Collaborative Food Safety Forum (CFSF)

Enhancing Early Outbreak Investigations—and Response: Draft Supply Chain Consultation Process

Background

The Collaborative Food Safety Forum (CFSF or Forum) brought together diverse stakeholders from federal agencies, industry, consumer advocacy groups, academia, and state health/regulatory bodies to discuss whether and how to establish a process for sharing information between the public and private sectors to develop more detailed hypotheses early in a foodborne illness outbreak. The intended outcome of such a process is to reduce the time necessary to form an accurate picture of what is causing the outbreak (source assessment), prompting a more rapid response and intervention (risk management), and thereby avoiding more illness (prevention).

Drawing on an agreement from a December 11, 2012 meeting to develop an information-sharing and consultation process, a January 16, 2013 meeting of a small, diverse group built on the draft principles document drafted by RESOLVE. This resulting draft was further refined in preparation for the February 27, 2013 CFSF meeting with the original, larger group. During the February meeting, the group reviewed the attached process graphic and considered the process using three case studies. This draft includes the feedback from that meeting.

The February 27, 2013 meeting concluded with a commitment from the stakeholders to test and refine the process over the next six months. At the end of this trial period, the group agreed to convene again to debrief the status of the process and lessons learned if it still made sense to do so.

This draft describes the process in detail, including principles and the flow of decision-making, consultation, information sharing, and conclusion. It is intended to be a foundational document for reference and background, complementing the short description document.

This Consultation process will work in conjunction with the communications that take place between FDA, FSIS, CDC and their industry partners. For the regulatory agencies, Subject Matter Experts (SMEs) and district offices have working relationships with industry partners and collaborate with them on a routine basis. The proposed Supply Chain Consultation process does not override or circumvent the normal federal agency relationships with industry partners.

Principles for a Supply Chain Consultation Process

Purpose and Goals

- Rapid identification of the source of contamination

- Rapid intervention/response
- Improved public health through a reduction in foodborne outbreak associated illnesses
- Minimized erroneous implications of foods (and any associated erroneous guidance to the public and economic harm caused by such implications)
- Increased understanding of food production practices by federal and state regulatory and public health representatives
- Increased understanding of public health protections and regulatory process, response, and practice by industry
- Enhanced public health through collaborative actions including root cause determination and subsequent broad industry communication to prevent future, similar outbreaks
- Institutionalized and supported ongoing increased outreach – among agencies and between the public and private sectors

Outcomes and Expected Value Added by the Supply Chain Consultation Process

- Reduction of time between identification of a foodborne disease outbreak to identification of the food source and effective intervention (i.e., reduced exposure to contaminated food)
- Reduction of time needed to narrow recalls to the precise brands, lot numbers, package details, and consumer exposure points relevant to the contaminated product
- Establishment of a well-functioning process – when needed, for more rapid gathering of information, identification of the problem, and a quicker response
- The Supply Chain Consultation process is viewed as trustworthy, useful, effective, and efficient by all stakeholders

Context

Establishment of the Supply Chain Consultation ("Consultation" or "Process") institutionalizes a process for information sharing that has relatively predictable procedures while also being sufficiently flexible to be useful in a variety of outbreak scenarios. The Consultation would most likely be convened early in an outbreak investigation, when the list of plausible vehicles has been narrowed to perhaps 2–3 (e.g., evidence available to public health and regulatory officials is unlikely to reveal the source, case counts are insufficient to implicate with certainty, or protracted investigatory efforts would be required), such that information available from producers or distributors may represent the most expeditious means of identifying the food and the source of contamination. It is intended to both increase the speed of the investigation and ensure greater accuracy. The type of information needed will be determined by the particular outbreak, and could include production practices, distribution patterns, consumer purchasing information, and other relevant information, such as food production, manufacturing, product testing, distribution, and supply chain information provided by private companies and trade associations. Such Consultations could also be useful during large, rapidly expanding outbreaks with severe health implications e.g. botulism) where investigators have not yet narrowed the focus to plausible vehicles, but early in an

investigation have information suggesting certain sectors of the food industry might be involved.

