

Board of Scientific Counselors, Office of Infectious Diseases

Food Safety Modernization Act Surveillance Working Group

Annual Report to the Secretary, Department of Health and Human Services

2012

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**FSMA Surveillance Working Group
Report to HHS Secretary
2012**

SUMMARY

The Food Safety Modernization Act (FSMA) authorized CDC to create a diverse Working Group of experts and stakeholders to provide routine and ongoing guidance to improve foodborne illness surveillance systems in the United States. This report summarizes the Working Group's activities during its first year, FY 2012.

The Working Group met twice for two days each at CDC, providing guidance on selection criteria for the FSMA-mandated Integrated Food Safety Centers of Excellence, reviewing and providing feedback on the Interagency Food Safety Analytics Collaboration strategic plan and on several CDC FSMA-related initiatives to enhance foodborne disease surveillance, and identifying priority areas to focus on in the coming years. The Working Group recognized that since the passage of FSMA, considerable progress has been made in collaboration around foodborne illness surveillance, but felt further improvement in surveillance is needed and could be made in a number of areas including

- Interagency linkages and coordination at local, state, federal, and tribal levels;
- Development and use of meaningful foodborne illness surveillance performance measures;
- More complete collection, standardization, and analysis of information on factors contributing to foodborne illness;
- Response to the potential loss of the ability to track and link organisms to detect outbreaks and suspect foods due to increased use of culture-independent diagnostic tests;
- Building of state and local surveillance capacity on which national surveillance is based; and
- Communication with partners and external stakeholders, especially when investigating and responding to widespread outbreaks affecting many states.

In the course of its work, the Working Group repeatedly noted the importance of national and state/local surveillance for foodborne illness and that the data gathered are critical to detecting outbreaks and new food vehicles causing illness; to monitoring the safety of the food supply; and to directing risk-based food safety efforts by CDC, FDA, and USDA. Further, the Working Group noted the recent loss of capacity at state and local levels due to the recession and that additional resources will be needed to build on existing surveillance systems, better integrate them, and fill existing and emerging data gaps.

INTRODUCTION

An estimated 48 million people (1 in 6 Americans) get sick, 128,000 are hospitalized, and 3,000 die each year from (largely) preventable foodborne diseases, according to data from the Centers for Disease Control and Prevention (CDC)¹. Translating these numbers into actionable information is a function of the national public health surveillance system.

Foodborne illness data collected at the local and state levels provide essential information for our public health and food control system. CDC compiles the information from local and state agencies and works with these agencies to identify and link outbreak-associated illnesses, leading to management and control of contaminated foods. This coordination between the local, state, and federal government is essential to protecting consumers.

The data emerging from this system, aggregated by CDC, are essential for many other functions, such as informing evidence-based policy, providing assessments of public health risk, and developing prevention messages for food safety improvements. Over the years, differences in data collection and reporting among the states, along with issues regarding integration between the various government agencies, have led to calls for improvements to ensure that foodborne illness surveillance systems are providing the data needed to assist government agencies, industry, and other food safety stakeholders in their risk management activities.

The Food and Drug Administration's (FDA's) Food Safety Modernization Act (FSMA), the most sweeping reform of food safety laws in more than 70 years, provides FDA with new enforcement authority designed to achieve higher rates of compliance with prevention and risk-based food safety standards to better prevent contamination events as well as respond to and contain problems when they occur. Additionally, the law directs FDA to build an integrated national food safety system in partnership with state and local authorities who may need capacity building in investigation, surveillance, and/or monitoring the effectiveness of interventions. On January 4, 2011, FSMA authorized CDC to create a diverse Working Group of experts and stakeholders to provide routine and ongoing guidance to improve foodborne illness surveillance systems in the United States and to provide advice on the criteria for the designation of five Integrated Food Safety Centers of Excellence (CoEs). In response, the FSMA Surveillance Working Group (FSMA-SWG) of the Board of Scientific Counselors (BSC), Office of Infectious Diseases (OID), CDC, was created, with Dr. James Hadler of Yale University's School of Public Health as Chair. FSMA-SWG membership comprises a total of 21 persons representing the local, state, and federal government, academia, industry, and consumer groups (**Appendix 1**). According to FSMA legislation regarding improvement of foodborne illness surveillance systems, areas for discussion and provision of guidance are

- (A) the priority needs of regulatory agencies, the food industry, and consumers for information and analysis on foodborne illness and its causes;
- (B) opportunities to improve the effectiveness of initiatives at the Federal, State, and local levels, including coordination and integration of activities among Federal agencies, and between the Federal, State, and local levels of government;
- (C) improvement in the timeliness and depth of access by regulatory and health agencies, the food industry, academic researchers, and consumers to foodborne illness aggregated, de-identified

surveillance data collected by government agencies at all levels, including data compiled by the Centers for Disease Control and Prevention;

(D) key barriers at Federal, State, and local levels to improving foodborne illness surveillance and the utility of such surveillance for preventing foodborne illness;

(E) the capabilities needed for establishing automatic electronic searches of surveillance data; and

(F) specific actions to reduce barriers to improvement, implement the Working Group's recommendations, and achieve the purposes of this section, with measurable objectives and timelines, and identification of resource and staffing needs.

