



FDA's CORE: A Food Safety Network 2011-2012

Acknowledgements

The story of the Coordinated Outbreak Response and Evaluation (CORE) Network is the story of partnerships. We wish to thank the many teams at the state, local and federal level that come together through CORE to identify, respond to and prevent outbreaks of foodborne illness. In addition, we would like to acknowledge all those on the following teams, because they played a major role in the outbreak responses highlighted in these pages. Without their efforts, these successes would not have been possible.

International Partners

- Public Health Agency of Canada
- Canadian Food Inspection Agency
- Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria (Mexico)

Federal Partners

- U.S. Department of Agriculture – Food Safety and Inspection Service
- U.S. Department of Agriculture – Food and Nutrition Service
- Centers for Disease Control and Prevention

State Partners

- Public Health and Agriculture Laboratories
- Arkansas Department of Health
- California Animal Health & Food Safety Laboratory System
- California Department of Food and Agriculture
- California Department of Public Health
- Colorado Department of Agriculture
- Colorado Department of Public Health and Environment
- Connecticut Department of Public Health
- Georgia Department of Public Health
- Illinois Department of Public Health
- Indiana State Department of Health
- Indiana State Department of Agriculture
- Iowa Department of Public Health
- Kansas Department of Agriculture
- Kansas Department of Health and Environment
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- Maryland Department of Health and Mental Hygiene
- Massachusetts Department of Public Health
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- Michigan Department of Community Health
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- New Jersey Department of Health
- New York State Department of Health
- Ohio Department of Agriculture
- Ohio Department of Health
- Rhode Island Department of Health
- Rhode Island Division of State Health Laboratories
- South Carolina Department of Agriculture

- South Carolina Department of Health and Environmental Control
- Texas Department of State Health Services
- Virginia Department of Agriculture
- Virginia Department of Health
- Washington State Department of Health
- Wisconsin Department of Health Services
- Wisconsin Division of Public Health
- Wisconsin State Laboratory of Hygiene
- Wisconsin Department of Agriculture, Trade and Consumer Protection- Bureau of Laboratory Services

Local Partners

- Alleghany County Health Department (Pa.)
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- Austin-Travis County Health and Human Services (Texas)
- City of Milwaukee Health Department (Wis.)
- City of Milwaukee Health Department Laboratory (Wis.)
- City of Wichita (Kan.)
- Dallas County Health and Human Services Department (Texas)
- Denton County Health Department (Texas)
- Fond du Lac County Health Department (Wis.)
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- New York City Department of Health and Mental Hygiene
- New York Wadsworth Laboratory
- Prowers County Department of Health (Colo.)
- Public Health – Seattle and King County (Wash.)
- Region I New Orleans Parish Health Unit (La.)
- Region II East Baton Rouge Parish Health Unit (La.)
- San Bernardino County Public Health Department (Calif.)
- Stonington Department of Public Health (Conn.)
- Waukesha County Division of Environmental Health (Wis.)
- Wauwatosa Health Department (Wis.)
- West Allis Health Department (Wis.)
- Williamson County and Cities Health District (Texas)

FDA

- Office of the Commissioner
- Office of Food and Veterinary Medicine
- Office of Regulatory Affairs
- Center for Food Safety and Applied Nutrition
- Center for Veterinary Medicine
- Office of Emergency Operations
- Office of External Affairs
- Office of the Counselor to the Commissioner

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Introduction



From the Deputy Commissioner for Foods and Veterinary Medicine

With the signing of the FDA Food Safety Modernization Act in January of 2011, President Obama signaled the formal beginning of a new era of food safety in the United States. That newly enacted law gave FDA new tools and new authority to execute its food safety mission, what I think of as its public health mission.

Since that time, we have been working to fully develop the foundation upon which the new era's food safety system will stand. We are developing the rules that will implement this new system focused on fully integrating the food safety infrastructure at the federal, state and local levels, leveraging the efforts of our counterparts in other countries, improving our response to outbreaks of foodborne illness, and most importantly, focusing more effort on prevention of foodborne illness.

As we move toward fully implementing the FSMA, FDA's Coordinated Outbreak Response and Evaluation Network (CORE) plays a critical role in Investigating and controlling outbreaks and learning from the outbreaks to prevent future ones from happening. This is an important part of a food safety system that truly protects public health. CORE does this through teamwork—marshaling all the resources it has available within and outside FDA.

There is still work to be done creating our new, prevention-based food safety system. Our progress with CORE is an example of how we are on the right path.

Michael Taylor
Deputy Commissioner for Foods and Veterinary Medicine

Our Commitment



A Message from the Chief Medical Officer

Every second counts. Nowhere is that more true than when dealing with illness outbreaks. A faster response to a disease outbreak can mean fewer illnesses.

With that in mind, the Food and Drug Administration set about creating an organization that would accelerate and streamline the agency's foodborne illness response. After just over a year of planning and development, FDA's CORE stood up in August of 2011. With the creation of CORE, FDA was testing a new concept. The idea was to coordinate FDA's efforts with a dedicated team of professionals from a number of health-related disciplines, and to incorporate the lessons learned by this team to improve outbreak response and to help prevent future outbreaks.

In this first report on the highlights of CORE's activities, the success of this concept is readily apparent. CORE was tested immediately with a major outbreak of listeriosis related to Jensen Farms cantaloupe, and CORE's quick response certainly saved lives. With each outbreak, CORE has evolved, adding new tools and techniques to the toolbox. The tremendous growth and constant improvement is detailed in the pages of this report, but there is something else in these pages as well.

CORE is a network, and that is one of the major strengths of CORE. The goal is to prevent and minimize foodborne illness, but no organization can go it alone. It takes many teams working in concert to find, stop and prevent outbreaks of foodborne illness.

Those teams are within the FDA - the District offices and their Regional Emergency Response Coordinators who work with our state partners; the Office of Crisis Management at FDA; FDA's Offices of Public Affairs and External Relations; the subject matter experts at FDA's Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine.

Those teams are at the federal level, with FDA and the Centers for Disease Control and Prevention (CDC) and the U.S. Department of Agriculture (USDA). Those teams are at the state and local levels, and those teams are in industry as well. With CORE, the FDA has made a commitment to working with our partners in food safety, a commitment to continuous improvement, but most of all a commitment to the health of consumers in the United States.

When President Obama signed the Food Safety Modernization Act into law, the FDA was tasked with building an integrated national food safety system in partnership with state and local authorities. The CORE Network is proving to be a successful step in that direction.

Kathleen Gensheimer
CORE Chief Medical Officer

Summary



Since CORE began in 2011, it has evaluated 211 potential foodborne illness incidents and responded to 63 incidents that were determined to involve FDA-regulated products. The major response actions are summarized below, and covered more fully in the text of this document.

***Listeria monocytogenes* in Cantaloupe (2011)** - 147 illnesses and 33 deaths. Recall of Jensen Farms cantaloupe crop. Environmental Assessment conducted.

***Salmonella* Bredeney in Peanut Butter (2012)** - 42 illnesses. Recall of hundreds of products. First use of FDA's authority to suspend a company's food registration.

***Salmonella* Bareilly and Nchanga in Raw Tuna (2011)** - 425 illnesses. Recall of more than 58,000 pounds of raw tuna. Import alert issued to detain raw tuna from the company is not imported unless it meets safety standards.

***Salmonella* Infantis in Pet Food (2011)** - 49 illnesses. Coordinated use of Veterinary Medicine's Veterinary Laboratory Response Network (VetLRN) during the response. Recall of 17 brands of pet food estimated at 30,000 tons.

***Listeria monocytogenes* in Frescolina Marte Cheese (2012)** - 22 illnesses and 2 deaths. Recall of Frescolina Marte cheese in the U.S. and other countries. Import Alert issued to detain the company's cheese products unless they meet safety standards.

***Salmonella* Typhimurium and Newport in Cantaloupe (2012)** - 261 illnesses and 3 deaths. Recall of Chamberlain Farms cantaloupe crop. Environmental Assessment conducted.

***Salmonella* Braenderup in Mangoes (2012)** - 127 illnesses. Recall of mangoes by U.S. distributors. Import Alert issued to detain the company's mangoes unless they meet safety standards.

***Salmonella* Agona in Papayas from Mexico (2010-2012)** - 256 illnesses. Import Alert issued to detain papayas from Mexico unless they are shown to meet safety standards.

***Mycobacterium* in tattoo ink (2012)** - 19 illnesses. Recall of tattoo ink by two companies. First CORE response to an outbreak linked to a cosmetic product.

Our Network



When the Food and Drug Administration (FDA) began operating CORE in August 2011, it brought together a full-time team with expertise in medicine, public health and science that is constantly looking for potential outbreaks in the U.S., investigating those outbreaks, and developing policies and guidance to prevent future outbreaks.

Part of a nationwide, integrated food safety system

To accomplish its mission, CORE integrates into the national food safety system. In addition to partners in regulatory, public health and agricultural agencies at the federal, state and local levels, CORE interacts with all the key FDA resources – the District offices and their Regional Emergency Response Coordinators who work with our state partners; the Office of Crisis Management at FDA; FDA's Offices of Public Affairs and External Relations; and the subject matter experts at FDA's Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine.

A new approach for FDA

In the past, FDA would assemble a response team once an outbreak was identified, and those staff would go back to their usual jobs once the response was over. With CORE, full-time teams work on various aspects of investigations from Signals to Post-Response, and can hit the ground running on new outbreaks. This new structure speeds the response, ensures continuity and standardizes processes.

Just weeks after CORE became operational, proof of the concept was evident in the response to the tragic outbreak of listeriosis, which was linked to whole cantaloupe from Jensen Farms and more than 30 deaths nationwide. The quick, coordinated response by CORE, state health agencies and the Centers for

Disease Control and Prevention (CDC) is widely acknowledged to have reduced the severity of the outbreak. This new approach saved lives.

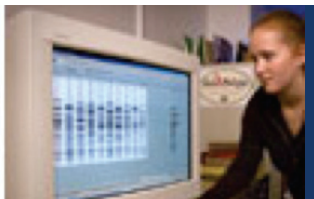
Three-pronged effort: Detection, response, prevention

CORE divides outbreak response activities into three phases:

- Phase One: Find the outbreak.
- Phase Two: Stop the outbreak.
- Phase Three: Prevent the next outbreak.

CORE has created a Signals and Surveillance Team, three Response Teams and a Post-Response Team, each with responsibility for a specific phase of the outbreak response. CORE Communications Specialists work across all team activities, coordinating communications and outreach.

