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How Did We Get Here?

On January 9, 2009, the Minnesota Department of Health reported the discovery of *Salmonella typhimurium* contamination in a container of King Nut peanut butter at a nursing home. Manufactured by the Peanut Corporation of America (PCA), King Nut is a brand distributed to institutions and food manufacturers in many states (but not available at the retail level). Salmonella was subsequently found in other PCA products by the Connecticut Department of Health and the Georgia Department of Agriculture. These reports initiated an investigation of the PCA processing facility in Blakely, Georgia, by the U.S. Food and Drug Administration (FDA). Within a week, the Blakely facility was implicated in the outbreak and a limited recall of peanut paste and peanut products was put in place. As the FDA investigation widened, the amount of tainted peanut butter identified grew, leading to more extensive recalls of an even wider range of products and the removal of a host of items containing peanut paste from the grocery shelves. By February 2009, a PCA facility in Texas was identified as an additional source of peanut butter contaminated with Salmonella and, by the third week of that month, six weeks after the Minnesota Department of Health first discovered the Salmonella in the container of peanut butter, the company issued a statement asking customers to cease all use and distribution of products from their Georgia and Texas plants. In the end, the company recalled all peanut products produced at the plant since January 1, 2007.

Even though public health officials connected illnesses to a source in January of 2009, the first illnesses from the tainted peanut products began to appear as early as September 6, 2008, and peaked in December 2008. The U.S. Centers for Disease Control and Prevention (CDC) first noticed small and highly dispersed multistate clusters of *Salmonella typhimurium* in early November 2008 and

began to identify a source. What was initially a relatively small set of outbreaks grew by early December 2008 into a fairly widespread outbreak of nearly 70 cases. In the end, more than 700 people were sickened in 46 states and nine people died from the tainted peanut products from the Blakely plant. Before the outbreak was contained, contaminated peanut products were shipped to almost every state, and beyond U.S. borders, and found their way into snack products, school lunches and pet snacks.

In Blakely, Georgia, the impact of the outbreak was devastating. Blakely is a community in southwest Georgia with a long history of peanut production. Early County, where Blakely is located, is the largest producer of peanuts in the country, and the PCA plant represented a significant employer for the people in the county. In the wake of the outbreak and the pursuit of criminal charges, as well as civil liabilities, PCA declared bankruptcy, depriving the community of a major employer and the surrounding region with a market for a dominant crop. The shuttering of the peanut processing facility, and the taint that the PCA plant left on peanut products, could be felt in the peanut farms across the region.

The PCA Salmonella outbreak is noteworthy for several reasons, including the large number of affected products and the nationwide recall. Moreover, the investigation into the plant's food safety practices revealed considerable variance from accepted best practices as well as deliberate behaviors that undermined what safeguards were in place. Investigators inspecting the plant after the recall reported finding mold and roaches. More disconcertingly, it was revealed that PCA had sold peanut products even after laboratory tests indicated high coliform results, and that the company both resubmitted samples for retesting (multiple times in at least one instance) or sent samples to a different lab following these positive results to receive favorable outcomes.

The Blakely episode, while significant, is not unique. The past decade has witnessed a number of remarkable food-borne illness outbreaks, including a 2006 *E. coli* outbreak in spinach that sickened more than 200 people in 26 states and caused the death of at least three people, and a 2008 *Salmonella saintpaul* outbreak—initially linked to tomatoes but eventually isolated to jalapeño peppers—that was responsible for more than 1,400 illnesses. Changes in the way food is produced, marketed and consumed have contributed to a food safety environment that is vastly different from that of just a few decades ago.

The Development of Food Safety

Food safety is governed at the federal level by legislation and regulations that were established in the 1900s and substantially updated in the 1930s and again in 1996. Food safety regulations at the state and local level date back to the 17th century (Massachusetts Bay Colony established requirements for the inspection of beef, pork and fish in 1641), but most of these efforts were intended to minimize adulteration or prevent the sale of spoiled goods. By the start of the 20th century, the federal government had been pressured for decades to improve the standards found at slaughterhouses across the country and end the practice of adding non-food items (including brick dust, floor sweepings and lead salts) to foods. It was not until the 1906 publication of Upton Sinclair's *The Jungle* that Congress passed the Pure Food and Drug Act and the Beef Inspection Act. Sinclair, who spent weeks working in a meat processing plant to expose labor conditions, had intended to set off an uproar over the abuse of workers. Instead, he brought to light the distressing state of the food supply and prompted Congress to take action. The Food, Drug and Insecticide Administration (which eventually was shortened to the Food and Drug Administration) was established in 1927 to oversee enforcement of the provisions of the Acts. In 1938, Congress passed the Pure Food, Drug and Cosmetics Act, which replaced the previous Pure Food and Drug Act, prohibiting the sale of any food deemed to be unsafe in interstate commerce.

The 1938 law continued to govern food safety activities at the federal level with little alteration until 1996, when Congress passed the Food Quality Protection Act, which established new requirements for food processors in terms of assessing risks and implementing plans to prevent contamination. Even with this recent activity, the food safety system in the United States remains governed in many ways by policies and practices that are, in some instances, more than a century old. What recent food safety scares have driven home is the persistence of holes in the food safety system and the degree to which the food safety system is due for an update. The passage of the Food Safety Modernization Act (FSMA) in early 2011 is intended to remedy some of these systemic gaps.

Americans enjoy the safest, lowest-cost food anywhere in the world. For decades, the primacy of the American food supply system was unchallenged and unparalleled. Following reforms put in place in the 1900s and 1930s to guarantee against the adulteration of food and provide a stamp of wholesomeness, American consumers have been able to stock their kitchens with little concern for the presence of harmful bacteria and contaminants in their food. Food safety garnered very little attention for much of the post-war period, even as the food system underwent radical transformation and American eating habits changed to reflect new social realities. Then, in 1993, hundreds of people were sickened and four children died after eating hamburgers sold in Seattle-area Jack-in-the-Box restaurants that were contaminated with *E. coli* O157:H7, and Americans' relationship with their food subtly changed. This was the largest and deadliest such outbreak since the advent of the U.S. food regulatory system and cost the restaurant chain millions of dollars in litigation and lost business.

