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

2016

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# BSC/OID FSMA Surveillance Working Group 2016 Report to HHS Secretary

## SUMMARY

The Food Safety Modernization Act of 2010 (FSMA), signed into law on January 4, 2011, authorized the Centers for Disease Control and Prevention (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. Accordingly, in fiscal year (FY) 2012, CDC established a FSMA Surveillance Working Group (FSMA-SWG) under the Board of Scientific Counselors, Office of Infectious Diseases (BSC/OID), a federal advisory committee. This fifth annual report summarizes the FSMA-SWG's activities and recommendations during FY 2016.

The FSMA-SWG held two 2-day meetings at CDC in FY 2016, convening in December 2015 and again in May 2016 to review, respond to specific questions on, and provide guidance on foodborne illness and outbreak surveillance projects in the following areas:

- Improving governmental coordination, integration, and collaboration

- Evaluating and improving surveillance systems

- Enhancing external stakeholder collaboration and communication

The December 2015 Working Group meeting focused on a review and discussion of how industry could be better engaged in foodborne surveillance and how foodborne illness attribution activities could be further improved. Specific guidance was provided on how to enhance foodborne illness and outbreak surveillance via improvements in

- Engaging industry in enhancing foodborne illness surveillance and outbreak response activities. Specific topics reviewed included 1) the food industry's role in preventing microbial illness in the United States; 2) types of industry data available to enhance surveillance and the associated challenges; and 3) perspectives from CDC, the U.S. Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) on engaging industry

- The Interagency Food Safety Analytics Collaboration (IFSAC) proposed strategic vision, direction, and project plans

The May 2016 meeting focused on a review and discussion of how tracebacks to sources of foodborne illnesses, activities and outcomes of the Integrated Food Safety Centers of Excellence (CoEs), and antimicrobial resistance surveillance activities could be further improved. Specific guidance was provided on how to improve foodborne illness and outbreak surveillance via

- Enhancing foodborne illness traceback surveillance and outbreak response activities, specifically regulatory tracebacks/traceforward conducted by FDA and USDA/FSIS, and informational tracebacks conducted by CDC and state and local health departments

- Improving activities of the integrated Food Safety CoEs

- Expanding foodborne antimicrobial resistance surveillance activities

In the course of its work, the Working Group continued to note the importance of national and state/local surveillance for foodborne illness and emphasized that the data gathered from this surveillance are critical for detecting outbreaks and identifying new vehicles for foodborne illness; monitoring the safety of the food supply; and directing risk-based food safety efforts conducted by CDC, FDA, and USDA. Further, the Working Group noted the loss of capacity at state and local levels and underscored the need for additional resources to build on and better integrate existing surveillance systems and fill existing and emerging data gaps. The Working Group is pleased that initial funding was appropriated in FY 2014–2016 to help move forward the important tasks authorized by FSMA, and hopes that the programmatic efforts uniquely directed by CDC and implemented by state and local health departments to meet FSMA's enhanced surveillance requirements can continue. Finally, the Working Group also stressed that conducting foodborne illness surveillance and outbreak investigations to determine root causes can lead to better hazard analysis and more targeted food safety controls at food production, processing, and distribution levels. The absence of this information undermines the effectiveness of preventive control programs mandated by FSMA for the food industry.

# BSC/OID FSMA Surveillance Working Group 2016 Report to HHS Secretary

## INTRODUCTION

This report describes the fiscal year (FY) 2016 activities of the Food Safety Modernization Act Surveillance Working Group (FSMA-SWG) of the Board of Scientific Counselors, Office of Infectious Diseases (BSC/OID), a federal advisory committee at the Centers for Disease Control and Prevention (CDC). This Working Group was established in FY 2012 under authorization by the Food Safety Modernization Act of 2010 (FSMA). Membership comprises 21 experts representing local, state, and federal governments; academia; industry; and consumer groups (Appendix 1).

During FY 2016, the Working Group reviewed activities, responded to specific questions, and provided guidance on how foodborne illness surveillance could be improved by enhancements in 1) engaging industry; 2) assessing attribution of foodborne illnesses to their root causes; 3) implementing foodborne illness traceback investigations; 4) utilizing the Integrated Food Safety Centers of Excellence (CoEs) to provide training for other states; and 5) expanding antimicrobial resistance surveillance and control activities. The Working Group also reviewed, discussed, and provided guidance on several other CDC FSMA-related projects to enhance foodborne surveillance. For reference, previous topics covered by the Working Group are summarized in Appendix 2 and a summary of selected CDC activities conducted in FY 2016 to address FSMA is included in Appendix 3.

## BACKGROUND

> *Each year, an estimated 48 million people in the United States (1 in 6 Americans) get sick, 128,000 are hospitalized, and 3,000 die from (largely) preventable foodborne diseases.[1,2]*

Foodborne illness is costly. According to a 2015 study,[3] 15 pathogens alone are estimated to cost $15.5 billion in the United States per year. This includes medical costs (doctor visits and hospitalizations), and productivity loss due to illness and time lost from work as well as premature death. Globally the World Health Organization estimated that each year as many as 600 million, or almost 1 in 10 people in the world, fall ill after consuming contaminated food. Of these, an estimated 420,000 people die, including 125,000 children under the age of 5 years.[4]

Public health surveillance is necessary for improving food safety. Timely detection and control of foodborne disease cases and outbreaks can directly reduce their public health impact; identify new food safety hazards; and enable investigators, regulators, and the food industry to learn more about ways to prevent these diseases.

Foodborne illnesses and outbreaks are reported and investigated at the local and state levels. These investigations help identify and prevent foodborne illness in local/state jurisdictions and provide essential information for national public health and food safety systems. CDC compiles information from local and state agencies and works with them to identify and link outbreak-associated illnesses, leading to identification of contaminated foods and management and control of outbreaks. Outbreak data are collected, analyzed, and shared with many stakeholders. Data from these outbreaks serve as a foundation for action by CDC, regulatory agencies, the food-producing industry, and others interested in improving food safety.

Foodborne disease and outbreak surveillance data aggregated by CDC are essential for many functions, including informing evidence-based policies, effectively assessing public health risk, and developing prevention messages for food safety improvements. These data are relied upon by other government regulatory agencies and analyzed by

the media, public health, and consumer organizations that provide food safety advice to consumers and policymakers. In January 2013, CDC released the first [comprehensive set of estimates](#) of the food categories responsible for foodborne illnesses acquired in the United States from 1998–2008.[5] Building on the 2011 estimates, which showed that about 48 million people (1 in 6) get sick each year from food, these newer estimates along with annual foodborne illness trend data from the Foodborne Diseases Active Surveillance Network ([FoodNet](#)) help regulators and industry identify the groups of foods most responsible for foodborne illness. These data also provide a historical baseline of estimates that can be further refined over time as more data and improved analytic methods become available.

Over the years, differences in data collection and reporting among states, along with issues regarding integration among various government agencies, have led to calls for improvements to ensure that foodborne illness surveillance systems provide the necessary data to assist government agencies, industry, and other food safety stakeholders in their risk-management activities.

## CDC and FSMA

The Food Safety Modernization Act of 2010 provided the U.S. Food and Drug Administration (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 directed FDA to build an integrated national food safety system in partnership with state and local authorities. Recognizing the critical role of foodborne illness surveillance data in informing prevention efforts and CDC's expertise in this area, FSMA also directed CDC to improve governmental coordination and integration, evaluate and improve foodborne illness surveillance systems, and enhance external stakeholder collaboration.

Signed into law 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 CoEs. In response, the FSMA-SWG of CDC's BSC/OID was created, with BSC/OID member Dr. James Hadler of Yale University's School of Public Health serving as Chair from November 2011 through December 2013 and BSC/OID member Dr. Harry Chen, Commissioner, Vermont Department of Health, serving as Chair from January 2014 to the present.

According to FSMA legislation regarding improvement of foodborne illness surveillance systems, areas for working group 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 to the Secretary, Department of Health and Human Services (required by FSMA) highlights the FSMA-SWG's activities and recommendations in FY 2016 and summarizes priority areas for focus in the coming year.

## WORKING GROUP ACTIVITIES—FY 2016

During its fifth year, the FSMA-SWG met twice at CDC to consider several recent and ongoing developments in foodborne illness surveillance that are key to maintaining and improving surveillance systems. The December 2015 meeting focused on two primary issues: 1) engaging industry in enhancing foodborne illness surveillance and outbreak response activities; and 2) a review of the Interagency Food Safety Analytics Collaboration (IFSAC) proposed plans. The May 2016 meeting focused on 1) enhancing foodborne illness traceback surveillance and outbreak response activities; 2) reviewing progress of the Integrated Food Safety CoEs, and 3) proposed activities and plans for foodborne antimicrobial resistance surveillance funding. These issues and working group discussions are summarized as follows. Previous annual reports and topics reviewed are listed in Appendix 2 and posted on the BSC FSMA SWG website.

## I.  Engaging Industry in Enhancing Foodborne Illness Surveillance and Outbreak Response Activities *(Discussed at the December 2015 FSMA-SWG Meeting)*

### Objective

Strengthen food safety through improved information sharing and collaboration with industry partners

### Background

**Improving Foodborne Illness Surveillance Systems: Food Industry's Current and Future Role in Preventing Microbial Illness**

Over the past 150 years, major changes in the way food is produced, processed, transported, retailed, and consumed have emerged as the world became increasingly urbanized and modernized. As advances in food science and technology coincided with developments in the basic sciences and public health, mortality from infectious diseases, in general, and enteric disease, in particular, dropped dramatically in the more economically developed countries. Nevertheless, morbidity due to foodborne illness remains quite common, and diarrheal diseases can still result in hospitalization and death as the emergence of Shiga-like toxin-producing *Escherichia coli* (STEC) in the 1980s and 1990s has demonstrated.

At a minimum, food producers and processors generally comply with regulatory food standards and recommended food safety practices; at a maximum, companies with strong commitment to food safety may exceed government requirements/recommendations for themselves and their suppliers. Companies may make substantial investments in microbiologic food safety through their company policies on environmental, ingredient, and end-product testing, auditing their suppliers; funding food safety research; and investigating root causes of problems identified (e.g., the U.S. Department of Agriculture [USDA], Food Safety and Inspection Services [FSIS] collects approximately 100,000 samples every year, but industry may conduct a

hundred times this amount of testing). To the extent that companies do not "compete on food safety" and openly share their best food safety practices with their competitors, the public's health is well served. However, these food safety policies and practices are often unrecognized or unknown to members of the public and to government officials. During this session, the workgroup explored current and future industry roles in preventing foodborne illness with a focus on industry sharing data to help guide public policy and improve emergency responses.

**CDC-Food Industry Safe Foods Forum**

In 2007, recognizing the critical role that the private sector plays in producing safe food, CDC approached the University of Georgia's (UGA) Center for Food Safety for help in identifying key food companies with which CDC could engage to better understand the food industry and potentially collaborate in areas of mutual interest. From this engagement, communications with industry have improved, in general, and in particular, industry sharing of expertise and information has been promising especially in the areas of environmental and food microbiology, food production, and ingredient sourcing and distribution.

**VoluntaryNet**

Standardized pulsed-field gel electrophoresis (PFGE) methods within the public health laboratory community (i.e., CDC's PulseNet) has revolutionized the detection and investigation of foodborne outbreaks. The public health community is detecting more multi-state outbreaks, and these investigations are identifying foods and ingredients not previously recognized as being linked to illness. However, industry has not generally had access to PulseNet information outside the context of an outbreak/recall. VoluntaryNet is a collaboration between CDC's PulseNet and UGA's Center for Food Safety, providing food industry partners with indirect access to current PulseNet data. This collaboration was formally launched in FY 2013. VoluntaryNet allows a food company to share results of "anonymous testing" of food, ingredients, and the environment with other food industry partners. A company can also share their data anonymously with CDC without fear of adverse marketplace, civil, or regulatory actions. The company can compare its test results with data from PulseNet without violating state or federal patient privacy laws. Potential benefits include

- Education: Helping the food industry and CDC identify emerging trends or pathogens of concern and better understand the public health significance of these pathogens in specific foods

- Primary Prevention: Enabling companies to perform better by conducting more thorough food safety risk assessments, regarding food products, pathogens of concern, and country of origin

- Outbreak Detection and Investigation: Enabling CDC and state health departments to improve hypothesis generation for questionnaires/case-control studies used in investigating illness clusters and outbreaks.

  o Identify and control emerging public health problems early, protect public health, and limit potential damage to industry

To date, relatively few samples have been submitted to VoluntaryNet, so some potential benefits remain unrealized. However, at least one company was able to test, hold, and later dispose of a product that tested positive for a PFGE pattern that matched human illness in the PulseNet database. In another instance, a company was able to determine if farm animal foodborne pathogens were potentially associated with its product and with human illness.

**Early Engagement during Outbreaks**

Advances in information and laboratory technology have led to increasing recognition of multi-state outbreaks. For a number of reasons, these investigations can be more challenging than the classic point-source investigation. In addition to being multi-jurisdictional, more and more of these outbreaks are becoming multidisciplinary, resulting in multi-agency investigations because of the different types of evidence required to link illness with a vehicle. In addition to epidemiologic (statistical) evidence, product/ingredient distribution and environmental or food microbiological evidence is being sought.

Food industry experts are important for many reasons, including their knowledge of food production practices, distribution patterns, consumer-purchasing information, and other relevant information, such as product testing and supply chain information. Consultation with industry experts early in an outbreak investigation can provide important clues to help focus the investigation on the foods or food ingredients that may be making people sick. Insights from industry can increase the speed and ensure greater accuracy of the investigation.

An initiative entitled "[Enhancing Outbreak Investigations:  Principles for Developing an Industries/Agencies Information-Sharing Process](#)" was developed to consult with food industry representatives early during multistate foodborne outbreaks. This process was created from a series of meetings through the [Collaborative Food Safety Forum](#) hosted by the [Pew Charitable Trusts](#) and the [Robert Wood Johnson Foundation](#), and involving CDC, FDA, USDA/FSIS, and industry and consumer groups. Participants include federal government public health and regulatory officials, food industry subject matter experts, and other experts, such as persons from industry associations or academia. Not every investigation requires the use of this process. If a decision is made to use the process, one or more telephone calls with consultants are held over the course of an investigation. Typically, the process happens early in an outbreak investigation, when the list of possible contaminated foods has been narrowed to two or three.

**Constraints on Food Industry Collaboration with Public Health**

Improvements in laboratory technology are already detecting increasing numbers of food contamination and illness events than in the past. Timely sharing of data between industry and government agencies provides necessary information for reducing illness due to food contamination, but could also introduce proprietary challenges. Industry is not monolithic and varies widely in size and function (producers, processors, manufactures, distributors, wholesalers, etc.). This often makes standardization difficult and adds an impediment to collaboration and coordination.

Industry may decrease involvement in collaborative food safety activities because the potential risks may outweigh the perceived benefits to a company. For example, industry may not share more microbiologic data than the law requires because of the fear that sharing such information with federal agencies can result in unanticipated areas of liability for the company.

*CDC perspective on engaging the food industry*

- When PulseNet detects a foodborne outbreak, consultations with industry partners often help public health responders generate hypotheses about the outbreak's source, traceback contaminated products, and take action to stop the outbreak

- Use of industry data to guide outbreak responses and develop public policy on food safety is facilitated by data-sharing platforms such as VoluntaryNet. Industry partners also participate in the CDC-Food Industry Safe Foods Forum.

- Data sources have become indispensable for multiple aspects of foodborne outbreak investigations. For example, public health use of data generated by store loyalty (or "shopper") cards was highlighted in a recent CDC *Vital Signs* report *(Safer Food Saves Lives: Stopping multistate foodborne outbreaks*).

- Challenges to use of industry data during investigations of multistate outbreaks include insufficient data on product distribution; varying levels of consumer support for shopper-card programs; difficulties with traceback activities (especially when outbreaks are associated with produce); and lack of microbial subtyping conducted by industry.

