

Collaborative Food Safety Forum (CFSF)

Enhancing Early Outbreak Investigations Using a Supply Chain Consultation Process

This document is a brief description and update on the use of the Supply Chain Consultation Process developed by participants in the Collaborative Food Safety Forum (CFSF), hosted by The Pew Charitable Trusts and the Robert Wood Johnson Foundation, and involving the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), US Department of Agriculture (USDA), industry and consumer groups. This consultation process is intended to expedite foodborne outbreak investigations by providing a mechanism early on in a foodborne illness outbreak (i.e., when several candidates have been identified as the potential contaminated food source or sources, and no single entity, supply chain, or brand has been determined) for industry to share real-time food production supply chain and distribution information with federal government agencies. By doing so, preliminary hypotheses can be validated, modified, or otherwise informed and more rapid identification of the source or sources can be accomplished.

The Supply Chain Consultation Process has been deployed in at least three known outbreak situations, including 1) during an outbreak of *Salmonella* Saintpaul in the spring of 2013 (ultimately identified as associated with cucumbers from Mexico), 2) during an outbreak of *Listeriosis* thought to be associated with deli meat, and 3) during an outbreak over the summer of 2014 of *Salmonella* Newport traced to cucumbers in the Delmarva region of Maryland's Eastern shore. Use of this process was considered in several other foodborne illness outbreak instances but not pursued for a variety of reasons, including identification of the contaminated food prior to convening a Consultation. Another reason noted for pursuing this process was the lack of familiarity by other parts of various federal agencies (i.e., during a *Cyclospora* outbreak, which turned out to be associated with raspberries, the use of the Supply Chain Consultation Process was proposed but not used. One factor could be the CDC staff who work on parasitic outbreaks were not familiar with this mechanism).

Those who are familiar with, and have been directly involved in some of the Consultation Process examples mentioned above have confirmed the value of this process, citing key pieces of information garnered from industry food production experts regarding real-time insights that aided the outbreak investigation ultimately leading to more rapid identification of the source. The February 20, 2015 *Morbidity and Mortality Weekly* issued by CDC documented the investigation of the *Salmonella* Newport outbreak and noted the following:

“Consultation with independent industry experts early in an outbreak investigation also can provide important clues to help focus the investigation on certain suspected foods. Because of the suspicion that this outbreak was caused by a novel vehicle for this Salmonella Newport PFGE pattern, an industry consultation was held on September 11, 2014, with three independent experts from the produce industry to obtain

information regarding cucumber harvesting and distribution on the Delmarva region. The consultants provided information regarding crop production and distribution practices that also helped assess the plausibility of cucumbers as an outbreak vehicle.”

While not mentioned by name, the “industry consultation” was confirmed to be the Supply Chain Consultation Process developed by the participants of the Collaborative Food Safety Forum. The full article can be found on the following link:

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6406a3.htm?s_cid=mm6406a3_e

Several participants in the Collaborative Food Safety Forum have noted (including in two letters attached) the critical support of the Forum in facilitating the development and implementation of the Supply Chain Consultation Process, and providing the critical ingredient for overcoming long-standing hurdles in accomplishing such a process that has been identified as a longstanding need. The combination of a neutral, facilitated platform to collaboratively conceptualize how such a process could and should work, along with a trial period during which the key stakeholders committed to trying this process, as well as a follow up session to debrief the trial efforts (two of the three mentioned earlier had been conducted (*Salmonella* Saintpaul) or partially conducted (*Listeriosis*)), fine tune it, and determine next steps to assure its use as a regularized mechanism was the critical approach to establish the Supply Chain Consultation Process, and gather documentation of its usefulness and ongoing value.

The unique features of the Supply Chain Consultation Process, distinct from other mechanisms or strategies (such as consultation with subject matter experts internal to the Agency, or informal outreach to personal contacts include:

- Coordination among the key federal Agencies to determine and agree upon a candidate outbreak and work together over the course of the Consultation Process;
- Rapid access to information with low administrative burden through largely informal structures and procedures;
- Promotion of problem-solving through deliberation, involving not only information exchange, but applying different expertise to sharpen questions and insights for improved hypotheses; and
- Inclusion of a continuous improvement feedback loop in the Consultation Process involving all stakeholders with an evaluation de-brief session to identify insights and lessons learned to refine and improve the Process over time.

Below is more description of how the Supply Chain Consultation Process works, along with an associated graphic of the Process.

Initiation of the Supply Chain Consultation Process

The Supply Chain Consultation Process will be initiated early in an investigation when the Agencies (i.e., CDC, FDA, and/or USDA) have 2-3 plausible hypotheses but need additional information quickly, particularly supply chain related data, to narrow the possibilities. Typically prompted by CDC given that it will be early in the investigation, the Agencies will

coordinate among one another to decide if and when initiating a Consultation would be useful. If there is disagreement, the decision will be made at the Interagency Foodborne Outbreak Response (IFOR) level. The Consultation Process does not replace current, ongoing Agencies communication with subject matter experts. Rather, it augments those conversations with a more standardized outreach process that has clear protocols and is able to be adapted to the unique traits of the different outbreaks. An initial industry group comprised of industry representative who took part in the development of the process during CFSF deliberations, but now has been expanded through the Safe Food Forum.

The Consultation(s)

The lead agency identified during the decision to initiate a consultation will provide logistics to participants. Agency staff will select from the industry list for a preliminary call. During the Consultation call, the Agencies will provide relevant information on the outbreak (including preliminary hypotheses) and questions about supply chain information that would aid the investigation. Industry participants are expected to provide insights on the supply chain, pose additional or modified questions, and either confirm or suggest alternative hypotheses. The information provided and discussed either during or after the call will be confidential and only shared among the Agencies involved in the investigation.

During the outbreak investigation, the individual consultation sessions will be iterative if necessary. As the investigation continues, the Agencies may need to call additional sessions to continue narrowing the plausible hypotheses. The information needs will become more specific and the participant selection will reflect the more focused hypotheses. The standing industry group may suggest additional industry participants given the nature of the outbreak. They will notify the lead Agency of the request for an additional industry participant or participants and will be responsible for briefing any new participants on the process and expectations.

Process Conclusion

Once the Agencies can either determine a source or industry information can no longer speed the investigation, the Consultation Process is complete. Agencies will maintain a distinct line between the investigation process and regulatory processes. Agencies will notify industry of the conclusion of the process and conduct debrief sessions regarding the operation of the process and its effectiveness in speeding the investigation. These sessions will include 1) a debrief among the Agencies, and 2) a debrief with the Agencies and the industry representatives involved in the Consultation Process. These debriefs will contribute to more thorough review of the lessons learned from major outbreaks and their root causes. This information will be disseminated, along with corrective actions or improved preventive control strategies, to relevant industry. Additional communication with stakeholders not directly involved in the consultation process, including other public health officials, industry peers, members of academia, and the public, is important for engendering trust in this process. Industry and Agency staff should be transparent about the use of the process when describing outbreak investigations, including evaluation of the public health benefits.

*A more detailed document describing the consultation process and the principles underlying it can be found at <http://www.resolv.org/site-foodsafety/>. **RESOLVE** is the facilitator for the Collaborative Food Safety Forum.*