

Collaborative Food Safety Forum

Small Group Meeting: Collaborative Implementation of FSMA: Brief Summary and Next Steps Memo – October 2014

Thanks again for participating in the small group meeting September 29th to build on the CFSF deliberations held in June and help develop a proposed focus and work plan for the CFSF to play an important role in supporting successful implementation of FSMA. A great deal of good work was accomplished, and a couple of summary documents will be developed to capture the discussion, including the following:

- 1) This memo highlighting next steps; and
- 2) A draft principles document for guiding and framing future deliberations of the CFSF as they relate to FSMA implementation.

Potentially, an overview document or slide deck for presentation to the larger dialogue group meeting on November 14th also will be developed.

Over the course of the day's deliberations, next steps identified included:

- 1) A document outlining principles for successful implementation of FSMA;
- 2) A work plan to articulate the CFSF's role in supporting successful FSMA implementation; and
- 3) Key next steps for moving forward.

Development of Principles Document

The work group thought it would be useful to draft a statement of principles governing the deliberations of the CFSF efforts regarding the successful implementation of FSMA, including identifying goals and metrics for success. Such a document could establish and serve as a framework articulating the goals and expectations for the CFSF collaborative deliberations.

For example, the work group confirmed that improved public health outcomes are the primary goal of FSMA, but also reaffirmed that other goals are also critical to various stakeholders, such as:

- Better alignment of the food safety oversight systems;
- Minimizing unintended consequences, such as unduly burdening smaller producers; and,
- Sharing best practices to encourage compliance and catalyze continuous improvement.

Additionally, working group participants concurred that there is a sequence of goals and associated metrics necessary to consider in moving toward and achieving improved public health outcomes, and attention and evaluation could mirror progression of successful implementation of FSMA in the following order:

- 1) Education and outreach;
- 2) Implementation of good practices/compliance with requirements; and

3) Improved public health as the ultimate goal.

The small group thought that goals and metrics for successful implementation of FSMA should first focus on education and outreach to inform regulated entities about what is expected of them, their understanding of standards and requirements, and tools or technical assistance for meeting those expectations. For example, measures of success could include preparedness to do self-assessments based on risk to identify what practices are positive, as well as areas where improvements may be needed to reduce risk. Goals and metrics should next include increased use of practices that meet the standards. Progress with outreach, education, and adopting practices that meet the standards should then lead to enhanced public health outcomes.

The work group acknowledged that developing metrics, near and longer term, with direct correlation to improved public health outcomes will be challenging, will likely include both quantitative and qualitative benchmarks and measures, and are critically important to evaluating progress. Additionally, such benchmarks or measure can potentially highlight where change or re-thinking regarding requirements or practices is necessary if/when the anticipated improvements do not materialize. While the principles of such an approach may be consistent across the entire food production system, farm- and facility-specific activities will most likely, and necessarily, look quite different.

These challenges reinforce the need for collaborative discussion of metrics that assess FSMA implementation. Through deliberations organized within this framework, ideas will emerge for how best to encourage and catalyze change and improvement.

Next Steps: RESOLVE will develop and circulate a draft principles document to the working group for review and comment in the next couple of weeks with the goal of having a draft document ready to discuss at the November 14th CFSF meeting.

Substantive Focus and Proposed Activities for the CFSF related to FSMA Implementation

Working group participants identified the opportunities to leverage the shared history and strengths of the CFSF. One participant suggested that the implementation effort can and should build on the trust that has been established among the cross-section of stakeholders over the three-plus years of activity. Over that time, there have been multiple conversations engaging stakeholders from different points of view and interests, and participants have had the opportunity to raise issues and concerns, share information, and consider possible solutions to identified challenges. These deliberations have largely revealed that the stakeholders have agreed on more than they have disagreed, and this bodes well for future efforts to achieve successful implementation of FSMA.

Other participants concurred that the opportunity to continue having multi-stakeholder dialogue on key topics identified as important for successful implementation is the particular niche for the CFSF. The group hopes to build on this good working dynamic; providing leadership as they chart a successful course for implementation moving forward.

Potential activities for the CFSF discussed included the following:

- Developing consistent messages;
- Problem-solving (serving as a “sounding board”) by providing feedback and insights to FDA and each other;
- Minimizing unintended consequences;
- Sharing best practices across the entire food system;
- Fostering continuous improvement of implementation of FSMA and working toward improved public health outcomes by leveraging the different strengths of various CFSF members and their organizations.

The working group also highlighted top substantive areas listed below for deliberation and ideas for how best to shape those discussions, in particular, through prioritizing metrics for evaluating FSMA implementation.

Prioritizing Metrics for Evaluating Successful Implementation Progress

Working group participants reaffirmed the need to prioritize and, when necessary, develop metrics for successful implementation of FSMA. FDA is currently developing a results-oriented management systems (ROMS) or framework for developing and evaluating effective FSMA implementation. Participants converged around the notion of reviewing the framework, beginning with the Preventive Controls rule (PC ROMS) to better understand FDA’s priorities and thinking, provide suggestions for improvement, and develop metrics of success. The working group proposed that part of the November 14th session could focus on review and discussion of the PC ROMS as well as a continued discussion on metrics.

Additional suggested activities to develop metrics included engaging additional personnel within FDA, such as the CORE team, as well as CDC, the Interagency Food Safety Advisory Committee, and others, to further consider appropriate near and longer-term metrics for public health outcomes.

Next Steps: RESOLVE will work with stakeholders to develop a draft agenda and focus for the November meeting to include a discussion of metrics development, informed by review and substantive analysis of the PC ROMS.

