Collaborative Food Safety Forum (CFSF)

Collaborative Implementation of the Food Safety Modernization (FSMA) Act, November Large Group Meeting: *Workshop Summary*

November 14, 2014
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, academia, and associations attended a workshop on November 14, 2014 to refine the CFSF approach for successful implementation of the Food Safety Modernization Act (FSMA) and discuss key elements and indicators to help define success. This session, the third in a series of implementation-focused meetings, built on conversations which came out of a small group meeting held on September 29, 2014 and a large group meeting in June (materials from both can be found on the CFSF website).

The proposed goals of the workshop included:

- Reviewing, discussing and refining proposed approach, principles, and next steps for the CFSF in supporting successful implementation of FSMA;
- Discussing the draft Preventive Controls Results-Oriented Management (ROM) framework and associated metrics to prioritize benchmarks for progress of successful implementation of FSMA; and
- Determining possible next steps.

The proposed outcome of the workshop was a summary document (this document) briefly capturing the key themes and main points of discussion, as well as next steps.

Opening Remarks

The workshop opened with a welcome and remarks from Sandra Eskin (Pew) and Pamela Russo (RWJF) followed by a review of background and the workshop's goals, outcomes, agenda, and ground rules by Abby Dilley (RESOLVE). Ms. Dilley noted that this was the 15th session of the Collaborative Food Safety Forum since its establishment in 2011.

Mike Taylor, Deputy Commissioner of Foods, U.S. Food and Drug Administration (FDA), thanked Pew and RWJF, as well as everyone else involved in the Forum to date for its continued input and efforts, and then provided context regarding FSMA policy development moving forward. Mr. Taylor noted that FSMA implementation will require a commitment by all stakeholders involved. He discussed the various phases of FSMA: phase 1, the rulemaking process; phase 2, the planning and policy of compliance; and phase 3, actual implementation, inclusive of a monitoring and evaluation framework.

Mr. Taylor identified three broad areas of activity that FDA will be focusing on in overseeing FSMA implementation:

- *Fostering compliance by m*aking sure expectations, rules, guidance, technical assistance, etc., are clear to help those who want to comply.
- *Providing oversight and establishing accountability*, which is central to FSMA, and it gave FDA tools to, among other things, verify compliance.
- *Conducting enforcement* as *one*, not *the*, tool in the tool kit. If compliance and oversight/accountability work, there will be less need for enforcement.

Mr. Taylor said that the discussion around metrics for success is critical, noting that it should include not only the long-term measure of decreased foodborne illness and improved public health, but also include intermediate measures necessary to make progress toward these ultimate food safety and public health goals.

Small Working Group Deliberations and Creation of Principles for the CSFS

Following Mr. Taylor's opening remarks, several participants summarized discussions that occurred during the September CFSF small working group meeting on FMSA implementation. A "principles document" was drafted based on the small group deliberations, and is meant to govern the CFSF efforts moving forward in supporting successful implementation of FSMA and remind people what the group has agreed to date.

Most participants agreed the principles document is useful to help establish the vision for successful FSMA implementation as well as frame future CFSF discussion. After reviewing the principles, several key themes and associated prioritized areas for deliberation were discussed and are highlighted below.

- *Flexibility is crucial*, particularly when advances in science and research (such as better understanding of risk profiles) move more quickly than the regulatory process. However, flexibility must be balanced with the need to have enforceable standards that are mandated by law. Flexibility can also help foster a system where lessons learned are easily shared and best practices are promoted. One solution might be finding creative regulatory tools, such as interim standards or sunset provisions. It was suggested that a case study effort could help establish such flexibility, drawing on the governance of other products or production systems where science is rapidly evolving. The group focused on the possible opportunity to establish flexibility in developing a manure standard. If such flexibility were established in the Final Produce Safety Rule, a group could work through all the considerations around standard-setting and updating, and how implementation in the face of such flexibility could be accomplished – thereby demonstrating how such regulatory flexibility could work in a new paradigm that gets to quantification in an effective strategy, while also advancing progress in practices. Such a case could help model how flexibility could be used in other areas of FSMA (such as with water quality standards) and be integrated with a continuous improvement objective.