### *USDA/FSIS perspective on engaging the food industry*

- USDA/FSIS collects approximately 100,000 environmental and product samples for analysis every year and uses these data to advance outbreak investigations, monitor current and emerging threats, prepare risk assessments and attribution models, inform food safety policies, and evaluate trends

- Industry partners collect 100 times as much environmental and product test data, providing a rich source of information that can help identify key drivers of foodborne illness related to food production and processing and enhance the safety of U.S.-produced meat and poultry products

### *FDA perspective on engaging the food industry*

- Communication is critical to build trust and share information to drive response and prevention initiatives. FDA and CDC utilize information from clusters, outbreaks, environmental assessments, surveillance assignments, and analysis of multiple outbreaks to help industry understand risk and learn from past events. FSMA is helping to build and increase industry food-safety cultures with a prevention focus.

- FDA supports an open, participatory approach to policy setting, discussion of food safety issues, and outbreak prevention and control. Activities include outreach to companies regarding disease clusters and outbreaks; dialogue with CDC to address questions about implicated food products or ingredients; and participation in professional and association meetings to identify opportunities to enhance food safety. FDA also provides food safety guidance to industry through the FSMA Technical Assistance Network (TAN).

## Discussion and Guidance

**How can we better engage industry in enhancing foodborne illness surveillance?**

The Working Group felt that, despite constraints, there are opportunities for engaging industry and that CDC and its public health partners should

- Maintain consistent and ongoing engagement with industry partners, keeping in mind CDC's mission and the priorities of each partner

- Establish criteria for data quality by standardizing and validating diagnostic tests. A third-party convener might help coordinate this process

- Identify "champion companies" with strong food safety corporate culture, supply-chain leverage, and resources and reach to make an impact on providing safer food

- Encourage companies to

    o Improve the quality and sharing of data (e.g., sales and consumption data, traceback data, and food/environmental data)

    o Provide assistance during outbreak investigations (e.g., by providing data from loyalty cards and product distribution)

    o Advance corporate policies that promote food safety (e.g., using suppliers who use food safety best practices)

    o Provide assistance with consumer alerts (e.g., through robo-calls) and mitigation (e.g., by supporting vaccination programs to prevent and control foodborne outbreaks of hepatitis A)

- Be aware of industry needs (e.g., to maintain profitability, avoid recalls and outbreaks, avoid liability due to outbreaks, and resolve outbreaks quickly). During outbreaks, industry partners may require assistance to interpret whole genome sequencing (WGS) data and communicate results to the public

## II. A Review of the Interagency Food Safety Analytics Collaboration (IFSAC) Proposed Plans *(Discussed at the December 2015 FSMA-SWG Meeting)*

### Objective

Enhance food safety through improved understanding of the sources of foodborne illness

### Background

CDC, FDA, and USDA/FSIS created IFSAC in 2011 to improve coordination of federal food safety analytic efforts and address cross-cutting priorities for food safety data collection, analysis, and use. Projects and studies aim to identify foods that are important sources of illnesses. Accordingly, the current focus of IFSAC's activities is foodborne illness source attribution, defined as the process of estimating the most common food sources responsible for specific foodborne illnesses. Federal agencies and food safety experts rely on attribution to inform strategic planning and risk-based decision-making and to estimate benefits and evaluate the impact of interventions. By bringing together data from CDC, FDA, and FSIS, and by developing sound analytical methods, IFSAC scientists identify, plan, and conduct selected food safety and foodborne illness analytic projects to improve estimates of the sources of foodborne illness.

At the beginning of the collaboration, IFSAC identified four priority pathogens as the initial focus of their foodborne illness source attribution work: *Salmonella*, *E. coli* O157:H7, *Listeria monocytogenes*, and *Campylobacte*r. Based on the needs of each agency, CDC, FDA, and FSIS identified needs related to foodborne illness source attribution, including short-term needs that focus on attribution estimates for the four priority pathogens and long-term needs that focus on plans for reducing uncertainty, improving data, and obtaining comprehensive estimates of foodborne illness source attribution.

Considering these needs, IFSAC designed and completed several initial projects including development of a shared understanding and statement of needs for foodborne illness source attribution, improvement of the food categories used to estimate attribution, determination of the sources of uncertainty and variability in estimated attribution fractions, and estimation of the proportion of *Salmonella* Enteritidis illnesses attributable to shell eggs and other major commodities.

Current IFSAC projects include comparing the characteristics of ill people and foods linked to outbreaks of these four types of infections with those associated with sporadic illnesses and foods consumed by the general population; evaluating a pathogen subtype model to better estimate the number of *Salmonella* illnesses associated with different food sources; improving the method of assigning foods implicated in outbreaks to food categories; communicating IFSAC activities to the public and its stakeholders; estimating foodborne illness source attribution for illnesses caused by *Salmonella*, *E. coli* O157:H7, *Listeria monocytogenes*, and *Campylobacter*, and exploring statistical modeling approaches to evaluate changes in attribution estimates.

**Discussion and Guidance**

**Should IFSAC seek external technical input on individual projects, and if so, how and from whom?**

The Working Group felt that IFSAC should get additional external technical input on proposed projects from persons with expertise by expanding engagement with

- Academic institutions
- Non-academic research partners
- Integrated Food Safety CoEs

The Working Group also felt that IFSAC should consider developing a peer review or advisory committee consisting of members of the above groups.

**Are there analytical needs that IFSAC should consider as part of a new strategic plan?**

The Working Group identified several analytic needs that, if implemented, would enhance or increase the usefulness of data for a growing number of stakeholders:

- Include more granularity in categorization to help determine where to focus prevention and response efforts
- Analyze the impact of recalls (and the impact of recalls in preventing illness)
- Analyze the impact of speed in outbreak investigations
- Look at non-O157 STEC vs. O157 STEC sources
- Look at different points in the food chain where contamination occurs
- Improve access to food testing data particularly for produce to track effects of interventions

In terms of future directions the Working Group agreed to serve as a strategic advisory group to IFSAC and encouraged IFSAC to improve its collaboration and data sharing with the Interagency Risk Assessment Consortium (IRAC).

## III. Enhancing Foodborne Illness Traceback Surveillance and Outbreak Response Activities *(Discussed at the May 2016 FSMA-SWG Meeting)*

### Objective

Enhance food safety through improved information sharing and collaboration in the identification of the sources of a foodborne illness outbreak

**Background**

A traceback is conducted to identify the source of a foodborne illness outbreak. It traditionally starts after a food product has been implicated as the cause of an outbreak and involves the tracing of the implicated product along its distribution line back to its origin. In this context, product tracing can be used in support of regulatory action. Increasingly, tracebacks are conducted as part of an epidemiologic investigation to help implicate a specific food item or ingredient.

**Regulatory/Formal Tracebacks**

Formal traceback investigations are conducted by regulatory agencies such as FDA and USDA/FSIS, and rely on the collection of records, as well as information obtained from interviews and observations, to support possible public health control or legal actions. During regulatory tracebacks, investigators conduct a variety of activities to define where the contamination occurred. Starting at the point of purchase or point of exposure (stores, restaurants, or cafeterias where investigators believe the suspect food was bought or eaten), investigators ask managers about suppliers of the suspect food item. They then ask the food suppliers where they received the suspect food item. Investigators also review purchase and shipment information of firms to find food items that are most closely associated with the illnesses; investigators also conduct traceback activities at each point of the distribution chain.

The advantages of formal/regulatory tracebacks include

- Detailed review and documentation of shipment histories

- Definitive conclusions identified

- Ability to take regulatory action when complete

The disadvantages of formal/regulatory tracebacks include

- Labor/resource intensive

- Slow

- Require specific training

Regulatory traceback helps identify sampling locations for the product of interest, as well as the suppliers of the contaminated product. It builds a case for regulatory agencies to ask the firm for voluntary actions such as product recalls or ceasing of operations, or for taking regulatory actions such as enhanced facility inspections, increased frequency of microbial sampling, import or public health alerts, comprehensive food safety assessments, injunctions, seizures, an FDA mandatory recall, or a registration suspension.

**Traceforward**

While a traceback identifies who supplied the contaminated product, a traceforward identifies who received the contaminated product. Traceforwards are used to effectuate recalls, identify potential sampling locations of product remaining on the market to further build a regulatory case, and link contaminated product to case exposures.

**Epidemiological/Informational Tracebacks**

An epidemiologic or informational traceback refers to product tracing used as part of epidemiologic investigations to help identify an outbreak food vehicle. In some investigations, tracing the distribution pathway of suspect food items "may be the only way to obtain the food exposure specificity necessary to

identify the outbreak vehicle."[5] Epidemiologic investigations and the initial traceback efforts are usually initiated locally, as the first few foodborne illness cases are reported. As the outbreak expands, and it becomes apparent the distribution is beyond the local level, state and federal regulatory agencies are engaged to assist with a coordinated traceback effort.[6] The need for an epidemiologic/informational traceback is substantiated when, during the course of an epidemiologic investigation, it is revealed that

- Cases occur in multiple locations or jurisdictions (particularly in multiple states)

- Interviews of case-patients reveal no obvious common exposure, suggesting that the vehicle is a commercially distributed food item

- A vehicle cannot be clearly implicated with traditional epidemiologic, laboratory, and environmental investigation methods alone

- A pulsed-field gel electrophoresis (PFGE) or other molecular subtype cluster of cases likely represents a common source outbreak

Epidemiologic/informational product tracing starts with gathering food histories and product information from ill persons. This tracing determines whether food items consumed by multiple case-patients in subclusters have a common source or distribution point. It adds specificity to exposures and therefore assesses the plausibility of one or more vehicles. Investigators should initiate epidemiologic traceback inquiries with the manager who is responsible for ordering food at the facility that sold the suspect food product.

Some facilities may be dually regulated by the state and federal governments, or a restaurant may be regulated by the health department, but receive products from a company that is regulated by the agriculture department, with each entity abiding by its own regulatory authorities. Therefore, in a multijurisdictional outbreak and traceback investigation, a clear communication structure must be established to facilitate information sharing among agencies.[5]

Below are several advantages to product tracing, as identified by Smith, et al:[6]

- It can have a critical impact at a variety of points in an investigation

- It may be the only way to identify or confirm an outbreak vehicle

- It can substantially accelerate identification of a vehicle beyond what could be accomplished using traditional methods alone

- It can be used in conjunction with initial case-patient interviews to help generate (or rule out) hypotheses

- Results can be incorporated into analytic studies (e.g., evaluate a possible association with Food X from Producer Y)

- It can be an important tool to corroborate or refute an association with a food vehicle that has been identified by traditional investigation methods

**Traceability Challenges**

Several challenges exist in conducting tracebacks and traceforwards:

- During an ongoing outbreak there is a need to act fast, but tracebacks can be time consuming

- Resources are limited at the state/local level for laboratory analysis and interviews

- Because of legal issues, regulatory agencies sometimes have to redo tracebacks done at the local level

- Investigators may be faced with poor consumer recollection of consumption history and lack of specific product information, or may identify multiple product varieties or multiple sources of the same product at the point of sale
- When an ingredient is the cause of the outbreak, it can be more difficult for a traceback to identify the culprit, as the contaminated ingredient may be consumed as part of many different foods
- There is a lack of rapid and rigorous mechanisms to link shipments (or items in a shipment) from farm to fork, and poor record-keeping at firms within the distribution chain often limits the information gathered by investigators

**Lessons Learned**

Lessons learned from outbreak investigations provide opportunities to enhance the interagency response for future events. Strong relationships among federal, state, and local public health officials are essential, particularly when established prior to outbreak events. These relationships allow for a more coordinated effort and information sharing. Early engagement of industry through information sharing is crucial for efficiently/effectively identifying contaminated products and preventing further illness. Such coordination, coupled with early detection and an actionable traceback, allows for targeted and effective interventions.

**Steps Regulatory Agencies Are Taking to Ensure Firms Keep More Complete Records**

USDA/FSIS has record-keeping regulations, where firms are required to provide the requested information within 24 hours. USDA/FSIS can also take regulatory/legal action to obtain records from firms. FDA is currently working on a Traceability Rule; however, it will take some time to fully implement the new rule and have it be adopted by industry.

In an effort to further standardize the information collected during tracebacks/traceforwards, FDA established a workgroup which developed specific questions for investigators to ask when they visit various firms. They tailor their approach based on firm size (large vs. small firms). Investigators conduct interviews with owners and employees to get more information and clarification regarding their records. Industry sample data can also be helpful during an investigation. Although the isolates may no longer exist at the time of the investigation, regulatory agencies can still learn from the laboratory data whether a firm was aware of a history of a contaminant being in their product. Investigators also use the inspection opportunity to educate firms about how to maintain more complete records.

**Challenges**

A number of efforts are being undertaken at USDA/FSIS and FDA to improve traceability and documentation; however, some companies may not have the resources to maintain proper documentation, particularly if they are small firms. A lack of staffing, a lack of resources, and the inability to afford expensive tracking systems, such as bar codes, are barriers for some firms.

Additionally, there are unique challenges with traceability involving imported products. It is sometimes difficult for regulatory agencies to get the required information from firms in other countries; however, FDA is working on a Foreign Supplier Verification Program and rule that should help improve this process. If necessary, the agency can take action against a country, such as putting the country on alert, if the agency is unable to obtain information about a specific firm in the country.

**Intergovernmental Coordination**

USDA/FSIS and FDA have different authorities for establishing certain agreements with states, but coordination is a priority for both agencies. FDA's Rapid Response Teams (RRT) Best Practices Manual aims to improve/streamline outbreak responses. The manual is targeted to states and RRTs, but following the guidance is voluntary rather than required. FDA encourages RRTs to coordinate with each other, as well as with state/local partners, to enhance response efforts and lessen the resource burden. CDC is also a key partner to further coordinate investigation efforts among all entities. Training opportunities are available: FDA developed a train-the-trainer traceback training program for states to train their local investigators; the National Environmental Health Association (NEHA) is developing an online traceback training; and CoEs provide individualized training and consultation to support active outbreak investigations.

## Discussion and Guidance

**How can informational/epidemiological tracebacks be improved?**

After review, the Working Group made several recommendations on how governmental agencies could improve tracebacks, including

- Enhancing coordination and communication among all partners

- Identifying statutory strategies that allow for an emergency declaration that suspends normal procedures and permits enhanced information sharing among partners and industry

- Using lessons learned from previous outbreak investigations to implement the FSMA traceability rule (record keeping)

- Taking advantage of consumer desires to require better labeling/transparency in food sourcing

- Using all contact opportunities to educate industry on the importance of tracebacks and need for adequate record keeping

- Addressing the challenges with traceability of imported foods

- Further strengthening the relationships/collaboration among food safety partners and government agencies, by exploring the use of the Industry Workgroup of the Council to Improve Foodborne Outbreak Response (CIFOR) to produce non-regulatory model practices for traceability and the use of Integrated Food Safety COEs to develop traceback training and exercises

## IV. Progress of the Integrated Food Safety Centers of Excellence *(Discussed at the May 2016 FSMA-SWG Meeting)*

### Objective

Review implementation of previous Working Group recommendations and assure agendas and activities are addressing the greatest food safety needs

### Background

The Integrated Food Safety CoE program was established by FSMA to address insufficient capacity in foodborne disease programs at state and local health departments. The six CoEs are headquartered at state health departments and have formal partnerships with academic institutions:

- Colorado Department of Public Health and Environment and the Colorado School of Public Health

- Florida Department of Health and the University of Florida and the University of Georgia

- Minnesota Department of Health and the University of Minnesota School of Public Health

- New York State Department of Health and Cornell University

- Oregon Health Authority and Oregon State University and the University of Minnesota

- Tennessee Department of Health and the University of Tennessee–Knoxville

The Integrated Food Safety CoEs were chosen through a competitive review process and are funded through the Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) Cooperative Agreement. Colorado, Florida, Minnesota, Oregon, and Tennessee were designated as CoEs in 2012; New York was added to the program in August 2015 to address a regional need in the Northeast.