"Our teams include epidemiologists, microbiologists, veterinarians, environmental health specialists, consumer safety officers and policy analysts," explained Dr. Kathleen Gensheimer, chief medical officer and director of CORE. "By dedicating experienced staff from a range of pertinent fields to each phase, we create a consistent, continuous operation. I think this has been key to the efficiency and success of this three-pronged effort to fight foodborne illness."



PulseNet is a valuable surveillance tool. This database has information from a national network of public health and food regulatory agency laboratories, and is coordinated by the Centers for Disease Control and Prevention (CDC).

On the lookout

It all starts with the Signals and Surveillance Team. This team is all about early detection that will limit or prevent illness linked to food, including dietary supplements, for both people and animals and cosmetics regulated by the FDA.

Team members comb through information that is reported into various databases by local and state health agencies and even search through news stories. One of the databases with valuable information for surveillance is PulseNet. PulseNet is a national network of public health and food regulatory agency laboratories coordinated by the Centers for Disease Control and Prevention (CDC). The network consists of state health departments, local health departments and federal agencies (CDC, USDA/FSIS, FDA). PulseNet participants perform standardized molecular subtyping (or “fingerprinting”) of foodborne disease-causing bacteria by pulsed-field gel electrophoresis (PFGE).

The team members look for “signals” or “red flags” that could be an early warning of a pending outbreak. They discuss emerging disease surveillance trends directly with CDC and FDA subject matter experts, and, through FDA field offices, with state health agencies. In addition, the Signals Team searches FDA data for historical information on firms, such as past inspections or sampling results, all in an effort to “connect the dots.”

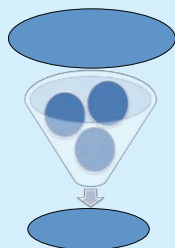
Once an outbreak related to an FDA-regulated product is identified, all of the available information is handed over to one of the three response teams.

On the hunt

Response Teams have one goal: to control and stop the outbreak. First, they must find the source and then they must ensure contaminated product is taken out of circulation. To do that, a Response Team works directly with the FDA field offices and their investigators on a response strategy. In a combined effort, the team, field offices and state and local agencies track down leads, and trace product distribution. The information provided through this detective work is evaluated against the information on illnesses to make sure the investigators are on the right track. Close coordination among the FDA, CDC, and state and local regulatory, public health and agriculture departments is crucial to stopping an outbreak.

An eye to prevention

What did we learn? How can we prevent this from happening again? These questions guide the mission of the Post-Response Team. This team looks at all aspects and factors of the outbreak, from ingredient sourcing to production and distribution, including from foreign countries. Team members build a working group, recruiting experts from FDA centers and field offices, to identify the source of an outbreak and to determine how the contamination could be prevented in the future. Their work may lead to new research on how contamination can occur, or it may lead to outreach to industry and other food safety agency partners on new ways to prevent future outbreaks. Improving FDA internal processes is also a key interest of the team, which, along with other federal and state partners, evaluates the FDA response in order to incorporate lessons learned and constantly improve future responses.



Since CORE began in 2011, the Signals and Surveillance Team has evaluated 211 potential incidents, collecting information from a number of sources. The team weighs several factors before passing the incident on to a response team. Among the factors considered are whether the outbreak is linked to an FDA-regulated product, the scope and severity of the outbreak, whether that product is still available and if control measures are known, the extent of external agency involvement and whether there has been or there is a need for press activity. In 2011 and 2012, the team passed 63 incidents to response teams.

Our Beginning



In August 2011, the Food and Drug Administration launched CORE after a 12-month long planning and development effort. In staffing CORE, FDA recruited from its pool of experts who had previously responded to outbreaks, therefore ensuring that hard-won experience was the very foundation of the new group.

From the beginning, no one in FDA doubted the concept, but certainly nobody could have predicted that the concept would be tested and proven to work the very next month. Yet, on September 14, 2011, the same day the FDA officially announced in a press release that CORE was operational, the FDA was also issuing another news release warning consumers of what would become the deadliest U.S. outbreak of foodborne illness in decades.

Through this early test of the concept, CORE along with its partners at the CDC, the state of Colorado and other states would save lives.

“Within CORE, it all starts with signals,” said Jeffrey Brown, head of CORE’s Signals and Surveillance Team.

During the 2011 listeriosis outbreak, which made 147 people ill and killed 33, the Signals Team was able to provide information garnered from internet research showing that Jensen Farms had not yet completed harvesting cantaloupe in the region of the country where many illnesses were being reported.

From there, the CORE Response Team took over in pursuit of their single-minded goal – stop the outbreak. The information passed on from the Signals Team to the Response Team led to the quick mobilization of FDA investigators who, along with key partners like the CDC and Colorado state officials, inspected Jensen Farms and collected samples confirming the farm as the source of the listeriosis outbreak. By September 14, Jensen Farms had initiated a recall of their entire 2011 crop, which had reached at least 24 states.

“The response doesn’t end with a press release announcing the recall, though,” said Roberta Hammond, CORE’s response manager. “Once the recall starts we continue coordinating efforts with those of other FDA offices to monitor the outbreak, inform the public and ensure the effectiveness of the company’s recall.”

In monitoring the effectiveness of the recall, the FDA audited nearly 100% of the firms directly receiving Jensen Farms cantaloupe and many additional secondary receivers of the product. A month after it began, FDA deemed the recall complete.

While the Response Team was still actively involved with the outbreak, the Post-Response Team coordinated a vitally important task: an environmental assessment of Jensen Farms to determine what factors might have contributed to the outbreak. The purpose of this type of assessment is to determine how the environment may have contributed to the introduction, spread, growth and transmission of pathogens that have caused illness.

“This was the first time we had seen listeriosis transmitted by whole cantaloupe,” said U.S. Public Health Service Capt. Sheila Merriweather, who was a CORE representative on the environmental assessment team.

“So it was very important that we were able to assess the processes and conditions on the farm and determine what lessons we could take away from this tragedy.”

With the cooperation of Jensen Farms, officials from FDA, CDC, the Colorado Department of Public Health and Environment, the Colorado Department of Agriculture and the Prowers County Department of Health conducted the environmental assessment at Jensen Farms in the latter part of September.

The team conducting the assessment had expertise in produce safety, agriculture, veterinary medicine, epidemiology, environmental health and sanitation. This team identified the following factors as those that most likely contributed to the introduction, spread and growth of *Listeria monocytogenes* in the cantaloupes:

- There could have been low level sporadic *Listeria monocytogenes* in the field where the cantaloupe were grown, which could have been introduced into the packing facility.
- A truck used to haul culled cantaloupe to a cattle operation was parked adjacent to the packing facility and could have introduced contamination into the facility.
- The packing facility’s design allowed water to pool on the floor near equipment and employee walkways.
- The packing facility floor was constructed in a manner that made it difficult to clean.
- The packing equipment was not easily cleaned and sanitized; washing and drying equipment used for cantaloupe packing was designed for and previously used for postharvest handling of another raw agricultural commodity.
- There was no pre-cooling step to remove field heat from the cantaloupes before cold storage. As the cantaloupes cooled there may have been condensation that promoted the growth of *Listeria monocytogenes*.

The findings of the environmental assessment have subsequently been used for educational outreach and guidance to the cantaloupe industry.

“A major goal of the Post-Response Team is to provide information to update and improve agency policy or industry guidance that can help prevent future outbreaks,” said Katie Vierk, the acting leader of the Post Response Team during this outbreak.

“When thinking about CORE, it is crucial to remember that the benefits extend beyond FDA,” said Dr. Gensheimer. “The CORE response teams are coordinating FDA resources with the resources and efforts of agencies at every level of government.”

FDA regularly partners on outbreak response with federal agencies like the U.S. Department of Agriculture and the Centers for Disease Control and Prevention, as well as with state departments of health and agriculture and with local health and safety agencies.

Since that first test of its capability, CORE has responded to more than 60 incidents of varied degree.

“Outbreaks can vary in size and in the severity of the illness, and a major challenge with some outbreaks is the scarcity of information,” said Hammond. “Sometimes there is not enough information to determine the cause, but we take each incident as far as we can.”

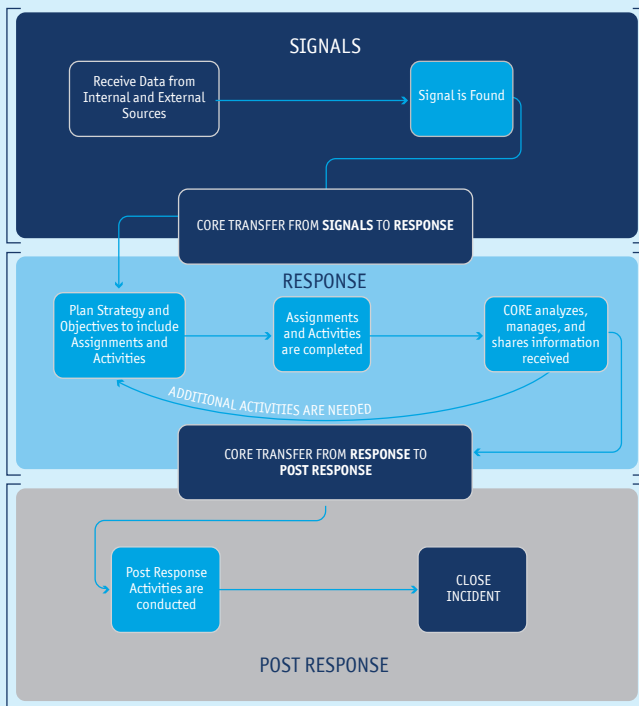
Major Investigation Partners

- Colorado Department of Public Health and Environment
- Colorado Department of Agriculture
- Prowers County Department of Health (Colo.)
- Centers for Disease Control and Prevention
- FDA Denver District Office

Our Evolution



“With every incident, we evolve. Our Signals and Surveillance Team, our Response Teams and our Post-Response Team are all typically evaluating or responding to several outbreaks at any moment,” said U.S. Public Health Service Retired Rear Adm. Brenda Holman, the deputy director of CORE. “Once one outbreak is winding down, the Response Teams get feedback from our partners, and the Post-Response Team makes sure that we take what we have learned and apply it to preventing or responding to future incidents. To me, that’s a recipe for providing the nation with a nimble, flexible capacity to more rapidly respond to, investigate and prevent foodborne outbreaks. CORE is a proven concept, and it will only get better with each response effort.”



Continuous improvement is a key component of the CORE concept, and the articles that follow each demonstrate at least one aspect of the organization’s continuing evolution.