This annual report, which FSMA requires, highlights the FSMA-SWG's activities for FY 2012 and summarizes priority areas for focus in the coming years.

WORKING GROUP ACTIVITIES – FY 2012

In the 2012 fiscal year, the FSMA-SWG met twice at CDC to provide guidance on selection criteria for the FSMA-mandated Integrated Food Safety CoEs; review and provide feedback on the new Interagency Food Safety Analytics Collaboration (IFSAC) strategic plan and several other CDC FSMA-related initiatives to enhance foodborne surveillance; and identify foodborne illness surveillance priority areas to focus the Working Group's attention in the coming years.

Selection Criteria for Integrated Food Safety Centers of Excellence

FSMA tasks these centers to

- Serve as a resource for frontline public health professionals;
- Analyze surveillance systems for timeliness and effectiveness;
- Provide laboratory, epidemiologic, and environmental continuing education training for state and local personnel;
- Provide academic epidemiology and food safety training support for future workforce development;
- Strengthen capacity in surveillance and environmental assessment information systems; and
- Improve communication and prevention about foodborne illness through program evaluation and outreach.

In light of these requirements, the Working Group provided guidance to CDC regarding potential selection criteria for the CoEs. Members emphasized that for the CoEs to be successful and capable of meeting FSMA requirements, they would need to demonstrate the ability to

- Provide strategic coordination and leadership beyond state borders;
- Network across the CoEs;
- Engage and collaborate with a variety of food safety stakeholders;
- Utilize and link existing resources and food safety surveillance systems;
- Identify and address gaps in the food safety system; and
- Support neighboring states and ensure geographic/regional coverage.

The Working Group also noted that to successfully complete activities designed to build a stronger food safety system in the areas of surveillance and response, each CoE would need to provide strong leadership in convening stakeholders and building consensus to support potential solutions, and use both innovation and experience to generate creative solutions to address gaps in the system.

The Working Group identified specific capabilities needed to ensure that the CoEs are able to meet FSMA requirements. For example, project management skills are needed to ensure that performance goals are met and funds allocated appropriately. Strong leadership is needed to ensure that linkages are made and partnerships strengthened across food safety-related disciplines. Robust technical knowledge and experience are needed, including in the areas of information systems and technology, to provide scientific guidance and training support as the CoEs are implemented. Strong relationships between state health departments and academic institutions can help in this area, as well. Finally, performance measurements will be important to monitor progress of the CoEs and build on successes. A graphic description of the capabilities may be found in **Figure 1** and further details in **Appendix 2**.

Figure 1: Desired CoE capabilities based on the commentary of the BSC FSMA-SWG



*Cross-disciplinary training to include laboratory, epidemiology, environmental health, and agriculture components

Interagency Food Safety Analytics Collaboration

IFSAC was established to use data and expertise of CDC, FDA, and the U.S. Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) to connect or “attribute” foodborne illness to specific foods and settings. This type of analysis provides information to identify high-risk foods. IFSAC has invested in attribution analyses to inform risk-based decision-making, estimate the benefits of intervention, evaluate the impact of interventions, and provide regulatory agencies a means of assessing policy effectiveness. The process of attributing illnesses to specific foods can be quite complex, involving a large number of pathogens and commodities, as well as complex statistical analysis.

The FSMA-SWG was tasked to review the IFSAC strategic and operational plan for attribution analyses and provide suggestions to CDC, FDA, and FSIS to improve the plan. The Working Group commented on the importance of the work of IFSAC to overall food safety efforts and the progress already made. The Working Group noted a need to simplify the information in the IFSAC plan so it could be understood by a variety of stakeholders, including the public. The estimates need to be generated and shared rapidly for use by policymakers and partners. Additional individual comments were submitted directly to the authors to clarify and improve content of the plan.

Improving Foodborne Illness Surveillance Systems: Focus Areas for Future Discussion

To address ways to improve foodborne illness surveillance systems, the Working Group participants discussed gaps and needs in the areas of primary CDC responsibility covered by the FSMA legislation: *governmental coordination and integration, evaluating and improving surveillance systems, and external stakeholder collaboration*. For reference, CDC shared highlights of selected areas where it has made progress in addressing FSMA requirements during the past year (**Appendices 3-5¹⁻¹⁰**).

After listing a number of surveillance areas that needed to be addressed based on the gaps, the Working Group selected a smaller number of priority focus areas for more in-depth discussion upon which to base future recommendations during the coming 1-3 years, as outlined below.

Governmental Coordination and Integration of Foodborne Surveillance

CDC and the regulatory agencies (FDA and FSIS) play complementary roles in the federal food safety effort. FDA and FSIS are responsible for regulatory oversight of food production, processing, and distribution, whereas CDC leads federal efforts to investigate and gather data on foodborne illnesses and outbreaks as the basis for science-based prevention and control policies and to monitor the effectiveness of these policies in reducing foodborne illnesses. FSMA recognizes the critical role of state, tribal, territorial, and local health and agriculture departments in all aspects of food safety. CDC has a key function in building the epidemiology, laboratory, and environmental health capacity of these jurisdictions to support foodborne disease surveillance and outbreak response at the state and local levels.