The Integrated Food Safety CoEs build capacity in other state and local health departments by providing training, educational opportunities, and peer-to-peer consultation. FSMA outlines seven activity areas for the CoEs; two of the activities are similar and were combined, creating the following six main activity areas:

- Strengthen surveillance and outbreak investigations

- Analyze timeliness and effectiveness of responses

- Train public health staff in proven investigative techniques

- Educate the future food safety workforce

- Improve capacity of information systems

- Evaluate and communicate best practices

With these activity areas in mind, the Integrated Food Safety CoEs have developed nearly 100 online tools and trainings that can be accessed at CoEFoodSafetyTools.org. They have also conducted evaluations of other health departments using the CIFOR metrics; helped other health departments work through the Focus Areas of the CIFOR Toolkit; delivered in-person collaborative team trainings (Epi Ready); and provided one-on-one assistance on surveillance, outbreak response, and data management.

In addition to the individual work the Integrated Food Safety CoEs have done in these areas, they also work collaboratively through five subject area workgroups that provide a forum for the CoEs to discuss and implement a variety of projects:

- Metrics

- Training

- Communications

- Academic Coordination

- Informatics

The workgroups are not FSMA-mandated, but serve as a mechanism to provide better integration and may evolve over time to accommodate the changing needs of the Integrated Food Safety CoE program.

**Objectives**

The main objective of the Integrated Food Safety CoE program is to reduce the burden of foodborne illness by improving the ability of state and local health departments to identify and respond to foodborne illnesses and

outbreaks. The six main activity areas help the CoEs achieve this main objective. Within the first activity area—strengthen surveillance and outbreak investigations at other health departments—the CoEs are addressing FSMA objectives by conducting needs assessments and developing products to fill the identified gaps, such as tools to improve collection of exposure data. Examples of the fifth activity area (improving the capacity of information systems) include developing a toolkit of resources to improve foodborne illness complaint systems at other health departments and providing consultation to improve databases and surveillance systems. The sixth CoE activity area carries out the evaluation and communication of best practices while seeking resources to conduct scientific research in areas such as attribution and antimicrobial resistance.

To track progress in the six activity areas, the CoEs provide monthly reports to CDC and include annual reports in their ELC applications. Additionally, updates are provided during monthly conference calls and at an annual 2-day vision meeting.

## Discussion and Guidance

**How are the Integrated Food Safety CoEs planning to address research needs?**

*Discussion*

The workgroup is working to develop a proactive research agenda. In addition, because CoEs are currently funded through the ELC cooperative agreement, which cannot be used for research, alternate mechanisms to for research funding for the CoEs are being pursued.

*Guidance*

The Working Group encouraged its members and their respective organizations to provide the Integrated Food Safety CoEs with ideas and funding for research projects to pursue. The Working Group noted that the lack of funding for public health and food safety research is causing a decrease in the number of public health staff who are trained in food safety research methods. While there is still a need in food safety for descriptive research, the working group felt that additional funding for analytic research is needed to explore unanswered questions and to train the future food safety workforce in such methods.

**What are the Integrated Food Safety CoEs doing to engage additional partners?**

*Discussion*

There are no restrictions on the number of academic partners a CoE has nor on the location of those partners; two of the six CoEs formally partner with universities outside of their state. Additionally, CoEs may partner with other health departments and non-academic institutions such as NEHA. Because of limited funding, some connections to additional schools and organizations may be more intellectual than financial. The CoEs are becoming more integrated and engaged with each other's work. This momentum will likely continue in the form of engaging additional partners outside of the CoEs.

*Guidance*

As the Integrated Food Safety CoEs obtain additional funding for research, they should engage additional partners to increase the reach and impact of these funds. The Working Group encouraged the CoEs to engage additional partners beyond the existing academic partners, including additional schools of public health to encourage new ideas and to share CoE products that can be used in the classroom.

**What is the reach of Integrated Food Safety CoE products? What are the CoEs doing to market and promote their products?**

*Discussion*

The Training and Communications Workgroups are using Google analytics to track the use of Integrated Food Safety CoE training courses and web traffic. The CoEs share this information internally through monthly reports to CDC that include metrics on the number of people trained and the number of downloads of CoE products. To capture the reach of academic work of the CoEs, the Academic Workgroup does a survey of the number of students trained through CoE food safety certificate programs as well as the number of field placements and capstone opportunities.

The first step to improve promotion of CoE products was the development of the website that houses all of the CoE online products. Most product users are indifferent about which CoE developed a product, and it was difficult to determine whether a particular CoE product existed because they were scattered across the various CoE websites without a central catalog. There is a need for continued promotion of the website. Going forward, the all-products page will be made more user-friendly with the development of toolkits and curriculums to make the information easier to understand and find.

In their product promotion efforts, Integrated Food Safety CoEs have focused less on local health department staff than on state health department staff. To help address this difference, a CoE presentation was planned for the 2016 annual National Association of County and City Health Officials (NACCHO) conference (held in July) and the CoE newsletter will be distributed via NACCHO listservs. The CoEs are beginning to routinely send out short summaries of the purpose and functions of the CoEs and of the tools and services the CoEs provide. The CoEs continue to pursue new avenues to share these messages.

*Guidance*

The Working Group concluded that Integrated Food Safety CoEs should frequently and extensively share news of their tools and services with the workforce, because public health professionals need to know about the available products. Promotion efforts should extend beyond state health departments to local health departments and schools of public health. The Working Group stated that the CoEs should reach out to the Association of Schools and Programs of Public Health (ASPPH) to request a feature in its Friday Letter to promote CoE training and products. The Working Group also suggested that the CoEs consider Google optimization to improve searchability of the CoEs' products.

## V. Proposed Activities and Plans for Foodborne Antimicrobial Resistance Funding *(Discussed at the May 2016 FSMA-SWG Meeting)*

### Objective

Assure antimicrobial resistance funding supports activities that strengthen food safety

### Background

In 2013, CDC issued a [landmark report](#) that gives a first-ever snapshot of the burden and threats posed by the antibiotic-resistant germs having the most impact on human health. In 2015 the White House released a National Action Plan for Combating Antibiotic Resistance, and in fiscal year (FY) 2016, Congress appropriated $160 million for the U.S. public health system to help control antibiotic resistance (AR). Of that appropriation, approximately $18 million was allocated to the Division of Foodborne, Waterborne, and Environmental

Diseases (DFWED) to improve surveillance and control efforts for four enteric threat agents (*Campylobacter*, non-typhoidal *Salmonella*, *Salmonella* Typhi, and *Shigella*) and *Candida*. These funds will help support the foodborne antibiotic resistance strategy for Combatting Antibiotic Resistance Bacteria (CARB), which has three components:

- Improve national surveillance for antimicrobial resistant foodborne illness and outbreaks

- Improve state epidemiology capacity to identify and investigate clusters of antimicrobial resistant foodborne illness

- Improve state laboratory capacity to use advanced molecular detection methods (AMD), such as whole genome sequencing (WGS), to detect AR enteric pathogens

DFWED will use part of the $18 million in funding to maintain and expand the current National Outbreak Reporting System (NORS), to build internal staff capacity, and to support focused AR surveillance activities; however, most funding (approximately $14 million) will go to build state and local WGS laboratory (~$12 million) and epidemiologic (~$2 million) capacity to detect and respond to outbreaks of AR enteric pathogens. Once laboratory equipment is obtained, some of the lab capacity funds will be shifted to expand epidemiologic support over subsequent years.

In addition, CDC will continue to work closely with USDA and FDA to coordinate and stay informed of CARB-related activities across agencies representing animal, human, and agricultural health. In collaboration with other federal agencies, CDC also plans to perform training needs assessments with practicing veterinarians to determine the type of information needed to update educational and communication messages to improve antibiotic use in farm and companion animal settings. Support will also go to external partners (other than state and local public health partners) to assist in assuring quality data transfer and to improve collaboration and communication among stakeholders.

## Discussion and Guidance

**How can surveillance for foodborne antimicrobial resistance be enhanced?**

*Discussion*

1. **Whole genome sequencing**

   - The CARB initiative will greatly increase state WGS capacity; however, traditional phenotypic AR testing will need to continue. With the availability of genomic databases and WGS, sequences can be screened for AR retrospectively. This is useful when looking for genes known to cause resistance, but resistance conferred by other resistant genes that are not currently known could be missed. For that reason, traditional phenotypic testing is needed to identify new resistance genes and improve the accuracy of available reference databases.

   - In addition to sequencing information, it is important to identify the reservoirs and mechanisms for AR transmission from the farm. Unfortunately, there are data gaps on antibiotic use on farms, creating a significant barrier for epidemiologists to examine associations between illnesses and potential sources.

   - Since WGS is being used across other federal agencies, such as USDA and FDA, there is a great opportunity to identify previously unrecognized reservoirs. However, this is dependent on partner regulatory agencies' receiving sufficient funding to do comparable WGS AR work. As a stop gap until resources become available, USDA has started sampling gut flora in the ceca of slaughter animals to bank the DNA for later WGS analysis.

2. **Federal partner gaps**

- While CDC received increased AR funding, the lack of AR funding for USDA and FDA leaves gaps in collection of information on antibiotic use on farms and assessment of how this use is related to rates of AR in human illnesses. Additionally, it will be difficult to measure the effects of changes in antibiotic use and resistance as new regulations are implemented. Opportunities exist to collect some antibiotic use data from veterinarian feed directives (VFDs), but with no funding appropriated for standardized data systems, data collection will be very challenging.

3. **WGS, AR, and cluster detection**

- Enhanced cluster detection and identification of AR will require increased effort from all agencies involved. Enhanced investigation is needed so that control activities can focus on drug resistant pathogens, which will help reduce rates of these illnesses over time.

- With future use of WGS for AR determination, much of the same information that was provided by traditional methods will continue to be available, but the work will be done more rapidly and include more information. As PFGE is replaced by WGS, AR information will be available simultaneously rather than weeks to months later, as was often the case with PFGE in the past. WGS will enable pathogen identification, serotyping, subtyping, and resistance data available at the same time, thus allowing for improved detection and investigation of more outbreaks.

- Understanding antibiotic use practices in animals and how antibiotic use contributes to resistance is important. Through NARMS, federal agencies have seen clonal expansion and plasmid mediated resistance transferred between microbial populations. More work is needed to look across microbial populations to fully characterize these interactions.

- Through the NARMS database, new information on antibiotic resistance will be shared with partners as it becomes available. PulseNet users will also be able to use the information to inform outbreak detection and investigation.

4. **Data collection and data sharing**

- Increased data collection and reporting to CDC is needed to fully understand the scope of AR, so current AR data collection needs to be assessed before moving forward.

- Part of the foodborne CARB strategy is to improve epidemiological data. Some core elements are already collected through routine surveillance, but there are other data elements that may require Office of Management and Budget approval before they can be collected. CDC is currently cataloging the data states collect and assessing how best to streamline the process. CDC is re-vamping data systems to collect additional data from OutbreakNet Enhanced sites, FoodCORE sites, and FoodNet sites and to merge those data with other data related to AR surveillance. In partnership with the Council and State and Territorial Epidemiologists (CSTE), CDC will work with states to consolidate the data elements in one place, but this very large and involved process will take time.

- It is important that AR data collected is useful for epidemiologic purposes and actionable at the state level. Currently, NARMS data are very passive and infrequently used by states. State public health labs process, batch, and ship isolates to CDC, but there have been delays in providing AR results in an actionable time frame. Public reporting of these results through NARMS is currently 2 years behind. With WGS, a significant increase in timeliness is expected as states will be able to conduct and access sequencing in their own labs.

- CDC is exploring ways to inform veterinarian practices about best practices for antibiotic use. To do this CDC is working with the CoEs to conduct surveys of veterinary prescription practices, perceptions, and factors influencing usage of antimicrobial drugs. This assessment will inform the future development of effective trainings, tools, and resources for the mitigation of AR, including the development of online training materials.

### Guidance

Following discussion, the Working Group identified four priority areas for focused attention in the coming years:

1. Implement WGS to identify AR while continuing traditional phenotypic resistance monitoring to recognize new resistance patterns

2. Leverage existing data systems to expand standardized data collection of antibiotic use associated with human clinical isolates submitted to NARMS

3. Improve integration and sharing of AR data from food animals, retail meat, and human clinical specimens with partners in a timely manner

4. Support USDA and FDA efforts to access and collect on-farm data on antibiotics used in food animals and to measure the effects of regulatory changes on food animal antibiotic use

## RESOURCES

The FSMA-SWG acknowledged that additional resources are required to integrate environmental data into foodborne illness surveillance; engage industry in enhancing foodborne illness surveillance and outbreak response; enhance traceability of food products; develop human resource capacity of state and local health departments to conduct timely exposure assessments to enhance the value of new technologies, including DNA sequencing; find, investigate, and quickly stop multistate foodborne outbreaks; and build on and better integrate existing surveillance 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 in capacity, including hiring experienced foodborne epidemiology, laboratory, and environmental personnel. This effort includes the need to engage schools of public health to train the existing workforce and the next generation of state and local food safety public health scientists and practitioners.

The Working Group is pleased that partial funding has been appropriated in 2014–2016 to address the important tasks authorized by FSMA (as outlined on pages 2-3) and hopes that the programmatic efforts uniquely directed by CDC and implemented by state and local health departments to meet the enhanced surveillance requirements continue to be funded. Recent investments in AR and AMD will also have positive impacts for advancing food safety, as outlined in section V. However, these funds are not solely focused on improving food safety surveillance. To effectively advance food safety, sustained investments in CDC's food safety efforts are needed.

## NEXT STEPS

To provide additional guidance on these and other emerging priority areas, the Working Group will devote time at future meetings to explore priority areas in more depth and provide associated advice for future actions.

These reviews will include expert presentations on the current status and progress of each priority followed by a discussion on possible enhancements to improve foodborne illness surveillance in that area. Potential future topics may include

- Providing culture-independent diagnostic test (CIDT) and WGS updates

- Providing ongoing IFSAC review

- Examining FoodNet Population Survey and uses

- Promoting/enhancing integrated data systems among CDC, FDA, and USDA

- Providing periodic Integrated Food Safety CoE, Interagency Foodborne Outbreak Response Collaboration (IFORC), and norovirus updates

- Addressing challenges with imported foods

- Addressing orphan illnesses (e.g., toxoplasmosis, cryptosporidiosis, hepatitis A)

- Measuring the impact of FSMA (Integrated Food Safety CoEs and other activities)

- Addressing food allergy and anaphylaxis

- Improving root cause analysis

- Outbreak messaging

- Consumer issues

- Focus on *Salmonella*

- State of state and local health departments

- Future leader training – including Schools of Public Health

- Risk analysis

- Examining "food testing" surveillance systems

In conclusion, the Working Group believes that important progress has been made in the implementation of FSMA, but that significant gaps remain that impact the quality of foodborne illness surveillance data.

It is essential that we ensure state and local health departments have the staff and resources to fully investigate outbreaks by

- Identifying both the food and pathogen responsible

- Effectively conducting product tracing

- Reporting these data to the National Outbreak Reporting System (NORS)

Enhanced state capacity, coupled with improvements in industry record keeping, and the integration/sharing of data are prerequisites to the formulation, implementation, and evaluation of science-based disease prevention and control policies, and to an improved overall integrated food safety system.