It is important to distinguish this process from the regulatory process of foodborne outbreaks. The Supply Chain Consultation process occurs before the regulatory phase, and is solely focused on expediting the investigation by rapidly providing accurate industry information. When the investigation is at a point that the regulatory process will begin, the Consultation process is closed and all communications will occur through the normal regulatory channels.

Successful Sharing of Information Requires Trust

Essential to the design and implementation of the process is the development of trust, not only among the parties directly involved in the process, but also among those dependent upon the process to achieve the stated goals and purpose. Trust can be strengthened over time and through many avenues, such as the following.

- A clearly defined process with explicit and transparent goals, expectations, procedures, and outcomes, while also adaptable to particular circumstances of an outbreak.
- Opportunities to practice this process in model sessions, inclusion of debriefing sessions to review and refine the process, mentoring sessions by seasoned participants for those new to the process, and evaluation sessions including a broader cross-section of stakeholders to analyze the value of such as process based on experience and attributable impacts or benefits.
- A clear understanding of how the data and information will be shared among the participants, who other than the participants will have access to the information, and how it will be retained for any future use.
- Development of relationships among key entities, including among and between governmental agencies (federal and state), private organizations and companies, academia, and advocacy organizations. Relationship building will be supported by interactions that are respectful, productive, and non-punitive, and through recognition and realization of all parties contributing to and solving early outbreak investigations and associated appropriate interventions.
- Positive experiences and accomplishments from successful implementation of such a process, as well as the mitigation of unintended consequences and continuous improvement with such a process.

Process Overview/Design

Generally, the process will consist of convening meeting/s or call/s, and additional follow-up or debriefing. Each of these phases (which may overlap in some situations) is further described below. See also the attached process map.

Supply Chain Consultation

The Supply Chain Consultation process will be initiated when, (1) based on the preliminary epidemiological investigation of an outbreak , where more than one plausible hypothesis has been identified regarding the vehicle responsible, or (2) investigators are unable to identify a single likely vehicle due to co-linearity among 2-3 foods consumed by ill persons,

and additional information related to product distribution or production could be helpful in pinpointing the food source and/or point of contamination.

CDC and USDA and/or FDA staff investigating an outbreak will jointly discuss if and when to initiate the process. These coordination and decision-making discussions will likely not include local and/or state agency participation, but may according to the circumstances (e.g., all reported cases in one state) and who has been conducting the investigations. Likewise, involvement of FDA District staff will be determined by the nature of the outbreak. Depending upon preliminary information and whether candidate foods are determined and clearly fall into only one regulatory agency's jurisdiction, involvement of FDA and/or USDA with CDC will be routine. If disagreement exists among the involved agencies, then the question of whether and when to initiate an Supply Chain Consultation will be brought to the Interagency Foodborne Outbreak Response or "IFOR" team, known as the "Principals" in this process (currently, Chris Braden, CDC; Kathleen Gensheimer, FDA; and Regina Tan or David Goldman, USDA), for deliberation and decision making. Any of the Principals also can bring a case for initiating a Supply Chain Consultation to their IFOR colleagues for consideration and decision making.

Coordination Among and Between Agencies

In preparation for a Supply Chain Consultation, the involved agencies (CDC with FDA and/or USDA) coordinate among themselves and determine:

1) Who will be invited to join the Consultation (see next section);
2) Who is convening the meeting;
3) Who is moderating the meeting;
4) How the agenda will be organized;
5) What information will be shared, in addition to the basic epidemiological data and other relevant background; and,
6) The nature of the questions to be asked, and what data will be requested of industry.

Coordination among the agencies is important and will be established early on and continue throughout the Supply Chain Consultation process, including through any series of meetings or calls, and the debriefing phase activities.