Over the years, Presidential working groups, Congressional members, consumer groups and food safety advocates, academic and industry partners, and others have emphasized the need for improved coordination, integration, and communication among all food agencies, including CDC.

While the Working Group recognized that considerable progress has been made in this area compared with past years, there are still areas that could use further improvement and will be the focus of future discussions, including

- Interagency linkages and coordination

While existing surveillance systems are managed by well-qualified staff and take advantage of current information technology, links between the systems are sometimes weak, making it difficult to fully utilize surveillance data and coordinate activities across agencies. There is thus a need for better interagency linkages and definition of roles to put priorities into action and make the most efficient use of existing resources.

The Working Group noted a need for better integration of existing foodborne illness surveillance programs and related information systems. This should be facilitated by better definition of roles, responsibilities, and expectations for these surveillance systems at all levels of public health practice (local, state, and federal). The 2010 Institute of Medicine and National Research Council Enhancing Food Safety report provides a useful perspective in this regard.¹¹

The Working Group felt that other priorities needing coordination included attribution, antimicrobial resistance, and the need to address local and state capacity building. These priorities should be considered in collaboration with existing interagency workgroups such as IFSAC, the National Antimicrobial Resistance Monitoring System (NARMS), FDA's National Integrated Food Safety System, and the FDA FSMA State and Local Capacity Working Group.

- Performance measures

Evaluating the timeliness and effectiveness of foodborne disease surveillance is a critical factor in improving the U.S. capacity to control foodborne disease. To support this effort, CDC is enhancing metrics at the state and local sites funded by the Epidemiology and Laboratory Capacity for Infectious Diseases Cooperative Agreement (ELC) and working with the Council to Improve Foodborne Outbreak Response (CIFOR) to develop performance measures for its *Guidelines* metrics for states to use in their outbreak investigations.

The Working Group strongly endorsed the use of meaningful foodborne illness surveillance metrics (performance measures) at the local, state, and federal levels to show progress in reducing foodborne illness and encourage programmatic accountability. They also noted that these metrics will help quantify the impact of national food safety efforts. The Working Group also emphasized the importance of metrics to quantify the impact of other foodborne surveillance programs, policies, and regulatory changes and to track progress and improvements.

- Factors contributing to foodborne illness

Contributing factors which lead to foodborne illness include contamination during production or processing, cross-contamination during preparation, inadequate cooking or cooling, secondary contamination by infected food workers, etc. While local and state health and agriculture department officials often capture some of this information during outbreak investigations, it is often incomplete and may not be used, evaluated, and reported optimally.

The Working Group noted the need to standardize outbreak information on suspect foods reported from the states so that it can be linked more rapidly with information needed to trace food back to the source. More complete collection and analysis of information would also facilitate identifying targeted prevention policies for incorporation into process control plans, industry guidance and best practices, and food safety education messages. Additionally, even when the food that caused a foodborne outbreak is identified, specific details on the food are often not captured, such as whether the food was imported or produced domestically. Such details tie into the implementation of FSMA, which gives FDA tools to strengthen its risk-based oversight of the food supply chain.

Evaluating and Improving Surveillance Systems

The Food Safety Modernization Act includes a number of provisions to improve the quality of epidemiologic, laboratory, and environmental foodborne illness data that merit additional attention.

- Laboratory improvements and challenges

Over the past 20 years, PulseNet, a database collecting standardized DNA fingerprinting information on each bacterial foodborne disease isolate and used by state health departments and others to detect foodborne outbreaks, has proven a very powerful tool in improving food safety. Clusters of bacteria with common DNA fingerprints point to a possible outbreak. States submitted more than 70,000 DNA “fingerprints” to PulseNet in 2011, and the database tracked nearly half a million isolates of bacteria from food, the environment, and human foodborne illness. However, the use of culture-independent diagnostic methods threatens the viability of PulseNet and our national foodborne disease surveillance system because these systems are based on bacterial isolates, which are obtained through traditional culture methods, but not through use of the new culture-independent methods. Alternate laboratory methods to capture the detailed information including fingerprints needed for public health surveillance are critically needed to replace culture-based systems.

The Working Group saw the importance of coordination among CDC laboratories and local, state, and federal laboratories to find interim solutions to retain cultures for the current DNA fingerprinting method, pulsed-field gel electrophoresis (PFGE), and to begin development of new methods to replace PFGE that are compatible with new diagnostic tests entering the marketplace. The new methods will require utilization of emerging

technologies (e.g., amplified target sequencing, metagenomics, single-cell sequencing) that promise great improvements in preventing, detecting, and controlling foodborne illness outbreaks. A genomics and bioinformatics infrastructure needs to be built at the federal and state levels to accommodate standardized next-generation PulseNet tools. Since food safety is a global problem, a successful solution will require coordination and synchronization of state, federal, and international development efforts.