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# APPENDIX 1: FSMA SURVEILLANCE WORKING GROUP MEMBERS

## Meetings held in December 2015 and May 2016

**BSC Representative Members:**

Chair, Harry Chen, MD—Commissioner, Vermont Department of Health

Member, Kristy Bradley, DVM, MPH—State Epidemiologist and State Public Health Veterinarian, Oklahoma State Department of Health

Member, Timothy Jones, MD—State Epidemiologist, Tennessee Department of Health (also CSTE representative)

**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

**Public Health Partner Agency Members:**

Natalie Adan—National Association of State Departments of Agriculture

Robyn Atkinson, PhD, HCLD—Association of Public Health Laboratories

Thomas S. Dunlop, MPH, REHS—National Environmental Health Association

Timothy Jones, MD—Council of State and Territorial Epidemiologists

Heidi Kassenborg, DVM, MPH—Association of Food and Drug Officials

Nathaniel Smith, MD, MPH—Association of State and Territorial Health Officials

Joseph Russell, MPH, RS—National Association of County and City Health Officials

**Consumer Partner Members:**

Barbara Kowalcyk, PhD—Center for Foodborne Illness Research and Prevention

Dara Alpert Lieberman—Trust for America's Health

Karin Hoelzer, DVM, PhD—The Pew Charitable Trusts

**Industry Partner Members:**

Catherine Adams Hutt, PhD, RD—Food Industry Consultant

Scott K. Hood, PhD—General Mills

Joan Menke-Schaenzer—McDonald's Corporation

**Academia Partner Members:**

Craig Hedberg, MS, PhD—University of Minnesota

Michael P. Doyle, PhD—University of Georgia

Elaine Scallan, PhD—University of Colorado, Denver

# APPENDIX 2: FY 2012–15 FSMA SURVEILLANCE WORKING GROUP ANNUAL REPORTS AND MEETING TOPICS

## FY 2012 Annual Report

**Main topics:**

- Selection Criteria for Integrated Food Safety Centers of Excellence
- Interagency Food Safety Analytics Collaboration
- Improving Foodborne Illness Surveillance Systems: Focus Areas for Future Discussion

**Supplementary topics:**

- Overview of the human illness surveillance requirements of FSMA – CDC
- Summary of Nov 3–4, 2011 Pew Food Safety Forum's surveillance workshop
- Overview of foodborne illness surveillance systems and challenges – CDC
- Overview of multistate foodborne outbreak investigations and challenges
- Economic analyses on FoodNet and PulseNet – CDC
- Website improvements to make data more accessible to the public
- Improved outbreak reporting mechanisms: PulseNet portal and Palantir – CDC

## FY 2013 Annual Report

**Main topics:**

- Culture-independent diagnostic tests (CIDTs)
- Performance Measures to Enhance Federal, State, and Local Foodborne Illness Surveillance

**Supplementary topics:**

- CoE Congressional Report
- Attribution of Foodborne Illnesses, Hospitalizations, and Deaths to Food Commodities
- Vital Signs and recent communication updates

## FY 2014 Annual Report

**Main topics:**

- Foodborne illness and outbreaks caused by norovirus
- Antimicrobial resistance surveillance for foodborne illness

**Supplementary topics:**

- Whole genome sequencing listeria surveillance project
- Cyclosporiasis

## FY 2015 Annual Report

**Main topics:**

- Governmental Coordination, Integration, and Collaboration
- Environmental Factor Surveillance for Foodborne Illnesses

**Supplementary topics:**

- Cyclosporiasis surveillance
- *Vibrio* surveillance

# APPENDIX 3: SELECTED CDC ACCOMPLISHMENTS IN IMPLEMENTING FSMA SURVEILLANCE REQUIREMENTS

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 at the local, state, and federal levels. FSMA directs the Centers for Disease Control and Prevention (CDC) to

    I.    Improve governmental coordination and integration

   II.    Evaluate and improve foodborne illness surveillance systems

  III.    Enhance external stakeholder collaboration

CDC supports the implementation of FSMA in many ways. For instance, in fiscal year (FY) 2016, with the help of new antimicrobial resistance and food safety funding, CDC significantly increased support for existing infrastructure for laboratory, surveillance, and outbreak response activities and continued the activities of the [Integrated Food Safety Centers of Excellence](#) (CoEs).

The following summary discusses selected CDC accomplishments that support FSMA. While the majority build on existing infrastructure and labor capacity, some 2016 initiatives, like expansion of the OutbreakNet Enhanced sites and the plan to convert PulseNet's pulsed-field gel electrophoresis (PFGE) to whole genome sequencing (WGS) testing, greatly expand CDC's surveillance capabilities under FSMA.

## I.   Improving Governmental Coordination and Integration

Food safety is a shared initiative among local, state, and federal public health partners. FSMA recognizes that strong coordination among partners is essential to rapidly detect food safety problems, determine where issues are occurring, and identify and use effective strategies to prevent foodborne illness. CDC is working to strengthen coordination and data sharing across government agencies and with external partners.

### A.  Coordinating federal, state, and local foodborne illness surveillance systems

- ***Multistate foodborne illness outbreak investigations***

  In FY 2016, CDC supported federal, state, and local health agencies to monitor between 15 and 40 clusters of potential foodborne illness per week, resulting in approximately 18 major multistate outbreak investigations (Table 3.1).

  CDC continues to improve foodborne illness and outbreak metrics through the [Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) Cooperative Agreement](#) sites and by working with the [Council to Improve Foodborne Outbreak Response](#) (CIFOR) to use performance measures and associated targets as guidelines for states to use in their outbreak investigations. The council serves many professional organizations focused on state and local health department activities.

**Table 3.1 Selected Multistate Foodborne Illness Outbreaks, United States, FY 2016\***

| Pathogen | Distribution | Vehicle |
| --- | --- | --- |
| *Escherichia coli* O157:H7† | 11 illnesses reported from 5 states; 7 hospitalizations, no deaths | Beef products produced by Adams Farm |
| Hepatitis A virus† | 134 illnesses reported from 9 states; 52 hospitalizations, no deaths | Frozen strawberries |
| *Salmonella* Reading and Abony† | 30 illnesses reported from 9 states; 5 hospitalizations, no deaths | Alfalfa sprouts |
| *Escherichia coli* O121 and O26† | 46 illnesses reported from 21 states; 13 hospitalizations, no deaths | Flour |
| *Listeria monocytogenes* | 9 illnesses reported from 4 states; 9 hospitalizations, 3 deaths | Frozen vegetables |
| *Listeria monocytogenes* | 2 illnesses reported from 2 states; 2 hospitalizations, 1 death | Raw milk produced by Miller's Organic Farm |
| *Salmonella* Montevideo and Senftenberg | 11 illnesses reported from 9 states; 2 hospitalizations, no deaths | Wonderful brand pistachios |
| *Escherichia coli* O157 | 11 illnesses reported from 2 states; 2 hospitalizations, no deaths | Alfalfa sprouts produced by Jack & The Green Sprouts |
| *Salmonella* Muenchen and Kentucky | 26 illnesses reported from 12 states; 8 hospitalizations, no deaths | Alfalfa sprouts from one contaminated seed lot |
| *Salmonella* Virchow | 33 illnesses reported from 23 states; 6 hospitalizations, no deaths | Garden of Life RAW Meal Organic Shake & Meal products |
| *Listeria monocytogenes* | 19 illnesses reported from 9 states; 19 hospitalizations, 1 death | Packaged salads produced at Springfield, Ohio, Dole processing facility |
| *Salmonella* Paratyphi B variant L(+) tartrate(+) | 13 illnesses reported from 10 states; no hospitalizations, no deaths | Jem Raw brand sprouted nut butter spreads |

| Pathogen | Distribution | Vehicle |
|---|---|---|
| *Escherichia coli* O157:H7 | 19 illnesses reported from 7 states; 5 hospitalizations, no deaths | Rotisserie chicken salad made and sold in Costco Wholesale stores |
| *Escherichia coli* O26 | *Initial, Larger Outbreak:* 55 illnesses reported from 11 states; 21 hospitalizations and no deaths *Second, Smaller Outbreak:* 5 illnesses reported from 3 states; 1 hospitalization and no deaths | Chipotle Mexican Grill restaurants |
| *Listeria monocytogenes* | 30 illnesses reported from 10 states; 28 hospitalizations, 3 deaths | Soft cheese distributed by Karoun Dairies |
| *Salmonella* Poona | 907 illnesses reported from 40 states; 204 hospitalizations, 6 deaths | Cucumbers |
| *Salmonella* I 4,[5],12:i:- | 192 illnesses reported from 5 states; 30 hospitalizations, no deaths | Pork |
| *Salmonella* Enteriditis | 5 illnesses reported from 1 state; 2 hospitalizations, no deaths | Stuffed chicken entrees from Aspen Foods |

*Pathogens listed in chronological order of outbreaks
†Data through 09/30/2016

- ***CDC support of U.S. Food and Drug Administration (FDA) implementation of FSMA***

    CDC works closely with FDA to support FSMA implementation efforts by providing expert participation in a number of FDA-led activities and workgroups. These efforts include the following:

    o **Participating in the FDA-led FSMA Implementation State Strategy Workgroup**. A CDC representative serves on this workgroup aimed at strengthening federal/state integration to focus on FSMA deliverables.

    o **Serving on the Network Advisory Committee to the FDA Rapid Response Teams (RRTs)**. In FY 2016, CDC representatives, in collaboration with FDA and its RRT network operating in 18 states, participated and provided updates on CDC-related food safety activities at the Annual RRT Face-to-Face Meeting (held in New Orleans, Louisiana, on October 27–29, 2015). CDC representatives participated and presented on CDC's outbreak investigation teams and protocols during monthly RRT calls. (FSMA Sections 202, 205[c], and 209)

    o **Inviting active participation by FDA and the U.S. Department of Agriculture (USDA)/Food Safety and Inspection Service (FSIS) representatives in the Integrated Foodborne Outbreak Response and Management (InFORM) Conference.** FDA actively participated in this November 2015

meeting of laboratorians, epidemiologists, and environmental health/regulatory personnel involved in foodborne and enteric disease outbreak responses at the state and national levels.

- o **Serving on the FDA-led Partnership for Food Protection (PFP) Governing Council.** A CDC representative serves as a voting member on the Council in monthly telephone conferences and at an annual face-to-face meeting.

- o **Serving on the PFP Surveillance, Response, and Post-Response Workgroup**. CDC representatives participate in this workgroup aimed at strengthening and enabling faster and more effective surveillance, response, and post-response efforts through coordination among strategic partners.

- *The* Listeria *Initiative*

To better detect and investigate illness clusters, CDC continued to work with states to identify ways to improve the timely reporting of epidemiologic and laboratory data. In FY 2016, each state was notified of recent uploads of *Listeria* isolates to [PulseNet](link) (a national laboratory network that connects foodborne illness cases to detect outbreaks) from their state on a weekly basis to increase the percentage of isolates that had linked epidemiologic data. These efforts led to improvements in *Listeria* reporting during calendar year 2016, as indicated by increases in the proportion of all listeriosis cases with linked epidemiologic and laboratory data. In addition, CDC

- o Led a roundtable discussion at the June 2016 annual meeting of the Council of State and Territorial Epidemiologists (CSTE) to discuss WGS and data transmission enhancements for the *Listeria* Initiative

- o Continued to work with states to identify ways to improve timely reporting of *Listeria* cases with linked epidemiologic and laboratory data to better detect and investigate illness clusters

- o Led laboratory efforts to build capacity at state laboratories for WGS of *Listeria* isolates

- o Continued to contact states weekly to notify them of recent uploads of *Listeria* isolates to PulseNet from their state to increase the percentage of isolates that have linked epidemiologic data

- o Continued to strengthen integration of epidemiologic exposure data with WGS data to better detect and solve outbreaks

- o Continued to work with the PulseNet laboratory to integrate *Listeria* Initiative data into BioNumerics software to perform rapid epidemiologic and WGS analyses and better identify foods responsible for outbreaks

- o Developed a pilot module of Enterics Direct, an application to allow direct uploading of *Listeria* Initiative data from state databases to CDC

- o Investigated outbreaks of *Listeria* infections, including identification of new food vehicles such as frozen vegetables

- o As a direct result of the WGS project, improved the number of listeriosis cases linked to food source and the number of solved outbreaks

- o Continued routine, near-real-time WGS of all food, environmental, and clinical isolates in integrated farm-to-table listeriosis surveillance through collaboration with FDA, USDA/FSIS, the National Institutes of Health (NIH), and state partners

- o Coupled traditional epidemiologic data from the *Listeria* Initiative with WGS data to solve five outbreaks during WGS year 3. By comparison, an average of two outbreaks per year were solved during the pre-WGS year (Figure 3.1).

**Figure 3.1. Comparison of listeriosis cases before and after advanced molecular detection (AMD)**



The Impact of Advanced Molecular Detection: Investigating *Listeria* Outbreaks
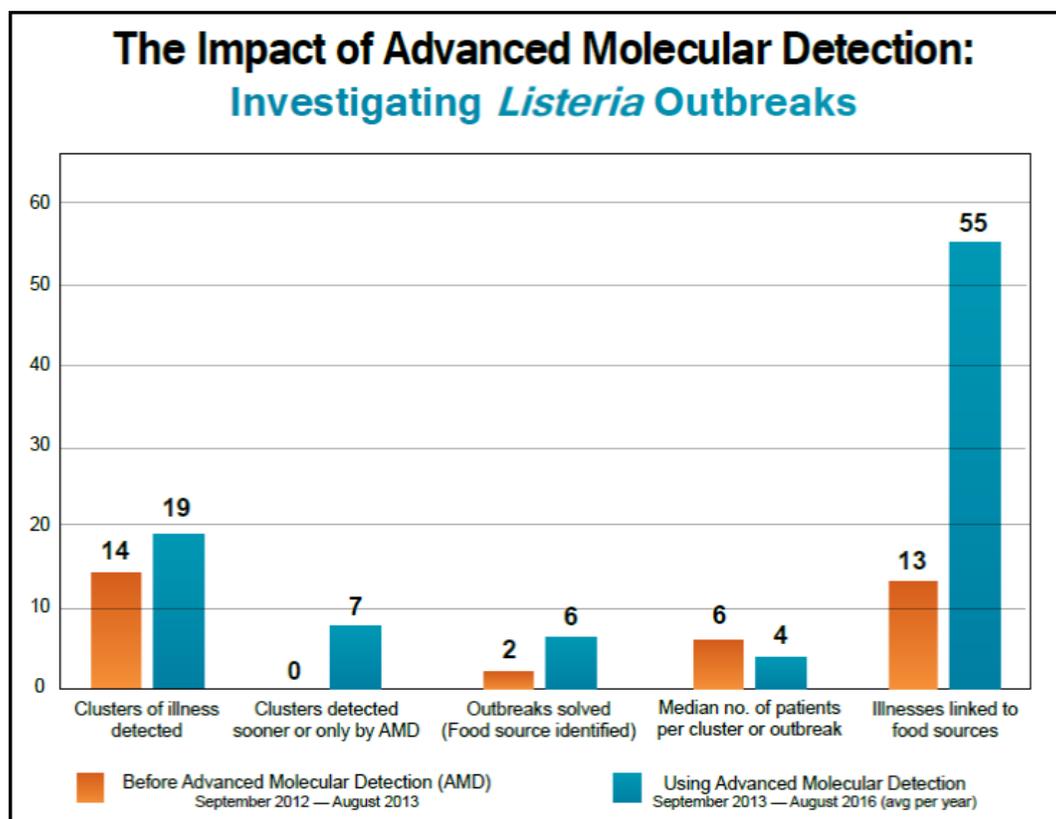
- **Toxoplasma gondii** *surveillance*

  In FY 2016, CDC's Division of Parasitic Diseases and Malaria (DPDM) continued to collaborate with multiple agencies to conduct toxoplasmosis surveillance including

  o Completion of *Toxoplasma gondii* sero-surveillance testing using serum samples from the 2013–14 National Health and Nutrition Examination Survey. This expansion allowed completion of the periodic 6-year sample period (2009–2014) to adequately stratify the data by race/ethnic group, gender, and region, and to fully evaluate trends. This survey is a collaboration at CDC among DPDM, the Center for Global Health, and the National Center for Health Statistics' Division of Health and Nutrition Examination Surveys. Results are expected in the spring of 2017

  o Continued collaboration with the USDA Agricultural Research Service to conduct a national survey of *T. gondii* contamination in field-raised and "organic" pork and lamb

- *Interagency Collaboration on Genomics and Food Safety (Gen-FS)*

  During FY 2015, CDC, FDA, NIH/National Center for Biotechnology Information (NCBI), and USDA/FSIS began to formalize their ongoing collaboration on the application and use of WGS to improve food safety. They established the Interagency Collaboration on Genomics and Food Safety for timely access to foodborne epidemiologic, food and traceback, environmental, and laboratory data for the following applications:

  o Clinical, food, and environmental foodborne pathogen surveillance

- o Quick, accurate detection and mitigation of outbreaks

- o Removal of contaminated food sources to prevent additional illnesses

- o Studies that attribute foodborne illnesses to food sources

- o Regulatory food safety research

  – **The strength of Gen-FS is** built on the complementary roles and responsibilities for protecting food safety of the four federal agencies, with state and other partners:

    ▪ CDC oversees foodborne Illness surveillance.

