

Collaborative Food Safety Forum (CFSF)

Enhancing Early Outbreak Investigations—Information sharing and Response: Workshop Summary

December 11, 2012
Washington, D.C.

Background

The Pew Charitable Trusts (Pew) and the Robert Wood Johnson Foundation (RWJF) are co-sponsors of the [Collaborative Food Safety Forum](#) (CFSF or Forum). Invited representatives from federal and state agencies, industry, consumer advocacy groups, and academia attended a workshop on December 11, 2012 regarding improving information sharing early in a foodborne illness outbreak to enhance risk assessment and risk management. The workshop—the first in the second phase of the CFSF—builds on previous CFSF workshops that focused on surveillance (November 2011) and food source attribution (February 2012), as well as many years of informal conversation among stakeholders on this topic. The premise of the meeting was that pooling information – particularly input from industry data – earlier in a foodborne illness outbreak or possible outbreak, via a “scoping” mechanism such as the U.K. uses, would quicken investigations and better protect public health. This meeting tested that premise and began to outline a more formal information-sharing process. Below are the goals and outcomes proposed for the workshop.

Goals:

- Discuss goals and objectives of adopting more formal information-sharing and response process in the US
- Review, identify and discuss key aspects of the UK Scoping process
- Based on the goals for a US process, identify opportunities and challenges for adapting and implementing such a process
- Develop a straw proposal for the process and any next steps for addressing identified challenges and leveraging possible opportunities

Outcomes:

- Clarified goals and objectives for a more formal information-sharing and response process
- As appropriate, a proposed concept for such a process
- A summary of the deliberations, key themes and any identified next steps

This workshop opened with a welcome and remarks from the project funders and food safety leaders at the U.S. Food and Drug Administration (FDA), U.S. Centers for Disease Control and Prevention (CDC), and U.S. Department of Agriculture (USDA), followed by a review of the workshop’s goals, outcomes, and agenda by RESOLVE.

Early Outbreak Investigation – Current Processes and Potential for Enhancement

Federal agency and industry representatives presented the current processes for sharing information in the early stages of an outbreak investigation. Included in the presentations and comments were descriptions of increasing efforts to share information and data, as well as examples of where information have or have not been shared early on and some of the subsequent impacts.

Kathleen Gensheimer (Chief Medical Officer and Outbreak Director, CORE) described the development of the FDA's Coordinated Outbreak Response and Evaluation (CORE) network. Consisting of signals and surveillance, response, and post-response teams, this multidisciplinary effort includes microbiologists, epidemiologists, environmental health specialists, and policy analysts, among other experts at the Agency. CORE has made a concerted effort to coordinate within FDA and with CDC during outbreak investigations. They regularly share information and coordinate actions as appropriate while carrying out their individual roles and responsibilities in the process. Following Dr. Gensheimer's remarks, participants raised the following points in a brief question-and-answer session.

- CORE receives data from CDC, FDA field staff, state and local health departments, State Departments of Agriculture and Food Protection, open sources such as the news and social media, and conducts trend analyses.
- Industry information is, to some extent, an input for CORE via subject matter experts at the Agency. These internal experts stay current with industry information through their networks and contacts.
- The processes of the agencies are parallel and complementary, but they do move at different paces. For example, CDC is heavily involved in the beginning when gathering and analyzing epidemiological data to determine a likely source of an outbreak, while the regulatory agencies' processes follow on the CDC investigation, consistent with their oversight and enforcement authorities.
- Extensive progress has occurred regarding collaboration between CDC, FDA, and USDA during outbreak investigations. What used to happen occasionally and through personal contacts is now becoming, increasingly, standard operating procedure.

Regina Tan (Director, Applied Epidemiology Division) described how the Food Safety and Inspection Service (FSIS) at USDA conducts an investigation. Notification, evaluation, and product sampling are key components, as is tracing the outbreak channels through the supply chain. Her presentation is available as a PDF on the [CFSF Website](#). Following her presentation, participants raised the following points in a question-and-answer session.

- USDA first coordinates with internal FSIS offices (Office of Program Evaluation, Enforcement and Review; Office of Field Operations; and Office of Public Health Science) before communicating with industry. Also before communicating with industry, FSIS closely coordinates with CDC and its state affiliates as they gather epidemiological information.

- Much of the information gathering with industry at this point in the process is “person-to-person,” not “Agency-to-company.” Generally, companies self-identify the best point of contact.
- A contaminated food that is comprised of multiple ingredients makes the investigation even more complicated and sometimes the implicated product cannot be proven.