Quick Action

In early September 2012, the CORE Signals and Surveillance Team spotted signs of trouble involving an outbreak of *Salmonella* Bredeney.

According to Jennifer Beal, MPH, a CORE epidemiologist, early reports for a cluster of *Salmonella* Bredeney illnesses showed that many of the ill were children. “Whenever we see that something is primarily affecting children, we mobilize quickly. It’s a big red flag,” noted Beal.

FDA and CDC joined forces with state and local public health and agriculture agencies. Food exposure data started coming in from the states to CDC, and it wasn’t long before this information pointed to a common source, Trader Joe’s Valencia Creamy Peanut Butter.

This peanut butter was produced by a contract manufacturer whose identity during the early phases of the investigation was unknown. CORE experts researched U.S. production of Valencia peanuts and discovered that almost 100% of this crop is grown in and around Portales, NM.

FDA’s district offices—part of the Office of Regulatory Affairs (ORA), the agency’s field operations—were informed about the investigation. Fortunately, a consumer safety officer from the FDA Denver District Office, which covers New Mexico, was already conducting an inspection of a plant in Portales that was known to make peanut butter for Trader Joe’s. It was the Sunland plant, which FDA soon learned was the sole producer of the peanut butter linked to the outbreak. Five more FDA consumer safety officers were soon dispatched to join the investigation.

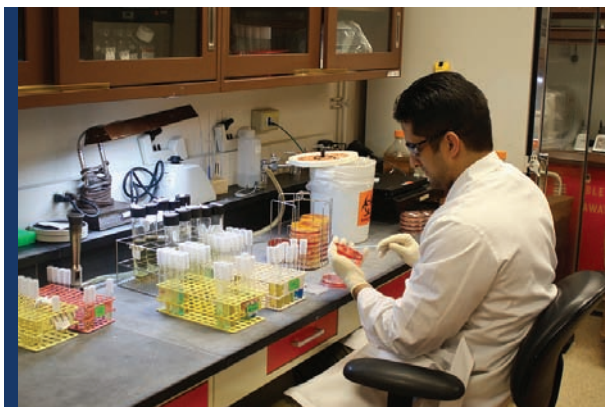
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Cmdr. William Boden of the U. S. Public Health Service, the emergency response coordinator for the FDA’s Denver District Office, says FDA consumer safety officers collected hundreds of environmental swabs from the equipment, floors and other surfaces in the facilities and dozens of samples from finished products. The officers also inspected Sunland’s records.



Microbiologist Julie Bentzoni performing DNA fingerprinting using PFGE (pulse field gel electrophoresis). This PFGE tool separates DNA molecules by applying an electrical field to a gel matrix.

The consumer safety officers sent the samples to FDA’s Denver District Laboratory and its Pacific Regional Northwest Laboratory. *Salmonella* matching the outbreak strain was found in an environmental sample and several finished product samples.



Microbiologist Andrew Gonzales streaks a growth medium containing nutrients onto a Petri dish. The *Salmonella* being analyzed will flourish in this medium.

Donald Zink, Ph.D., a senior science advisor at FDA, says that peanut butter is particularly vulnerable to *Salmonella* contamination. “*Salmonella* is in the soil and peanuts come right out of the ground,” he says.

Great care has to be taken to produce peanut butter in a “highly sanitized” environment, he says. Special protections have to be in place to make sure the finished product isn’t contaminated after the nuts are roasted, the only “kill step” for the *Salmonella*.

During the inspection, however, FDA inspectors found unsanitary conditions, including unclean equipment coming into contact with food, employees who didn’t wash their hands or wear clean gloves, and the use of totes to transport both raw and roasted peanuts without any cleaning or sanitizing process.

Ultimately, Sunland recalled hundreds of products manufactured in its facilities. These recalls also prompted related recalls by other companies which had used Sunland products to manufacture their own brands.

“More people would have fallen ill if not for fast action by federal and state public health agencies,” said Stelios Viazis, Ph.D., CORE’s lead coordinator on the outbreak response.

This was not the first time that FDA has found problems at Sunland. Investigators noted objectionable conditions during FDA inspections in 2007, 2009 and 2010. Sunland’s history of violations led FDA to return on multiple occasions to re-inspect the company’s facility and procedures.

Because of the outbreak and Sunland’s inspection history, on Nov. 26, 2012, the FDA suspended the food facility registration for Sunland Inc. This was FDA’s first use of the suspension-of-registration authority provided by the FDA Food Safety Modernization Act. This new authority enables FDA to suspend a facility’s registration when the agency has determined, in part, that a food that is manufactured, processed, packed, or held by a facility is likely to cause serious illness or even death. If a facility’s registration is suspended, that facility is prohibited from introducing food into interstate or intrastate commerce.

On November 30, when CDC reported that the outbreak appeared to be over, the outbreak was linked to 42 reported illnesses in 20 states, and the majority of those who were made ill were under age 10.

“CORE’s rapid response in coordinating, communication, and mobilizing internal and external partners helped to limit a significant outbreak involving one of our most sensitive populations, children,” said USPHS Lt. Cmdr. Willie Lanier, a veterinarian and the leader of the response team for this outbreak. “It also led to the historic first use of a new authority granted by the law.”

Major Investigation Partners

- Centers for Disease Control and Prevention
- California Department of Health
- Washington State Department of Health
- Virginia Department of Health
- New Mexico Environment Department
- New Jersey Department of Health
- Connecticut Department of Public Health
- Minnesota Department of Health
- Rhode Island Department of Health
- New Jersey Department of Health
- Texas Department of State Health Services

Leveraging Partnerships

Pets in the United States are a very real part of the American family. Though most pet owners don't give it much thought, when a pet becomes ill, there is a real risk to the pet owner and their family. This point was driven home during CORE's response to the 2011-2012 multi-state outbreak of *Salmonella* Infantis infections linked to pet food manufactured by Diamond Pet Foods at its production facility in Gaston, South Carolina.

This response also highlights the fact that the FDA has developed partnerships with public and private animal laboratories across the country, and that CORE can take advantage of those partnerships to help stop foodborne illness outbreaks.

FDA became involved in early April of 2012 when the Michigan Department of Agriculture and Rural Development reported detecting *Salmonella* from an intact package of Diamond Naturals Lamb and Rice Formula for Adult Dogs, collected during retail surveillance sampling.

Diamond Pet Food was notified of the sampling results, and recalled this product on April 6, 2012. At that time, there were no known dog illnesses reported. However, the positive test resulted in a domino effect of FDA inspection of the facility, individual and large scale recalls, increased state product testing, and detection of human cases with the same strain of *Salmonella*. The FDA inspected the Gaston production facility. Samples of Diamond Puppy Formula dry dog food collected yielded *Salmonella* Infantis, leading to a recall of the product on April 30, 2012. Violations were observed at the firm.

On April 6, the CORE Signals and Surveillance Team noted the naming of a new cluster of *Salmonella* Infantis cases in PulseNet.

A few days later, on April 10, the *Salmonella* Infantis isolate from the Michigan sample of Diamond Naturals Lamb and Rice Formula for Adult Dogs was entered into PulseNet. It matched the isolates from human cases using the PFGE analysis.

According to CDC reports, a total of 49 people were infected with the outbreak strain of *Salmonella* Infantis between October 2011 and July 2012. Forty-seven illnesses were reported in 20 states in the U.S. and two illnesses in Canada which provided further support in identifying the source of the outbreak.

The link between the product, dog illness and human illnesses was supported by *Salmonella* isolation from a sample taken by the Ohio Department of Agriculture, from an opened bag of Diamond Brand Chicken Soup for the Pet Lover's Soul Adult Light Formula dry dog food collected from the home of an ill person, and an unopened bag of the product collected from a retail store.

"We believe this outbreak spread to people through either the handling of contaminated pet food or through the care and handling of infected pets," said Dr. Dave Rotstein, a veterinarian and CORE's lead coordinator for this outbreak. "Once the outbreak was identified, we moved quickly to remove the contaminated pet food and stopped the outbreak."

Ultimately, Diamond Pet Foods recalled 17 brands of dry dog and cat food because they had the potential to be contaminated with *Salmonella*, recalling an estimated 30,000 tons of pet food. An additional recall occurred on May 21, 2012 from the Diamond plant in Meta, MO when a surveillance sample of Diamond Naturals Small Breed Adult Lamb and Rice collected by the state of Ohio showed the presence of *Salmonella* Liverpool.





Several other companies with products manufactured at the Gaston plant also issued voluntary recalls, since some of their products were produced during the time frame of the recalls and had the potential to be contaminated with *Salmonella*.

The distribution chain for all recalled products reached 40 states and 26 countries worldwide.

During its investigation, the FDA leveraged its Center for Veterinary Medicine's Veterinary Laboratory Response Network (VetLRN) to confirm the illnesses in four dogs and a cat owned by people made ill by the outbreak strain of *Salmonella* Infantis as well as to follow up on consumer complaints for potential widening of the recall.

VetLRN coordinates facilities, equipment and professional expertise of government and veterinary diagnostic laboratories across the U.S. and Canada in response to high priority chemical and microbial animal feed and animal drug contamination events.

The pets from which the outbreak strain of *Salmonella* Infantis was cultured had eaten the recalled pet food, thus completing the link between the pet food, the pets and their owners.

"Typically, pets with milder gastrointestinal signs are not taken to the vet and even if they do get seen, most mild cases are not cultured. Additionally animals can harbor *Salmonella* and not have any clinical signs, so it is difficult to confirm an outbreak of disease among pets," said Renate Reimschuessel, DVM, a research biologist in the FDA's Center for Veterinary Medicine. "Using resources of the Veterinary Laboratory Response Network, we were able to test these animals, helping to connect all the dots."

Additional investigational steps included analyzing consumer complaints to determine if they were related to this outbreak and continued state surveillance to determine whether any recall expansion would be required. Consumer complaints provided further support of the source of the outbreak based on the animal signs and dog food lot code information.

"The response to this outbreak was a great step in the evolution of CORE," said USPHS Lt. Cmdr. Carla Tuite, the leader of the response team for this outbreak. "We were able to coordinate effectively with the FDA Center for Veterinary Medicine and collaborate with VetLRN, sharing resources to confirm the outbreak affected both pets and humans."