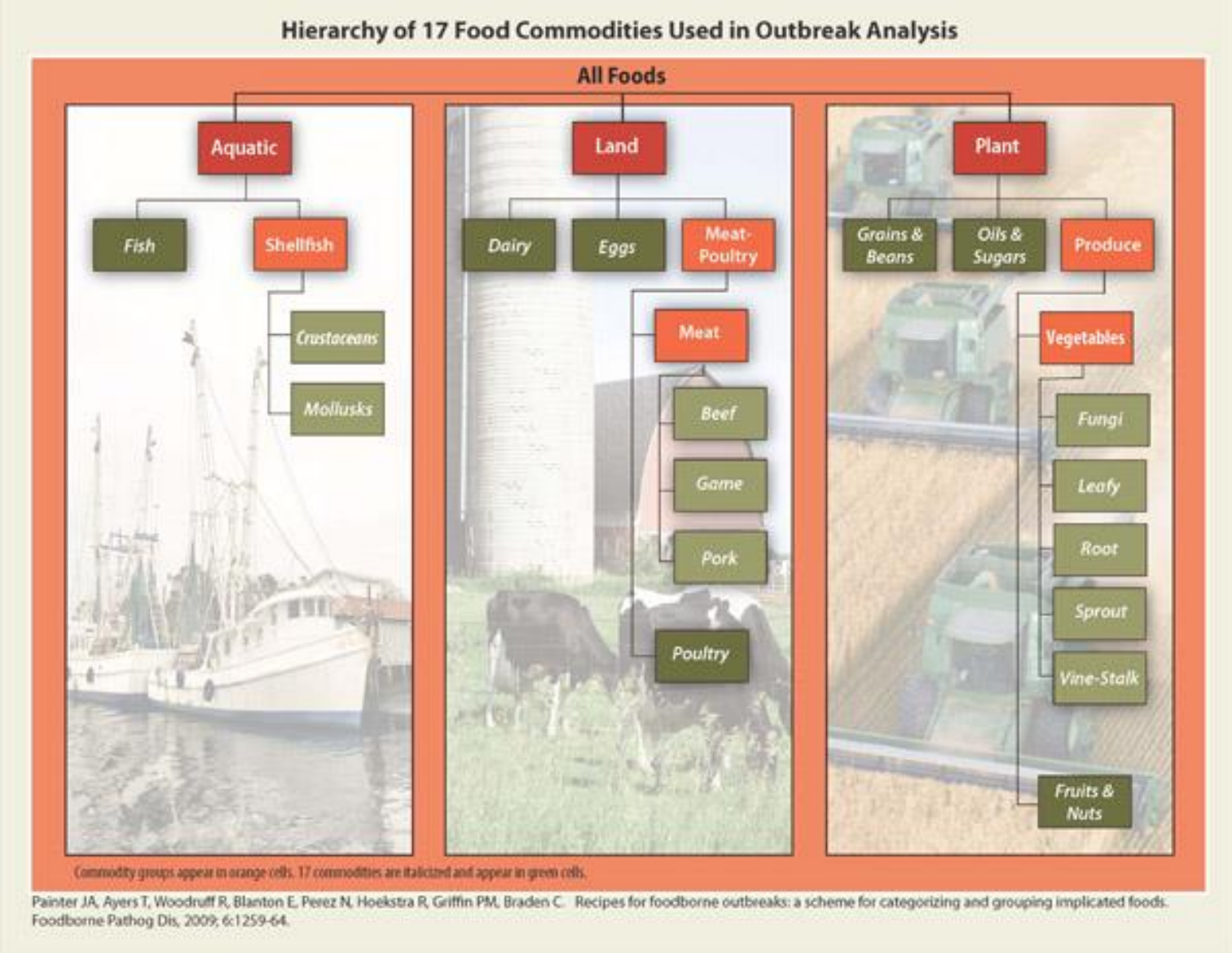
Participants in the Supply Chain Consultation

Participants will include public health and regulatory officials (federal and district, state, and local government as appropriate) and private sector representatives, as well as other potential subject matter experts, such as persons from industry associations or academia, who may provide expertise needed, given what is known about the outbreak. In general, the number of participants should be small (perhaps 6–20) to enable efficient and effective information sharing, as well as to simplify the meeting and/or call logistics. At the same time, the size and composition of the group will depend upon:

- Distribution and scope of the outbreak (geographic, and any insight from the food production industry and supply chain that might be involved, including food production facilities, transportation, retail, commercial establishment, etc.);

- Preliminary food source information, such as whether the outbreak is meat, fish, poultry, egg, a processed product, or fresh produce; and, when relevant, types of facility (or facilities) involved; and
- Early indications that some portions of the supply chain beyond food production (i.e., storage, transportation, etc.) may be relevant to the particular event.