    ▪ FDA oversees regulatory oversight and surveillance of produce, seafood, dairy products, processed foods, nuts, and other foods.

    ▪ USDA/FSIS has regulatory oversight and surveillance of meat, poultry, processed eggs, and catfish.

    ▪ NIH/NCBI provides the big data infrastructure for data storage, curation, bioinformatics analytics, and other expertise necessary to use integrated data from different sources.

- ● *During 2016 progress was made in a number of areas including the following:*

- o Sequencing of isolates of foodborne pathogens from clinical, food, feed, and environmental sources; storing the information; facilitating analysis and use of the data for disease surveillance, regulatory testing, and oversight of food safety; and conducting food safety research to improve public health

- o Implemented policies so pathogens from clinical sources may be sequenced at FDA-supported laboratories, and so food and environmental pathogens may be sequenced at CDC-supported laboratories to save time and shipping costs

- o Development and harmonization of laboratory procedures, protocols, and standards

  – Harmonized protocols for WGS analyses at FDA- and CDC-supported laboratories

  – Combined FDA and CDC proficiency testing programs for WGS analysis

- o Streamlining of data sharing among partner agencies, and when possible, with the public

  – Revised the data sharing agreement with all PulseNet laboratories to upload pathogen WGS data to the NIH public database as soon as the results are available

- o Comparing, interpreting, and using WGS and metadata for analytical studies

  – Developed and publically posted standard WGS datasets for direct comparison and assessment of various analytic tools

  – Assessed and enhanced CDC and FDA analysis tools based on analyses against standard WGS datasets

- o Supporting state food safety agencies in their adoption of WGS technology

  – Harmonized and combined CDC and FDA WGS training and certification workshops

  – Trained and certified 72 laboratory staff from 27 public health laboratories in 24 states on WGS analysis

- o Launching real-time WGS surveillance for *Listeria monocytogenes* (Lm) isolates

  – The WGS database at NIH includes 5,859 food and environmental Lm isolates and 2,882 clinical isolates

  – NIH is developing software tools to provide preliminary analyses of Lm clusters based on WGS data

- **Foodborne Diseases Active Surveillance Network (FoodNet) surveillance**

  CDC, FDA, USDA/FSIS, and 10 state health departments participate in the Foodborne Diseases Active Surveillance Network and collaborate to provide critical data for policymakers, the scientific community, and the public. This collaboration resulted in the following:

  - o Published preliminary 2015 FoodNet data on the incidence and trends of infection with pathogens transmitted commonly through food in the April 2016 *Morbidity and Mortality Weekly Report* (*MMWR*) and online in data facts and figures tables

  - o Provided data updates for monitoring the Healthy People 2020 goals on the incidence of infection with *Campylobacter*, *Listeria*, *Salmonella*, Shiga toxin-producing *Escherichia coli* (STEC) O157, *Vibrio*, and *Yersinia* and on the incidence of hemolytic uremic syndrome

  - o Participated in the Healthy People 2020 progress review

  - o Continued to provide quarterly reports on the incidence of *Salmonella* serotype Enteritidis to support the HHS High Priority Goal aimed at reducing foodborne illness in the population by decreasing the rate of *Salmonella* Enteritidis illness in the population to 1.9 cases per 100,000 by December 2015

  - o Published a more interactive format of the 2014 annual report in spring 2016

  - o FoodNet continues to monitor the use of culture-independent diagnostic tests (CIDTs) for enteric bacterial pathogens through active isolate-based surveillance and laboratory surveys conducted on all laboratories serving the FoodNet catchment area.

    – FoodNet data showed that the average annual percentage of bacterial infections under FoodNet surveillance diagnosed by CIDTs increased from 7% in 2012 to 16% in 2015 (Figure 3.2).

  - o FoodNet 2015 CIDT data have shown that use of CIDTs is increasing, uptake varies by pathogen, and there is growing use of multiplex PCR panels that test for multiple pathogens from one specimen.

  - o FoodNet has developed a statistical model to incorporate cases diagnosed by CIDTs, incorporating sensitivity and specificity of test type to estimate true cases and analyze incidence trends. Manuscripts describing this model are currently in CDC clearance.

**Figure 3.2. Percentage of bacterial infections diagnosed by CIDTs, United States, 2012–2014, 2015**



2012–2014

Only 2015
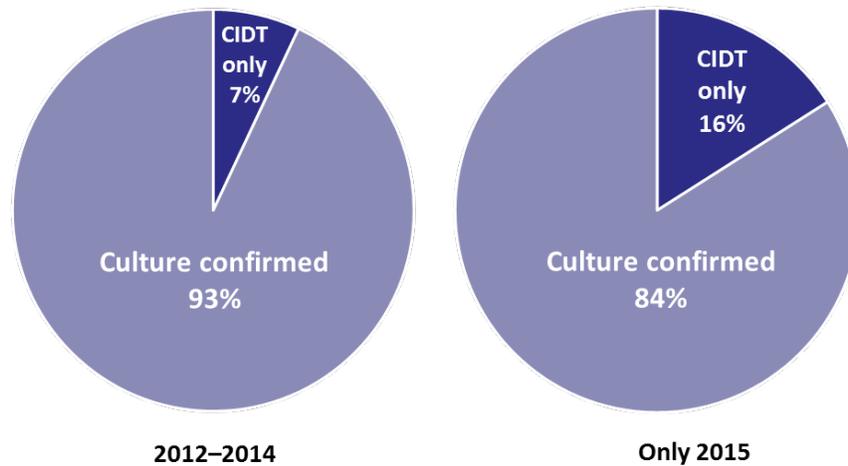
- **Shigella** *surveillance*

  From January to September 2016, CDC led 19 multistate shigellosis outbreaks and clusters and assisted with 10 single-state shigellosis outbreaks and clusters. Outbreak case counts ranged from 6 to 1,625 and were detected in as many as 37 states and Puerto Rico. PulseNet assisted with identifying 21 clusters and outbreaks. Health departments requested assistance with 8 clusters and outbreaks.

  National Antimicrobial Resistance Monitoring System (NARMS) testing has been completed for 18 outbreaks (230 isolates) to date, and in those instances, *Shigella* was resistant to a variety of antibiotics including ampicillin, ciprofloxacin, azithromycin, trimethoprim/sulphamethoxazole, streptomycin, sulfisoxazole, nalidixic acid, tetracycline, and ceftriaxone.

  *MMWR* and *Emerging Infectious Diseases* articles published in 2016 highlight the emergence of multidrug-resistant shigellosis among high-risk groups and provide guidance to medical and public health practitioners on infection prevention and control, testing, treatment, and counseling. Additional *Shigella* program activities included

  o Tracking, investigating, and reporting multistate shigellosis outbreaks

  – Collaborated with PulseNet on outbreaks transmitted person to person, including those in the community, in childcare settings, and among men who have sex with men (MSM)

  – Worked with the Waterborne Disease Prevention Branch (WDPB) to conduct interviews and analyze data on recreational water–associated outbreaks

  – In concert with NARMS, facilitated antibacterial resistance testing for shigellosis isolates associated with outbreaks

  – Reported shigellosis outbreaks to the National Outbreak Reporting System (NORS) and assisted with data-cleaning efforts

- o Supporting state and local health departments with shigellosis outbreaks and prevention
  - – Provided epidemiologic consultation
  - – Reviewed interview forms
  - – Facilitated molecular and antibiotic susceptibility testing
  - – Created prevention and [communications materials](#) for the general public and for specific risk groups
- o Strengthening detection of *Shigella* clusters by leveraging existing division-level resources
  - – Piloted the use of Computer-aided Ontology Development Architecture (CODA), an algorithm designed to detect clusters of enteric disease using laboratory-based surveillance data
  - – Enlisted the support of PulseNet to assist with cluster detection, classification of the organism, and reporting
  - – Incorporated *Shigella* into an existing outbreak management system (CDC's Outbreak Response and Prevention Branch [ORPB] Outbreak Management Database) to enhance communications with internal and external partners
  - – Integrated *Shigella* into an existing online platform called the System for Enteric Disease Response, Investigation, and Coordination (SEDRIC), which enhances management of multistate outbreaks by streamlining communication and data sharing between external partners
- o Communicating *Shigella* research and guidance to professional and lay audiences
  - – Updated content and references for *[Shigella](#)* and hygiene pages on the CDC website
  - – Presented research at the 2016 STD Prevention Conference in Atlanta on the sexual transmission of shigellosis and increasing burden of disease among U.S. MSM
- o Fostering research collaborations with internal and external partners
  - – Analyzed data from the Laboratory-based Enteric Disease Surveillance (LEDS) system to identify trends in shigellosis and identify risk groups
  - – Partnered with CDC modeling experts to estimate the economic burden of shigellosis childcare exclusion policies
  - – Worked with FoodNET to describe severe shigellosis among adults and children
  - – Combined FoodNET and NARMS data to determine the prevalence of quinolone-resistant shigellosis among travelers
  - – Collaborated with CDC laboratory colleagues and public health laboratories to study genetic changes in *Shigella* organisms over time
  - – Supported a Minnesota Department of Health project to determine risk factors for antibiotic-resistant shigellosis among MSM by combining enteric disease and STD data
  - – Supported a New York City Department of Health and Mental Health project to identify risk factors for and clinical outcomes among patients infected with azithromycin-resistant shigellosis

**B. Increasing participation of public health and food regulatory agencies and laboratories in national foodborne surveillance networks**

Local and state health departments serve as the foundation of food safety efforts by investigating outbreaks, conducting disease surveillance, and implementing local control measures. FSMA recognizes the critical role of local, territorial, tribal, and state agencies in a national food safety system and incorporates provisions to coordinate, integrate, and enhance surveillance and outbreak response activities at all levels.

CDC provides resources to enhance and integrate critical national surveillance, outbreak detection, and response networks. Scientists need strong data to quickly identify the source of outbreaks and inform prevention efforts. In FY 2016, CDC provided approximately $36 million to local and state public health departments through the

> CDC provides funding, tools, training, and strategic leadership. These enhancements are expected to do the following:
>
> - Improve the quality of data obtained at the state and local levels
> - Ensure that data are analyzed and shared quickly to aid in the rapid response to food safety gaps

Epidemiology and Laboratory Capacity for Infectious Diseases Cooperative Agreement and the Emerging Infections Programs (EIP) to support critical foodborne illness surveillance efforts. This funding was essential to maintain capacity to track, detect, investigate, and respond to emerging foodborne disease threats. Other activities to support national networks included the following:

- ***Supporting enteric disease labs***

   PulseNet is a network of local, state, and federal public health laboratories that can analyze DNA fingerprints of bacteria to quickly detect a foodborne illness that otherwise might have gone undetected. PulseNet laboratories use PFGE to detect DNA fingerprints as well as WGS, a newer method that provides the most accurate bacterial fingerprinting data possible today. Scientists can study these DNA fingerprints and post their findings on the PulseNet message board so that laboratories across the country have access to and can use the findings.

   PulseNet USA has 83 laboratories in seven regions of the United States (Figure 3.3). It includes public health laboratories in all 50 states (including the U.S. territory of Puerto Rico) and food regulatory laboratories within FDA and USDA.

   PulseNet USA headquarters are at CDC in Atlanta. PulseNet USA works with PulseNet International by supporting and participating in strategic planning meetings, training international participants at PulseNet USA headquarters, and sharing protocols and software customization.

   The PulseNet Web Portal was updated in April 2016. This electronic analysis system, developed in collaboration with USDA, the Association of Public Health Laboratories (APHL), and Carnegie Mellon University, allows for sophisticated electronic queries, allows for analyses and presentation of PulseNet data, and has been updated with enhanced reporting features.

**Figure 3.3. U.S. map showing regions and locations of PulseNet laboratories**
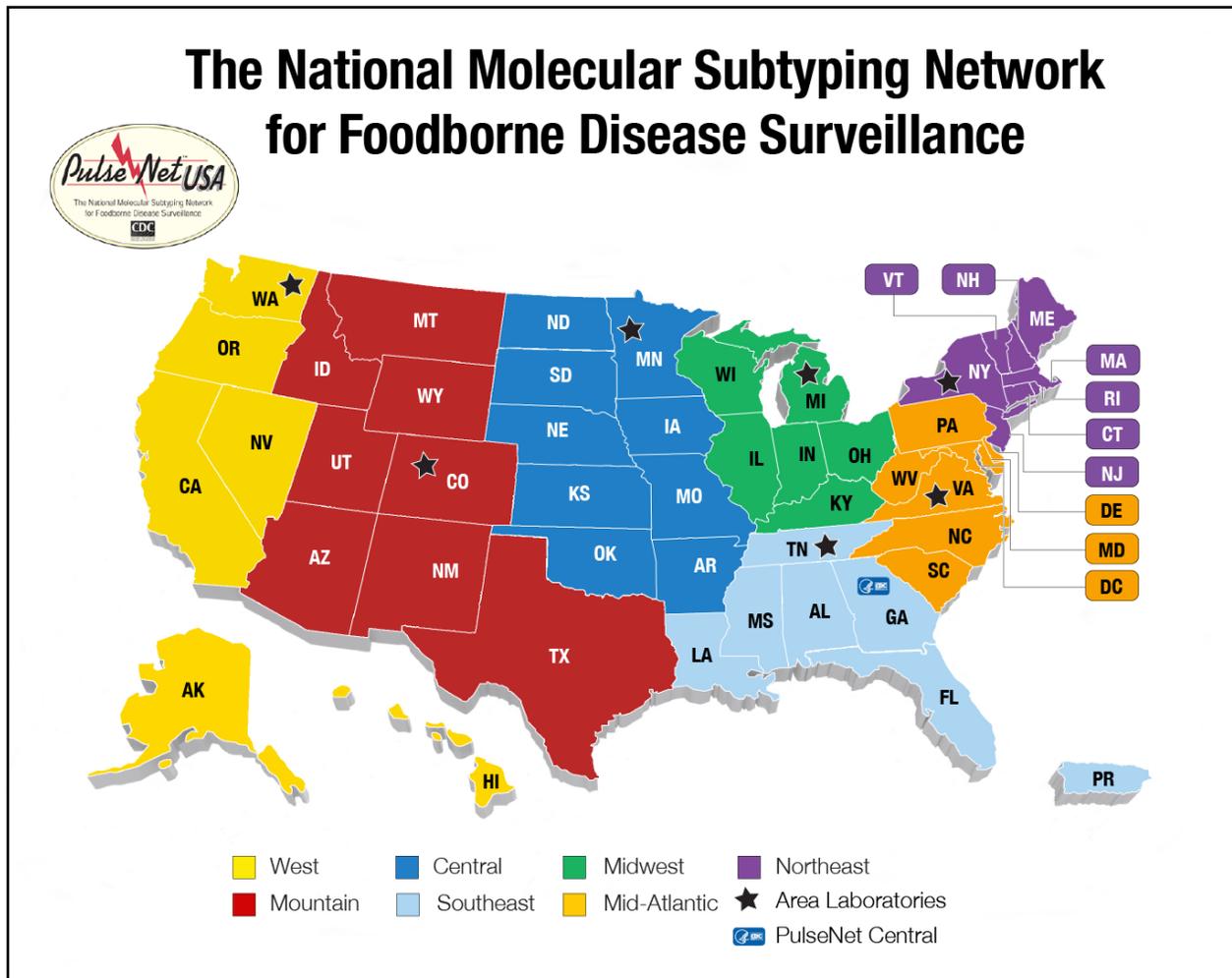


- *Whole genome sequencing*

    WGS is beginning to replace PFGE for subtyping of foodborne pathogens from stool samples and other specimens for outbreak surveillance. Progress in implementing WGS during FY 2016 included the following:

    o  Twenty-seven laboratories in 24 states have been certified and are performing WGS analysis (as close to real-time as possible), an increase of 17 laboratories over last year.

    o  During FY 2016 states sequenced 7,525 isolates (150% of the 5,000 target) including 3,115 STEC, 3,207 *Salmonella*, 787 *Campylobacter*, 394 *Listeria*, 18 *Vibrio*, and 4 *Yersinia* isolates.

    o  WGS is now used routinely for real-time surveillance of listeriosis. Pipelines for analyzing WGS data at CDC and for other federal and state participants have been developed and are being piloted to be implemented routinely in the states with sequencing capacity.

    o  WGS is used routinely for the investigation of outbreaks detected by other means caused by *Salmonella*, STEC, and *Campylobacter jejuni*.

o   Sequences of genomes gathered as part of the foodborne disease surveillance system are being uploaded to a public database at NCBI and made available to the food industry, academia, consumers, and the public in addition to public health and regulatory agencies as soon as test results are available.

o   CDC is finalizing a WGS-based enteric reference identification database and organism-specific databases for *Campylobacter* and *E.coli*.

o   Software developer Applied Maths and NCBI are engaged to assist international partners in the development of analytical tools.

o   CDC has received CLIA approval to report patient test results derived from WGS for species-level identification of enteric pathogens including *Listeria*, *Campylobacter*, and *E. coli*.

o   Antimicrobial resistance gene prediction databases were evaluated, and CDC is supplementing the ResFinder tool developed by the Center for Genomic Epidemiology with in-house resistance mutation tools used routinely in NARMS.