- *Consideration of unintended consequences and continuous improvement,* including long-term impacts, is also critical. Many participants noted that while improving public health is the overarching goal, reduction of foodborne illnesses is only one component of that. All potential consequences should be considered, including the identification of proposed practices that are not improving food safety. An example noted was the proposed removal of carpet from pick up trucks to transport melons to reduce surface areas that could harbor and spread microbial contaminants. This practice proved to, in fact, increase problems due to bruising of the fruit, increasing rather than decreasing potential contamination. In such situations, hopefully, the

negative impact is noted quickly and adjustments in requirements are made. Such a course correction would demonstrate a system valuing continuous improvement. Another example given was the potential to place additional financial burdens on producers, without the benefit of significant improvements in food safety, which could drive some out of business, as well as increase food costs, thus further disincentivizing the consumption of fresh fruits or vegetables.

Participants acknowledged that some of this conversation rehashed discussions from the June, as well as September meetings and reaffirmed the need for a principles document – framing the multiple components and perspectives of what successful implementation of FSMA entails. Additionally, the discussion highlighted the challenges and concerns regarding such a complex and multi-faceted law that will require all stakeholders working together collaboratively and effectively, and the regulatory and systems flexibility to adapt, evolve, and improve over time and as new information and lessons learned are gathered and integrated.

Prioritizing Metrics for Evaluating Progress of Successful Implementation

Participants discussed an approach for prioritizing and developing metrics for evaluating implementation progress using FDA's Preventive Controls Results-Oriented Management (PC ROM) framework and associated draft metrics. While the CFSF group focused on the PC ROM, partially because it is most likely the first actively evaluate progress with the Preventive Controls Rule finalized earlier than other rules and therefore implementation moving forward on a faster track, there is interest in the whole spectrum of metrics associated with the other main rules, as well as metrics spanning full FSMA implementation.

Roberta Wagner, Deputy Director for Regulatory Affairs, FDA, gave an introductory overview stating that the draft document for the Preventive Controls performance measures reflects their thinking to date and is a work in progress. She also stated that public health outcomes are a priority for FDA and work is underway to develop these metrics, including conversations with the Centers for Disease Control and Prevention (CDC). Ms. Wagner also commented that some results measures are more advanced than others and that a variety of considerations come in to play in establishing measures and metrics for progress, including whether a measure can be established and is a strong indicator of progress, whether data for that measure exist to establish a baseline, as well as to evaluate progress, and whether the Agency has access to the best data. Following some brief questions and discussions, the PC ROMs framework and metrics were presented and feedback and questions occurred throughout the overview.

Priya Rathnam, Consumer Safety Officer, Office of Compliance, Center for Food Safety and Applied Nutrition, and Dianne Milazzo, Consumer Safety Officer, Center for Veterinary Medicine, FDA, presented an updated draft PC ROM framework outlining intermediate steps for both industry and FDA to measure success, including identifying strategic goals, such as reduced foodborne illness, reduced contamination from facilities, increased industry implementation of preventive controls rules, and more rapid and effective recalls. Many participants highlighted the importance of developing a compact, prioritized set of useful metrics, which can help measure success, as well as drive continuous improvement.

Additionally, Ms. Rathnam and other FDA staff reviewed, in more detail, associated draft performance measures which identify key specific measures, referred to as "metrics," that could be used to indicate success towards achieving strategic objectives and results outlined in the PC ROM Framework.

Determining Metrics

Metrics were/are being determined based on four main criteria:

- **Direct**—what most directly measures the result.
- **Objective**—data that could be measured in an objective, precise, and unambiguous way.
- **Practical**—data could be collected in a cost effective, timely, and reliable manner.
- **Adequate—**data that could be used to sufficiently understand whether progress is being made.

Additionally, considerations for how near-term metrics build towards or enable longer-term metrics are also part of developing the ROM framework. As this was a preliminary draft, the measures will continue to be developed, refined, and prioritized. Ultimately, a finalized metrics plan will be used for monitoring and evaluation of the strategic framework.

Following the presentation, participants reviewed the draft metrics and gave a variety of comments and feedback, including broad observations, as well as detailed feedback per result area and performance measure. While not captured in this summary, feedback will be collected and compiled by RESOLVE and forwarded to FDA for their consideration as they continue to develop a next iteration and come back to the group with a new draft.