Major Investigation Partners

- Public Health Agency of Canada
- Centers for Disease Control and Prevention
- Connecticut Department of Public Health
- Michigan Department of Agriculture and Rural Development
- Michigan Department of Community Health
- Ohio Department of Agriculture
- Ohio Department of Health
- South Carolina Department of Agriculture
- FDA Center for Food Safety and Applied Nutrition
- FDA Office of Regulatory Affairs
- FDA Central Regional Office
- FDA Pacific Regional Office
- FDA Southeast Regional Office
- FDA Southwest Regional Office
- FDA Atlanta District Office
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- FDA Philadelphia District Office
- FDA San Francisco District Office
- FDA Seattle District Office

Leveraging FDA Resources

In its simplest terms, an investigation can be described as the search for the right answers to the right questions.

In the case of foodborne illness outbreak investigations, those questions might be:

- Is food the cause? What food?
- Where was that food distributed?
- Who produced it? Where and how?
- How did the contamination occur?

Of course, in practice it is not that simple, and in fact, the answers to those questions can in turn generate new questions. Also, the complex nature of food distribution in the United States and internationally can serve as an obstacle to answering those basic questions.

In 2012, the complexity of the investigation into the multi-state *Salmonella* outbreak linked to frozen raw tuna from India was such that CORE needed to fully leverage FDA response capabilities. This outbreak, which ultimately involved 425 illnesses in 28 states, called for the establishment of an FDA agency-level Incident Management Group (IMG). Typically, an IMG is established when an incident involves multiple FDA organizational components or involves complex incident management and coordination.

In early March, 2012, members of the CORE Signals and Surveillance Team were alerted through PulseNet, a national network of laboratories, to a cluster of illnesses caused by *Salmonella* Bareilly bacteria. By March 8, the state of New York reported 7 illnesses and 9 other states reported 11 additional illnesses, all of which had the same DNA fingerprint.



Immediately, the Signals and Surveillance Team researched the historical laboratory information on *Salmonella* Bareilly, finding that *Salmonella* Bareilly was rare in the U.S. From 1980 through 1999 this pathogen had been seen primarily in seafood from Southeast Asia, and from 2001 to 2009 it had been seen 8 times in seafood and once in pet treats.

The CORE Signals and Surveillance Team contacted the CDC, and by March 6, CDC believed the outbreak may have been associated with seafood, possibly with tuna sushi. The CDC then deployed a more focused questionnaire for use by state agencies when interviewing patients made sick by this bacterial strain.

On March 15, CORE transferred the investigation to a response team. At about that time, 53 cases of the illness had been reported in 15 states and 80% of those interviewed reported eating seafood, and 55% reported eating sushi.

However, sushi contains a number of ingredients beyond tuna. The CORE team considered everything that goes into making the sushi to identify the common ingredients used by the restaurants. To do so, the CORE response team developed questions on ordering, receiving and preparing spicy tuna sushi, which was a likely source as a result of interviews with those who were sick. These questions included inventory procedures at restaurants and ingredients used to prepare the meals consumed by ill cases. FDA sent information to state agencies through the CDC. States provided FDA with information on ingredients used to make spicy tuna rolls, which included mayonnaise, sesame seeds, fresh and/or frozen tuna, hot sauce, seaweed and rice.

The large number of ingredients used in making a dish like sushi complicates efforts to identify and track the item that is causing illness during an outbreak.

By comparing the brand names of ingredients used by the restaurants being investigated at the time, FDA excluded mayonnaise, rice, seaweed and sesame seeds as suspect ingredients. The CORE response team's detective work left just two ingredients for FDA to investigate: tuna and hot sauce.



To track down the source of the *Salmonella* Bareilly outbreak, FDA assembled more than 30 experts from FDA offices across the agency in the Emergency Operations Center at headquarters in Silver Spring, Md.

At the same time, FDA was collecting information on tuna imports from March 2011 to March 2012. FDA then began to trace the distribution of imported tuna to states with illnesses and develop a strategy for taking samples of imported tuna for pathogen testing.

By this time, CORE had increased the number of people working on the incident from 4 to 9, more than doubling the CORE resources devoted to the investigation. By early April, the FDA had established an agency-level incident management group consisting of 30 FDA staff members at its headquarters and an estimated 70 FDA staffers in the field responding to the incident.

On April 4, enough information was available for the FDA and CDC to post information online to inform media and consumers.

Those involved in the investigation at this time were gearing up to conduct a traceback, which would require a great deal of effort by state and federal resources to collect records of product shipments and deliveries from the restaurants where ill consumers were exposed to the sushi. By April 6, four restaurants with clusters of illness had been identified as starting points for traceback activities.

When determining which illness clusters to trace, FDA considered, among other factors, whether there was:

- Reliable information on products consumed by cases
- Confirmed exposure dates at a single restaurant
- A complete list of meal items consumed
- Early access to shipment records

As part of FDA's traceback, the agency reviewed thousands of invoices and records from 44 different companies that could have supplied the four restaurants.

Ultimately, the FDA determined that three of four traceback restaurants received tuna from one manufacturer, Moon Fishery Pvt. Ltd. in India. The FDA then began to trace the product forward from the manufacturing firm to its customers to confirm shipment to the fourth restaurant and to collect product for sampling.

By April 11, the FDA had begun to mobilize resources for inspection of Moon Fishery in India. The next day FDA confirmed shipment of tuna from Moon Fishery to the fourth restaurant. On April 13, the firm began a recall, and the FDA began to hold shipments of this product at the border by issuing Import Alerts.

From April 19 to April 24, FDA inspected the tuna production facility of Moon Fishery Pvt Ltd. in Aroor, India. At the time of the inspection, FDA was informed that April 12 was the last day of tuna processing at the firm due to the seasonal nationwide ban of tuna harvest from the Indian Ocean. However, based on the initial tour of the facility, inspectors identified several deficiencies at the plant. The plant lacked controls to prevent decomposition and histamine formation when the firm received product. Histamine buildup in fish can cause people to have scombrototoxic fish poisoning. The inspectors also observed a lack of controls for *Clostridium botulinum* during storage, and several concerns about sanitation.



As a result of the CORE-led investigation more than 58,000 pounds of potentially contaminated tuna was recalled, and an import alert was issued to prevent the entry of tuna from Moon Fishery into the United States.

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On May 9, FDA sampling at the border of a shipment of “tuna strips” from this same company found *Salmonella* Bareilly, leading to a company recall of that product. The detention of tuna products from this company remains in force. “This was a landmark response by CORE,” said Dr. Tracy DuVernoy, a veterinarian and CORE’s lead coordinator on the investigation. “CORE worked within an IMG for the very first time. Because of that, we were able to quickly verify the cause of the outbreak, in spite of the many ingredients that went into making the sushi. In the end, working together, 58,000 pounds of contaminated tuna was recalled and kept from reaching consumers.”

Major Investigation Partners

- Centers for Disease Control and Prevention
- Arkansas Department of Health
- California Department of Public Health
- Connecticut Department of Health
- Kansas Department of Agriculture
- Kansas Department of Health and Environment
- Louisiana Department of Health and Hospitals
- Massachusetts Department of Public Health
- Maryland Department of Health and Mental Hygiene
- Mississippi State Department of Health
- New York State Department of Health
- New York City Department of Health and Mental Hygiene
- Rhode Island Department of Health
- Rhode Island division of State Health Laboratories
- Texas Department of State Health Services
- Austin-Travis County Health and Human Services
- Dallas County Health and Human Services Department
- Denton County Health Department
- Williamson County and Cities Health District
- Virginia Department of Agriculture
- Virginia Department of Health
- Wisconsin Department of Health Services
- Wisconsin Division of Public Health
- Wisconsin State Laboratory of Hygiene
- Wisconsin Department of Agriculture, Trade and Consumer Protection – Bureau of Laboratory Services
- City of Milwaukee Health Department (Wis.)
- City of Milwaukee Health Department Laboratory
- City of Wichita (Kan.)
- Fond du Lac Co Health Department (Wis.)
- Region I New Orleans Parish Health Unit (La.)
- Region II East Baton Rouge Parish Health Unit (La.)
- Stonington Department of Public Health (Conn.)
- Waukesha County Environmental Health (Wis.)
- Wauwatosa Health Department (Wis.)
- West Allis Health Department (Wis.)
- FDA Center for Food Safety and Applied Nutrition
- FDA Office of International Policy
- FDA India Office
- FDA Atlanta District Office
- FDA Baltimore District Office
- FDA Chicago District Office
- FDA Dallas District Office
- FDA Florida District Office
- FDA Kansas City District Office
- FDA Los Angeles District Office
- FDA Minneapolis District Office
- FDA New Orleans District Office
- FDA New England District Office
- FDA New Jersey District Office
- FDA New York District Office
- FDA Philadelphia District Office
- FDA San Francisco District Office

Industry Cooperation

Identifying and stopping an outbreak of foodborne illness takes a team effort. Unfortunately, if the team consists only of government epidemiologists, laboratorians and sanitarians, we are ignoring a hugely important team member.

Often, in football, people talk about the importance of the crowd in games as the “twelfth man.” Often the contributions of that twelfth man can mean the difference between success and failure. In an outbreak investigation, the twelfth man, is often industry.

The contributions of industry can provide the crucial factor needed to solve an outbreak.



A perfect example of this was the investigation into the 2012 outbreak of *Listeria monocytogenes* infections linked to an imported cheese, Frescolina Marte Brand Ricotta Salata Cheese. The government team members involved in the investigation, the epidemiologists, the laboratorians and the sanitarians, had hit a dead end in the investigation of the outbreak, which ultimately made 22 people sick in 13 states and the District of Columbia, and, tragically, killed two people. Without the cooperation of the food industry, the solution to stopping the outbreak may not have ever been found.

In early July, local and state authorities began reporting illnesses in this outbreak to the Centers for Disease Control and Prevention (CDC). The CDC, working with information provided by state health agencies, found a link between the DNA patterns of the *Listeria monocytogenes* bacteria that, at the time, had caused six illnesses in New York, Minnesota, Maryland, the District of Columbia, New Mexico and Ohio.

Around mid-July, FDA became involved in the investigation because it was suspected that the outbreak might be linked to an FDA-regulated product, soft cheese. At this point, nothing was certain. People who had gotten sick said they had bought soft cheese at a variety of stores. No common thread among the cheeses or the retailers existed.

“Cheese distributors and retailers met with the FDA whenever we asked them to,” said Dr. Brian Garalde, a medical doctor and CORE’s lead coordinator on this outbreak response. “They were very forthcoming with information on their processes and their distribution. This collaboration was vital to progress in this outbreak.”