Leaders from the agencies will work through and with existing relationships/contacts to identify appropriate representatives from industry. A roster of industry representatives will be established for quick contact and supplemented by other appropriate representatives, based on the particular circumstances of the outbreak and supply chain considerations. The standing industry group is responsible for identifying the right participants as the investigation narrows its focus. Such a roster and a decision tree for identifying Consultation process participants could be based on the categories of food as outlined below and as organized in the attached slide.



Painter JA, Ayers T, Woodruff R, Blanton E, Perez N, Hoekstra R, Griffin PM, Braden C. Recipes for foodborne outbreaks: a scheme for categorizing and grouping implicated foods. Foodborne Pathog Dis, 2009; 6:1259-64.

It is critical that the purpose of this meeting and the information sought is clearly communicated to individuals and/or groups selected to participate, prior to the consultation, so that the most appropriate representatives can be included in the meeting. To help industry participants prepare for the meeting, the convening agency will provide general background to invitees and ask for a representative that can talk knowledgeably about the relevant topics. It should be understood the commercial confidential information can not be shared by federal agencies with the consultants and information discussed during the Consultation should remain relatively private. Every person involved in a Supply Chain Consultation session should participate and contribute to problem solving during the meeting or call. These criteria set expectations and keep the meeting or call to a smaller group of key individuals.

Fundamentally, determination of who is on the roster and which additional industry representatives participate in the process should be based on the following:

- Ability to discuss, access, and provide key pieces of information to the designated agency in follow-up to the meeting.
- Ability to constructively contribute to the problem-solving deliberations with extensive knowledge of their respective industry/production/distribution practices of the potential food source. A colleague respected by industry peers would be maximally effective in this process.
- Willingness and commitment to participate actively.

Given that development of trust is critical to the success of this process, the members of the standing industry roster will be familiar with how the process was developed and are expected to be consistent participants. However, changes in personnel will be inevitable, and every effort should be made to minimize disruption to the process by bringing participants up to speed on how the process works and how best to prepare and participate. Mentoring opportunities, to increase understanding of the process and better prepare new participants should also be included.

Leadership and consistency of participation early on is also important for the government agency representatives too, especially during the establishment of such a process.

Information Identification, Provision, Access, and Use

At the core of this process is the rapid gathering of information to help narrow the list of hypotheses about the likely source of a foodborne disease outbreak. Tools to assist in effective sharing of information include clear messaging of expectations, process, and updates as the Supply Chain Consultation process is underway; standardized templates for communication and follow-up; limited distribution during an active case, and in particular, in the case of commercially sensitive information (confidentiality agreements and other tools may be necessary under these circumstances, as well but the group did not delve in to this topic); and, communication with the broader set of stakeholders and the public about this process, its intent, results, and evaluation of its value.

Some information necessary to accomplish these goals will likely be commercially sensitive, and it is imperative that this information be protected from inappropriate access or use. During the Consultation meetings and calls, agencies will not name brands and/or companies in order to protect those involved. Concerns that information shared will either be used to trigger enforcement actions otherwise not taken, or result in violations of the law being ignored, will also undermine trust in this process. Therefore, it is critical to establish parameters around the identification, provision, access, and use of the important data sought through this Consultation process and essential for rapid identification of the food source and point of contamination. Part of the coordination between agencies before the Supply Chain Consultation will be to determine any sensitivities, such as information that cannot be shared throughout the meeting or call or the follow up activities.

