, is primarily directed at improving the safety of food at the point of production rather than strengthening capacity to respond. While FSMA calls for much-needed steps to improve surveillance, which are key to halting outbreaks, more work remains to improve public health systems for detecting outbreaks, determining their source, and responding to prevent further illness, loss of life, or economic damages.

As Congress and relevant agencies move forward with implementation of FSMA, they should explore additional opportunities to strengthen response capacity at the local, state, and federal levels, including ways to enable private and secure data sharing between public health agencies and private industry (eg, supply chain data), improving the ability to trace contaminated food products, and restoring funding to federal, state, and local departments to support outbreak investigation and response.

5. The US government should improve integration of existing foodborne illness surveillance efforts.

A first priority for improving surveillance for foodborne illness outbreaks should be to improve the integration of the food-related surveillance initiatives that exist across the federal government. There are many different separate national surveillance systems that, if integrated, could provide a better

understanding of the occurrence and possible causes of foodborne illness outbreaks. Federal agencies should digitally connect and automate the comparisons of data from the food, animal, and human health surveillance programs that are operated by CDC, FDA, and USDA, which may provide earlier indication of a link between human and animal infections. At the very least, there should be a way to directly compare isolate patterns that are in animal and human health surveillance programs. CDC's PulseNet and USDA's VetNet programs should be linked and equipped to automate analysis of these 2 data streams for evidence of similarities that may indicate a common exposure.

The US government should also continue to work to improve public health officials' access to data from healthcare providers that would expedite the speed of their response to foodborne illness outbreaks. In many places, reporting of foodborne diseases from the clinical sector continues to be incomplete or delayed. As the nation builds a national framework for EHRs, there is a great opportunity to develop critical connections between the public health and healthcare sectors to enable earlier detection of cases of gastrointestinal illness that may have been caused by consumption of contaminated food. In particular, EHR development efforts should focus on expediting disease reporting by clinical laboratories to public health agencies.

Conclusion

Foodborne illness outbreaks continue to have significant consequences in the United States and provide continual real-world reminders both of the extraordinary costs of infectious disease outbreaks and the ways in which costs can be exacerbated when there is insufficient capacity to rapidly detect and help contain such events. Responses to these events represent critical opportunities to assess our readiness for future large-scale outbreaks, including bioterrorist attacks. They underscore the importance of having in place strong public health systems that enable rapid detection of an outbreak and identification of its source. Although the US has made much progress in improving surveillance for foodborne illness outbreaks, much more work is necessary.

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Appendix A. Participating Organizations

State and Local Public Health Agencies:

Colorado Department of Health

Connecticut Department of Public Health

Maryland Department of Health and Mental Hygiene, Public Health Laboratory

Michigan Department of Agriculture

Minnesota Department of Health

New Mexico Department of Health

New Jersey Department of Health and Senior Services

New York City Department of Health & Mental Hygiene

Ohio Department of Health

Oregon Health Authority

Pennsylvania Department of Health

Tennessee Department of Health

South Carolina Department of Health and Environmental Control

Wisconsin Department of Health Services

U.S. and International Governmental Agencies:

US Centers for Disease Control and Protection

US Department of Agriculture

US Food and Drug Administration

The White House

Robert Koch Institute - Germany

Academic, Industry, Professional and Nongovernmental Organizations:

Center for Science in the Public Interest

Council of State and Territorial Epidemiologists (CSTE)

Council to Improve Foodborne Outbreak Response (CIFOR)

General Mills, Inc.

National Center for Food Protection and Defense—University of Minnesota

The Pew Charitable Trusts

United Fresh Produce Association

Appendix B.

Food Safety Modernization Act—A Primer

Introduction

While the “combined efforts of the food industry and government regulatory agencies often are credited with making the US food supply among the safest in the world,”^(p1) widely publicized food safety problems and illnesses linked to various foods have led some to criticize the US food safety system for lacking the organization, regulatory tools, and resources to adequately combat foodborne illness.¹ Thus, in 2010, the US Congress passed the Food Safety Modernization Act (FSMA),² the first major reform of the food safety regime in more than 70 years. This Appendix describes FSMA and aspects of the law that changed the ways that the US Food and Drug Administration (FDA) regulates food safety.