FDA began to pore through the distribution records of numerous retailers and distributors. Using these records, analysts developed a prioritized list of those cheeses that would be the best candidates for laboratory sampling. FDA and CDC continued to analyze what was known to uncover some link that could explain why people were getting sick without eating the same food. A leading theory emerged that some sort of cross contamination between cheese products was occurring.

In early August, a break in the investigation came when a cheese distributor recalled a cheese because testing done by the State of California had found *Listeria monocytogenes* in it. FDA, CDC and California authorities confirmed that the strain of bacteria causing the outbreak was the same as the strain found in the recalled cheese.

The FDA and the California Department of Food and Agriculture inspected the facility where this distributor would package cheese for sale. Their investigators took laboratory samples of other cheeses. The selection of these cheeses was based on the analysis of records done earlier in the investigation. Ultimately, the laboratory analysis identified the outbreak strain of *Listeria monocytogenes* in an unopened wheel of Frescolina Marte ricotta salata cheese, which was made by an Italian firm, Fattorie Chiarappa. The cheese was removed from the U.S. market and the FDA issued an alert to inspectors at ports of entry to detain this company's cheeses. The FDA contacted authorities in Italy, and by October, a recall had taken place in other countries as well.

Although the outbreak strain of bacteria was found in the Frescolina Marte ricotta salata cheese, no one knew why people who had not eaten that cheese were sick. Indications are that, as various distributors and retailers portioned and packaged the Frescolina Marte ricotta salata cheese, cross contamination may have occurred if other cheeses were packaged on the same surfaces or using the same cutting tools. As a result the FDA alerted retailers to this possibility and reiterated its advice in preventing cross contamination of food by *Listeria monocytogenes*.

In November of 2012, the CDC reported that the outbreak appeared to be over. In the final analysis, through cooperation and tenacity, state, local, federal, international agencies and industry, were able to limit the threat of a deadly bacteria presented to the health and well-being of people around the world. This investigation called on these agencies to adapt and respond to a highly complex and evolving situation. The techniques and knowledge gained from this investigation will inform our actions as we respond to new and potentially more complex outbreak investigations.

Of prime importance, though, is the contribution that industry can make during a foodborne illness outbreak investigation.

Government officials should engage with industry early and often. Having that 'twelfth man' on the field can make the crucial difference.

Major Investigation Partners

- Centers for Disease Control and Prevention
- California Department of Food and Agriculture
- California Animal Health & Food Safety Laboratory System
- Minnesota Department of Agriculture
- Alleghany County Health Department (Penn.)
- FDA Center for Food Safety and Applied Nutrition
- FDA Office of International Policy
- FDA Office of Regulatory Affairs
- FDA Baltimore District Office
- FDA Cincinnati District Office
- FDA Dallas District Office
- FDA Denver District Office
- FDA Chicago District Office
- FDA Kansas City District Office
- FDA Minneapolis District Office
- FDA New England District Office
- FDA New Jersey District Office
- FDA New York District Office
- FDA Philadelphia District Office
- FDA San Francisco District Office
- FDA Seattle District Office

Collaborative Investigation

Helen Keller is quoted as saying,
“Alone we can do so little;
together we can do so much.”

That sentiment is a vital component of the CORE concept, and it is amply demonstrated through a review of the cooperative efforts between the U.S. Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and state and local officials as they investigated the multi-state outbreak of *Salmonella* Typhimurium and *Salmonella* Newport infections linked to cantaloupe from Chamberlain Farms of Owensville, Indiana in 2012.

CORE became involved after being notified that laboratory testing conducted by the Kentucky Division of Laboratory Services isolated an outbreak strain of *Salmonella* Typhimurium from two cantaloupes collected from a retail location in Kentucky. Traceback investigations conducted by Kentucky indicated that these cantaloupes originated from Chamberlain Farms.

“The state health agencies are usually at the forefront of an outbreak investigation,” said Dr. Rich Kanwal, a medical doctor on the CORE response team that responded to this outbreak. “When it is determined that they are dealing with a multi-state outbreak or that the product crosses state lines, we all work together to stop that outbreak.”

During a joint inspection with the Indiana State Department of Health from August 14-16, investigators collected samples of cantaloupe at Chamberlain Farms. They also took environmental samples in the farm’s cantaloupe packinghouse from surfaces that would likely harbor bacteria.

Although the results of the samples taken by investigators could take up to two weeks to be completed, as cultures must be grown in a laboratory setting to confirm the presence of bacteria, the investigators did note the following:

- Food contact surfaces were built in a way that did not allow for adequate cleaning.

- Debris (including trash, wood, food pieces, standing water, mud, dirt, and other buildup) was on and under packing line rollers and conveyor belts.
- There was standing water and algae growth in the packing shed.
- The processing water line pipes and spray nozzles were found to be leaking and displayed rust accumulation.
- The firm was not monitoring the effective levels of the chlorine sanitizer in the water within the dump tank of the cantaloupe processing line.
- There was a failure to remove litter and waste that might attract pests.

On 16 August, Chamberlain Farms had begun removing cantaloupe from the market, and had decided to cease distributing cantaloupe for the rest of the growing season. On August 22, 2012, after officials from the FDA and the state of Indiana briefed Chamberlain Farms on the current status of the investigation, Chamberlain Farms recalled its cantaloupe from the market, thus ensuring the widest possible awareness of this action. FDA’s review of records indicated that the Chamberlain Farms cantaloupe had initially been shipped to Indiana, Iowa, Kentucky, Missouri, Tennessee, Ohio, Illinois and Wisconsin, although further shipment was likely.

On August 28, FDA announced that samples of cantaloupe collected at Chamberlain Farms showed the presence of *Salmonella* Typhimurium with a DNA fingerprint that was the same as the outbreak strain. Additionally, by September 13, 2012, FDA had determined that samples of cantaloupe collected at Chamberlain Farms also showed the presence of *Salmonella* Newport with a DNA fingerprint that was the same as the outbreak strain of *Salmonella* Newport that sickened 33 of the 261 people affected by this outbreak. The link was supported by traceback information collected by state officials in Indiana and Illinois showing that patients consumed cantaloupe bought at stores supplied by Chamberlain Farms.



The collaboration on the investigation continued, when the state of Indiana had reported that sampling of watermelon from a field at Chamberlain Farms showed the presence of *Salmonella* Newport with a different DNA fingerprint, which also was under investigation by the CDC and FDA. After authorities notified Chamberlain Farms of this information, Chamberlain Farms asked stores to remove its watermelons from store shelves as a precaution.

On September 20 and 21, 2012, the FDA, along with Indiana State Department of Health officials, conducted an environmental assessment inspection at Chamberlain Farms, in Owensville, Indiana.

According to the assessment, the initial contamination of the cantaloupes likely occurred in the production fields and was spread by operations and practices within the packinghouse. It is also likely that the contamination proliferated during storage and transport to market.

In the packinghouse, the assessment team found conditions that may have contributed to the *Salmonella* contamination of the cantaloupe.

- The design of the packinghouse allowed water to pool on the floor near equipment, and the floor was not easy to clean.

- There was evidence that birds were roosting in the building's rafters. Bird droppings were seen on the equipment and floor below the rafters, which were directly above food contact surfaces (e.g., brush rollers, conveyor belts, grading table), or directly above the product during conveyance, grading and sorting.
- The drip-line of the packinghouse roof extended over the conveyor belt and brush washer, so rain water and related roof debris were likely to have run-off from the roof on to food contact surfaces.
- The firm did not pre-cool the cantaloupes before storing and shipping, and cantaloupes were packed while still moist from washing on the packing line. Wet fruit, packed still warm with field heat, potentially created conditions that would allow *Salmonella* to live and grow.
- The firm did not adequately monitor or control wash water disinfectant levels to control, reduce or prevent the potential for cross contamination, and it also failed to empty garbage receptacles, resulting in an area where pests could live.

On October 5, 2012, CDC reported that the outbreak appeared to be over. By the end of this outbreak, the CDC had reported a total of 261 people infected with the outbreak strains of *Salmonella* Typhimurium and *Salmonella* Newport in 24 states. A total of 94 people had been hospitalized and three deaths were reported in Kentucky.

"We were able to identify the food that was transmitting the *Salmonella* and remove it from the market because local, state, and federal agencies were working together," said Joey Blankenship, CORE's lead coordinator on the investigation. "By combining our resources we create a whole that is greater than the sum of its parts."

Major Investigation Partners

- Centers for Disease Control and Prevention
- Indiana State Department of Health
- Indiana State Department of Agriculture
- Kentucky Department of Public Health
- FDA Office of Regulatory Affairs
- FDA Center for Food Safety and Applied Nutrition
- FDA Central Regional Office
- FDA Southwest Regional Office
- FDA Southeast Regional Office
- FDA Chicago District Office
- FDA Cincinnati District Office
- FDA Detroit District Office
- FDA Florida District Office
- FDA Kansas City District Office
- FDA Minneapolis District Office
- FDA New Orleans District Office

Cooperative Enforcement

On September 14, 2012, FDA warned consumers against eating mangoes from Agricola Daniela, a mango supplier with multiple farms and a single packing house located in Sinaloa, Mexico. That warning was the result of CORE's coordination efforts and cooperation between U.S. federal and state authorities and their counterparts at the provincial and federal level in Canada.



The first warning of an international outbreak came from north of the border, when Canadian provincial and federal investigators linked an outbreak that ultimately made 23 people sick with *Salmonella* Braenderup to imported mangoes.

This provided a clue that allowed U.S. federal and state authorities to advance their investigation of an outbreak associated with *Salmonella* Braenderup. This outbreak, which ultimately caused 127 *Salmonella* Braenderup illnesses in 15 U.S. states, had been linked to mangoes through epidemiology, but a distributor had not been identified.

"In California, state authorities had identified mangoes as a suspect food," said USPHS Lt. Cmdr. Kari Irvin, CORE's lead coordinator on this outbreak. "However, there were no illness clusters apparent which is vital to a successful traceback effort. Without illness clusters to focus a traceback, you can spend a lot of time running down blind alleys. The Canadian traceback benefited from the fact that they could identify two clusters of illnesses."

With the recall announcement from Canada, the assigned CORE response team worked with authorities from the U.S. and Canada to tie their efforts together. This helped the California Department of Public Health trace several illnesses of the outbreak strain of *Salmonella* Braenderup through the supply chain to Agricola Daniela.

While that traceback was being conducted, CORE coordinated with internal and external partners to further the investigation. On August 29, in response to the Canadian recall, Splendid Products, of Burlingame, Calif., recalled certain lots of mangoes produced by Agricola Daniela. These mangoes had been sold between July 12, 2012 and August 29, 2012 at various stores throughout the United States.