- Economic analyses to document impact

In a time of fiscal restraint, competing priorities, and reduced governmental support, it is crucial to review which programs are most successful and deliver the most benefits at the lowest cost. This information then needs to be communicated to policymakers who allocate resources.

The Working Group recommended that CDC consider the potential development of a business/economic case for national foodborne illness surveillance programs based on cost-effectiveness and public health impact studies that assess and communicate the effectiveness and value of public health foodborne illness surveillance systems.

- State and local capacity

A long-standing goal of CDC and national public health organizations has been to build state and local surveillance capacity for detecting and preventing foodborne illness. The vast majority of foodborne outbreaks occur within state and local jurisdictions, and are appropriately investigated by state and local officials. Although large multistate outbreaks often capture the most visibility and are critical to identifying systemic gaps on food safety, they contribute only 2% of reported outbreaks and are also investigated by the coordinated effort of state and local officials.

The Working Group noted that current surveillance systems, networks (e.g., FoodNet [Foodborne Diseases Active Surveillance Network], FoodCORE [Foodborne Diseases Centers for Outbreak Response Enhancement], PulseNet, FDA Rapid Response Teams), and associated skilled personnel at the state and local levels should be strengthened and expanded. The newly designated Integrated Food Safety Centers of Excellence should be utilized to help train current and future public health workers in best practices and evaluation methods for foodborne disease surveillance. CDC should continue to work with local, state, and federal partners to align and integrate foodborne disease surveillance efforts with other food emergency response capacity development efforts (e.g., FDA Rapid Response Team Program).

- Attribution

Determining the source of illnesses provides a model to assess the effectiveness of food safety interventions, including new regulations. For example, it is a critical component of the HHS High Priority Performance Goal to assess the effect of the 2010 FDA Egg Safety Rule in decreasing the incidence of a type of *Salmonella*, called *Salmonella* Enteritidis. This type of *Salmonella* has historically been associated with contaminated eggs, but can also come from poultry meat and other sources. Thus determining the

proportion of illnesses from contaminated eggs is critical to measuring the effectiveness of the Egg Safety Rule. This type of analysis may also be used to measure the effectiveness of other regulations implemented as a result of the Food Safety Modernization Act, such as the Produce Rule.

CDC, FDA, and FSIS are continuing joint work on IFSAC to address complex analytical issues that require cross-agency cooperation and agreement. CDC and its local, state, and federal partners have also identified new food vehicles during foodborne outbreak investigations. Information on risks from these foods, which have never before been tied to outbreaks or illnesses, provide a feedback loop to industry and regulators to allow creation of better safety standards. Since 2006, CDC and its partners have identified 15 new foods that have become contaminated with germs and made people sick (**Appendix 5**).

While the Working Group had already spent time discussing and reviewing the IFSAC strategic plan, it recognized the importance of attributing foodborne illnesses to specific food sources and of devoting more time to evaluating this CDC FSMA requirement.

Enhancing Communication and Collaboration among Partners and External Stakeholders

CDC's public and private partners and stakeholders depend on timely and complete national foodborne illness surveillance data to determine risks, to establish preventive policies, and to develop educational messages on the steps that can be taken to reduce illness. It was noted that considerable progress had been made in improving timeliness and availability of such data over the past year. For example, CDC worked collaboratively with state and local partners in all states to collect, analyze, and post multiple years of surveillance reports for over 20 key pathogens that had previously been backlogged. CDC also launched the newest online version of the Foodborne Outbreak Online Database (FOOD), a CDC-maintained database of foodborne outbreaks with data collected through state and local health department reporting to FDOSS (Foodborne Disease Outbreak Surveillance System). Data placed in the FOOD tool is used by regulators, industry, consumer groups, and academia to search and download data on foodborne disease outbreaks reported to CDC from 1998 through 2010. The FOOD tool web site has received over 5,000 page views per month since its launch.

While significant improvements were noted, the Working Group mentioned that systems integration, measurement, and financial support need to be tied together with strong communications among all agencies and groups. They suggested a need to strengthen communications with external stakeholders and share foodborne illness surveillance data, especially during outbreaks. They said communications efforts should initially focus on developing flexible, pre-packaged, and user-friendly communication materials for legislative groups, stakeholder groups, and public audiences.

The Working Group also discussed the critical need for higher quality, timely, detailed data that can be quickly disseminated to the public. Members specifically noted the need for faster and better data sharing practices during outbreaks and the need for more timely analysis and sharing of attribution data. They suggested that better integration of existing surveillance systems could result in more complete data that could address some of the existing data gaps and reduce the time it takes to share information.

Specific areas to devote attention at future meetings included

- Addressing barriers to data sharing—Further addressing legal, cultural, and clearance barriers that prevent the timely sharing of foodborne illness data with external partners;
- Providing more timely and detailed data—Improving the timeliness and level of detail of data available to the public and other food safety stakeholders who wish to do their own, independent analyses, including attribution data and data on imported and organic foods; and
- Rapid communication during outbreaks—Strengthening plans for rapid communication and information sharing with external partners during emergencies, including outbreaks.