The Jack-in-the-Box episode served as an alarm signal for a number of reasons. Heretofore, deaths from foodborne illnesses tended to be isolated to clear risks (uncooked foods or unrefrigerated items) and to those highly susceptible to illness (the very old and the very young), whereas this episode involved a cooked food product from a respected chain sickening, and eventually causing the deaths of, otherwise healthy, young people. Furthermore, the bacterial contamination was in a food that possesses a central cultural place in American life. Moreover, changes in American lifestyles had driven a rise in the number of meals eaten outside the home over the previous decade, placing establishments like Jack-in-the-Box into the meal mix for more and more American families.

Following the Jack-in-the-Box episode, action was taken by food manufacturers and retailers to improve the standards for the food they sold. The chain became an industry leader in food safety, increasing the cooking time and temperatures for their burgers, changing food storage and handling procedures, and establishing food safety protocols that quickly spread across the food supply system. No regulatory actions were pursued in the aftermath, however, and the food safety system at the state and federal remained relatively unchanged until the institution of the 1996 federal legislation requiring Hazard Analysis and Critical Control Points (HACCP) plans for seafood, meat, poultry, juice and dairy.

HACCP plans are a preventative approach to manage food safety systemically through the analysis of points in the food production cycle during which biological, chemical and physical contamination or adulteration might occur. Each HACCP plan reviews each step of a food product's life, from raw material production, purchasing and han-

dling, processing or manufacturing, distribution, sale and consumption, determines the potential risks at each step and develops procedures to eliminate them. In this manner, the production system becomes a tool to ensure food safety and reduce risks that accumulate along the food chain. In part, HACCP plans are implemented in situations in which end-of-cycle testing is insufficient, inefficient or inadequate to ensure the safety of the food supply. Such systems are particularly important for foods that are highly perishable, for which traditional testing protocols do not provide swift enough results to identify contamination before the product must be at market. The use of these plans does not eliminate the need for inspections and testing of finished products, but helps to minimize the opportunity for contamination to occur. While HACCP plans are required for meat, seafood, dairy and juice sold in the United States, manufacturers of many other food products use them as a means to demonstrate compliance with safe processing and handling.

Overview of the New Federal Law

On January 4, 2011, President Obama signed into law the Food Safety Modernization Act, the first major rewrite of federal food safety legislation since the 1930s. The bill gives the FDA new authority over food safety and changes the underlying approach to food safety enforcement, shifting from a distributed, response-oriented model to an integrated, risk-oriented system. The new legislation addresses all food facilities except meat, poultry and some egg producers, which remain under the purview of the U.S. Department of Agriculture (USDA). Under the new law, the FDA now has the authority to mandate recalls of food products under certain conditions (previously, the agency was dependent on negotiated voluntary recalls by manufacturers). Moreover, the FDA now has a legislative mandate to establish a scientifically supported, prevention-focused food safety system across the entire food supply. The federal law does not supersede state authority on food safety, but is intended to build upon established strengths within those various elements and knit the components together into a single system.

The federal government remains responsible for inspections mandated by the new law, which are substantial. Prior to the legislation, food facilities had to register once with the FDA and only were required to re-register if they made relevant changes to their operations. The new law requires biennial registration of all food facilities (excepting farms and restaurants) and increases the frequency of facility inspections. The FDA is required by the Act to establish a risk-based inspection frequency schedule for food facilities, with high-risk facilities (identified as such either because of the food that they process or due to poor compliance histories, or other risk-based factors) inspected within five years of enactment, and reinspections of these facilities

occurring every three years thereafter. Furthermore, the Act requires food facilities to implement prevention plans that evaluate hazards that could affect food safety, outline the preventative measures that will be implemented to minimize or eliminate the threat of contamination, stipulate the monitoring and recordkeeping that will be in place to gauge the plan's effectiveness, and provide for corrective action should contamination occur.

The Act works to strengthen the partnerships that exist between federal, state, local, territorial, and foreign food safety agencies. This is done in part through training and grants to build the capacity of these entities and enhance their ability to cooperate and collaborate on prevention, surveillance and response activities. This capacity-building component is crucial in order to fulfill another aspect of the law: testing by laboratories that meet new FDA accreditation standards. The Act provides for improving the capacity of overseas partners as well and provides for inspections by other federal, state, and local agencies to achieve the goal of increased surveillance outlined in the legislation.

Under the new legislation, in addition to new recall authority, the Act gives the FDA the ability to "hold" products that are suspected of being in violation of the law through expanded administrative detention. The FDA has been charged under the Act with creating a system that will enhance the agency's ability to track and trace imported and domestic foods, as well as establish special record-keeping requirements for facilities involved in the production of foods that are deemed to be high-risk.

Finally, the Act provides the FDA with new authority over imported foods. Included in this is a new, explicit requirement for importers to ensure that foreign suppliers have in place satisfactory safety measures that protect the imported food against contamination or adulteration. The Act allows for third-party certification of foreign food facilities to ease the entry requirements on imports, so long as the outside certification agency is accredited through the FDA. The FDA also is required to establish a qualified importer program for foods from certified facilities that will expedite entry from participating importers. The Act additionally provides the FDA with the authority to require high-risk foods to have third-party certification or other assurance of compliance and can deny entry to any food product from a foreign facility to which the FDA has been denied access.

A Federal-State-Local Partnership

Responsibility for the safety, wholesomeness, and sanitary handling of food in the United States falls onto the numerous food manufacturers, distributors and retailers. Local, state and federal government entities, along with international bodies, provide regulatory support and enforcement. This arrangement has served to provide consumers with confidence in the safety of the food supply and producers with the ability for efficient delivery of food to consumers that meets high standards.