Divided Federal Responsibility for Food Safety

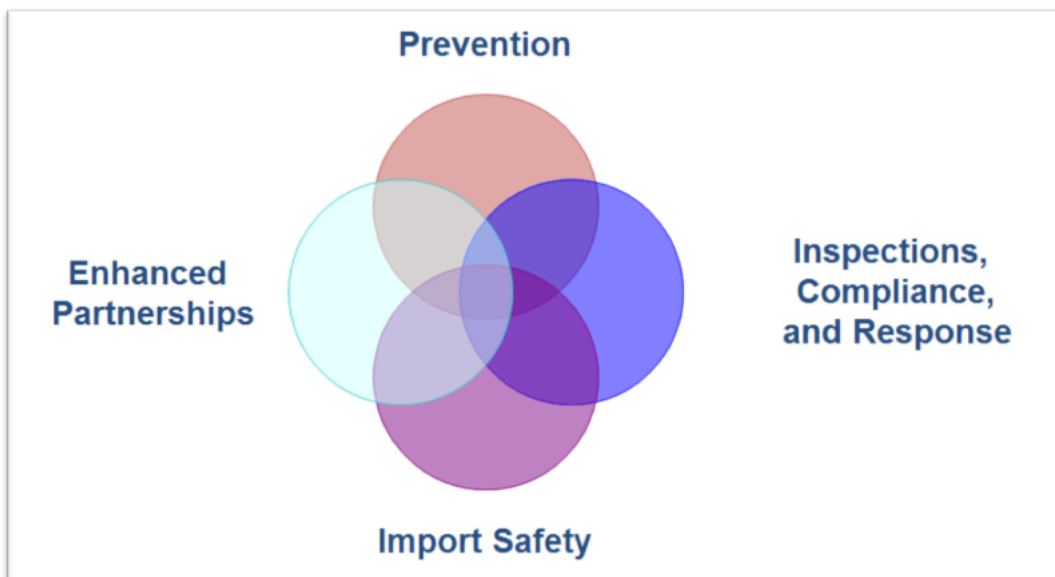
While FDA and the US Department of Agriculture (USDA) share primary federal responsibility for food safety, a total of 15 agencies collectively administer at least 30 food-related laws.³ The FDA is responsible for ensuring the safety of at least 80% of the US food supply, including essentially all domestic and imported food products, except most meats and poultry.¹ USDA’s Food Safety and Inspection Service (FSIS) is responsible for the remaining 10% to 20% and regulates most meats and poultry.¹

The division of food safety responsibility between FDA and USDA dates back to 1906, when Congress enacted separate statutory frameworks: the Pure Food and Drugs Act and the Meat Inspection Act. The Pure Food and Drugs Act tasked the USDA’s Bureau of Chemistry with regulating the marketing of intentionally adulterated foods, and, under the Meat Inspection Act, the USDA’s Bureau of Animal Industry monitored the sanitary conditions of meatpacking plants. Then, in 1940, responsibility for safe foods and drugs, other than meat and poultry, was transferred from USDA to the Federal Security Agency (which would later become HHS), further exacerbating the division of federal food safety responsibility and establishing the divided system that exists today.⁴ FSMA focuses on changes related to FDA, not USDA.

Comprehensive Reform

FSMA represents the first comprehensive reform of the US food safety system since President Franklin Roosevelt signed the Federal Food, Drug, and Cosmetic (FDC) Act in 1938. FSMA enhances FDA’s authority in 4 primary areas: prevention; inspections, compliance, and response; import safety; and partnerships.

Figure 1: Components of FSMA Legislation



Source: Overview: FDA Food Safety Modernization Act, PowerPoint Presentation. FDA. Available at <http://www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM266989.ppt>. Accessed March 29, 2012.

Prevention

The FDA's approach to food safety has long been criticized for being reactive, rather than preventive.⁵ Under FSMA, the FDA's focus incorporates more preventive controls.

Under FSMA, FDA has a legislative mandate to require comprehensive, science-based controls across the food supply. Like the preventive approach employed by the USDA, which requires hazards analysis and critical control point (HACCP) plans from meat and poultry establishments, FSMA requires food processing, manufacturing, shipping, and other regulated facilities to analyze the most likely food safety hazards and implement risk-based preventive controls. FDA's mandate under FSMA includes mandatory preventive controls for food facilities and mandatory produce safety standards.

Preventive controls for food facilities: Under FSMA, food facilities are required to develop food safety plans that evaluate production practices to determine likely origins of food safety hazards, identify and implement preventive controls to minimize or prevent the hazards, monitor effectiveness of the controls, and maintain routine records of food safety planning activities.⁶

Produce safety standards: FSMA directs the FDA to “establish science-based, minimum standards for the safe production and harvesting of fruits and vegetables.”⁷ These standards are to consider both natural and unintentionally or intentionally introduced hazards, including those emanating from soil additives, hygiene, packaging, temperature controls, waste from animals in the growing area, and water.⁷ FDA must also issue regulations protecting against the intentional adulteration of food.⁷ Commodities determined to be low risk when produced or harvested by a small or very small business may be excluded from these standards.⁷

Inspections, Compliance, and Response

According to a 2011 Congressional Research Service report:

Overall, FDA has oversight of more than 44,000 US food manufacturers, plus well over 100,000 additional registered food facilities such as warehouses and grain elevators. In addition, some 200,000 foreign food facilities are registered with the agency. Various estimates of unannounced compliance inspections of domestic establishments by FDA officials range from once every five years to once every 10 years, on average, although the agency claims to visit about 6,000 so-called high-risk facilities on an annual basis.^{1 (p2)}

FSMA establishes a mandated inspection frequency, based on risk, for food facilities. The agency also grants FDA more access to records regarding plant safety and requires certain food testing to be carried out by accredited laboratories.