The Working Group concluded by stating that ongoing discussion, performance monitoring, and assessments of data collection, analysis, and communication enhancements will drive future recommendations, priorities, and action items.

RESOURCES

The Working Group acknowledged the need for additional resources to build on existing surveillance systems, better integrate the systems, and fill existing data gaps. There is also a critical need to build capacity at the state and local levels that have experienced severe losses (reduction of 52,000 personnel from 2008-2011), including experienced foodborne epidemiology, laboratory, and environmental personnel. The Working Group continues to be concerned about lack of attention to adequate funding for programmatic efforts uniquely directed by CDC and implemented by state and local health departments. Specifically, none of the surveillance requirements authorized by FSMA have received corresponding additional appropriations to allow for adequate implementation.

NEXT STEPS

To provide additional guidance on these and other emerging priority areas, the FSMA-SWG will devote time at its future meetings to explore each priority and associated recommendations in more depth. These reviews will include expert presentations on current status and progress of each priority followed by a discussion on what enhancements could be made to improve foodborne illness surveillance. Examples of some priority themes to be covered in the next year include

- How to prepare and respond to implementation of culture-independent diagnostics and their threat to eliminate the detection of outbreaks using PulseNet DNA fingerprinting;
- How to improve surveillance and analysis of antimicrobial resistance in foodborne disease pathogens;
- How to adequately collect and analyze surveillance data to attribute illnesses to specific food items;
- How to improve foodborne disease surveillance capacity and performance measures at the state and local levels; and
- How to enhance surveillance for emerging pathogens such as norovirus, toxoplasmosis, cryptosporidiosis, vibrio, and newly identified pathogens.

In conclusion, the Working Group has had a successful and productive year, but believes that more can be done to improve the quality of foodborne illness surveillance data that are critical to the formulation of science-based prevention policies. The Working Group will convene two times in FY 2013 to further address some of the priority focus areas.

Working Group Members

Meetings in November 2011 and April 2012

BSC Representative Members:

- Chair: James Hadler, MD, MPH – Associate Professor, Yale University
- Matthew Boulton, MD, MPH – Associate Professor, University of Michigan*
- Harry Chen, MD – Commissioner, Vermont Department of Health†

Federal Partner Members:

- Dale Morse, MD, MS – Centers for Disease Control and Prevention
- Jeffrey Farrar, DVM, MPH, PhD – Food and Drug Administration
- David Goldman, MD, MPH – United States Department of Agriculture Food Safety and Inspection Service

Other Working Group Members:

- Catherine Adams Hutt, PhD, RD – National Restaurant Association
- Robyn Atkinson, PhD, HCLD – Association of Public Health Laboratories
- Caroline Smith DeWaal, JD – Center for Science in the Public Interest
- Thomas S. Dunlop, MPH, REHS – National Environmental Health Association
- Sandra Eskin, JD – The Pew Charitable Trust
- Russell S. Flowers, Jr., PhD – Mérieux NutriSciences Corporation
- Craig Hedberg, MS, PhD – Professor, University of Minnesota
- Leeann Jaykus, PhD – Professor, North Carolina State University
- Timothy Jones, MD – Council of State and Territorial Epidemiologists
- Heidi Kassenborg, DVM, MPH – Association of Food and Drug Officials
- Barbara Kowalczyk, PhD – Center for Foodborne Illness Research and Prevention
- Mary Currier Mallette, MD, MPH – Association of State and Territorial Health Officials
- John Glenn Morris, Jr., MD, MPH&TM – Professor, University of Florida
- Joseph Russell, MPH, RS – National Association of County and City Health Officials
- John Tilden, Jr., MS, DVM, MPH – National Association of State Departments of Agriculture
- Joan Menke-Schaenzer – ConAgra Foods, Inc.

* Past member of group; attended only November 2011 meeting

† Replaced Matthew Boulton as member of group; attended only April 2012 meeting

Appendix 2: Centers of Excellence Duties and Capabilities

	Project Management and Coordination	Leadership, Coordination, and Mentoring	Information Systems	Performance Measurement	Training	Robust Technical Knowledge and Experience	Cross-disciplinary Partnerships
Provide a designated full-time project director and/or coordinator	✓						
Demonstrate subject matter expertise in foodborne illness surveillance and participation in national foodborne illness surveillance systems		✓				✓	
Demonstrate capacity for grants administration/management	✓						
Coordinate and build cross-disciplinary projects and linkages	✓	✓					✓
Demonstrate ability to collaborate with state and local health departments	✓						✓
Establish relationship with at least one academic institution	✓						✓
Demonstrate working relationships and effective cross-communications with stakeholders including industry, non-governmental organizations, and consumer groups	✓						✓
Establish regional leadership and capability for coverage	✓	✓	✓			✓	✓
Demonstrate ability to implement/manage effective onsite and web-based public health training	✓				✓	✓	

Appendix 2: Centers of Excellence Duties and Capabilities (continued)