On August 30, 2012, the FDA advised consumers not to eat Daniela mangoes distributed by Splendid Products of Burlingame, Calif. due to potential *Salmonella* contamination.

The FDA was able to determine which companies distributed Daniela mangoes and begin sampling. This sampling effort showed the presence of *Salmonella* in Daniela mangoes.

"Although our sampling did not identify the outbreak strain of *Salmonella* Braenderup in the mangoes," explained Irvin. "The sampling identified *Salmonella*, and the presence of a pathogen means those mangoes are not fit for food."

On September 12, the FDA placed Agricola Daniela on Import Alert, meaning that the firm's mangoes would be denied admission into the United States unless the importer shows they are not contaminated with *Salmonella* by using private laboratories to test the mangoes, or by other means.

By September 27, 2012, four distributors of mangoes imported from Agricola Daniela initiated recalls of mangoes received from Agricola Daniela. As a result

of the recalls, 19 firms supplied by these distributors initiated recalls for mangoes and products containing mangoes. By early October, the CDC felt confident that the outbreak had ended, with the last *Salmonella* Braenderup illness occurring in early September.

“CORE worked to link together evidence from several agencies. We had epidemiology pointing to mangoes from Canada. We had the traceback from the state of California, and we had confirmation from FDA samples that there was *Salmonella* in mangoes from Agricola Daniela,” said Roberta Hammond, CORE’s Response Manager. “With this evidence, we felt confident in taking regulatory action.”



Major Investigation Partners

- Centers for Disease Control and Prevention
- Public Health Agency of Canada
- Canadian Food Inspection Agency
- California Department of Public Health
- FDA Center for Food Safety and Applied Nutrition
- FDA Office of Regulatory Affairs
- FDA Chicago District Office
- FDA Los Angeles District Office
- FDA Dallas District Office
- FDA New Jersey District Office
- FDA San Francisco District Office
- FDA Southwest Import District
- FDA Office of International Policy
- FDA Latin America Office

Leaning Forward

Most of us gather what we know of the tropics from vacation post cards of a canopy of trees in the idyllic scene. Thomas Hill, though, knows a different version of that scene. It was 2011, and he was in the tropics. However, he was there for a food safety inspection.



“We were inspecting a papaya farm in southern Mexico,” explained Hill, a captain in the U.S. Public Health Service and the senior environmental health officer with CORE’s Post Response Team. “We were shaded by a lush canopy of trees, but the heat, the humidity and the insects were oppressive.”

Not to mention the rain.

“When I got there, I wondered why the curbs in town were all a foot high,” explained Hill. Yet, every afternoon at 3 o’clock while he was there, he got the answer. Torrents of rain would come each afternoon and flood the streets in less than a half hour. All that water, he would later find, was the real reason he was there, but in 2011, he was at the mid-point of a journey that had begun a year earlier with an outbreak of *Salmonella* Agona in the United States.

Between May and September, 2010, an outbreak of 119 human cases of *Salmonella* Agona infection from 14 states had been identified by the CDC. The outbreak was caused by four rare strains of the bacteria which had closely related DNA patterns. At the time, the investigation found that most cases were either Hispanic or had recently shopped at Hispanic grocery stores or traveled to Mexico.

Mango, papaya, and melons were suspected as possible vehicles for the illnesses, but no clear link existed between a specific type of produce and the outbreak.

In April, 2011, the CDC began investigating a new *Salmonella* Agona outbreak, which ultimately would sicken 106 people in 24 states. Initially, the outbreak involved 18 illnesses in 10 states with no more than 3 cases in a single state. Although the cases were spread among many states, the CDC epidemiologists realized that they were seeing three of the four DNA patterns associated with the *Salmonella* Agona outbreak in 2010.

As in the 2010 outbreak, interviews of patients indicated produce as a vehicle for the illness, with the leading suspects being mangoes, papayas and melons. Typically, the standard process was that the FDA would not begin sampling of products without a strong link provided by epidemiology. However, it was clear that epidemiology alone would not identify the type of produce causing the 2011 outbreak.

“We decided it was important to start leaning forward on this type of outbreak,” said Roberta Wagner, who at the time was the Assistant Commissioner for Field Operations in the FDA Office of Regulatory Affairs. “That made a huge difference.”



Animals can be a source of food contamination in growing fields. In 2012, FDA investigators found signs of raccoons and jaguars in their 2012 papaya farm investigation.

In May, the FDA increased sampling of imported produce from Mexico and Central and South America in an attempt to find the cause. By the end of July, the sampling effort had paid off. FDA identified the *Salmonella* Agona on papayas coming from a specific firm in Mexico. The firm recalled the papayas, and the last illness associated with this outbreak occurred on July 22, 2011.

The FDA then sent an inspection team to Chiapas, Mexico to conduct an inspection at the farm that grew the contaminated papaya to find the source of the outbreak. Although the team was able to point out deficiencies that could contribute to contamination of the papaya, they did not find the outbreak strain of the bacteria on the farm.

The FDA investigation team provided the managers at the farm with a list of deficiencies that needed correction, but the response to the 2011 outbreak was far from over. The increased sampling effort of imported produce had a far greater impact than just identifying a single farm shipping contaminated papayas to the U.S.

The FDA's sampling effort had uncovered a country-wide *Salmonella* problem with papayas imported to the U.S. from Mexico. For example, from May 12, 2011, to August 18, 2011, FDA analysis found a 15.6 percent *Salmonella* contamination rate among papayas tested. The positive samples were from 28 different firms and included the major papaya producing regions in Mexico.

In late August, 2011, the FDA issued an import alert. Under this import alert, the FDA ordered that Mexican papayas should be detained at the border unless the importer shows proof that the shipment is not contaminated with *Salmonella*. Typically, the exporter does this by providing private laboratory testing results showing that the shipment is free of *Salmonella* bacteria.



FDA microbiologist David Gomes, samples water from a drainage ditch on a papaya farm in Mexico. Evidence indicates that these ditches can serve as reservoirs for *Salmonella* bacteria. When heavy rains cause the ditches to overflow, *Salmonella* can spread to the fields.

This regulatory action proved important the following summer as the CDC identified a new cluster of *Salmonella* Agona illnesses, and indications were that it might be linked to eating papaya. At about the same time the CDC was identifying a new papaya-related outbreak, the FDA's import alert had identified a shipment of papayas contaminated by a strain of *Salmonella* Agona that was the same as one of the outbreak strains identified in 2010 and 2011. This strain was also the same as the outbreak strain recently identified by the CDC.

Although the shipment contaminated with *Salmonella* Agona was from a different farm than the one linked to the prior year's outbreak, it was owned by the same export company. FDA immediately informed the company, which stopped shipping papaya to the United States from the farm that grew the contaminated shipment.

Hill returned to Chiapas with another team of experts to inspect three papaya farms owned by the exporter of the papaya shown to be contaminated with the outbreak strain.

This time the team was armed with an improved testing method, and was able to recover the outbreak strain of *Salmonella* Agona from environmental samples on one of the farms. Those samples were key to identifying the source of contamination.

"Confirming the presence of the outbreak strain of *Salmonella* Agona on one of the farms, helped us

put the pieces of the puzzle together," explained Hill. "On each of the farms linked to the outbreaks of 2011 and 2012, there were drainage ditches, which could easily serve as reservoirs for *Salmonella* bacteria. In 2011, we had seen that ditches could overflow, which could spread *Salmonella* to the fields. The samples we collected from ditches and soil in 2012 that showed the outbreak strain support that hypothesis."

The FDA inspectors provided their observations to the management of the papaya exporting firm so that the firm could work to correct deficiencies. In the meantime, the nation-wide import alert for papayas from Mexico is still in place protecting U.S. consumers.

"CORE coordinated the response to the 2012 outbreak, and with the import alert in place, we were able to hold a recurring outbreak that had made hundreds of people sick in 2010 and 2011 to just 31 illnesses in 2012," explained USPHS Retired Rear Adm. Brenda Holman, CORE's deputy director. "But that wasn't the end of our involvement. The CORE Post Response Team, and other FDA investigators were also instrumental in identifying the source of the contamination so that it could be prevented in the future."

Major Investigation Partners

- Centers for Disease Control and Prevention
- Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria (Mexico)
- California Department of Public Health
- Georgia Department of Public Health
- Illinois Department of Public Health
- Maryland Department of Health and Mental Hygiene
- Texas Department of State Health Services
- FDA Center for Food Safety and Applied Nutrition
- FDA Office of Regulatory Affairs
- FDA Southwest Regional Office
- FDA Southwest Import District
- FDA Office of International Policy
- FDA Latin America Office

Breaking New Ground

Got any ink? Two hundred years ago, you might have asked that question before writing a letter. Today, it's a question more likely asked in reference to a popular form of self-expression, tattoos.

Approximately 45 million Americans have at least one tattoo. This represents 14% of the population with adults aged 18 to 40 representing 75% of those with tattoos.



As demand for tattoos increases, a better understanding of the tattooing process and the steps required to reduce the risk of infections becomes important in preventing some public health problems.

The 2012 FDA investigation of non-tuberculosis mycobacterial infections in people getting tattoos is a case in point. During the investigation, CORE led FDA's program and field activities, coordinated national investigative and response efforts with CDC, as well as state and local health departments and laboratories.

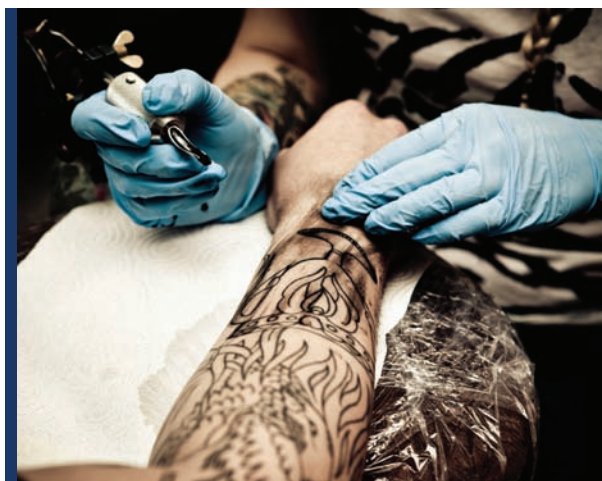
The investigation began when adverse events related to administration of tattoos were received

in CFSAN's Adverse Event Reporting System from Monroe County, New York in January 2012. The outbreak involved 19 people who developed a rash over recently placed tattoos. These individuals had reportedly been tattooed in a New York tattoo parlor, by the same artist, who had used the same brand and color ink on all individuals.