The U.S. food safety system has developed over a lengthy period, often in response to health concerns or threats. Because of this, the system does not have a coherent, strategic focus, but is a patchwork of legal and regulatory activities that distributes the responsibility for, and information about, food safety across numerous federal, state and local entities. There are at least 30 federal laws related to food safety, which are administered by approximately 15 federal agencies. The two agencies primarily responsible for food safety are the FDA and the USDA, which have authority to oversee inspections and regulatory compliance on a range of products. Each agency conducts inspections of food production facilities and, in some instances, these facilities may be subject to inspection by both agencies.

Under the current system, states and localities conduct the great majority of public sector food safety activities (including inspections, investigations and enforcements). State and local departments of health, public health laboratories in various states, and state departments of agriculture conduct inspections for prevention and response purposes. Also on the prevention side, local departments of health are the primary inspector of retail food establishments, such as restaurants and groceries. State level inspectors conduct compliance and prevention inspections of non-retail food establishments and are responsible for nearly 80 percent of all non-retail food manufacturing inspections annually. State agencies also are contracted by the FDA to conduct federal food manufacturing facility inspections. Federal inspectors, under the auspices of the USDA, are responsible for the inspection of meat, poultry and some egg inspections and must be present on-site during production or processing. Federal authorities also conduct inspections of food manufacturing facilities independent of state level inspections (and those under contract). Depending on the facility and the product, inspection frequency can vary. Production facilities are expected to conduct their own compliance activities, which may include system reviews and the testing of random samples, although the results of these are not necessarily subject to disclosure to local, state or federal authorities. In general, state laboratories have the responsibility for analyzing samples for foodborne illnesses, a task they share with a few local laboratories, as well as privately contracted labs,

to conduct monitoring of manufactured products. The federal role in these activities centers on coordination and information sharing, with the CDC operating three networks that collect, analyze and share information on foodborne illness: FoodNet, PulseNet, and OutbreakNet.

With respect to response activities, local public health agencies are almost always the first line in the detection of an outbreak and the key link in reporting suspected cases to the state and federal components of the system. Local agencies also play a key role in outbreak investigations, seeking out potential sources for the infection, as well as the implementation of recalls and interaction with food establishments and the general public. State agencies are essential links between local and federal public health systems, operating several networks designed to share information across jurisdictions, and have the primary responsibility in enforcement of recall actions. At the federal level, the government plays a lead role in the identification and traceback of the source of contamination and helps to coordinate multijurisdictional recalls and response.

The importance of coordination and cooperation of local, state and federal officials in foodborne illness response cannot be exaggerated. The highly mobile nature of the food system, and the degree to which products and ingredients are collected, processed and distributed to and from multiple locations, means that contaminated food is unlikely to create an isolated, single event. Due to this wide-reaching impact, responses to contaminated processed foods, meat, poultry or produce differ from responses to contamination due to poor handling or storage at retail establishments, insofar as a local public health response may be all that is required in the latter instance. And while local public health investments are targeted at these risks, the threat of broader enteric disease from the distribution of contaminated food or food products places greater numbers of people at risk and is much more difficult to trace and contain. Without clear coordination of efforts from the national level, identifying and reporting potential vectors for illness and tracing them back to their source, as well as effective and timely recalls, are impractical, if not impossible.

Coordination is of sufficient significance that it has catalyzed changes, at the CDC in particular, to be more focused on multijurisdictional coordination of outbreak response. For this to be effective, however, states will need to agree to a protocol for the investigation, reporting and response to potential outbreaks, a process that has been begun by the Association of State and Territorial Health Officials, the Association of Food and Drug Officials, and the Association of Public Health Laboratories. A critical roadblock to this collaboration is the lack of a mandate at the state or federal level for the various components of the food safety system to work as part of an integrated whole, as well as

the presence of rules that restrict staff from working on projects directed by other agencies or other states and rules that restrict the sharing of information outside of the state or agency. Beyond this practical hurdle is the limited interaction state and local public health officials have with their counterparts in other jurisdictions, hindering the flow of information and expertise. Because of the ad hoc nature of incident response, these individuals are likely to encounter one another only during a crisis, a time when it is critical for each party to be comfortable with, and aware of, the capacity of all the partners in the team. However, absent coordinated planning and training, there is little opportunity to develop this relationship.

Given the number of “moving parts” in the food system in the United States, the complexity of the food safety endeavor is inevitable. Also, it creates a need for a high degree of coordination and cooperation among the partners involved, each of which brings a set of assets and limitations to the process. Creating a coordinated system that focuses on prevention requires a partnership that supports information collection and sharing at all levels. Unfortunately, the nature of the current system also means that there is a high degree of inconsistency among the capacities of the very sources of field information and activities that are at the heart of the system. Developing a system that works effectively means, at least in part, closing the capacity gaps that exist in both prevention and surveillance/response components of state and (especially) local agencies, or identifying mechanisms to minimize or mitigate, where possible, the limitations that exist because of these gaps.

Is This A Problem? The Economic Impacts Of Foodborne Illness

The U.S. Centers for Disease Control and Prevention estimates that each year about 48 million Americans, or one in six, are made ill by foodborne disease. According to the CDC, 128,000 Americans are hospitalized for a foodborne illness, and 2,000 die as a result of their disease. The USDA calculated the costs of illness and premature death of Salmonella outbreaks at more than \$2 billion alone, a figure that does not include the impact on the overall economy. Economist Robert L. Scharff of The Ohio State University estimated in 2010 that the total economic impact of foodborne illnesses to the economy is \$152 billion each year.