	Project Management and Coordination	Leadership, Coordination, and Mentoring	Information Systems	Performance Measurement	Training	Robust Technical Knowledge and Experience	Cross-disciplinary Partnerships
Demonstrate experience with performance metrics and using established metrics to evaluate programs, including process improvement for foodborne disease surveillance systems				✓			
Create the ability to award academic degrees and professional certifications with financial support for student mentorship and applied opportunities	✓				✓	✓	
Provide information system development, plans for IT usage, and training and staffing in informatics	✓		✓		✓	✓	
Demonstrate experience in systems evaluation, consumer behavioral research, research in risk communications, prevention effectiveness, and capacity for public health economics	✓					✓	

The Food Safety Modernization Act (FSMA) recognizes that robust foodborne illness surveillance data are needed to inform prevention efforts. FSMA directly links surveillance with prevention and highlights the need for stronger partnerships. Relying on CDC's expertise in this area, FSMA directs the agency to improve coordination and data sharing with public health partners and the public; expand and integrate national surveillance systems to increase state and local participation; enhance laboratory and epidemiological methods for agent identification, outbreak detection, and investigation; and improve the attribution of specific illnesses to specific foods. All are critical components of surveillance.

CDC is supporting the implementation of FSMA and has provided a summary of highlighted accomplishments for FY 2011 and early FY 2012 to supplement this working group report. Despite reduced resources at the local, state, and federal levels, in FY 2011 and early FY 2012, CDC met ongoing requirements and supported existing infrastructure for laboratory, surveillance, and response activities and allocated \$1M to initiate activities of the five Integrated Food Safety Centers of Excellence. Most of these activities build upon existing infrastructure and labor capacity, but some are new and exclusively address CDC surveillance responsibilities under FSMA.

Improving Coordination and Data Sharing with Public Health Partners and the Public

Food safety is a shared enterprise among local, state, and federal public health partners. FSMA recognizes that strong coordination among partners is essential to the rapid detection of food safety problems, determine where those problems are occurring, and identify and use effective strategies to prevent foodborne illness. To that end, CDC is working to strengthen coordination and data sharing across government agencies and with external partners. Selected examples are described below.

Stronger Coordination

CDC supported state and local health agencies through monitoring 15-40 clusters of potential foodborne illness per week, resulting in approximately 30 major multistate outbreak investigations—11 that directly led to recalls in 2011 (**Appendix 4**). Additionally, CDC is developing internal strategic priorities that will include outside entities in the future, as well as enhancing metrics in the Epidemiology and Laboratory Capacity for Infectious Diseases Cooperative Agreement (ELC) sites and with the Council to Improve Foodborne Outbreak Response (CIFOR) to develop performance measures for their *Guidelines* metrics for states to use in their outbreak investigations. The council serves many professional organizations focused on state and local health department activities.

In addition to establishing the FSMA Surveillance Working Group, CDC established an internal CDC FSMA Surveillance Committee, comprising experts throughout CDC, to better integrate and improve existing foodborne illness surveillance systems.

CDC has also worked with FDA and USDA to improve interagency coordination. Specifically, CDC entered into an agreement with USDA's Food Safety and Inspection Service (FSIS) to share PulseNet data in real time in support of USDA's Public Health Information System project aimed at identifying food processing facilities at risk for contamination events. CDC is also working closely

with FDA to support its FSMA implementation efforts by providing expert guidance to a number of FDA work groups, including produce, food defense, and state and local capacity.

The following shows a concrete example of these agencies' improved coordination efforts:

- In response to a recommendation by the Conference for Food Protection, CDC, FDA, USDA, and state and local food safety programs worked together to develop a recommendation that the U.S. FDA Food Code add nontyphoidal *Salmonella* (NTS) to the list of reportable illnesses for action by those in charge of food-service establishments.
- This recommendation was based on evidence that food workers are the source of these foodborne outbreaks, that food workers work while ill,² and that inadequate hand hygiene practices^{3,4} lead to the transmission of this illness.
- The recommendation was approved in 2012 as a result of these efforts, and will be fully published in the 2013 Food Code.

Data Sharing

CDC published the first comprehensive estimates of the burden of foodborne illness in more than a decade to guide FSMA's implementation. These estimates were derived using the latest analytical methods, integrating data from over 20 surveillance systems. Complex messages about these data—communicated to the media, policymakers, regulators, and the public— included the fact that 1 in 6 Americans (or 48 million people) become sick and 3,000 die each year because of a food-related illness.¹ In 2011, CDC also released the 15th annual “Report Card” for food safety, using data collected through 2010 via the Foodborne Diseases Active Surveillance Network (FoodNet), which policymakers, regulatory partners, and industry count on as a performance indicator for nine foodborne pathogens. These pathogens range from common and costly germs, such as *Salmonella* to one of the most deadly, *Listeria*. Soon thereafter in 2012, CDC performed a preliminary release of 2011 fiscal year data for the same nine pathogens. In 2011, CDC also developed estimates of the U.S. norovirus mortality burden, identified high-risk groups,^{5,6} and determined an increasing rate of hospital discharges due to norovirus.⁷

CDC published more than 100 peer-reviewed articles in journals and book chapters on foodborne illness to make the most recent scientific findings available to food safety stakeholders. CDC has also supported many other efforts to communicate the dangers of multistate foodborne outbreaks, pathogens, and products, including raw milk. These efforts have resulted in more than 5 million page views on CDC websites for food safety. CDC has also increased the frequency of web updates during outbreak investigations, so that consumers and partners have up-to-date information when there is an ongoing outbreak. CDC also has continued to support the Food Safe Families campaign, which the Ad Council and FSIS, in partnership with FDA and CDC, developed and launched. The campaign aims to raise awareness about the risks of foodborne illness and educate consumers, especially parents, about actions to reduce their personal risk.