- *Metagenomics*

  Applied research has begun to detect foodborne pathogens by metagenomics approaches including

  o   A project of metagenomic sequencing to identify pathogens in biological samples recovered from human cases of foodborne illness

  o   A project to identify targets in metagenomics samples that may be used to develop sequencing applications that efficiently and specifically identify and subtype a foodborne pathogen, beginning with *Salmonella* and STEC

- *Culture-independent diagnostic tests*

  In FY 2014, a consortium of five state and local health agencies and CDC was created to develop and test best practices for isolate recovery by state and local public health laboratories that use CIDTs. The group is in the final stages of analyzing data to optimize culture methods for isolation of *Salmonella* and STEC from CIDT positive specimens.

- *Establishing the Norovirus Sentinel Testing and Tracking network (NoroSTAT)*

  Since 2009, CDC has received epidemiologic and laboratory data on norovirus outbreaks from state health departments through NORS and CaliciNet (the national norovirus outbreak surveillance laboratory network), respectively. Because of reporting lags and an inability to reliably link records in NORS and CaliciNet, in 2012 CDC established NoroSTAT. State health departments that participate in NoroSTAT report suspected norovirus outbreaks through NORS and CaliciNet within 7 business days of being notified about the outbreak, thereby providing near-real-time assessment of norovirus activity. NoroSTAT reporting also allows norovirus strain data uploaded through CaliciNet to be rapidly linked with epidemiologic characteristics of outbreaks reported through NORS by using consistent outbreak identifiers in each system.

During the first 3 years of implementation, five states participated in NoroSTAT: Minnesota, Ohio, Oregon, Tennessee, and Wisconsin. A recently completed evaluation compared 3 years of data before and after implementation of NoroSTAT. States participating in NoroSTAT reduced their reporting lag to NORS from a median of 22 to 2 days and to CaliciNet from a median of 21 to 3 days. Meanwhile, non-participating states had no change in the reporting lag to NORS with a median of 26 days both pre- and post-NoroSTAT and a more modest reduction of reporting lag to CaliciNet from a median of 21 to 11 days. CaliciNet reports that were linkable to NORS reports increased from 86% to 95% (p <.0001) for NoroSTAT states versus from 29% to 33% (p = 0.016) for other states.

> NoroSTAT information can be used to
>
> - Quickly evaluate current norovirus outbreak activity
>
> - Compare outbreak activity with activity in previous years
>
> - Assess strain-specific characteristics of norovirus outbreaks, including the impact of new strains on outbreak frequency and severity

Increased food safety funding enabled expansion of NoroSTAT to seven states in August 2015 with the addition of Michigan and South Carolina and further expansion to nine states in August 2016 with the addition of Massachusetts and Virginia. The nine states currently participating in NoroSTAT include approximately 64 million residents, representing 20% of the U.S. population. Summaries of data reported through NoroSTAT are publically posted on the CDC website and updated monthly.

- *Enhancing CaliciNet*

  In FY 2016, data on 776 laboratory-confirmed norovirus outbreaks were uploaded to CaliciNet. Of these, 665 (86%) outbreaks were uploaded by the 33 CaliciNet-certified laboratories in 28 states and the District of Columbia, and 111 (14%) outbreaks were from the remaining 22 states, and typed and uploaded by the five regional CaliciNet support centers. Of the norovirus outbreaks reported in 2016, 17% could epidemiologically be identified as foodborne. The predominant genotype until January 2016 was Pe-GII.4 Sydney, which was replaced by a new GII.4 strain: P16-GII.4 Sydney. A dual typing (partial polymerase and partial capsid gene) protocol for noroviruses has been shared with all CaliciNet certified laboratories, which are on schedule to begin this novel typing in the 2016–2017 season.



CaliciNet: Participating States

CaliciNet-Outbreak Support Centers (CN-OSC)
California   Tennessee
Idaho        Wisconsin
New York     CDC

FDA Seafood Laboratory

State laboratories certified (n = 28 + DC)
State laboratories pending certification (n = 1)
State laboratories submitting to CN-OSC (n = 21)

CaliciNet certified laboratories (n=33 in 28 states and the District of Columbia) and regional support centers (selected through competitive award) include departments of health in California, Idaho, New York, Tennessee, and Wisconsin.

- *Developing CryptoNet*

  To improve cryptosporidiosis case surveillance and outbreak investigations, CDC's WDPB developed CryptoNet, a system (similar to PulseNet) that targets *Cryptosporidium* and integrates molecular typing and traditional epidemiologic data. In FY 2016, CDC collaborated with state public health departments, which continued to send outbreak and sporadic case specimens for molecular analysis and corresponding traditional epidemiologic data to CDC. Funding was provided through the ELC Cooperative Agreement to Alabama, Maine, Minnesota, Nebraska, New Hampshire, Tennessee, and Wisconsin to begin

building state laboratory capacity to molecularly type *Cryptosporidium*. Key accomplishments from the program included the following:

o   Improved collaboration with state partners as evidenced by an increased number of clinical specimen submissions (2015, n=75+; 2016, n=200+)

o   Launched a new case investigation form to capture exposure data

o   Included CryptoNet case investigation exposure questions in state case investigation forms

o   Increased reporting of traditional epidemiologic data

o   Trained representatives from Alabama, Nebraska, and Tennessee public health laboratories in how to conduct Sanger-based amplicon sequencing and subtyping

- *Cholera and Other* Vibrio *Illness Surveillance (COVIS)*

    In FY 2016, CDC continued to oversee the COVIS electronic database as well as did the following:

    o   Continued to engage state public health agencies and laboratories in COVIS through routine surveillance and cluster and outbreak investigations

    o   Continued to host a national workgroup of foodborne epidemiologists to improve communication across states to aid in outbreak and traceback investigations

    o   Used national surveillance to identify and close contaminated shellfish harvest areas associated with cases in multiple states

    o   Published the annual summary of 2014 data in May 2016, with measures for reporting timeliness and completeness

    o   Improved timeliness and frequency of data sharing between CDC and FDA by sharing case reports with FDA every week

    o   Changed the CSTE case definition to capture cases identified by CIDTs

- *National Botulism Surveillance System*

    Since 1973, CDC, in partnership with CSTE, has maintained the National Botulism Surveillance System for intensive surveillance for cases of botulism in the United States. The National Botulism Surveillance System collects reports of all confirmed botulism cases in the United States and is continuously monitored for early detection of outbreaks. In FY 2016, CDC did the following:

    o   Continued to oversee and manage the botulism surveillance and clinical consultation systems

    o   Coordinated a conference call with state epidemiologists, federal partners, and Cangene (the manufacturer of the botulinum antitoxin) to highlight the role of CDC's botulism consultation service and discuss post-marketing requirements for the antitoxin

    o   Conducted two systematic reviews to inform CDC's botulism clinical care guidelines that will report the foods implicated in single botulism cases and botulism outbreaks

- *Hepatitis A surveillance*

    As part of CDC's National Notifiable Diseases Surveillance System (NNDSS), viral hepatitis case reports are received electronically from U.S. state and territorial health departments via CDC's National Electronic Telecommunications System for Surveillance (NETSS), a computerized public health surveillance system that provides weekly updates to CDC.

Despite protection among young persons, due to universal infant vaccination since 2006, many older adults have not been vaccinated and are therefore susceptible to infection. From 2011 to 2013, an increase in the number of reported cases of hepatitis A virus (HAV) infection was observed. However in 2014, 1,239 cases of HAV were reported, representing a 30.4% decrease from 2013. This decline was the result of a large 2013 HAV outbreak among people who consumed imported pomegranate seeds in several southwestern states and Hawaii. After adjusting for under-ascertainment and under-reporting, the estimated number of new HAV infections in 2014 was 2,500. Data from 2015 are still being analyzed, and an increase in the number of HAV cases in 2016 is expected due to the following two large foodborne outbreaks:

o   In Hawaii, investigation of >250 cases of HAV, including >70 hospitalizations, showed an association with consumption of frozen scallops imported from the Philippines. Web postings were used to communicate information with the public, and multiple calls with the food industry and FDA led to a recall of the product.

o   Similarly, as of October 17, 2016, an investigation of 134 cases with 52 hospitalizations from 9 Mid-Atlantic States showed an association with consumption of frozen strawberries imported from Egypt. Multiple calls between CDC, FDA, and the food industry led to successful voluntary recalls of the implicated product. The public was updated with web postings by CDC and FDA and selected states.

## C.   Sharing surveillance information faster among federal, state, and local agencies

- *National Outbreak Reporting System*

    NORS is designed to receive foodborne outbreak surveillance data from public health departments in all 50 states, the District of Columbia, and each U.S. territory as well as from CDC's ORPB, which investigates multistate foodborne disease outbreaks.

    o   In 2015, NORS received 897 foodborne outbreak reports. These reports included information on 15,018 illnesses, 922 hospitalizations, and 14 deaths associated with foodborne illness that occurred in the United States during that year.

    o   NORS data serve as a key data source for attribution studies conducted by CDC, FDA, and USDA/FSIS. NORS staff members are developing ways to improve data quality, such as outbreak definition standardization, to strengthen these studies.

    o   NORS and NARMS continue to link data from the two surveillance systems to provide outbreak investigators with summary resistance data and to improve reporting by states to NARMS.

    o   NORS staff members are working with their counterparts in 12 states and CDC's ORPB to define reporting criteria that will help clarify which data should be reported to the surveillance system. These criteria will be used by each reporting site, further standardizing outbreak reporting.

    o   NORS staff members are designing an online dashboard to provide outbreak investigation tools to state, territorial, and local public health departments. The tools will help with food vehicle hypothesis generation, pathogen prediction based on clinical signs and symptoms, antimicrobial resistance prediction by pathogen subtype, and a list of contributing factors by location of contamination.

    o   NORS staff members are working with state public departments that have low outbreak reporting rates on ways to improve and reduce barriers to reporting. NORS staff members also are designing clearer guidance on reporting requirements and revising reporting metrics.

- o The [Foodborne Outbreak Online Database](#) (FOOD Tool) provides public access to NORS data. It includes foodborne outbreak data from 1998 through 2015, and can be searched by year, state, location of preparation, food or food ingredient, and pathogen. The 2015 NORS data were uploaded to the FOOD Tool on September 1, 2016.

- **National Antimicrobial Resistance Monitoring System for Enteric Bacteria**

  NARMS, established in 1996, is a collaboration among CDC, FDA's Center for Veterinary Medicine (CVM), USDA, and state and local health departments. The NARMS program at CDC monitors antimicrobial resistance among enteric bacteria isolated from humans. Other components of NARMS include surveillance for resistance in enteric bacteria isolated from retail meats, conducted by FDA/CVM in collaboration with selected state health departments, and surveillance for resistance in enteric bacteria isolated from animals, conducted by USDA's Agricultural Research Service and FSIS. The goals of NARMS include

  - o Monitoring trends in antimicrobial resistance among foodborne bacteria from humans, retail meats, and animals

  - o Disseminating timely information on antimicrobial resistance to stakeholders in the United States and abroad to promote interventions that reduce resistance among foodborne bacteria

  - o Conducting research to better understand the emergence, persistence, and spread of antimicrobial resistance

  - o Assisting FDA in making decisions related to the approval of safe and effective antimicrobial drugs for animals

  - o At CDC, NARMS conducts surveillance among the entire U.S. population. Public health laboratories in each state systematically select every 20th nontyphoidal *Salmonella*, *Shigella*, and *E. coli* O157 isolate as well as every *Salmonella* ser. Typhi, *Salmonella* ser. Paratyphi A, and *Salmonella* ser. Paratyphi C isolate received, and forward these isolates to CDC for antimicrobial susceptibility testing.

  - o Public health laboratories in the 10 state health departments that participate in CDC's FoodNet forward a frequency-based sample of *Campylobacter* isolates to CDC for susceptibility testing. In 2009, NARMS began susceptibility testing of all *Vibrio* isolates other than *V. cholerae*. Beginning in 2011, NARMS enhanced testing of isolates from enteric disease outbreaks.

    In 2012, NARMS launched a web-based surveillance database for human isolates that was adopted by >95% of states within 6 months. Since 2013, states have been able to view and download results for their isolates.

  - o In August 2015, NARMS launched NARMS Now: Human Data, a public access tool that allows users to visualize the data graphically and download the latest resistance data on enteric bacteria from humans. Isolates received by NARMS are tested to determine the minimal inhibitory concentration (MIC) for each antimicrobial agent on the NARMS panel. Each year, NARMS reports the susceptibility results for human isolates in an annual report published by CDC and in an Executive Report published by FDA/CVM. In addition, results from NARMS surveillance and studies are published in peer-reviewed journals.

  Significant accomplishments in FY 2016 included

  - o CDC NARMS continued to work with federal NARMS partners at FDA and USDA to integrate surveillance data.

