A LOOK AT FDA'S FOODBORNE OUTBREAK RESPONSE IMPROVEMENT PLAN

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Because foodborne disease is a significant public health issue in the United States, FDA recently developed the Foodborne Outbreak Response Improvement Plan (FORIP) to help the agency and its partners enhance the speed, effectiveness, coordination, and communication of outbreak investigations. "Tackling foodborne illnesses faster and revealing their root cause is essential to the prevention of future outbreaks," says Frank Yiannas, FDA's deputy commissioner for food policy and response. "We are confident that these actions outlined in the plan will contribute to bending the curve of foodborne illness in this country by helping to prevent future outbreaks."

The plan is a necessary component of the agency's strategy to ensure that the most effective tools and procedures are being used to streamline outbreak investigations and alleviate the effects of foodborne illness.

KEY AREAS OF THE OUTBREAK RESPONSE PLAN

FORIP focuses on four specific priority areas in which improvements will have the most impact on outbreaks associated with human food:

1. Tech-enabled product traceback,
2. Root cause investigations (RCIs);
3. Analysis and dissemination of outbreak data; and
4. Operational improvements within the agency.

Yiannas notes that the plan focuses specifically on reducing the time needed to identify contaminated product; gathering and sharing critical investigational findings and recommendations to prevent future outbreaks more quickly and fully; more rapidly identifying a source and providing earlier and more open communications with government partners, industry, and the public; and measuring, streamlining, and continuously improving FDA's performance.

David Goldman, MD, MPH, chief medical officer in FDA's Office of Food Policy and Response, notes that FDA learns something new with each outbreak that occurs and then tries to incorporate that knowledge into its response. "Metrics are being addressed across the entire foods program," he says. "We're looking at a combination of operational and public health metrics—which, together, we intend to translate into faster response, earlier action, and secondary prevention—that are preventing further illnesses during an outbreak."

Craig W. Hedberg, PhD, professor in the division of environmental health sciences at the University of Minnesota in Minneapolis, who conducted an independent review of FDA's foodborne outbreak response processes, notes that FORIP was necessary to address new food safety challenges

that continue to emerge and to take better advantage of new developments in public health surveillance methods. "In particular, the development of whole-genome sequencing for bacterial pathogens such as Salmonella, Shigatoxin-producing E. coli, and Listeria provides more information to better identify outbreaks with small numbers of cases, to link cases to food or environmental isolates, and to identify recurring patterns over time that highlight persisting problems that may not have been adequately addressed," he says.

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Liz Sertl, senior director of community engagement for GS1 US, a nonprofit standards organization, notes that FORIP is an extension of the work that FDA already has in place with the Food Safety Modernization Act and its New Era of Smarter Food Safety. "FORIP is focused on multi-state outbreaks that require significant engagement coordinated by FDA's Coordinated Outbreak Response and Evaluation (CORE) Network," she says. "The plan seeks to enhance the speed, effectiveness, coordination, and communication of those outbreak investigations. Ultimately, the plan is intended to complement two of the blueprint's core elements, "Tech-Enabled Traceability" and "Smarter Tools and Approaches for Prevention and Outbreak Response."

The positive impact of this work is made possible, she adds, by using smarter ways of digitizing information to help get to the root cause of foodborne illness more quickly due to the speed of information available. "Data that's identified, captured, and shared in a standardized, digitized manner is key for FORIP, as this enables trading partner collaboration and systems interoperability, and can help members meet the requirements of FDA regulations," Sertl adds.

NEW ELEMENTS OF THE PLAN

FORIP aligns closely with FDA's existing New Era of Smarter Food Safety Blueprint, which was established in 2020. The blueprint includes four core elements, including tech-enabled traceability, smarter tools and approaches for prevention and outbreak response, new business models and retail modernization, and food safety culture.

FORIP includes actionable steps to implement the strategies and principles of the blueprint specifically related to foodborne illness outbreak response. Some of the key components of the plan include reducing the time needed to identify contaminated product, accelerating the gathering and sharing of findings and recommendations, disseminating pertinent information quickly, and—ultimately—raising the bar to continually improve performance in this area. "At the core of all three of these new factors will be technology that helps food manufacturers to determine exactly how to predict, identify, and stop foodborne illnesses from coming to fruition," says Joe Scioscia, VP of Sales for VAI, an organization that offers software for tracking and traceability in the food industry. "FORIP's new elements will work to cover all the bases of a potential foodborne illness process, including identifying its origins, detailed analysis, and determining areas of weakness so that distributors can better prevent another incident from occurring."

FDA is also trying to improve tracebacks of food items during outbreak investigations by defining data elements that can be tracked electronically without requiring field staff to physically visit every establishment and review documents. Outbreak responses will be sped up by digitizing processes for collecting consumer purchase data and leveraging advanced analytics tools. “Being able to rapidly assemble records for shipment of food products through the distribution system to the point of service will greatly increase the speed and reliability of traceback efforts and make it more feasible to incorporate traceback data into the epidemiologic investigations,” Dr. Hedberg says. “Increasing the speed and efficiency of tracebacks and incorporation of traceback data into epidemiologic investigations are critical areas for improvement.”

In the plan, there are also detailed steps for systematizing the agency’s root RCIs and adopting a continuous improvement approach for food safety operations.

Additionally, FORIP facilitates a streamlined process for analyzing and disseminating outbreak data to the Centers for Disease Control and other regulatory partners. “Many of these additional efforts will increase the amount of information available from outbreak investigation partners and increase the timeliness of the information, so that contaminated food products can be more rapidly identified and removed from commerce,” Sertl says.

MEASURING SUCCESS

FDA is using both performance and outcome metrics to identify the level of success it achieves in reaching its goal of enhancing the speed, effectiveness, coordination, and communication of outbreak investigations. While the individual metrics are important, the true progress indicators will be reduced cases of sickness, hospitalization, and death related to foodborne illness outbreaks.

Scioscia calls FORIP a necessary step forward, both for the safety of food suppliers and distributors working alongside the various touchpoints throughout the supply chain and for consumers at the receiving end. “Without food safety track and trace technologies and plans in place, food distributors cannot identify and remove contaminated food items in time,” he says. “The FORIP is necessary for suppliers to gain access to IoT technology and food [enterprise resource planning] ERP applications with AI and predictive analytics, that will help prevent contaminated foods from reaching restaurants and store shelves and getting into the hands of consumers.”

According to Yiannas, successfully implementing the series of actions outlined in FORIP will enable FDA to respond more quickly and more efficiently to foodborne outbreaks and reduce the number of foodborne outbreaks that go unsolved in the future.

Dr. Hedberg says that success of FDA’s plan will be measured by the increased speed and effectiveness of investigations to identify the source of outbreaks and by the improved ability to provide insights to industry on how they can develop preventive controls based on better understanding of the root causes of outbreaks. “For that to happen, we need time, continued investment in the public health system that supports these efforts, and the continued belief that these efforts matter.”