The cumulative impact of outbreaks—massive as it is—can mask the localized impacts of individual events. In spring 2008, when the Salmonella outbreak sickened thousands, tomatoes were initially implicated (it was later determined that jalapeño peppers were the source). Fresh tomatoes were pulled from grocery shelves and restaurants just at the point when producers in Florida, Georgia and Alabama were gearing up for harvest. Producers watched as their crops—not directly implicated in the contamination event since they were only just then coming to market—declined in value until it became economically unfeasible to harvest them. The impact to Florida growers has been estimated at more than \$100 million (other sources place the total impact at \$500 million), with losses in Georgia set at close to \$14 million. In the wake of the recall, overall demand

FoodNet, PulseNet, and OutbreakNet

There is an extensive range of cooperative and collaborative activities on food safety that serves to share information among all partners in order to facilitate a stronger food safety system. Among these systems, FoodNet, Pulsenet and OutbreakNet represent a significant shared asset for federal-state-local work.

The Foodborne Disease Active Surveillance Network, or FoodNet, is a program involving 10 states (including Georgia and Tennessee) participating in the Emerging Infections Program of the CDC. By conducting active, population-based surveillance on outbreaks for nine identified pathogens in the participating sites, the program helps in the standardization of methods among laboratories to provide accurate estimates of foodborne illness.

PulseNet is a collaboration between state public health laboratories and the CDC to provide an “early warning

system” for foodborne disease outbreaks by establishing a network of labs across the country that conduct DNA fingerprinting on suspected bacterial infection “culprits.” The system allows for a rapid analysis of each disease-causing organism and allows for sub-type matching with existing samples in a national database so that public health officials can connect outbreaks to a possible common source, greatly increasing the speed at which traceback (and recalls) can be conducted.

OutbreakNet is a national network comprised of federal, state and local public health officials engaged in the investigation of foodborne illnesses. Coordinated by the CDC, OutbreakNet helps to streamline the discovery and reporting of foodborne illness outbreaks through the National Outbreak Reporting System, which, in conjunction with Pulsenet, provides invaluable information in the identification of the source and kind of contamination.

for fresh produce dropped, causing losses for farmers across the spectrum. A fall 2006 recall of spinach literally cleared fresh packaged spinach from grocery shelves coast-to-coast, wiping out a growing season for hundreds of farmers in the Central Valley of California, as well as in the mid-Atlantic, with an estimated initial impact of between \$37 million and \$74 million, plus a lingering impact of \$350 million in losses and a 20 percent reduction in sales.

The Peanut Corporation of America outbreak in 2009 caused widespread disruption in the heart of peanut country. The bankruptcy of PCA left hundreds of peanut farmers without a market for their crop, and the possibility of a long-term drop in consumption. The overall impact of the outbreak was pegged at nearly \$1 billion by the Georgia Peanut Commission and changed the economy of the area in a profound way, shuttering local businesses harmed by the loss of peanut farmer revenue and causing declines in the local economy that continues to be felt.

The costs of foodborne illnesses and outbreaks are clearly significant, and the overall losses to the U.S. economy are quite possibly larger than estimates when lost productivity and increased morbidity and mortality, as well as undetected illnesses, are factored in. It is in large part because there are significant costs associated with foodborne illness that improvements to the existing system, which are not without costs themselves, can be viewed best as investments that will be recouped over time.

Protecting the food supply is not without costs, of course. Consistent data on state inspection and monitoring expenditures does not exist, but the FDA reported that it spent \$129.6 million and distributed an additional \$16.5 mil-

lion to states to conduct inspections of domestic facilities in 2010, exclusive of the costs of laboratory tests and investigations. In many states, fees collected by inspecting agencies cover a significant portion of the cost of inspection programs. Covering increased costs due to more frequent or expanded inspections through increased fees could prove difficult for smaller facilities, which also are those that are likely to need the greatest assistance coming into compliance with any update in food safety standards. Thus, there likely will be a gap between increased costs for new inspections and the fees that realistically can be collected to pay for them. While the federal government has increased the amount of funds it makes available to states to conduct inspections, new state funds for inspections and training likely will be needed as the food safety system is reformed.

Building Local Capacity, Strengthening Transparency and Expanding Information Sharing

The food safety system in the United States distributes responsibilities across a huge range of agencies and offices, including four federal agencies (FDA, USDA, U.S. Department of Homeland Security and U.S. Environmental Protection Agency), multiple agencies and departments at the state level, and nearly 3,000 local health departments. The reliance on this network is necessary, in part, because the number of inspections and amount of analysis is beyond the capacity of the federal government and is best accomplished by agents working close to the facilities being inspected. The current system provides tremendous penetration of the food safety surveillance and response sys-

Canada's Coordinated Food Safety System

With a federal system similar to the United States, Canada offers a possible model for an integrated food safety system. Canada's Foodborne Illness Outbreak Response Protocol (FIORP) stipulates the roles and responsibilities for all parties involved in multijurisdictional outbreaks, outlining the manner in which the various levels will interact as well as the roles and responsibilities for cooperation and action at the federal level. In particular, the Protocol specifically outlines the framework for interaction among federal agencies with food safety responsibilities.

Within the FIORP structure, provincial and territorial health authorities enjoy the same frontline position as state authorities do in the United States to conduct prevention, surveillance and response. The framework places a single agency (Public Health

Agency of Canada) at the helm of response to multi-jurisdictional events, directing an Outbreak Investigation Coordinating Council (OICC), with participants from the various responsible agencies at the federal level, which has a specific mandate to communicate with, and provide guidance to, provincial and local authorities. Moreover, the Protocol specifically authorizes OICC members to share information they hold, including industry information, with their partners in an investigation. The absence of this authority has been identified as a limitation to an integrated national system in the United States. The Protocol also provides guidance for how members of the OICC will come to consensus on outbreak response in order to support a coordinated action while respecting the policy mandates and legal prerogatives of the individual members of the OICC.

tem into the food system, reaching out to farms and food manufacturing facilities across the country.

Unfortunately, this system also has inherent weaknesses because of its diversified nature. Local health departments vary greatly in their capacity to inspect facilities, collect and analyze samples and report findings. Because local public health officials are at the base of the nation's food safety surveillance and response network, this unevenness risks delays in food contamination prevention and food-borne disease identification and response. Indeed, it is this inconsistency in enforcement and surveillance capacity that has enabled a number of recent outbreaks to develop and expand, if not undetected, then unreported and unremarked, until the impacts were felt in communities with more robust food safety systems. In small, rural counties in particular, the local capacity to support inspections of food processing facilities is exceedingly limited, a situation that is particularly problematic because of the high percentage of food processing facilities that are located in these areas.