CDC worked collaboratively with state and local partners in all states to collect, analyze, and post over 20 surveillance reports from data collected and reported by state and local health departments from 1997-2010 for key pathogens. In coordination with all states, CDC also launched the newest online version of the Foodborne Outbreak Online Database (FOOD), a CDC-maintained database of

foodborne outbreaks with data collected through state and local health department reporting to FDOSS (Foodborne Disease Outbreak Surveillance System). Data placed in the FOOD tool from FDOSS is used by regulators, industry, consumer groups, and academia to search and download data on foodborne disease outbreaks reported to CDC from 1998 through 2010. The FOOD tool web site has received over 5,000 page views per month since its launch.

Increasing State and Local Participation in National Surveillance Networks through Expansion and Integration

Local and state health departments are the foundation of food safety efforts, because they investigate outbreaks, conduct disease surveillance, and implement local control measures. FSMA recognizes the critical role of local, territorial, tribal, and state agencies in a national food safety system with provisions to coordinate, integrate, and enhance surveillance and outbreak response activities at all levels. Therefore, CDC is using existing resources to enhance and integrate these critical national surveillance, outbreak detection, and response networks by providing funding, tools and training, and strategic leadership. These enhancements are expected to improve the quality of data obtained, which are needed to quickly identify the source of outbreaks and inform prevention efforts, and to ensure that data are analyzed and shared quickly to help in rapid response to food safety gaps. Specifically, CDC provided approximately \$14 million in FY 2011 funding to local and state public health departments through the ELC program and the Emerging Infections Program (EIP) to support critical foodborne illness surveillance efforts. This funding was critical to maintain core infectious disease capacity needed to track, detect, investigate, and respond to emerging foodborne disease threats. CDC also equipped local and state public health laboratories with the latest technology to track Shiga toxin-producing *E. coli* in clinical specimens and food samples.

CDC also continued to support critical training activities needed to ensure that the United States has a

trained, prepared, and capable public health workforce. Since 2003, CDC has provided training to state and local public health officials in foodborne illness outbreak detection and response through Epi-Ready Team Training managed by the National Environmental Health Association (NEHA). To date, more than 2,700 professionals from all 50 states have been trained through the 2-day Epi-Ready Course (see map to the left).⁸



CDC-funded course in red

Non-CDC-funded course in blue

Specialists Network) program, a group of eight sites that work together to understand the environmental causes of foodborne and waterborne disease and improve the practice of environmental health. EHS-Net participants include the California Department of Public Health/Public Health Foundation Enterprises; Minnesota State Department of Health; New York State Department of Health; New York City Department of Health & Mental Hygiene/Fund for Public Health; Rhode Island Department of

Health; Tennessee State Department of Health; Cerro Gordo County Department of Public Health, Iowa; and County of San Mateo Health Services Agency, California. EHS-Net has completed 13 food safety projects focused on understanding the environmental causes of foodborne illness and outbreaks and/or on improving environmental public health practice. Seven additional projects are currently in progress.

CDC also offered an annual CaliciNet⁹ workshop to train state and U.S. military laboratorians on detection and typing of norovirus and expanded the number of CaliciNet-certified states to 25. Through the Council of State and Territorial Epidemiologists, CDC funded 19 sites (14 states, 2 counties, and 3 cities) to conduct training on the use of the CIFOR toolkit, which provides guidelines for the investigation of foodborne outbreaks. More than 750 staff participated in 2011.

Since hepatitis A vaccine was licensed in 1995 and adopted for widespread use in the United States, there has been a greater than tenfold decrease in incidence and mortality, with only 1398 cases reported in 2011 (the lowest ever recorded).¹⁰ While no large hepatitis A foodborne outbreaks have occurred since 2005, there were six episodes in the past 12 months of restaurant patrons receiving preventive vaccination after potential exposure to a hepatitis A-infected food worker.

Diagnosis of parasitic infections, some of them foodborne, is conducted through CDC's DPDx, which is tied to ELC funding and acts as a training activity for local and health department staff. CDC websites also shared expertise on 40 food-related pathogens, comprising bacterial, parasitic, viral, and fungal pathogens, including some with antimicrobial resistance.