Identifying and Addressing Unintended Consequences of FSMA Implementation

Highlighting and exploring whether and how requirements and recommended practices to achieve compliance with FSMA could create unintended consequences that unnecessarily burden certain segments of the industry, in particular small and sustainable operations, or how these requirements are not having the intended improvements to food safety was another area identified by the group for deliberations. Discussion of practices potentially requiring improvements or revision to achieve better public health outcomes is part of supporting continuous improvement of food safety oversight. For example, in an effort to improve sanitation, a requirement to remove carpeting from trucks carrying melons was implemented, which resulted in other unintended consequences, such as increased bruising of melons. This

group focused on the need to further discuss and understand provisions which may result in similar unforeseen consequences.

An additional particular focus in this category highlighted by the working group is the exploration of market dynamics and access. Some are concerned that requirements/practices to improve food safety could drive them out of the market because compliance is too challenging given limited resources and access to knowledge and tools. Working group participants also noted that an aspect of this discussion could include incentives to encourage voluntary adherence and compliance, as well as alternative approaches to meeting the requirements that are not burdensome. The working group also discussed the potential unintended consequence of consumer confusion if food safety was used as a competitive issue, with some indicating that their food is safer than others even if all are meeting the FDA requirements or standards. Exploring the relationship between regulatory compliance and market access and articulating potential challenges and solutions, was identified as an area of interest and potential discussion.

Working group participants noted that while FDA does not have direct authority to address market access, it can consider it when deciding the best approaches to implementing FSMA.

Next Steps: Meeting participants recommended that a cross section of stakeholders hold a conference call to further develop the charge to a working group to engage on this topic of unintended consequences. RESOLVE will help organize the call after the November 14th meeting.

Sharing Best Practices, Capacity Building and Access to Resources

The working group discussed the value of the CFSF providing opportunities to share what is working well and how to scale up best practices. Additionally, brainstorming how to best prioritize resources to spur action and fill existing gaps in sharing best practices and capacity building through leadership and initiatives of CFSF members in their respective sectors was highlighted as an area of potential effort.

Next Steps: This area of focus will be included in the overview to the participants of the November 14th meeting and will require further development as to outcomes for this effort which add value to other activities focused on these issues.

Fostering Culture Change for Improving Food Safety

Meeting participants identified “culture change” as an important area of deliberations and suggested additional work to help foster it. Culture change is important for FSMA implementation to be successful and includes, but is not limited to, change within FDA and other governmental agencies at the federal and state levels, and within the food industry.

Working group participants also discussed the value of sharing perspectives on metrics for culture change. For example: How will progress be noted across stakeholders with regard to

FDA's culture change. How are different stakeholders evaluating this? Can there be a common set of metrics for assessing culture change?

Next Steps: Meeting participants recommended that an interested group of stakeholders hold a conference call to further develop the charge to a working group to engage on this topic of culture change. RESOLVE will help organize the call after the November 14th meeting.

Additional Next Steps

The next opportunity to further refine the scope and activities of the CFSF in addressing successful FSMA implementation is the November 14th full group meeting. As mentioned above, the agenda for the meeting was proposed to include the following goals:

- Presentation, discussion, refinement and confirmation of CFSF scope and work plan, including priority next steps;
- Review and discuss the Preventive Controls Results-Oriented Management System for:
 - Overall feedback on approach;
 - Input on prioritized metrics for progress with PCs specifically;
 - Initial discussion of metrics across all areas of FSMA.

Next Steps: RESOLVE will work with a cross-section of stakeholders, including working group participants, to further develop and refine the agenda for the November 14th meeting. Additionally, RESOLVE will coordinate with working group members to develop supporting materials for presentation and discussion of the working group's conclusions and proposed next steps for the CFSF captured in this memo.

Appendix: Sept. 29 Small Group Meeting Participant List

Participants

Sandy Eskin

Project Director, Food Safety Campaign
The Pew Charitable Trusts

Donna Garren

Vice President, Regulatory and Technical Affairs
American Frozen Foods Institute

David Gombas

Senior Vice President, Food Safety and Technology
United Fresh

Jim Gorny

Vice President, Food Safety & Technology
Produce Marketing Association

Sophia Kruszewski

Policy Specialist
National Sustainable Agriculture Coalition

Joan Menke-Schaenzer

Global Chief Quality Officer
ConAgra Foods

Joe Reardon

Consumer Protection Assistant Commissioner
North Carolina Department of Agriculture and
Consumer Services

Martha Rhodes Roberts

Special Assistant, Government Affairs
University of Florida, Institute of Food and
Agricultural Science

Mike Robach (by phone)

Vice President, Corporate Food Safety &
Regulatory Affairs
Cargill

Pamela Russo (by phone)

Senior Program Officer
Robert Wood Johnson Foundation

Chris Waldrop

Director, Food Policy Institute
Consumer Federation of America

Steve Warshawer

Farmer
La Montanita Cooperative/Beneficial Farms CSA

FDA/USDA Observers

Kari Barrett

Advisor, Strategic Comms & Public Engagement
U.S. Food and Drug Administration

Joann Givens

Deputy Regional Food and Drug Director
U.S. Food and Drug Administration

Leanne Skelton

Produce Safety Staff on detail from
U.S. Department of Agriculture

Roberta Wagner

Deputy Director for Regulatory Affairs
U.S. Food and Drug Administration

RESOLVE Facilitation Team

Abby Dilley

Vice President of Programs and Senior Mediator

Chrissie Juliano

Senior Program Manager

Rachel Nelson

Program Associate