Mandated inspection frequency: Immediately upon the passage of the law, FSMA established a risk-based mandated inspection frequency for food facilities. Within 5 years of enactment, all high-risk domestic facilities must be inspected, with follow-on inspections at intervals of no less than every 3 years thereafter.⁸ Facilities are designated as “high-risk” based on, among other possible factors, “known safety risks of the food manufactured, processed, packed, or held at the facility,” or the facility’s “compliance history,” or the “rigor and effectiveness of the facility’s hazards analysis and risk-based preventive controls.”⁹ All other domestic food facilities are to be inspected within 7 years of FSMA’s enactment, then at least once every 5 years thereafter.⁹

FSMA also sets an aggressive implementation timeline for foreign facilities. Within 1 year of enactment, FDA is directed to inspect at least 600 foreign facilities, doubling the number of inspections every year for next 5 years.⁹

Access to records regarding plant safety: Under FSMA, FDA now has more access to food safety records, including industry food safety plans and records documenting implementation of food safety plans.

Testing by accredited laboratories: FSMA requires certain food testing to be carried out by accredited laboratories. Within 2 years of enactment, FDA is to establish a program for laboratory accreditation.¹⁰

Because of FSMA, FDA now has mandatory recall authority for all food products deemed to be adulterated or misbranded and capable of causing serious adverse health consequences or death to humans or animals.¹¹ FDA has stated that the authority is meant to be used only if a firm with suspect products fails to recall them voluntarily; thus, the authority is likely to be invoked infrequently because the food industry largely honors requests for voluntary recalls.¹²

Import Safety

The US food supply originates in more than 150 countries worldwide, accounting for 15% of the US food supply, including 60% of fresh fruits and vegetables and 80% of seafood.^{12,13} FSMA gives FDA authority to regulate some imported foods according to the same safety standards as foods produced domestically. FSMA provides FDA with new import authorities and mandates relating to importer accountability, third-party certification of foreign food facilities, certification for high-risk foods, a qualified importer program, and the authority to deny entry.

Importer accountability: Under FSMA, importers must verify that their foreign suppliers have adequate preventive controls in place.¹⁴

Third-party certification of foreign food facilities: FSMA calls for establishment of a program enabling qualified third parties to certify that foreign food facilities comply with US food safety standards, thus facilitating the entry of imported food.¹⁵

Certification for high-risk foods: FSMA grants FDA the authority to require that high-risk imported foods be accompanied by a credible assurance of compliance, such as a credible third-party certification.¹⁶

Voluntary qualified importer program: FSMA mandates that FDA establish a voluntary program for importers that provides for expedited review and entry of foods from certified facilities.¹⁷

Authority to deny entry: FSMA authorizes the FDA to deny entry of imported food from a foreign facility if FDA is denied access by the facility or the country in which the facility is located.¹⁸

Enhanced Partnerships

The FDA accomplishes its mission with the assistance of more than 400 state agencies that conduct a range of food regulatory activities.¹ FSMA strengthens FDA partnerships with state, local, territorial, and tribal food safety agencies by building capacity, sharing responsibility for inspections, establishing a consortium of laboratory networks, and improving foodborne illness surveillance.

State and local capacity building: FSMA establishes a new multiyear grant mechanism meant to develop and implement strategies that incorporate and improve the capacity of state and local food safety agencies.

Sharing responsibility for inspections: To meet the increased inspection mandate established by FSMA, FDA is authorized to rely on inspections performed by other federal, state, and local agencies. With respect to seafood facilities, FSMA authorizes FDA to enter into interagency agreements to leverage resources for seafood facilities, both domestic and foreign.

Establishing a consortium of laboratory networks: The national networks of laboratories currently in operation, including the Laboratory Response Network (LRN), the Food Emergency Response Network (FERN), and the National Animal Health Laboratory Network, are not explicitly authorized in law. FSMA calls for an integrated consortium of laboratory networks to be established by the secretary of Homeland Security, in consultation with the secretaries of HHS and USDA and the US Environmental Protection Agency (EPA) administrator.¹⁹

Improving foodborne illness surveillance: FSMA requires the secretary of HHS, acting through the director of the CDC, to enhance foodborne illness surveillance systems and to establish a working group, comprised of public- and private-sector experts and stakeholders, to meet and report at least annually and make recommendations for the improvement of foodborne illness surveillance systems.²⁰

Conclusion

With FSMA, Congress provided FDA with many of the tools required to accomplish the increasingly difficult task of regulating the US food supply. That said, implementation of the landmark legislation depends in large part on discretionary appropriations from Congress, and questions remain as to whether the \$1.4 billion over 5 years required for full implementation is available in the current fiscal environment.^{1,21}

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