General Metrics Considerations and Comments from the Group

Comments regarding the draft PC ROM framework and performance measures spanned a broad range and included very particular comments on language, sources of information and if they are the most relevant, and whether baseline date for particular measures were available, as well as the overall observation that the sheer number of measures is overwhelming. The brief summary below is only a sampling of comments or topics that came up during the discussion.

- Allergens were noted as a hazard that should be represented within the framework, as they are relevant for tracking food-related illnesses and pertain to public health impacts. Data on allergens may be able to be obtained from CDC.
- Recall actions may not be the best measure as an independent variable as the overall goal is less about regulatory action and more about the potential for exposure, i.e., how much contaminated product remains in the system and available for consumption and for how long once it is identified by an outbreak and/or testing.
- Whether reportable food reports (RFRs) are an important measure in and of themselves (i.e., as having been submitted). RFRs, in combination with other measures, can be very useful and one participant proposed a combination of RFRs, recalls, and percentage of an emerging issue or pathogens combined can provide insightful data.

Other general comments on the metrics as a whole are highlighted below.

- Some participants commented that while detailed conversations around FDA's metrics are important and useful, it may also be valuable to take a step back from focusing solely on the actions of the regulatory agency and also include the actions of others, such as industry, and develop overarching goals, metrics, or five to ten "commandments" of food safety for all parts of the food system.
- One participant suggested prioritizing metrics that are directly related to greatest public health risk and codifying language around these, while creating guidance for other, less public health-related components.
- Unintended consequences related to metrics, i.e. that the need to provide data may be an additional burden on small producers.

As the conversation unfolded, it was clear participants many more comments than there was time to address. Consequently, it was determined that a multiple step process would be the best approach to gathering feedback and continuing deliberations on metrics, which is laid out below.

Action Items Specific to Metrics

- Submit comments on draft PC metrics document or draft PC ROM **by Wednesday, Dec. 10, 2014 to Rachel Nelson at RESOLVE (rnelson@resolv.org).**
- Industry participants who use "scorecards" or various indices to evaluate their internal preventive controls food safety systems will share information with FDA (potentially through a webinar or conference call).
- FDA will continue to revise their PC ROM metrics and create a more targeted set to bring back to CFSF participants for additional discussion in future meetings.
- Other ROM frameworks and associated metrics for other FSMA components (Produce Safety and Imports) will be discussed during future CFSF meetings.
- Most likely, a small working group of CFSF participants will take the lead on advancing development of public health metrics discussions and come back to the larger group.

Potential Topics/Areas of Focus for the CFSF in Supporting Successful Implementation of FSMA

Participants discussed topics/areas of focus where the CFSF can add value, including: prioritizing metrics, addressing unintended consequences, sharing best practices, building capacity, leveraging resources, fostering culture change, and exploring flexibility in the regulatory process. The group agreed that the metrics discussion was the top priority, but did identify other opportunities (outlined below), where the CFSF can add value and play an important role.

Building Capacity and Alignment

Building overall capacity and alignment of oversight efforts has been a consistent important theme to CFSF participants and has been highlighted with regard to FDA and its capacity, as well as the capacity of others to supplement FDA's role, either in outreach and providing information on what is expected of the regulated community (in which the private sector and academic institutions play a significant role), or inspection and compliance (in which state and international authorities, as well as sister federal agencies play a significant role).

As a first discussion, it was noted that efforts already are underway to gather information on state capacity through a cooperative agreement between FDA and the National Association of State Departments of Agriculture (NASDA). NASDA is working with state departments of agriculture and other agencies to understand variations in the food safety models state-by-state. Ultimately, the goal of this effort will be to harmonize different approaches and reduce the number of models across states. As part of this effort, NASDA is also analyzing state capacity and resources to support other agriculture programs, such as organic certifications. While much of this research has been done, it will need to be reframed from a FSMA/outbreak prevention lens. NASDA is also partnering with the International Food Protection Training Institute (IFPTI), based in Battle Creek, MI, to develop strategies for increasing capacity and what is needed in terms of assistance (training, information distribution, websites, etc.).