- Developed the 2014 NARMS Integrated Report released in the fall of 2016
- Provided human surveillance data to FDA NARMS data for incorporation into the following:
  - An integrated database
  - NARMS NOW Integrated Data (publically accessible data)
  - Improved interactive data visualization tool (to be released with the upcoming Integrated Report)

o NARMS worked closely with PulseNet to provide antimicrobial resistance funding to state and local health departments via the ELC grant.
  - NARMS distributed approximately $11.8 million to support WGS capacity to improve detection of and surveillance for antibiotic-resistant intestinal bacteria found in ill people.
  - Funding paid for 32 whole genome sequencers. Every state is expected to receive whole genome sequencing equipment by September 2017 and work toward conducting whole genome sequencing on bacteria, including *Salmonella*, *Shigella*, and *Campylobacter*. These advancements will allow for faster identification and response to foodborne outbreaks and rapid identification of known markers of antibiotic resistance.

o In early 2016, NARMS antimicrobial susceptibly testing (AST) data were made accessible in SEDRIC.
  - The latest data are uploaded every week.
  - SEDRIC allows federal and state public health partners to view the latest resistance data for isolates that are a part of outbreaks.
  - AST data can aid hypothesis generation during outbreak investigations.

o NARMS and NORS databases were linked to aid attribution studies to determine
  - The food and animal sources for resistant *Salmonella* transmitted to humans
  - The difference between foods causing resistant infections versus foods causing susceptible infections

o All resistant 2014 nontyphoidal *Salmonella* were sequenced, and sequencing of all 2015 nontyphoidal *Salmonella* received by NARMS is in process.
  - Variables were developed in the database to house the identified resistance genes and variables that predict the phenotypic resistance profiles based on the genetic data.

o Published the CDC NARMS 2014 Human Isolates Surveillance Report (August 2016)
  - For the first time, the NARMS annual report included WGS data of bacteria from people with antibiotic-resistant nontyphoidal *Salmonella* infections. Genetic data provided by this sequencing can be used to identify resistance genes and predict antimicrobial resistance.
  - These data included a list of resistance genes (and predicted resistance) identified through WGS of 2014 resistant nontyphoidal *Salmonella* submitted to NARMS.

D.  **Identifying and proposing solutions to eliminate key barriers at federal, state, and local levels to improve foodborne illness surveillance**

- *National Center for Environmental Health Enhancements*

  The [National Environmental Assessment Reporting System](#) (NEARS) is a surveillance system that enables ongoing, systematic collection, management, analysis, interpretation, and dissemination of foodborne outbreak environmental assessment data. NEARS began data collection in April 2014. Program participation in NEARS has increased 90% since its 2014 launch (from 11 to 21 participating programs).

  o  Thirteen state programs currently participate in NEARS: Alaska, California, Connecticut, Iowa, Michigan, Minnesota, New York, North Carolina, Oregon, Rhode Island, South Carolina, Tennessee, and Wisconsin.

  o  Eight local programs currently participate in NEARS: Coconino County Public Health Services District (Arizona), Davis County Health Department (Utah), Fairfax County Health Department (Virginia), Harris County Health Department (Texas), Kansas City Health Department (Missouri), New York City Department of Health and Mental Hygiene (New York), Sharon Health Department (Massachusetts), and the Southern Nevada Health District (Nevada).

- *Beginning in 2015, CDC staff started working to integrate and improve coordination and linkage of foodborne outbreak data from NEARS and NORS. In 2016, activities included*

  o  Developing a plan to move the NEARS data collection system to the NORS information technology platform

  o  Linking and conducting data analyses of 2009–2014 NORS and NEARS data. These analyses revealed that 70% of the outbreaks reported into NEARS were also identified in NORS. Reports summarizing NEARS data in aggregate and for each participating NEARS site were released on the CDC NEARS website.

  o  Working with the National Network of Public Health Institutes (NNPHI) to develop and implement a Foodborne Illness Outbreak Investigation Environmental Assessment Training and Certification Program. This program builds the capacity of state and local food safety program staff to conduct environmental assessments during outbreak investigations. Additionally, information about NEARS is included in the program and an Environmental Assessment Toolkit has been developed to enhance the program. The National Environmental Health Association will host this program and will serve as the credentialing body for certification. The program will be free and available online in 2017.

  o  Exploring ways to share NEARS data online faster with the food industry, academia, consumers, and the public (potentially through the [Data.CDC.gov website](#)).

- *The Environmental Health Specialists Network (EHS-Net)*

  EHS-Net is a collaborative forum of environmental health specialists who work together to improve environmental health practice by developing and sustaining a network of environmental health specialists who collaborate with epidemiologists, laboratorians, and other public health professionals to conduct practice-based research to identify and prevent environmental risk factors contributing to foodborne illness.

  o  In 2015 and 2016, two sites were added to EHS-Net, bringing the total number of sites to eight. These include California; Harris County, Texas (the third most populous U.S. county);, Minnesota;

New York City; New York State; Southern Nevada Health District (includes 70% of Nevada's population); Rhode Island; and Tennessee.

- o EHS-Net sites are conducting activities that increase collaboration and communication between epidemiologic and environmental health programs during foodborne illness outbreak investigations, ensuring that environmental assessments are conducted during foodborne illness outbreak investigations, and reporting those environmental assessment data into NEARS. EHS-Net-funded research projects for food safety activities are under the jurisdiction of departments of health or other agencies responsible for regulatory oversight of retail food service including restaurants, delis, cafeterias, and schools.

## II. Evaluating and Improving Surveillance Systems

To implement FSMA requirements to evaluate and improve surveillance systems, CDC has improved epidemiologic tools and microbiological methods for obtaining quality exposure data and identifying and classifying cases. Selected CDC activities include the following:

### A. Tracking and analyzing laboratory use of CIDTs

- *Foodborne Diseases Active Surveillance Network*
  - o Continued to measure effects of CIDTs on foodborne illness surveillance
  - o Continued to collect information on laboratory methods used to diagnose FoodNet pathogens
  - o Continued to collect reports of infections diagnosed using CIDTs

### B. Developing better methods to detect, investigate, respond to, and control multistate foodborne outbreaks

- *System for Enteric Disease Response, Investigation, and Coordination*

  SEDRIC is customized, commercial, web-based software from Palantir Technologies. It facilitates collaborative multistate enteric disease outbreak investigations by integrating surveillance data in real time, visualizing outbreak data rapidly, and providing a secure platform for collaboration. Access to SEDRIC is provided free of charge to state, local, and other federal users. SEDRIC runs via a browser window and does not require the installation of additional software. The current system provides users access to outbreak dashboards, time trend maps, customizable traceback diagrams, historical human and non-human isolates in PulseNet, antimicrobial resistance information, and patient line list management capabilities. Progress in 2016 included the following:

  - o Successful deployment continued, with >600 (200 active) SEDRIC users from CDC, all 50 states (plus Puerto Rico and Guam), FDA, and USDA.

  - o States have obtained cluster-specific outbreak information 24–48 hours faster using SEDRIC than through typical laboratory communications.

  - o More than 10 SEDRIC training sessions covering approximately 200 users were conducted, including training at the CSTE Annual Conference.

  - o Routine integration of data was completed from NARMS into SEDRIC.

  - o The ability to use SEDRIC to rapidly collect epidemiologic data from ill persons via a web-based

questionnaire tool was investigated. This includes the ability to deploy online the National Hypothesis Generating Questionnaire, which collects information on more than 300 food items and other exposures commonly seen in multistate outbreaks.

- *Foodborne Diseases Centers for Outbreak Response Enhancement (FoodCORE)*

  The FoodCORE centers work together to develop new and better methods to detect, investigate, respond to, and control multistate outbreaks of foodborne diseases. Currently 10 centers participate, covering about 18% of the U.S. population.

  o FoodCORE supports enhanced laboratory, epidemiologic, and environmental health activities related to outbreak surveillance and response. Key findings from FoodCORE include the fact that from the first year of the program, which began in October 2010, to the end of the fourth year, in December 2014, the centers completed molecular subtyping for a higher proportion of *Salmonella*, STEC, and *Listeria* isolates (86% versus 92%) and reduced the average time to complete testing from a median of 8 to 4.1 days. The centers attempted epidemiologic interviews with more *Salmonella*, STEC, and *Listeria* case-patients (93% versus 99%), and the average time to attempt interviews was reduced from a median of 4 days to 1.1 days. During the fifth year, more than 325 environmental health assessments were conducted.

  o FoodCORE findings, data, and lessons learned have been presented at various national meetings and conferences, and in partnership with other food safety programs. Updated programmatic findings, including the fourth year of data and model practices, were presented at the CSTE Annual Conference in June 2016, at the National Conference on Health Communication, Marketing, and Media in August 2016, at the American Evaluation Association (AEA) Annual Conference in October 2016, and at the 2016 American Public Health Association (APHA) conference in November 2016. Data summaries and additional model practices will be made publically available during FY 2017. FoodCORE Center staff also presented their own center-specific experiences at a variety of local, state, and national conferences, meetings, and training sessions. Data and summary information from previous grant years are publically available on the FoodCORE website and updated annually.

- *OutbreakNet Enhanced initiative*

  OutbreakNet Enhanced is a CDC program started in August 2015 that provides support to state health departments to improve their capacity to detect, investigate, control, and respond to foodborne disease outbreaks. OutbreakNet Enhanced is coordinated by CDC's Capacity and Implementation Team and funded through the ELC Cooperative Agreement.

  o Currently, 18 states participate as OutbreakNet Enhanced sites. States use funds to hire additional epidemiologists and students to interview people with foodborne illness and travel to training events and conferences to build on outbreak response skills. The intent of funded activities is to implement faster and more complete review of surveillance data, improve interviewing and data sharing, and document improvements with performance metrics. Priority areas for improvement are detection and rapid interviewing of *Salmonella*, STEC, and *Listeria* cases. The ability to detect and respond to other bacterial, viral, and parasitic foodborne disease outbreaks is also strengthened. OutbreakNet Enhanced sites collaborate with each other and with CDC to share experience and insights to improve foodborne disease outbreak response.

- *Improving cyclosporiasis surveillance and outbreak investigation resources*

  CDC's Parasitic Diseases Branch (PDB) coordinates national surveillance and outbreak response for cyclosporiasis.

  o As of September 16, 2016, CDC had been notified of a total of 384 laboratory-confirmed cases of cyclosporiasis in persons with illness onset in 2016. Of these 384 case-patients, at least 134 with illness onset on/after May 1 became infected in the United States. These 134 persons were from the following 25 states: Arizona, Colorado, Connecticut, Florida, Georgia, Illinois, Indiana, Iowa, Maine, Massachusetts, Michigan, Minnesota, Missouri, Nebraska, New Hampshire, New Jersey, New York (including New York City), North Carolina, Ohio, South Dakota, Tennessee, Texas, Virginia, Washington, and Wisconsin.

  o Deployment of the web-based cyclosporiasis national hypothesis-generating questionnaire was expanded from 10 states in 2015 to 15 states in 2016. This expansion allowed for quicker analysis and dissemination of extended food exposure data to state and federal partners during the summer 2016 cyclosporiasis outbreak season.

  o CDC held weekly conference calls with FDA colleagues to provide updates on case and cluster investigations. CDC also held a 50-state call in early July to update all state and public health partners on case counts and current investigations. Information regarding the single cluster investigated in 2016 was disseminated to states in early August via email. Formal web postings were not utilized for the 2016 season, as there were fewer domestically acquired cases than in previous years, and no large and/or multistate outbreaks.

  o CDC staff expanded deployment of the web-based cyclosporiasis national hypothesis-generating questionnaire during May–August 2015 to 10 states (up from 0 states in 2014). Receiving extended food exposure data electronically allowed CDC to receive and analyze the data more quickly by eliminating the scanning/faxing of paper forms from states to CDC, and the data entry step at CDC.

  o There are currently no molecular methods with which to link *Cyclospora* cases to each other or to particular food vehicles or sources, which makes it extremely difficult to characterize the extent of particular outbreaks or to distinguish between multiple concurrent outbreaks. As part of a *Cyclospora* advanced molecular detection project that began in 2014, the PDB laboratory sequenced the near-complete genomes of *Cyclospora* samples obtained during recent and more distant outbreaks. Using comparative genomic sequence analysis, variable regions that could potentially be useful for a typing tool were identified. Pending continued funding, plans call for evaluation of these regions for epidemiologic value and development of a typing method for outbreak investigations.

  o More information about *Cyclospora* can be found on CDC's *Cyclospora* pages.

- *Microbial quality of irrigation water*

  CDC's WDPB (and collaborators at the University of Georgia and Emory University) was awarded a 2-year research project from the Center for Produce Safety in 2014. The project investigated the use of a large-volume water sampling technique (dead-end ultrafiltration) and methods for detecting pathogens (e.g., *Salmonella*, *Cryptosporidium*) and alternative microbial water quality indicators for irrigation water. Water samples were collected from May 2015 through April 2016 from three irrigation ponds located at farms in southeast Georgia. Initial statistical analyses indicate that the ultrafiltration method yielded more detections of pathogens (*Salmonella* and *Cryptosporidium*) and pathogen surrogates (bacteriophages, human-specific fecal markers) than

simple, 1-L grab sampling. Additional analyses are underway to assess the effects of seasonality and water quality parameters on the presence and concentration of pathogens and their surrogates.

- *Effect of produce wash water turbidity on chlorine disinfection*

  CDC's WDPB worked with produce industry partners to investigate the effect of produce wash water turbidity on the effectiveness of chlorination for inactivating pathogenic *E. coli* and *Salmonella*. The project focused on leafy greens wash water systems from three producers. The turbidity of water in produce washing flumes increases through the production day as increasing cumulative amounts of leafy greens are processed. The results from this study demonstrated that chlorine efficacy decreased as wash water turbidity increased. Statistical analyses are underway to quantify the extent of this effect for each producer's water source. Data from this project will provide producers with an evidence base for evaluating the need to manage turbidity in wash water systems.

## C. Improving attribution of foodborne illness outbreaks to specific foods

- *Interagency Food Safety Analytics Collaboration (IFSAC)*

  Since its creation in 2011, IFSAC, a collaboration of CDC, FDA, and USDA/FSIS, has focused its analytic efforts to develop methods to estimate foodborne illness source attribution for four priority pathogens—*Salmonella*, *E. coli* O157, *Campylobacter,* and *Listeria*. In 2016, IFSAC project teams, composed of members of each agency and coordinated by a steering committee, completed the following:

  o Published results of a study in *Emerging Infectious Diseases* comparing sporadic and outbreak-associated illnesses that informs how attribution estimates derived from outbreaks might be applied to sporadic illnesses

  o Completed and signed a revised charter that codified the roles and responsibilities of IFSAC's Technical Workgroup and Communications Workgroup and refined processes based on the initial years of experience

  o Created a new strategic plan to be finalized in the coming months that will continue to focus on foodborne attribution over the next 5 years of IFSAC, with an added focus on how attribution estimates change over time

  o Continued collaborative progress on several projects of tri-agency interest with implications on foodborne illness source attribution

  o Updated the IFSAC website regularly with past, current, and future activities on foodborne attribution illness efforts to inform federal, state, and local officials and other stakeholders

## III. Collaborating and Sharing Information with External Stakeholders

### A. Sharing surveillance information faster with the food industry, academia, consumers, and the public

Stakeholders—food producers, regulators, and consumers—depend on CDC for practical and understandable information about keeping the food supply safe. Historically, food safety communications included annual summaries with data from surveillance networks, scientific

publications and presentations, and outbreak alerts. Today, partners and the public want access to more information—more frequently, and through multiple channels.

Since the introduction of FSMA, CDC has integrated communication, science, and policy expertise to improve the exchange and dissemination of food safety information. This team-based approach supports FSMA's call to action to provide fast, accurate, and relevant information.

- *Selected activities that support CDC's effort to collaborate and share information*

  o **Public Health Grand Rounds:** Each month, CDC presents Public Health Grand Rounds to foster discussion on major public health issues and to encourage action based on the latest scientific findings. On October 18, the topic focused on how changes in clinical diagnostic tests have affected the ability of public health to identify foodborne disease outbreaks. Traditionally, culture testing has been the primary way to identify the specific pathogen responsible for foodborne illness. However, doctors and clinical laboratories are increasingly using rapid diagnostic tests that can identify pathogens causing foodborne illness without the need to grow live bacteria in culture. The use of culture-independent diagnostic tests poses a serious challenge to public health surveillance, particularly for STEC and *Salmonella*. The rapid tests do not produce the bacterial isolates needed to identify dispersed outbreaks, track trends in subtypes and antimicrobial resistance, and attribute illnesses to their sources. Two CDC experts joined a public health official from Colorado and a representative from the diagnostic device industry for the 1-hour Grand Rounds session, called **Changes in Clinical Diagnostics and Tracking Infectious Diseases**. It was heavily promoted through CDC websites and email announcements and through social media, and it was streamed live online. It was also archived for people to view later.

  o **PulseNet 20<sup>th</sup> anniversary:** PulseNet, a national laboratory network, is celebrating 20 years of public health achievements in transforming the way we detect and investigate foodborne disease outbreaks. PulseNet investigations have brought about lasting changes in food industry practices and new regulations that have made our food safer.