Enhancing Laboratory and Epidemiologic Methods for Agent Identification, Outbreak Detection, and Investigation

Consistent with FSMA, CDC is striving to strengthen foodborne illness surveillance with innovative epidemiologic and laboratory tools and methods. Development and implementation of these new tools and methods can result in better and faster outbreak detection. To support this objective through the PulseNet program, CDC tracked foodborne infections to identify bacterial pathogens causing illness and used DNA "fingerprinting" to identify clusters of illnesses faster. States submitted more than 70,000 DNA "fingerprints" to spot disease patterns in 2011, and CDC's system tracked nearly half a million isolates of bacteria from food, the environment, and human foodborne illness. CDC has also coordinated the first-ever PulseNet multiple-locus variable-number tandem repeat analysis multi-site validation study for *Listeria monocytogenes*. This study was an in-depth genetic analysis of this harmful microbe, and the information from this study can be used in the future to compare new laboratory specimens to those already catalogued. This effort is one of several significant network advances to boost preparedness for future foodborne disease emergencies. CDC also assisted different regions of the United States in building their immunomagnetic separation (IMS) testing ability through PulseNet area laboratories. IMS is a laboratory tool used to glean bacterial cells or DNA from patient samples or food, which PulseNet can analyze.

CDC has also expanded the Foodborne Diseases Centers for Outbreak Response Enhancement (FoodCORE) program, a group of seven sites that develop new and better methods to detect, investigate, respond to, and control multistate outbreaks of foodborne diseases and speed up the treatment of patients with possible food-related illnesses.

CDC continues to provide emergency response capacity for states through requests for assistance for epidemiologic and outbreak support during large-scale or unusual outbreaks.

Improving the Attribution of Specific Illnesses to Specific Foods

FSMA recognizes that to best target prevention efforts, including rulemaking and industry guidance, it is critical to understand which foods are causing illness and where in the farm-to-fork continuum contamination is occurring. To this end, CDC and partners are working to obtain better and more robust data on foodborne illness sources, referred to as source attribution. CDC and partner agencies have used surveillance data to advance the attribution of illnesses to food commodities to provide critical information to guide food safety policy. Specifically, CDC is partnering with FDA on the HHS High Priority Performance Goal to reduce the number of *Salmonella* illnesses attributed to eggs. CDC's FoodNet program is providing quarterly incidence data to track progress and developing methods to attribute illness to eggs.

CDC, FDA, and USDA-FSIS are continuing joint work on the Interagency Food Safety Analytics Collaboration (IFSAC) to address complex analytical issues that require cross-agency cooperation and agreement.

CDC and its partners also identified new food vehicles during foodborne outbreak investigations. Information on risks from these foods, which have never before been tied to outbreaks or illnesses, provide a feedback loop to industry and regulators to allow creation of better safety standards. For example, since 2006, CDC has identified 15 new foods that have become contaminated with germs and made people sick—including Turkish pine nuts that made 43 people from five states sick with *Salmonella* Enteritidis in 2011 (**Appendices 4 and 5**).

Integrated Food Safety Centers of Excellence

FSMA directs CDC to designate five Integrated Food Safety Centers of Excellence housed at state health departments to identify and implement best practices in foodborne diseases surveillance and to serve as a resource for public health professionals at state, local, and regional levels. Following a competitive process, CDC designated five Integrated Food Safety Centers of Excellence in Minnesota, Florida, Colorado, Oregon, and Tennessee that will initiate activities this fall.

Appendix 4: 2011 Recalls

Pathogen	Distribution	Vehicle/Recall
<i>Salmonella</i> 4,[5],12:i:-	140 illnesses reported from 26 states	Alfalfa sprouts/sprouts
<i>E. coli</i> O157:H7	8 illnesses reported from 3 states	Hazelnuts/shelled hazelnuts and mixed nuts containing hazelnuts
<i>Salmonella</i> Panama	20 illnesses reported from 10 states	Cantaloupe
<i>E. coli</i> O157:H7	14 illnesses reported from 5 states	Lebanon bologna
Multidrug-resistant <i>Salmonella</i> Hadar	12 illnesses reported from 10 states	Frozen, raw turkey burger
<i>Salmonella</i> Enteritidis	25 illnesses reported from 5 states	Alfalfa and spicy sprouts/sprouts
<i>Salmonella</i> Agona	106 illnesses reported from 25 states	Papaya/papaya from Mexico
<i>Salmonella</i> Heidelberg	136 illnesses reported from 34 states	Ground turkey
<i>Salmonella</i> Enteritidis	43 illnesses reported from 5 states	Turkish pine nuts
<i>Salmonella</i> Heidelberg	179 illnesses reported from 6 states	Kosher broiled chicken livers/broiled chicken liver products
Multidrug-resistant <i>Salmonella</i> Typhimurium	16 illnesses reported from 7 states	Ground beef

Appendix 5: New Food Vehicles in the United States Identified as Risk Factors

Food	Year
Bagged spinach	2006
Carrot juice	2006
Peanut butter	2007
Broccoli powder on a snack food	2007
Dog food	2007
Pot pies	2007
Canned chili sauce	2007
Hot peppers	2008
Raw cookie dough	2009
White pepper	2010
Whole, raw papaya	2011
Pine nuts	2011
Hazelnuts	2011
Kosher broiled chicken livers	2011
Raw tuna scrape	2012

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