Convening

The convener is determined when the agencies decide to engage the private sector. The convener provides logistics for the call(s) and meeting(s), issues invitations, and provides the basic information so that participants can prepare—often within hours—for a conversation. Coordination among the agencies provides guidance to the convener.

The moderator, identified during the inter-agency coordination, is the agency representative or individual who will moderate the Consultation discussion, including asking the questions, facilitating deliberations, and summarizing next steps determined. Depending upon the circumstances and stage of the outbreak investigation in which the Consultation takes place, the moderator could be CDC, FDA, or USDA. CDC is more likely to prompt the process since it will be used early in an investigation. Deciding who will moderate the meetings will be part of the coordination among agencies, with the Principals addressing any disagreements, and may change if a series of meetings is necessary.

The convener and moderator can, but do not have to be, the same agency or individual. The convener or the moderator will be responsible for updating Consultation participants during the outbreak investigation, as appropriate, and set up the debriefing activities discussed below.

Meetings

Once a decision has been made to initiate the process, a call may be organized within just a few hours for preliminary exchange of information. If necessary, follow-up calls or meetings will be held until the agency determines the process has yielded the information required for moving the investigation forward.

Meetings should be organized and an agenda, including key questions/information needs, structured for collaborative problem solving as much as possible. For example, after the moderator opens the meeting and reviews the process and expectations for the meeting, CDC, as well as FDA and/or FSIS might walk through a set of slides detailing what has been ascertained to that point by their investigation, and then open up the discussion to questions and insights that industry representatives may have. Information-gathering questions may be posed up front or emerge during the course of the discussion. The moderator or organizer will not take formal notes, but a brief document/email with

bulleted actions steps will be shared with participants, and follow-up comments could be made via email. The moderator will not focus on summarizing content that requires review and consensus from participants, but rather on the action steps determined during the deliberations as necessary to move the investigation forward. Documents should be brief, not require formal review from each participant (given the emphasis on speed), and be circulated only on a "need to know" basis.

Commercially sensitive information will not be solicited or gathered before the meeting; only through dialogue and joint analyses will the more targeted information be requested from specific participants.

Follow-Up

The Supply Chain Consultation process will conclude with several debriefing steps.

1. A communication (possibly via a meeting) to report on the investigation at the end of the outbreak.
2. An inter-agency debrief on and evaluation of the operation and effectiveness of the Consultation process as part of the investigation, including potential changes. This call will take place within a month of the final session of the Consultation.
3. A debrief with industry representatives to collectively learn from the experience in terms of both procedural and substantive issues. This call will ideally take place within a month of the final session of the Consultation and after the inter-agency debrief.

Information to be shared will be governed by each agency's particular requirements. The general principle will be to endeavor to share the same level of detail, and provide updates on where the investigation stands, whether the source of contamination has been determined, whether the continued engagement of the individual companies is required and whether their products have been eliminated from the list of hypotheses. As the investigation comes to a close, the agency or agencies will be in increased communication with the involved industry or company, which allows the latter to be proactive in addressing the problem and organizing their public communications.

Communications with the Public

Communication with stakeholders, particularly the public, is critical to building a trusted and effective process for all participants. The following is a list of measures that should be taken to provide transparency and engender confidence in the Consultation process, once it moves through the trial phase, is evaluated, and, if deemed useful, is initiated on an on-going basis.

- In any CDC/FDA/FSIS descriptions of the outbreak investigation process (website, written, presentations, etc.), the Supply Chain Consultation process should be added into the timeline or description of the full process.
- A written description (with charts) of the Supply Chain Consultation process should be posted on the CDC website where they discuss how they conduct outbreak investigations (this page for example: http://www.cdc.gov/outbreaknet/investigations/investigating.html). The same description should be included on the appropriate USDA/FSIS and FDA websites.

- The description should include an explanation of the public health benefits, either expected benefits in the early stages of using the Supply Chain Consultation process or realized benefits after some cases have concluded and evidence is gathered.
- When the agencies are discussing in a public setting an outbreak investigation that has used the Consultation process, they should be transparent about the use of the process.

Decision Tree for Outbreak Response