Skin biopsies from 14 of the 19 affected individuals identified the presence of a non-tuberculosis *Mycobacterium*. Further, 12 of the 14 isolates were confirmed as *Mycobacterium chelonae*, had identical DNA fingerprints, and were matched to an isolate from a sealed container of the same brand of ink used to tattoo the affected individuals.

Additional tattoo-associated mycobacterial infections, possibly indicating other cases, were identified in Washington, Arizona, Iowa, Colorado and South Carolina, following CDC's epidemiologic outreach efforts. An Iowa case and a Washington case may also have been related, however, despite extensive investigations, this was not confirmed.

"The Office of Cosmetics and Colors was actively engaged, contributing to the investigation, planning next steps with CORE, and advising on actions to be taken during the agency's response to the tattoo-related infections," said USPHS Capt. Kathy



Hollinger, an epidemiologist assigned to OCAC. "CORE provided leadership and cohesion to the investigation which involved so many different contributing partners."

"CORE brought out the best in all of us, negotiating with partners for resources where often there were none and getting the job done, and done right!"

In FDA's extensive response activities; ranging from New York and Connecticut to California and Arizona, from Washington State to Florida, between February and June 2012, FDA followed up with investigations at 5 tattoo ink related firms. Findings from sampling of unopened inks and pigments that were collected during these visits identified other microbial contaminants in inks. To learn more about the tattoo industry, FDA Public Affairs Specialists attended a tattoo trade convention, observed tattoo practices, and collected contact and source information from tattoo suppliers and manufacturers.

In response to the investigation, two manufacturers voluntarily recalled inks implicated in the outbreaks.

Like an intricate tattoo design, the pieces of the contaminated tattoo ink story are still being put together. "Mycobacterial outbreaks associated with tattoos appears to be an under-recognized issue," said Pamela LeBlanc, CORE's response team leader on this investigation.

FDA is working to increase awareness of tattoo related infections for consumers, the tattoo industry and the healthcare community, by publishing and contributing to articles in the New England Journal of Medicine, through FDA Consumer and Constituent Updates and outreach to the tattoo industry press.

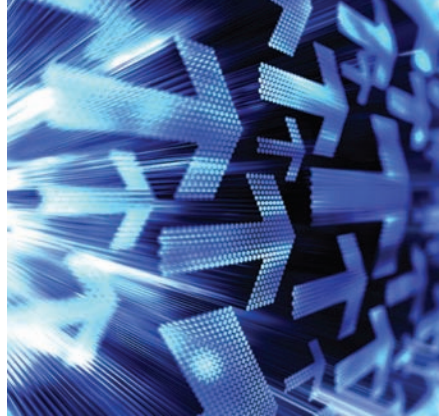
After the investigation, CORE contributed to an article published in CDC's Morbidity and Mortality Weekly Report informing state and local health departments of the investigation and its findings. FDA is also working to encourage adverse event reporting to the FDA's MedWatch program.



Major Investigation Partners

- Centers for Disease Control and Prevention
- Colorado Department of Public Health and Environment
- Iowa Department of Public Health
- South Carolina Department of Health and Environmental Control
- Monroe County Department of Public Health (N.Y.)
- New York Wadsworth Laboratory
- San Bernardino County Public Health Department (Calif.)
- Public Health – Seattle and King County (Wash.)
- FDA Center for Food Safety and Applied Nutrition
- FDA Los Angeles District Office
- FDA Kansas City District Office
- FDA New York District Office
- FDA Seattle District Office
- FDA Florida District Office
- FDA New England District Office
- FDA Southeast Regional Office
- FDA Pacific Regional Office
- FDA Northeast Regional Office
- FDA Southwest Regional Office

Our Future



A conversation with CORE Leadership

How would you describe the first year of CORE?

Kathleen Gensheimer (CORE CMO): Well, CORE has been operating close to a year and a half, and in that time we've done amazing things. We've seen the genesis of a new concept, after an extensive planning period, and then in the first months of operation we put those plans in place. We laid a strong foundation.

However – and this is a strength in CORE – we didn't just implement those plans and set the organization on autopilot. We have been constantly tweaking, modifying and improving our processes.

Brenda Holman (CORE Deputy Director): I agree completely. It has been a dynamic start, but in an operation like this there is no point where you can say "this house is built." You can't just turn over the keys and walk away. You have to listen to your partners carefully and you have to constantly evolve. With each outbreak we are learning more and we are adding tools to our toolbox. A perfect example of one of those tools is the environmental assessment.

Gensheimer: Absolutely, in fact, we would like to see this capability deployed across FDA. When we do that we are more flexible. We're faster and we better incorporate field resources and we can try to combine the assessment with the outbreak investigation.

Holman: Our goal is that an environmental assessment would not necessitate a deployment from FDA headquarters. Just think about what we can accomplish with the knowledge and ability and the resources for an environmental assessment available at each district office. That ability would be resident in each field office, and they could reach back for added assistance if needed.

With such a dynamic start, what's in the future of CORE?

Gensheimer: Our next step in the coming year will be to focus on how we at CORE can contribute to the prevention of foodborne illness. We want to build up that capability.

As exciting and productive as this first year has been, I think it will only get better. We have momentum and great energy in the staff. We have set a strong foundation and are committed to continuous process improvement.

Holman: We want to build on examples like the *Salmonella* Agona in papaya response. With that FDA came full circle. This occurred over a three-year period. In the first year, we saw a number of illnesses, but had yet to identify a vehicle. In year two, we had additional illnesses and were able to identify the vehicle. That prompted action, through a country-wide import alert on papayas from Mexico. In year three, there were new illnesses identified but quick action prevented a larger outbreak.

Gensheimer: There is also the example of the *Salmonella* Bredeney in peanut butter. Quick action there certainly prevented a larger outbreak. Sometimes we will be able to take quick preventive action, and other times the action will have to develop over a longer period of time.

Holman: In terms of prevention, I think we will focus on defining the vision of what CORE contributes to prevention of foodborne illness, and we will work on providing concrete recommendations and documenting what we learn from our response efforts.

Gensheimer: As exciting and productive as this first year has been, I think it will only get better. We have momentum and great energy in the staff. We have set a strong foundation and are committed to continuous process improvement.

Appendix



CORE Signals and Surveillance Statistics August 2011 – December 31, 2012

Table 1. Total Number of Incidents * Analyzed and Evaluated by the CORE Signals and Surveillance Team by Agent, August 2011 – December 31, 2012 (n=211)

Agent**	Total Number of Incidents Reviewed	Total Number of Incidents Transferred to a Response Team	Total Number of Incidents Closed (Not Transferred)	Total Number of Active Incidents
EHEC	33	8	23	2
<i>Listeria monocytogenes</i>	22	3	18	1
<i>Salmonella</i>	92	24	67	1
Intoxications	22	10	12	0
Other	33	15	18	0
Unknown	9	3	6	0
Total	211	63 (30%)	144 (68%)	4 (2%)

* Includes Active incidents

** EHEC includes E. coli O157:H7 and non-O157 E. coli serotypes (eg. O26) as well as unspecified EHEC outbreaks. "Intoxications" include scombrototoxin, ciguatera toxin, and botulinum toxin incidents; "Other" includes *Vibrio* species, Haff Disease, *Grimontia hollisae*, Norovirus, Yersinia, Campylobacter, *Cronobacter*, *Cyclospora*, atypical *Mycobacteria* non-infectious agents and *Shigella*.

Table 2. Number of Closed Incidents (Not Transferred to a CORE Response Team), by Agent, August 2011 – December 31, 2012 (n=144)

Agent	Total Number Closed (Not Transferred)	Vehicle was Not an FDA Regulated Product	FDA Response Activities Already Initiated and Completed *	Vehicle Never Identified
EHEC	23	5	4	14
<i>Listeria monocytogenes</i>	18	1	11	6
<i>Salmonella</i>	67	5	9	53
Intoxications	12	4	1	7
Other	18	6	8	4
Unknown	6	1	1	4
Total	144	22 (15%)	34 (24%)	88 (61%)

* Examples of situations in which an FDA Response activity could be initiated outside of CORE include as part of the RFR/RCR process, on behalf of a district assisting a state investigation (with product and cases limited to intrastate distribution), or as part of a cooperative FDA-state program (e.g. shellfish)

** EHEC includes E. coli O157:H7 and non-O157 E. coli serotypes (e.g. O26) as well as unspecified EHEC outbreaks. "Intoxications" include scombrototoxin, ciguatera toxin and botulinum toxin incidents; "Other" includes Vibrio species, Haff Disease, *Grimontia hollisae*, Norovirus, *Yersinia*, *Campylobacter*, *Cronobacter*, *Cyclospora*, atypical *Mycobacterium*, non-infectious agents and *Shigella*.

Table 3. % of Incidents Transferred to a CORE Response Team, by Vehicle Category, Aug 2011 - Dec 2012 (N=63)*