Resolving this inconsistency is a lynchpin of improving the overall coverage of the food safety system in the United States. Among the steps states are taking to improve this situation is the adoption of the most recent Food Code, model regulatory and technical guidelines for state and local use. The Food Code currently is in its fifth iteration, having most recently been updated in 2009. Not all states have adopted the same version of the Code, and a handful of states and territories have not adopted it at all. While technically a regulatory device, the Food Code and similar model codes developed by the Association of Food and Drug Officials help to orient all components of the food safety system toward common practice. However, the Food Code is limited in scope to enforcing activities at the retail level and, as such, does not address the need for state and local agencies to adopt more risk-based and prevention-oriented practices. There is a need for state developed food safety legislation that defines the roles and responsibilities of state and local agencies in a fully integrated national system and provides them with the authority to operate collaboratively among partners in other jurisdictions and with all levels of government. Additionally, adoption of common laboratory standards across states would improve the quality of both prevention and response activities by ensuring that equally high standards are met regardless of jurisdiction.

Training and Support

The FSMA provides for grants to states to train food safety inspectors. This funding is critical to developing the capacity required to effect a modernization of the food safety system, especially as the emphasis of the program moves to a risk-based assessment. It is perhaps indicative of the capacity of the system to conduct the kinds

and number of inspections required by the new law that high-risk facilities, which are to be inspected every three years following their initial inspection, have five years in which to be initially reviewed. Put simply, the system has insufficient capacity to conduct all of the inspections required. Moreover, while federal law requires FDA mandated inspections be conducted and paid for by the federal government, there is very little distinction between state and federal inspectors. In most instances, federal and state inspections are conducted by the same individuals, although they may use different protocols depending on the agency (federal or state) for which the inspection is being conducted. This is not, in and of itself, a problem, insofar as it increases the exposure of the facilities to trained eyes familiar with the production systems. On the other hand, because state inspectors have differing degrees of training, skills and credentialing, there is a high level of unevenness among state inspection quality, a situation that is problematic for a national system intended to provide an equal (and high) degree of competence. This system also may result in inspectors conducting reviews of facilities or products for which they are inadequately trained or prepared due to the vast range of processing plants under their purview.

To remedy this problem and improve the overall quality of the food safety system, the FDA has been authorized to provide states with multi-year capacity building grants. States and local health agencies will remain the backbone of the new food safety system, and the federal law provides for new resources, not yet allocated by Congress as of June 17, 2011, to achieve the ends of the law by supporting state and local implementers. Additional resources are authorized within the legislation to bolster the information-sharing system that adequate surveillance and response depend upon, as well as for a laboratory network that is capable of early and accurate detection and identification of foodborne illnesses. Even with this support from the federal level, states will need to push the development of statewide capacity, bolstering public health laboratories and providing training and access to infrastructure for local public health inspectors, if this national system is to reach its full potential.

Because much of the expertise and experience for food safety inspections and investigation exists at the local level, supporting the transfer of best practices and lessons learned among these frontline agents has been presented as the most effective means by which the current system can rapidly scale up its capacity. By using the strongest of these resource individuals to promote consistent standards for field and lab work—standards established and agreed upon at the national level—states can build the kind of close-knit network that encourages collaboration through established relationships and helps individual partners understand what resources are available to them to address specific needs and events.

As the standards and expectations for inspectors are increased, it is incumbent on states to have in place strong and consistent food safety standards for them to use and high and consistent qualifications for the inspectors reviewing facilities. Ensuring the system provides equal protection to all consumers and offers equal assurances to producers and food manufacturers requires a meaningful certification process that provides assurances that inspectors are fully versed in the inspection process as well as the specific requirements for the specific process or product being investigated.

A prevention-oriented food safety system places responsibility on manufacturers to deliver food products safely. The government role in such a system is largely focused on determining compliance with established standards and practices. This involves some of the same procedures involved in a response-oriented food safety system, including testing samples in facilities at the retail or consumer level, as well as extensive reviews of records and on-site inspection of practices and procedures under normal operating conditions. For such a system to function properly, there must be a high likelihood that departures from good sanitary practice will be detected by inspectors—and corrective actions put in place—to encourage manufacturer compliance. This, in the end, requires inspectors that are on the ground, in facilities large and small, equipped with the appropriate training and tools, and supported by accredited laboratories capable of delivering reliable results in a timely fashion.

According to data from the American Food and Drug Officials (AFDO), in 2008, states and the FDA conducted 4,619,256 inspections. This figure, however, includes 1.7 million state meat inspections and more than 2 million institutional, temporary, and retail food service and retail food store inspections. Food processing and repacking facilities, farm production, food salvage, fruit and vegetable packing houses, frozen dessert plants, shell egg facilities and food warehouse inspections accounted for 78,522 inspections, fewer than 2 percent of all food safety inspections. In addition, in 2008, states and the federal government conducted 55,882 investigations, collected and analyzed 394,070 samples, and coordinated 1,244 recalls.

State and local inspectors are responsible for the majority of all food safety inspections and investigations and, when the more than 2 million USDA inspections of meat, poultry and seafood are excluded from the count, constitute perhaps as much as 80 percent of the workforce in the field. To accomplish the full range of food safety activities, states reported having 3,379.60 full-time equivalent field staff in 2008, responsible for inspecting the 837,644 regulated and 793,281 licensed and permitted food establishments.