Ian Williams (Chief, Outbreak Response and Prevention Branch (ORPB), Division of Foodborne, Waterborne, and Environmental Diseases, National Center for Emerging and Zoonotic Infectious Diseases) described the CDC investigation process and how it links with FDA and USDA processes. He emphasized that understanding the culture differences between the agencies has been of critical importance to improved coordination. Efforts include a weekly tri-agency meeting about the clusters and outbreaks under investigation. USDA FSIS has a staff member located within ORPB at CDC to enable further coordination between CDC and FSIS. FDA also has a liaison at CDC to help facilitate coordination between CDC and FDA.

When to reach out to industry during an outbreak is a collaborative decision among the three Agencies, as FDA and USDA are experts in various food industries under their respective jurisdictions and can bring that experience to bear. There are three general types of evidence considered by investigators when determining if a food is a source on an outbreak: epidemiological evidence, traceback evidence, and laboratory evidence from the food suspected as the source. Dr. Williams stressed that collaboration is helpful to collect the necessary information for the decision of determining when a food has been implicated as a source of contamination in an outbreak. Following the presentation, participants raised the following points in a question-and-answer session.

- Traceback information can refer to either more informal (epidemiological) tracebacks or more formal regulatory tracebacks (such as chain of custody). Information relating to product distribution and epidemiological tracebacks can be very helpful in quickly identifying a likely source of an outbreak.
- CDC rarely opens communication with a company without involving the relevant regulatory agency.
- Federal, state, and local field entities are critical partners—FDA works with their districts and State regulatory partners; USDA works with their local field staff and State regulatory partners; and CDC works primarily with their state and local health agency partners and Federal partners.
- Differences between state health agencies and various points of contacts can be confusing for industry. Industry would prefer a more unified approach and earlier communication from federal agencies. Federal agencies strive to streamline the process as much as possible, but states are independent entities as well with their own mandates and authorities. Local and state agencies are primarily responsible for gathering information early in outbreak investigations, and the threshold for evidence to trigger information gathering and traceback varies from state to state.

Joe Scimeca (Director, Global Regulatory Affairs) discussed a Cargill recall of ground turkey to suggest the extent to which recall times could be shortened if industry were involved earlier in the investigation. Additionally, he discussed that the *Salmonella* Heidelberg outbreak occurred despite compliance with processing protocols, and Cargill has voluntarily improved processing practices and is disseminating those improvements industry-wide. His presentation is available as a PDF on the [CFSF Website](#).

Joan Menke-Schaenzer (Chief Global Quality Officer) provided insights from a few ConAgra recalls that highlighted the need for industry to be able to provide federal agencies with information earlier in the process. Her case studies indicated that increased and earlier communication resulted in a quicker recall by ConAgra and improved public health. Her presentation is available as a PDF on the [CFSF Website](#).

Will Daniels (Senior Vice President, Operations and Organic Integrity) echoed the sentiments of Mr. Scimeca and Ms. Menke-Schaenzer in a presentation about Earthbound's experience with a spinach recall in 2006. In addition to highlighting data and information sharing issues, Mr. Daniels emphasized the need for coordination among governmental agencies and trust among all parties as a critical—and often missing—element to interactions between industry and government agencies. His presentation is available as a PDF on the [CFSF Website](#).

Overview of United Kingdom Scoping Group Process Model

Two representatives from the United Kingdom presented their model for early outbreak investigations and the gathering of information from the private sector to supplement that obtained by the government as an example that could inform how the U.S. might construct its own process. The U.K. established their process, referred to as “scoping group process,” for a couple reasons. There was a need for improved relationships with industry, particularly after a bad recall experience. There also had been large funding cuts necessitating collaboration in order to make best of available resources.

Liz McNulty (Head of Incident Response, Incident Unit, Food Safety Group), U.K. Food Standards Agency (FSA), explained the Agency and policy background that supports the U.K. scoping group process. These scoping group process meetings with industry are to gather information early in an outbreak. She described what sort of events trigger such meetings and their timing; who convenes and participates; how invitations are extended; what types of information are requested and how; some lessons learned over the course of their four-year experience; and the benefits of the process. Her presentation is available as a PDF on the [CFSF Website](#).