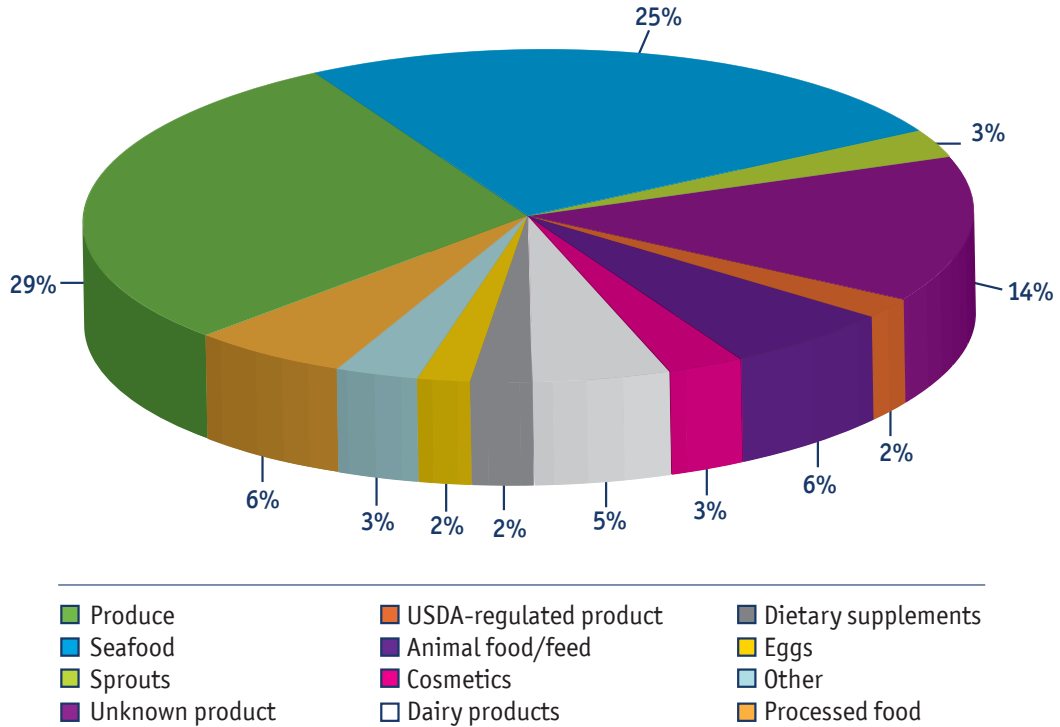
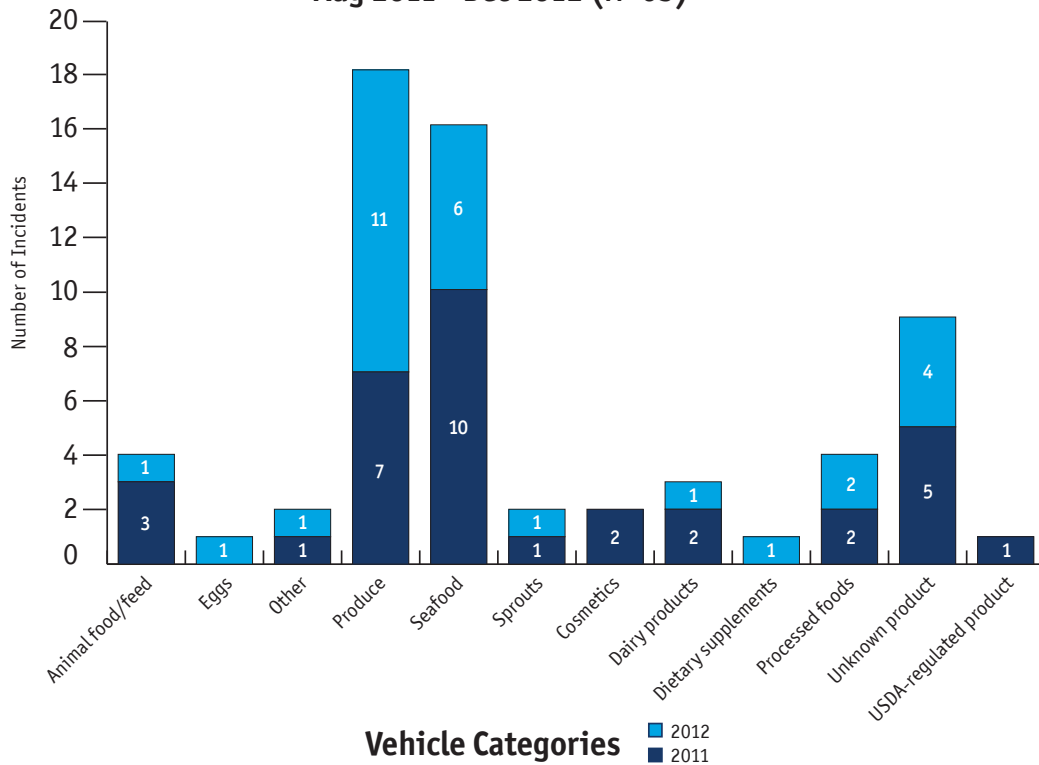


Table 4. Number of Incidents Transferred to a CORE Response Team, by Vehicle Category, Aug 2011 - Dec 2012 (N=63)*



* 63 incidents were coordinated by CORE between August 2011 and December 2012. These incidents represent both outbreaks associated with FDA-regulated products and other incidents that were coordinated by CORE but determined not to be outbreaks associated with FDA-regulated products.

Table 5. Number of Incidents Transferred to a CORE Response Team, by Genus/Species and Vehicle Category, Aug 2011 - Dec 2012 (N=63)*

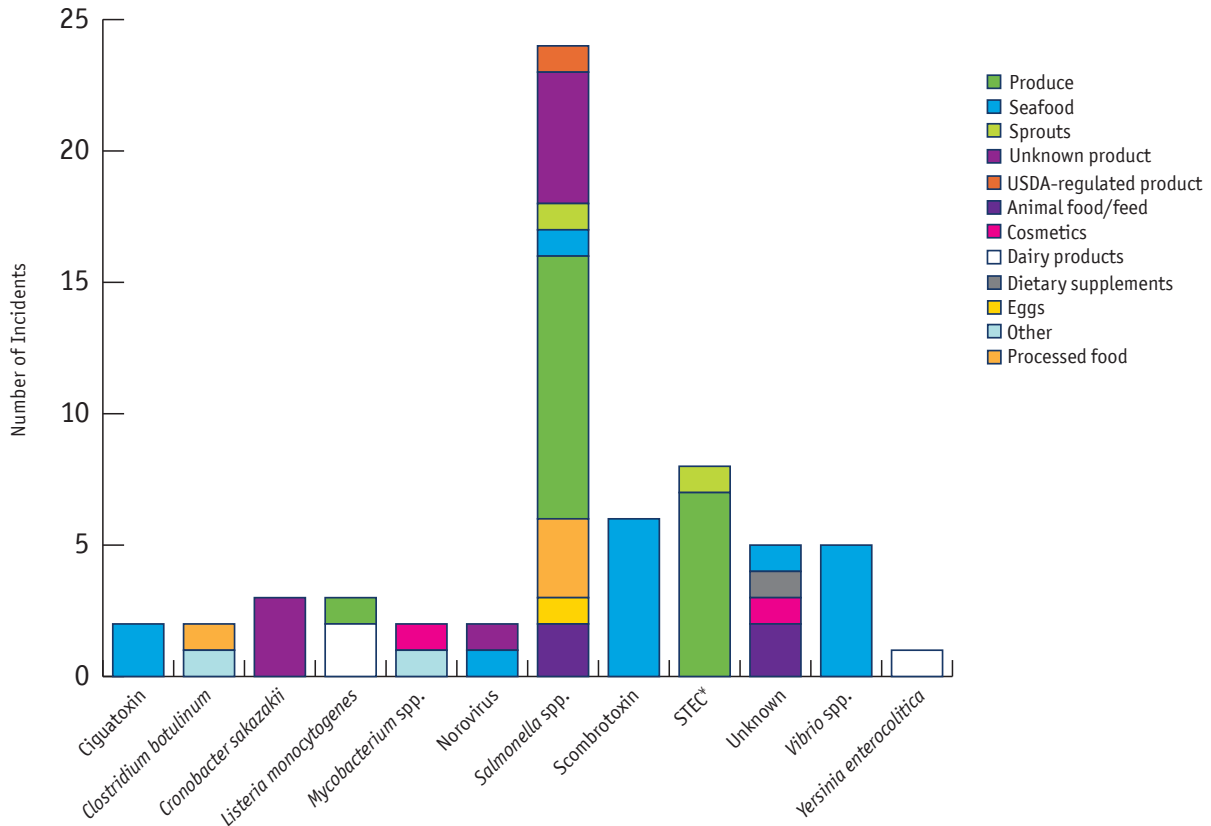
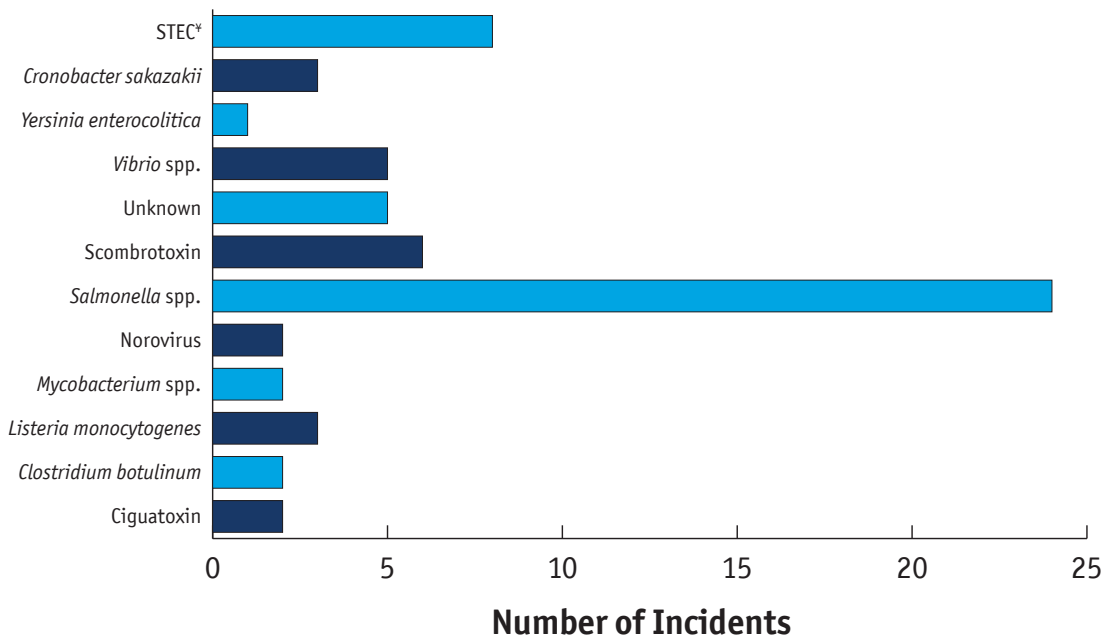


Table 6. Number of Incidents Transferred to a CORE Response Team, by Genus/Species type, Aug 2011 - Dec 2012 (N=63)*



* 63 incidents were coordinated by CORE between August 2011 and December 2012. These incidents represent both outbreaks associated with FDA-regulated products and other incidents that were coordinated by CORE but determined not to be outbreaks associated with FDA-regulated products.
 † STEC -Shiga-toxin producing *Escherichia coli* such as *E. coli* O157:H7

CORE Mission

To coordinate and improve FDA's detection, response, and prevention efforts related to FDA regulated food, feed, and cosmetic outbreaks in collaboration with our partners.

CORE Vision

A safer food supply through a systematic, science-based approach to preparedness, early detection, rapid response and post-response investigations of human and animal food outbreaks of illness.

CORE Values

Collaboration. Adaptability. Dedication. Excellence. Team Work.