Training and certification for state food inspectors is a patchwork. Most states require inspectors to have a four-

year degree and require entry level and on-the-job training along with some additional training or coursework. Laboratory certification is not yet a standard practice, although many inspectors now are accredited or seeking accreditation. Even with these standards, certification may be conducted by any one of a host of organizations using differing criteria. Recently, the CDC and AFDO have identified the International Food Protection Training Institute (IFPTI), which is endorsed by the FDA's Partnership for Food Protection Training Workgroup, to provide courses to train local, state and federal inspectors. The Institute established a Fellowship in Food Protection, which provides training to a select group of local, state and federal food safety officials who are identified as future leaders in the field. The Fellowship consists of three week-long professional development sessions, along with additional project-based training, to further develop the skills and expertise of field food safety staff. This Fellowship program, funded through grants from the W.K. Kellogg Foundation and the FDA, is extended at no cost to the participants and their agencies. The Fellowship is part of a larger effort by IFPTI to build capacity and establish uniform food safety standards. The Institute also provides career-spanning training to food safety officials—from basic training to advanced studies—to support the development of a highly skilled workforce in this field.

A Model of Excellence: Minnesota's Team Diarrhea

Almost any map of foodborne outbreaks in the United States shows high prevalence in Minnesota. This is not because the state has inherently less safe food, but rather reflects what is possibly the most robust food safety surveillance system in the country. Minnesota's system was responsible for identifying the contaminated peanut products from Georgia as well as contaminated jalapeños in an outbreak in 2008 that had eluded other public health systems.

Euphemistically referred to as Team Diarrhea, the Minnesota Department of Public Health's food safety investigative unit consists of six to eight graduate students from the University of Minnesota School of Public Health who work closely with state epidemiologists on more than a thousand cases annually. The program is supported by a state law that requires hospitals and clinic laboratories to submit a stool culture from suspected cases of intestinal illness so that its pathogens can be analyzed to determine relatedness to those on the PulseNet system.

As patterns begin to emerge—when patients are sickened by the same strain of a bacteria identified by its DNA “fingerprint”—the PulseNet system is able to help public health officials begin the process of finding the source. The team follows up with those made sick soon after their illness is reported to officials in order to collect information on

what foods they have come in contact with while it is still relatively fresh in their minds. As the information begins to build up, the team begins to look for patterns that can help isolate the contaminated product, continually refining their research until they are able, with confidence, to pinpoint the source of an outbreak. Minnesota's program often is cited as a model for a regional system of surveillance and reporting, but also stands out for the unique level of state commitment to food safety. The success of Team Diarrhea is built on a network of state investigators who can conduct the interviews and field work necessary to quickly follow up on illnesses that are reported by a connected local public health network.

Expanding the model found in Minnesota nationally has been the subject of some debate both at the state and federal level, but the cost of such a system is an obstacle, as is the limited capacity of segments of the existing national system. Furthermore, two key components contributing to Minnesota's success in identifying the sources of enteric outbreaks are the mandated clinical sample submission and the speed and thoroughness with which follow-up interviews are conducted. While mandating the submission of samples to state laboratories for analysis would require only a slight change to state law for the most part, increasing the capacity of these labs to handle the increased workloads in a timeframe sufficient to yield actionable results would require investments in staff and infrastructure. The same issues applies to the increased staff demands a comprehensive interview and investigation process requires, although Minnesota's strategy of deploying student-employees both achieves cost savings and provides valuable field training and networking.

Prevention and Surveillance

Monitoring for outbreaks of foodborne illnesses is referred to as surveillance, an apt term for a process which requires the filtering of information from a host of sources, including public health reports and private physician referrals, as well as on-the-ground sampling. Foodborne illnesses frequently are identified far from the source, through public health alerts based on medical practitioner reports of specific diseases. The limitation of this system is the dependence on post-release information—that is, data that is gathered (reports of infections) after the source of the contamination has entered the commerce stream and, quite likely, has been widely consumed. Such a system also struggles with rapid identification of the contaminated product and the high likelihood that the full scope of the outbreak is undiscovered, as only a portion of all affected individuals may seek medical care and, of those, only a portion will be cultured for infection (most particularly, emergency rooms, where acute patients may present themselves, are unlikely to conduct the necessary sample collection and analysis required for identification for a patient with gastrointestinal distress).

The second means by which foodborne contaminations are identified is through random sampling, either through quality control agents or inspectors at food facilities or retail establishments. For the former, compliance has been a very uneven process, with reports of producers resubmitting tainted samples for review by laboratories (who are, in turn, paid by the producers) until a clear result is obtained, or releasing perishable products prior to the availability of laboratory testing results. For the latter, sampling at the distribution point does not provide much protection for the consumer, as lab results indicating contamination very easily could be returned after the products under investigation have been sold and consumed. The sampling process for either method is only as strong as its methodology, with different products requiring samples to be gathered, handled and reviewed in specific manners demanding high levels of skill among field staff. Regardless of the methodology used, this model provides more of a check on the effectiveness of prevention systems than protection for consumers from tainted food. This notwithstanding, these methods provide absolutely critical information for enforcement and recall actions, and constitute an important feature of the surveillance system.

While federal, state and local officials conduct hundreds of inspections daily, the reality is that the current food safety system is still not as prevention-oriented as it can be. This is partly due to the sheer size of the food system in the United States in comparison to the number of inspectors available. The vastness of the system means that products that reach grocery shelves may contain ingredients assembled from across the globe, and processed in multiple locations before finally reaching a point of sale. At each stage in this process, there exists an opportunity for contamination and a need for superior food handling practice.

Technology is advancing opportunities for both minimizing risk and increasing compliance with best practices, including the use of tracking devices on individual lots of ingredients that can monitor times out of refrigeration, temperature, and provide tracking data. Innovative technology notwithstanding, however, the most effective and affordable means of preventing foodborne illness is improved practice and handling protocols and more extensive compliance of the best practices that already are in place. Furthermore, the food safety system offers opportunities to provide for a more risk-based approach, with increased reviews of procedures, practices and products that pose the greatest risk for contamination, and focusing the efforts and investments of public health agencies at all levels in a manner that delivers the greatest benefit. Moving to a risk-based system requires regulatory adjustments that would permit inspectors to adjust the frequency and intensity of inspections to the product being reviewed, the history of the producer or the processing facility, and the volume of the food or ingredient being produced. Such changes are a component of the FSMA, but changes to

state laws may be required to allow for the flexibility inherent in this approach.