Chris Lane (Head of Salmonella and VTEC Epidemiology), U.K. Health Protection Agency (HPA), described the Agency's role in the scoping group process. Similar to the CDC, the HPA is the primary investigator of foodborne illness outbreaks, working with field operatives to collect data. Once information is gathered and hypotheses are generated and narrowed, they take that package of information to the FSA to inform that Agency's decision to initiate a scoping group process, while the HPA remains involved as the investigation continues. He explained that one of the biggest barriers facing investigations

is trust—the HPA is holding individuals’ medical information and companies’ confidential business information. Without trust, the scoping process breaks down.

Following the presentations, participants raised the following points in a question-and-answer session.

Composition and Tenor of Meetings

FSA keeps the scoping group meetings small, with one representative from each company or trade group. While FSA does not expect one person to have expertise with all the products of their company or industry, the representative should be able to quickly access and gather the information from others in the company or sector. At this point, scoping group meetings are comprised of approximately 80% returning participants and 20% new participants. This familiarity has bred general comfort, collegiality, and trust during the meetings. FSA is open about their need for industry help and keeps the focus on information sharing, not finger pointing. While competitors sit together, the process focuses on information to protect public health rather than competitive advantage. Additionally, some of the information provided in follow-up, particularly potentially commercially sensitive information, is not shared all around, but remains with the FSA.

Additional U.K. Scoping Group Process Details

When exactly to call a scoping meeting—how “early” in an early outbreak investigation—is situational. To date, the earliest FSA has called a scoping meeting is ten weeks from an initial illness. Efforts are being made to shorten that timeframe. The number of and confidence in the hypotheses, the extent of the distribution networks, and information from European colleagues all determine when a scoping meeting occurs. Information industry shares as a result of scoping group meetings contributes to a FSA-tailored incidence database that links to other emerging risk and food fraud systems. The FSA provides a brief summary of the investigation to the local field officers when necessary and/or appropriate. As the process continues, they alert the companies not implicated that the investigation is progressing and their involvement is no longer required.

Assessing the Efficacy and Value of the Scoping Process

Anecdotally, the U.K. scoping group meetings have improved response times and illness rates. With approximately 15 meetings completed over the last four years, there are not yet many results to study. There are, however, both internal and external reviews taking place to assess the efficacy of the U.K. scoping group process; they will release the findings of these reviews shortly. Regardless of the formal findings, anecdotal evidence suggests improved collaboration and transparency may be benefit enough to justify the value of the scoping group process.

How the U.K. Process Translates to the U.S.

The U.K. scoping group process has many elements relevant to the U.S., but some differences in size, scale, and structure mean some dimensions of such a process would need to be designed, developed, or implemented differently. For example, relative to the U.S. agencies, the FSA has proportionally a much larger cadre of local field officers to collect environmental data for an outbreak. FSA does not have enforcement authority, but their

local field officers do, which differs from the structure of U.S. agencies. Regular collaboration occurs between FSA and HPA through a weekly meeting (includes other agencies) where the latest events and issues are raised and follow up is planned. While regular collaboration occurs between CDC, FDA, and USDA, the additional division of responsibilities adds another layer of complexity to any U.S. model.

The U.S. is thought to have a much broader and complex supply chain, larger geography, and multiple time zones, making the frequency of meetings and numbers of participants potentially higher, and in-person meetings on short notice somewhat impractical. However, the principles of targeted initiation of such a process, gathering the right composition of participants together to problem solve and retrieve critical information, and fostering relationship development and straightforward, problem-solving dialogue can translate equally.

Developing a Process for the U.S.

Meeting participants agreed that the U.S. could potentially improve hypotheses generation and response time to foodborne outbreaks during certain investigations, supplementing the already significant efforts underway, and the U.K. system could guide the development of a more formal information-sharing mechanism between agencies and industry. While the U.S. has made important progress in the last five to ten years, information sharing occurs through interagency networks and remains largely informal. Formalizing the mechanism is intended to establish a more consistent process so the information flow does not break down as relationships and personnel change. The group discussed pieces of the U.K. scoping group process that could be adapted for the U.S., developed a collective high level understanding (principles) of what the process might look like, and identified some long-standing hurdles to formalizing such a process.

Trust and Credibility

Many participants identified trust building as critical to accomplishing the intended goals of such a process. Trust between and among agencies and industry is key for encouraging exchange of information early in an outbreak - all will want assurance that their information is in trustworthy hands and not used for purposes other than what is intended. All parties have incentives to keep this information private during the investigation until verifiable results are determined. In addition to trust between parties, the process as a whole will need to build credibility, particularly with the public. Straightforward ground rules, expectations, and a clearly articulated purpose will help build trust and credibility. Active management of the process will also build credibility and is a shared responsibility of participants.