    

    A recent cost-benefit analysis of PulseNet estimated that it prevents more than 270,000 foodborne illnesses in the United States each year, saving about $500 million in medical costs and lost productivity. In contrast, the cost of running the network was estimated to be about $7 million, showing that PulseNet has a significant return on investment.

    CDC has communicated PulseNet's key role in making our food supply safer through a year-long outreach effort, including working with public health partners to share success stories through websites and newsletters; fact sheets on PulseNet's 20<sup>th</sup> anniversary and the cost-benefit analysis; a redesigned website; infographics; email newsletters; and social media.

  o **Foodborne disease outbreak notices to raise awareness to protect consumers' health:** CDC communicates with the public and media about outbreaks of foodborne illness through investigation notices. These notices include consumer advice, epidemiologic information, and details about the investigation.

  o **Communication on new and emerging antibiotic-resistant infections and threats:** CDC provided timely information to the public and stakeholders on emerging resistance threats, including the

*mcr-1* gene that confers resistance to colistin, a clinically important antibiotic of last resort, and *Candida auris.* Information was also shared with the public and physicians in response to outbreaks of antibiotic-resistant infections, including *Shigella* and *Salmonella* Heidelberg.

In addition, CDC did the following:

– Posted the NARMS Now: Human Data 2014 Report and shared highlights with stakeholders. NARMS studies have contributed significantly to our understanding of resistant intestinal infections and how antibiotic-resistant bacteria flow through the food chain to people.

– Helped raise awareness of antibiotic resistance in foodborne bacteria and the importance of antibiotic stewardship through a variety of activities, ranging from materials prepared for the UN General Assembly special session on antibiotic resistance and related events, to the Report to the President on Combating Antibiotic Resistant Bacteria. Public outreach included communications around the 20th anniversary of NARMS and activities for the stewardship-focused 2016 Get Smart Week.

o **Sharing food safety tips with consumers for holiday celebrations and awareness days**

– CDC prepared and posted feature articles, blogs, social media messages, and infographics throughout 2016 that coincided with seasonal celebrations and food safety awareness observances. CDC collaborated with external partners and within the agency to share important food safety messages widely for winter holidays, summer celebrations, and other seasonal occasions.

– For National Food Safety Education Month in September 2016, CDC created an animated video to promote the proper use of kitchen tools to keep food safe. Graphics and a feature with tips to help prevent foodborne illness were shared through CDC's website and social media channels and on FoodSafety.gov. In December 2015, CDC held the third annual holiday food safety Twitter chat with participation from federal and state partners, the food industry, and food safety advocacy organizations. Food safety messages reached about 8 million users in that and the previous year's Twitter chat.

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**Making Food Safety Information Accessible to a Broader Audience**

CDC's food safety website has had more than 3.8 million page views since January 2016, up 500,000 from 2015. The website provides information on preventing foodborne illness, improving food safety, and investigating foodborne illness outbreaks. Websites with prevention and outbreak investigation information for the major foodborne germs *E. coli, Listeria,* and *Salmonella* also drew a larger audience, with page views rising from 5.4 million in 2015 to 10.3 million in 2016.

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- *The Integrated Foodborne Outbreak Response and Management Conference*

  o   In November 2015, the InFORM Conference was held in Phoenix, Arizona. The meeting drew over 475 laboratorians, epidemiologists, and environmental health professionals from the United States and eight other countries. Participants represented federal, state, and local public health, food, and environmental regulatory agencies. CDC staff as well as partners from CSTE, APHL, USDA/FSIS, and FDA also attended the meeting. Meeting topics included discussion of WGS and its utility in foodborne surveillance systems, highlights on past outbreak investigations, and the emerging role culture-independent diagnostics have on current surveillance systems. Many more topics included the presentation of various training and assessment modules and discussion of the future challenges facing state and federal outbreak response networks. These shared experiences forged stronger partnerships among meeting attendees, demonstrating the interagency teamwork crucial to the long-standing success of the PulseNet, OutbreakNet, and environmental health networks.

- *Epi-Ready: team-based training approach*

  o   In September 2014, CDC funded the National Environmental Health Association (NEHA) to conduct a 2-day Epi-Ready team training course combined with a special 1-day train-the-trainer course. These two courses in St. Louis drew over 45 participants, including local and state public health officials. The primary purpose of both courses was to train three-member laboratory, epidemiology, and environmental teams from the six Integrated Food Safety Centers of Excellence.

  o   During FY 2016, with help from NEHA and CDC funding, the CoEs successfully conducted three Epi-Ready courses in non-CoE states. These courses covered foodborne disease outbreak topics such as team formation, planning, detection, and investigation by epidemiologists, laboratorians, environmental health specialists, public health nurses, communication experts, and others. Importantly, after participating in an NEHA Train the Trainer course, several CoEs conducted additional team training using their own trainers.

- *Food allergy and anaphylaxis management: collaborating on a common goal*

  To meet FSMA requirements to establish guidelines for voluntary food allergy and anaphylaxis management for use in schools and early childhood education programs, CDC convened a panel of federal, medical, and school-affiliated experts.[*] This panel informed guidance priorities and content, and summarized scientific and school health–related data and papers related to managing food allergies in schools. In 2013 guidelines were released, and in 2014 multiple food allergy publications for specific school audiences, including an allergy toolkit, tip sheets for school personnel, and downloadable PowerPoint presentations for specific school audiences, were created.

  During FY 2015, CDC launched the Food Allergies in Schools Toolkit, found on the new Healthy Schools website. Since then, the School Health Branch continues dissemination efforts of the food allergy guidelines and companion online toolkit. From April–September 2016, the food allergy guidelines were downloaded 2,007 times with almost half (n=955) in August and September, likely corresponding to the start of the new school year. In addition, in June 2016 the National

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[*]Panel members were from the following agencies and organizations: CDC; the U.S. Department of Education; USDA; FDA; NIH/National Heart, Lung, and Blood Institute; the Food Allergy and Anaphylaxis Network; the Food Allergy Institute; the American Academy of Allergy, Asthma, and Immunology; the National School Boards Association; the National Education Association; the National Association of School Administrators; the National Association of School Nurses; and the American School Health Association.

Association of School Nurses was awarded a 5-year cooperative agreement for technical assistance and professional development to states, their own constituents, and other stakeholders for managing chronic conditions in schools. Part of their activities will be to disseminate CDC resources including the food allergy guidelines and toolkit, and educate school nurses and others about how to use CDC resources. These activities can include webinars, live presentations, and establishment of a training-of-trainers network.

- ***Integrated Food Safety Centers of Excellence: sharing best practices for foodborne disease surveillance and outbreak investigation***

  The CoEs serve as resources for local, state, and federal public health professionals who respond to foodborne illness and outbreaks. They develop free online products and provide services including training sessions and peer-to-peer consultation to health departments across the country. The CoEs focus their work on the activity areas described in FSMA and lead workgroups to help integrate their efforts.
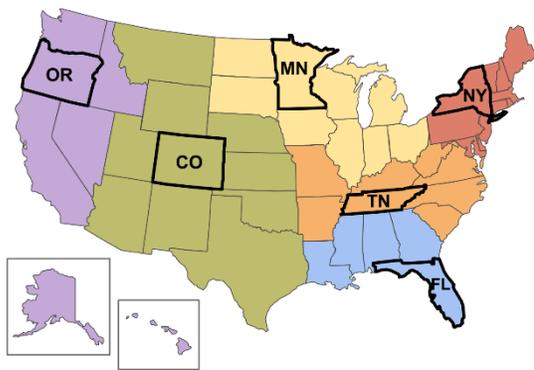


**Integrated Food Safety Centers of Excellence**

CDC named Colorado, Florida, Minnesota, Oregon, and Tennessee state health departments and their partner academic institutions as CoEs in 2012 under the authority of FSMA. New York was added in 2015 to fill in the gap in the northeastern United States.

In late 2015 the CoEs organized themselves according to geographic regions. These regions help the CoEs serve their mission by providing a point of contact to help guide jurisdictions to the CoE resources that best meet their needs. A health department is not limited to working with only their regional CoE, but should use their CoE to help them navigate the wide array of resources. Selected CoE projects in FY 2016 included the following:

### Colorado

- Released additional online resources including a new interactive laboratory QuickTrain: "A Day in the Life of a Stool Sample," which provides an introduction to what happens in a public health laboratory during a foodborne outbreak investigation.

- Organized and facilitated the first Foodborne Disease Outbreak ECHO (Extension for Community Health Outcomes) Learning Community. ECHO Learning Communities bring together public health professionals who work in foodborne disease to connect and learn about strategies and techniques used in managing outbreaks. Each community meets monthly for a six-part series.

- Hosted a foodborne outbreak challenge for Colorado School of Public Health students to work in multidisciplinary teams to solve an outbreak and develop a food safety intervention.

## Florida

– Developed four online videos on foodborne illness topics for novice investigators. These videos are part of a seven-part series started in 2014. The videos released this year cover the partners that protect the food supply ([federal](#); [state, general](#); [state, Florida](#); and [state, Georgia](#)). Spanish videos are also available for [federal partners](#) and [Florida partners](#).

– Continued to manage a [webpage](#) to house the online products of all the CoEs. The webpage is housed on the University of Florida website, but all centers are able to upload and edit their own products. Plans are in place to improve the usability of the website and improve the user experience.

– Advanced CoE efforts to promote resources and services by managing the CoE Twitter and LinkedIn accounts, and drafting a communications and social media plan for the CoEs.

## Minnesota

– Provided one-on-one peer mentoring to more than 20 health departments across the country. With the Minnesota CoE's help, Chicago successfully competed to become an OutbreakNet Enhanced site in August 2016.

– Released the results of their [2014 CIFOR metrics evaluation](#) for the state of Minnesota and the [background population exposure estimates](#) for Minnesota using *Salmonella* case interviews.

– Worked with university students to educate the future food safety workforce through scholarships; internships; a new experiential learning course; lecture courses at the University of Minnesota; and, in conjunction with the Oregon CoE, a certificate program in food protection.

## New York

– Launched a [CoE website](#).

– Held a 2-day [food safety symposium](#) at Cornell University. The symposium brought together laboratorians, epidemiologists, and environmental health specialists from across the Northeast and Mid-Atlantic. In addition to lectures and discussions, participants were able to tour the Cornell Diary processing facilities and practice environmental sampling techniques.

– Conducted a [needs assessment](#) of state epidemiologists, laboratorians, and environmental health specialists from every state in the region. Needs identified in this assessment were discussed at the food safety symposium.

## Oregon

– Promoted the [International Outbreak Museum](#) website by developing 20 videos and creating Instagram, Facebook, and Twitter accounts. The physical museum was also redesigned to better accommodate museum tours.

– Continued working on Project Mercury, a project to aggregate case exposure data from multiple sites to estimate background rates. Additional sites were added and questionnaires were mapped to allow for aggregation.

– Created an interactive application of the CIFOR Specimen Collection, Shipment, and Retention Guidelines for Foodborne [Outbreaks of Undetermined Etiology](#) (OUE) that is available for iPad and PC users.

– Conducted Epi Ready training courses throughout the region and hosted a Food Related Emergency Exercise Bundle tabletop exercise with participants from Tennessee, Georgia, and Alabama representing departments of public health (epidemiologists, nurses, emergency response coordinators, environmental health specialists, and laboratorians). Departments of agriculture, industry, and federal programs, such as at FDA and USDA, also participated in this exercise.

– Developed a downloadable activity to complement the outbreak training course series that is also being developed. The activity creates an opportunity for teams to come together throughout the online course series to build connections and identify specific areas for improvement.

– Continued to develop and promote quarterly CoE newsletters entitled *Centered on Food Safety* in collaboration with the other CoEs.

- *Council to Improve Foodborne Outbreak Response: developing and sharing guidelines, processes, and products that will facilitate effective foodborne outbreak response*

  o CIFOR is a diverse, multidisciplinary collaboration of eight national associations and three federal agencies that seeks to improve methods at the local, state, and federal levels to detect, investigate, control, and prevent foodborne disease outbreaks. CIFOR includes representatives from epidemiology, environmental health, public health laboratories, and regulatory agencies involved in foodborne disease surveillance and outbreak response. The food industry is represented on the standing CIFOR Industry Workgroup.

  o CIFOR underwent a strategic planning process during 2015 and early 2016 culminating in an agreement to create four Development Teams (Identify, Lead, Promote, and Evaluate) to improve the efficiency and completeness of new CIFOR products.

  o CIFOR held two face-to-face meetings, began development of new products, and released several products in FY 2016, including the following:

    – CIFOR OUE Guidelines suggest ways to determine the most appropriate specimens to collect when the etiology is not immediately known. The OUE Guidelines also provide suggestions on collecting adequate specimens for second-tier testing and pathogen discovery as well as CIFOR-developed universal recommendations on collection, shipment, rule-out testing, and long-term storage of outbreak specimens.

    – C-MET is a new online tool released in 2016 that enables states to easily enter their annual results for the 16 CIFOR metrics with target ranges.

- *Cooperative agreements*

  o The CDC Food Safety Office manages several cooperative agreements with national associations. Many, but not all, of the activities funded through these associations involve CIFOR Development Teams, workgroups, projects, and products. The overall goal of the work with the associations is to improve foodborne disease surveillance and outbreak response at the local and state levels, which directly affects federal disease control efforts. By funding these associations, CDC gains direct access to local and state front-line experts who provide guidance and extensive effort on Development Teams, in workgroups, and in meetings to develop solutions to current barriers that hinder outbreak detection and response.

- *Association of Public Health Laboratories*

  o APHL assists with many CIFOR projects, including management of the new CIFOR "Lead" Development Team; the CIFOR Lab-Epi Integrated Reporting software (freeware to help states and large cities more quickly identify clusters of enteric illness); C-MET, the web portal for states to upload their results for the 16 CIFOR metrics with target ranges; the OUE Guidelines for outbreaks of unknown etiology; and the APHL Food Safety Workgroup, which is actively addressing many issues, including WGS and CIDTs.

- *Association of State and Territorial Health Officials (ASTHO)*

  o ASTHO members and staff participate in development of all CIFOR products, such as the CIFOR Guidelines and the Guidelines Toolkit, CIFOR deliberations at all in-person meetings, development of a wide range of foodborne illness fact sheets and background materials for state health officials, and various food safety activities through the Environmental Health Policy Committee. ASTHO manages the CIFOR "Identify" Development Team.

- *Council of State and Territorial Epidemiologists*

  o CSTE was heavily engaged in the development and conduct of training courses for local and state staff on the Second Edition CIFOR Guidelines Toolkit, conducting webinars to publicize CIFOR products, convening the CIFOR Council and Governance Committee meetings twice a year, managing the CSTE Food Safety Fellowship (fellows are placed in state health departments for 2 years), leading the CIFOR strategic planning effort, and managing the CIFOR "Evaluate" Development Team.

- *National Association of County and City Health Officials (NACCHO)*

  o NACCHO actively maintains the CIFOR website, including the CIFOR Clearinghouse, and manages the standing CIFOR Industry Workgroup and co-manages (with NEHA) the new CIFOR "Promote" Development Team. NACCHO also has a very active Food Safety Workgroup, which is involved in a wide range of issues related to foodborne illness reporting and investigation at the local level, especially the environmental health aspect.

  o The CDC Food Safety Office manages several cooperative agreements with national associations. Many, but not all, of the activities funded through these associations involve CIFOR workgroups, projects, and products. The overall goal of the work with the associations is to improve foodborne disease surveillance and outbreak response at the local and state levels, which directly affects federal disease control efforts. By funding these associations, CDC gains direct access to front-line experts at the local and state levels to provide guidance to improve outbreak detection and response.