As the system moves toward a prevention-oriented and risk-based model of food safety, the hope is that the use of increased traceability and tracking (inherent in such data-rich approaches) will help food processors to identify weaknesses quickly in both their production system and supply chain and make corrections. Prevention plans in general must identify the potential hazards and provide for remedies to them, which also provides starting points when the testing required under a monitoring plan indicates a problem. Because contaminated food lots must be scrapped, the contamination represents a loss for the processor, which creates an incentive to closely manage and monitor both the supply chain and production process to minimize product loss.

Whose Job Is It?

Defining Appropriate Roles

With the passage of new legislation on food safety, Congress delegated authority for a comprehensive food safety system to the Food and Drug Administration. While the FDA had been responsible for many aspects of this work prior to the passage of the FSMA, the Act consolidates authority in a new way and makes the FDA responsible for a host of activities that heretofore it did not have. A key challenge the new federal law introduces is the increase in the number and frequency of inspections, which will tax the already thinly spread inspection network. Moreover, the new law will move FDA inspectors into facilities and operations with which they have little prior experience. This recently was the case with an expanded Egg Safety Rule requiring intensive inspections of every large egg farm in the country, a monumental undertaking in a short period that exposed the complications inherent in the expansion of an inspection regime (varied experience and capacity among the inspectors; distrust among the facilities), as well as a host of problems that the status quo had not brought to light. Moreover, the new federal law does not reduce (indeed, it may increase) the number of facilities subject to inspections by both USDA and FDA (such as those processing products containing meat and without meat), which provides opportunity for both cooperation and confusion in perhaps equal measure.

An interesting distinction between FDA and USDA inspections relates to frequency and familiarity. Operations or groups of facilities regulated by the USDA have a full-time government inspector assigned to them to provide final inspections and oversee general compliance with sanitary practices. The FDA generally has conducted infrequent (and often, until the current law was promulgated, announced) visits every three to five years, reviewing records and observing operations under what were often

optimal conditions. USDA inspectors, due to their presence in the facility, often are intimately aware of the points at which contamination may occur and are very familiar with the unique and distinct complexities of the processing practices associated with their assigned food product. FDA inspectors may be asked to review a range of food products within a brief period of time that have little or no commonality, regularly presenting unfamiliar or unusual protocols. The approach used by the USDA can develop a familiarity that potentially leads to inspectors overlooking key problems and incorporates the regulatory check very close to the regulated entity, a relationship that raises concerns on a host of levels. FDA inspectors, while perhaps unfamiliar with the specifics of the process, are able to review at arm's length the practices and protocols in place and determine both compliance and the overall effectiveness of the food safety practices. FDA's approach of placing producers in a position of responsibility for their own internal regulation of safety, with oversight of the process and systems from state and federal inspections, is more cost effective given the vast number of facilities in the United States that produce food for market.

By increasing the frequency of inspections, the federal law places FDA inspectors at facilities more often, providing opportunity for them to become more familiar with the nature of common practices. The role of these inspections remains largely unchanged; reviewing procedures for compliance and records for effectiveness, but the increased presence (and the opportunity to inspect "at will") provides these inspectors with a better sense of how food processing facilities are operating on a day-to-day basis. Although the FDA dedicated 1,100 full-time staff to food safety inspections and investigations, the scope of the project means that it must rely on state and local inspectors contracted to the FDA to fulfill its obligation to inspect and provide oversight for the more than 420,000 registered domestic and foreign facilities.

The coming years will establish how well the relationship between the many layers of the food safety system are integrated. There exist institutional and legal barriers to sharing information critical to food safety, including restrictions or prohibitions on releasing laboratory test results and medical information to out-of-state partners, limitations on the ability of states to compel disclosure of laboratory test results from out-of-state laboratories, and legal protections of broadly defined proprietary production information. Overcoming these barriers may require changes to state law as well as the application of federal authority in some instances.

Thus, given the multi-party nature of food safety, an important issue to resolve is that of authority. Not all food safety issues are inherently the purview of the federal government, and placing federal authorities at the helm of all food safety activities may well be both counterproductive

Food without Borders

Possibly the most striking change in the food system over the past few decades, and the one that has the greatest impact on food safety, is the growth of imported foods as a share of Americans' diets. Between 2000 and 2007, the value of imported foods doubled to more than \$2 trillion, and the sources and kinds of foods entering the American marketplace became as varied and far-flung as any elements of global commerce.

Under the Agreement on the Application of Sanitary and Phytosanitary Measures (part of the Final Act of the Uruguay Round of Multilateral Trade Negotiations which the United States signed in 1994), food imports to the United States do not need to meet U.S. regulatory standards so long as the exporting nation can demonstrate that their food safety requirements achieve the same level of protection as those in the United States. The United States retains the right to set the level of sanitary protection deemed appropriate, with the federal government making the final determination if our exporting partners' sanitary measures meet the objective of food safety equivalence to domestic standards.

Policing this vast system for American consumers is a very small cadre of U.S. inspectors who check selected products entering the United States and conduct a very limited number of inspections of foreign processing facilities. For the most part, the United States is dependent on the field inspection and compliance enforcement capacity of our trading partners to ensure that food for export to the United States is wholesome and safe. Point-of-entry inspections by the FDA for produce and processed foods are relatively rare and limited by both resource demands and logistical constraints.