Convener and Composition

The group shifted its thinking from a question of which agency has authority to convene such a process to one of who coordinates and manages it, which encouraged significant progress in conceptualizing how such a process could function effectively. Many agreed that CDC would most often convene a meeting early in an outbreak of illness suspected to be caused by foodborne microbial contamination because they take the lead early in an investigation, gathering information from the states, and developing hypotheses. Regulatory agency representatives are also engaged in tracking any signs of a potential

foodborne problem and maybe assisting with collecting data to traceback suspected foods early in outbreak investigations. Depending on the evidence implicating a food as a source of an outbreak, however, it may be more appropriate for a regulatory agency to convene. FDA, USDA, and district and/or state affiliates could be included in conversations initiated to problem solve and gather additional food production and distribution data.

Participants highlighted that selecting representatives from all sectors inclined to collaborate was important. Likewise, the right constellation of representatives from the food production and distribution supply chain, depending upon preliminary theories of the types of food involved, geographic region, etc. is also important, since the convener would likely draw from a large set of possible participants. There would need to be clarity about why the agencies selected certain organizations for participation. Given the broad U.S. food supply chain, having a few industry individuals who are product category experts, as well as those involved at different points in the production and distribution supply chain is important. They could be individual company contacts, trade association representatives for the likely industries implicated in the outbreak, distributors, or retailers. Trade association involvement may also provide some assurance for those who have not been involved in the early outbreak investigation process before. The issue of participation will be developed further by the small group charged with developing a proposed process.

When to Call a Meeting

Participants grappled with how to decide when to call a scoping meeting, and all agreed it was a key component to work through in the straw proposal. The agencies suggested that they would call a scoping meeting when they had identified where and how industry could help the investigation—essentially knowing enough about the outbreak, given epidemiological data, traceback information, and other evidence to indicate a general type or class of food as the source of an outbreak, but not enough to pinpoint the particular product and source of contamination. This level of information can at least guide what additional information might help narrow or firmly determine the source. Industry participants encouraged, and participants generally agreed, that asking for information sooner was preferable to waiting. The U.K. representatives encouraged the U.S. representatives that asking for more information upfront was better than asking for too little and having to make repeated asks. At the same time, the information requested must be relevant and not too overwhelming, causing delay in response or concern about the scope of the request.

One participant offered the following framework, which gained a measure of traction as a starting point to thinking about criteria for an early outbreak information gathering process:

- Single food, single product line, single company – scoping meeting *likely not necessary*
- Single food, single company – scoping meeting *likely not necessary*
- Single food but multiple companies – scoping meeting *likely necessary*
- Multiple foods and hypothesis testing phase – scoping meeting *likely necessary*.

After the Meeting

The group began to address the question of what happens after the early outbreak information-sharing meeting, in terms of agency process, additional information identified and requested, and the information provided during the meeting and as follow-up. The group acknowledged that while the process focuses on problem solving to target the source of contamination and taking action to protect public health, the information gathered in the process could eventually lead to regulatory action.

After investigations are complete, CDC may conduct after action reviews that include FDA, USDA, and state partners; and the information from a meeting process may be included. Industry representatives did express a concern that regulatory agencies could use the information supplied for an outbreak for an unrelated enforcement action. In terms of information from these meetings, agencies would hold it in a database for reference in future foodborne illness outbreaks. Agencies would not discuss company-specific information with other companies or other interested parties, though as acknowledged, this information could be subject to public release under the Freedom of Information Act.

The group also acknowledged a benefit to sharing some portion of the information with a broader range of interested parties in order to build transparency into the process, familiarity with how it functions, and to determine for what purposes and whether it is achieving its goals. The U.K. has established a Stakeholder Group Process for similar purposes and as a supplemental activity to their Scoping Group Process.

Next Steps

The group agreed on the following next steps:

- ➔ RESOLVE will constitute a subgroup of meeting participants to develop the straw proposal.
- ➔ In consultation with the subgroup, RESOLVE will coordinate the drafting of a straw proposal that captures principles, ideas, and criteria for participation; identifies other issues that need additional work (e.g., FACA, Paperwork Reduction Act, undue influence measures, other legal matters, alternatives to term “scoping,” etc.); and articulates the public health benefit. This work group will be convened shortly after the New Year.
- ➔ Once a straw process is drafted, CDC can use some recent case examples for the group to run through the process to help determine its workability, strengths, and weaknesses.
- ➔ A second CFSF workshop will be held in late February/early March to review and discuss the straw proposal.