One participant suggested that a map of contacts at the state level and what they oversee (for example, to better understand overlaps between departments of agriculture and health at the state level) would

be a helpful contribution. Another participant noted that it will be important to have a more in depth discussion around who (likely at the state level) will implement regulatory training and how best to align expectations for and communications during inspections and other regulatory visits. For example, will joint training be part of a strategy to align stakeholders?

Given the relatively recent launch of the NASDA work under the cooperative agreement, participants thought an additional update on what NASDA is doing at an appropriate time would be beneficial and that in the mean time, keeping in touch with NASDA will be helpful. Any efforts undertaken as part of the CFSF to support successful implementation of FSMA, particularly on state-federal capacity building, should complement rather than be redundant with what already is taking place.

Other areas requiring alignment have been identified, including across the public and private sectors, as well as international oversight systems and additional deliberations on alignment and capacity building most likely will emerge in future discussions.

Messaging, Communications and Outreach

Much discussion focused around communications for a variety of purposes, including outreach to the regulated community to understand the importance of FSMA, what it is intended to accomplish, and how they need to comply. For example, one participant noted that it would be essential to further develop messaging to small farmers/enterprises/facilities. Additionally, the group agreed more discussion and development of messages is critical for increasing knowledge about the overall effort around FSMA implementation and efforts to improve food safety. Consistent and thoughtful messaging could provide an overall framework through which the public can better understand food safety challenges, actions, and ongoing efforts to improve. If efforts to successfully implement FSMA are in place and working toward the overall public health outcomes mandated, then associated messaging to the public should help increase consumer confidence appropriate for that success.

The CFSF could potentially think through how to best tailor messaging for various stakeholders involved – both to convey messages to the regulated community (tapping networks of CFSF participants) and to the public. In addition to these areas of focus and goals for communications, FDA would like more input about how to best message successes and best practices to stakeholders and the public.

Moving Forward: Developing a Work Plan and Proposed Next Steps

Participants concluded by discussing a CFSF work plan to support successful implementation of FSMA and generating next steps to develop and implement such a plan. Participants agreed that collaboration among stakeholders is essential at many levels for successful implementation of FSMA and all indicated an interest in and ideas for best focusing this collaboration. Identified next steps are highlighted below. Note that some topics were further developed during the discussion and therefore have more details; others were less developed, but will be discussed at future sessions.

Topics for Further Deliberations

1) Metrics were a top priority, and next steps included:
    - RESOLVE will compile notes from the PC ROM metrics conversation, as well as those submitted to Rachel Nelson (rnelson@resolv.org) by *Wednesday, December 10th,* and send to FDA.
    - Food company representatives (through GMA) will share information on private sector metrics for preventive controls.

- FDA will draft a revised list of priority metrics, based on the information provided, to be discussed at a future CFSF meeting.
- Additionally, a CFSF working group will be convened to explore public health outcome metrics, in particular, and will include CDC representatives and others with relevant expertise.

2) Identifying and addressing unintended consequences.
    - Undue burden on small producers/entities.

3) Consumer confidence in the safety of the food supply.
    - Need consistent messages and a campaign-style effort both for the public and for those in industry.
    - *Action*: CFSF sessions will dedicate time to identifying key messages from the deliberations to take back to respective networks.

4) Alignment of different oversight systems (i.e., domestic and international/public and private).

5) Sharing best practices, near misses and lessons learned to promote continuous improvement.

6) Building capacity and ensuring adequate resources for effective oversight.
    - Funding for FDA.
    - State/federal capacity – role of states and associated resources necessary to implement.
        i. *Action*: CFSF to stay informed of state/federal effort through FDA/NASDA/AFDO Cooperative Agreement and associated grant to do the following:
            1. Develop an analysis of state authorities for food safety across the country, leading to a cohesive approach to food safety
            2. Determine the capacity of the states (i.e., laboratories, etc.)
            3. Develop a strategic plan to build capacity and coordination between the states and among state and federal entities.
        ii. May be a role in the future for the CFSF, but analysis needs to be conducted first.

7) Fostering culture change.
    - What culture change is particularly critical?
    - How can it be best catalyzed?
    - How is progress evaluated?

8) Summary (this document) drafted for review and circulated.

Appendix A: Final Participant List

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