The scale of the challenge facing the inspection of foreign food producers is daunting. Domestically, the FDA reports 167,033 registered facilities producing foods for sale in the U.S. market. The FDA has 254,088 foreign facilities registered, which are regulated under their own national food safety laws and must comply with U.S. regulations. In 2010, the FDA or its contractors inspected 25,214 domestic food facilities, but only 357 overseas operations. FDA inspectors physically examine just over 2.1 percent of all food import shipments to the United States, and only have 44 employees in their 13 field offices.

and unnecessarily cumbersome. It seems clear that multistate cooperation is perhaps best mediated through federal action, if only because no other entity has the level of interaction among state agencies. Mediation is not control, however, and multijurisdictional outbreaks could be managed by a state agency under cooperative agreements between states, agreements that would be advantageous to the sharing of essential resources and tools at all times. The determination of who should be "in charge" should not be an ad hoc decision, however, but one that is understood by all partners in advance as a matter of established and agreed upon policy, so that all parties can quickly respond even as the situation changes and authority and delegation powers shift.

Recent State Actions

Georgia

In response to revelations surrounding the 2009 PCA episode, the Georgia General Assembly passed SB 80 in 2009, which requires the commissioner of agriculture to establish requirements for regular testing of, and written food safety plans for, food manufacturing establishments. The plans can be similar to HACCP plans in describing the procedures used to prevent contamination and, if the producer complies with the requirements of an approved plan, it can supersede the testing regimen outlined by the state Department of Agriculture elsewhere. The legisla-

tion further provides the commissioner of agriculture with the statutory authority to require testing of food products for which there are "reasonable grounds" to suspect contamination.

Possibly the most significant element of the legislation is a requirement that any positive test results must be reported to the state within 24 hours. Under the previous system, manufacturers had the flexibility to request a retest (multiple times) before reporting results. In the PCA case, samples were resubmitted several times prior to a negative result being obtained, allowing the product's continued placement in the market even though the facility had received a positive test result for contamination. The Georgia law also provides inspectors immediate access to processing facilities, ending the practice of pre-announced inspection visits which often are seen as less than effective.

Under previous law, the definition of a food processing facility was broad enough to cover corner shops and large processors. In order to avoid including unintended operations in the move to address further processors of agricultural products, the state updated and defined what a food processor is, limiting the regulations to those facilities that process food that does not end up on the plate of the final consumer. Meat plants inspected by the USDA also were exempted so as to not interfere with that inspection process.

Louisiana

In 2009, the Louisiana Legislature approved Senate Bill 93, which requires every food processing plant in the state to maintain written food processing and recall plans. These plans are to be kept on site and must be available for review by inspectors upon request. Plans must, at a minimum, describe the procedures and controls to prevent hazards that contaminate foods, monitor protocols to measure effectiveness, maintain records of corrective actions, as well as any actions taken in response to known hazards. Plants with HACCP plans that meet or exceed these standards are considered to have satisfied the requirements of the law.

The legislation limits the scope of the regulatory requirements to those facilities that process agricultural products into finished products. The legislation also places responsibility for inspections of processors under the state Department of Health and Hospitals, which oversees the existing public health infrastructure, with the exception of inspections of plants inspected by the USDA, which are the purview of the Department of Agriculture. Food processors who maintain HACCP plans are deemed to have satisfied the processing plan component of the legislation, although they must still have a recall plan in place. The Louisiana legislation further requires any positive tests for contamination be reported by the firm producing the food to the state within 24 hours. Even though the legislation was passed in 2009, the law did not become effective until January 2011 in order to provide food manufacturing plants with sufficient time to adapt to the new regulations.

California

In 2006, the California Assembly passed Senate Bill 611, which requires meat and poultry suppliers or processors to notify the Department of Health Services when products they market are subject to a federal recall due to an illness. This falls far short of mandatory recall requirements, which were sought under Senate Bill 173 in 2009. This legislation, which failed to pass, would have required producers to maintain testing records for products for two years, mandated reporting of positive laboratory tests for contamination within one hour of the test result, and provided for stiff civil penalties on producers that did not comply with requirements to have food safety plans in place who were responsible for contaminated food that caused harm. The legislation also would have shifted the responsibility for food safety inspection and response to the Department of Health Services, moving it from the state Department of Agriculture, where these functions now reside. A second piece of legislation would have required grocery stores to stop the sale of any recalled item when it was scanned at checkout. This legislation also failed to reach the governor.

Conclusion

Building a national, integrated, risk-based food safety system will require a consistently strong local base of surveillance and inspection to support outbreak prevention and response. It also will require a formalized understanding of how federal, state and local agencies will integrate during an outbreak. This may be possible to accomplish through the Emergency Management Assistance Compact, which currently operates as a mutual aid agreement and partnership to respond to natural and man-made disasters. It also is possible that a separate compact would be more effective.

Currently, federal law provides the federal government with sufficient authority to act on food safety outbreaks, but the coordination of the response (and of prevention activities) is largely an ad hoc endeavor. A formal framework, with well-articulated roles for all parties, is largely absent, even though in the event of an outbreak the system generally moves swiftly to protect public health. Such a structure would need to remain flexible so as to allow outbreak response to be scaled to the most effective level while allowing partners in the system to understand the roles and responsibilities of everyone involved. Most particularly, this would involve clarity at the federal level for implementation and management of response to multistate outbreaks, with clear criteria for when federal authority would begin for response activities.

Establishing a prevention-oriented national food safety system will require investments at all levels, innovative use of existing technology, commitments among partners to share resources and responsibilities across both jurisdictional borders and institutional barriers, and initiatives to boost capacity across the system. Food safety requires an integration of public health, agriculture, the food processing industry, and the research community to achieve a truly seamless system where risks are assessed accurately, mitigated appropriately, monitored thoroughly and outbreaks are responded to effectively. The burden of supporting such a system is not for states to bear alone, but it is likely that, given the state and local foundation of the network, state support will determine the robustness of the surveillance and monitoring that will lead to success.

This report was prepared by Jonathan Watts Hull, senior policy analyst, for the Agriculture and Rural Development Committee of the Southern Legislative Conference of The Council of State Governments, under the auspices of Representative Terry England, Georgia, Committee Chair and Senate Majority Leader Mark Norris, Tennessee, SLC Chair.