

Collaborative Food Safety Forum (CFSF)

Collaborative Implementation of the Food Safety Modernization (FSMA) Act: *Workshop Summary*

June 18, 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 June 18, 2014 to discuss ideas and attributes of successful implementation of the Food Safety Modernization Act (FSMA) and the potential for ongoing collaborative engagement between FDA and a cross-section of stakeholders to achieve success, as well as the mechanisms through which to carry out such engagement.

The proposed goals of the workshop included:

- Identifying key attributes of the successful implementation of FSMA, along with metrics for measuring success in five and ten years, as well as for the long term;
- Discussing what different stakeholders across and within sectors are trying to accomplish, how they are preparing for successful implementation of FSMA, and what concerns exist within their own sectors, as well as with FDA's implementation of FSMA;
- Identifying areas of alignment and differences among stakeholders in their views of how best to achieve success;
- Exploring key aspects of a process for ongoing dialogue and input facilitating a successful strategy for the implementation of FSMA; and
- Determining possible next steps.

The proposed outcomes of the workshop were a summary document (this document) reviewing the presentations and main points of discussion, as well as a shorter one highlighting the key themes, outcomes, and next steps (sent July 2nd).

The workshop opened with a welcome and remarks from Sandra Eskin (Pew) followed by a review of background and the workshop's goals, outcomes, agenda, and ground rules by Abby Dilley (RESOLVE).

Key Attributes of a Successful Future (Five to Ten Years) Food Production and Oversight System

Representatives from a cross-section of stakeholder groups gave preliminary comments to help frame the discussion. These comments are briefly captured below. Dialogue following the brief comments focused on defining a vision for successful implementation of FSMA, including understanding measures of success (referred to as "metrics" during the course of the meeting), as well as challenges to successful implementation within respective sectors, organizations, companies, and other stakeholder groups.

Mike Taylor, Deputy Commissioner of Foods, U.S. Food and Drug Administration (FDA), thanked everyone for being involved and commented that the remarkable cross section of participants at the table to discuss successful implementation of FSMA gave him even more encouragement and confidence in the ability to achieve this goal. FDA has clear deadlines for finalizing the Rules, and as they come on line, the Agency's focus will shift to how best to achieve high levels of compliance, which is the

best path to encourage food safety. Mr. Taylor emphasized the value of collaboration in order to achieve successful implementation and that, while forums such as this are not substitutes for other interactions FDA has with its various stakeholders, they provide a place to come together to discuss issues and problem-solve. Additionally, from his perspective, metrics for success include not only rates of compliance, but also (1) people understanding what is expected of them so that they can know and do the right thing; (2) establishing adequate capacity to support doing the right thing; and (3) providing verification of compliance. He believes these goals can best be accomplished in a collaborative, synergistic system.

Steve Warshawer, Farmer, La Montanita Cooperative, Beneficial Farms CSA, shared his hopes for successful implementation, including building a common language among stakeholders and designing a process that will help shape the food system for years to come. He suggested that in considering measurements for evaluating success, it is important to consider public health, but also consider what's happening throughout the food production process and supply chain, in addition to meeting customers' interests. Mr. Warshawer further elaborated, pointing out that people not only need safe food, but they need access to safe and healthy food, and the implications of the regulatory oversight structure should not result in decreased access to food or other barriers to safe food produced in a multitude of ways – i.e., locally produced, organically produced, etc. Additionally, Mr. Warshawer spoke about the importance of considering and working with producers of all sizes, with metrics that correlated accordingly. Meeting regulatory requirements are not size neutral, he emphasized, and tools and outreach need to be developed and deployed accordingly to ensure that all enterprises are supported in being successful. This attention to size, he stressed, is critical to achieve and maintain a vibrant, diverse food production system.

Chris Waldrop, Director, Food Policy Institute, Consumer Federation of America emphasized that the ultimate measure of success is reduction in foodborne illness and improvement in public health. He sees strong parallels with hazard analysis and critical control points (HACCP) implementation. While high levels of compliance are an important outcome, he would also add as important continuous strides in quality improvement in the safe production of food in all sectors and by all stakeholders, including FDA. Mr. Waldrop also identified faster response to, and intervention of, foodborne illness outbreaks as an outcome measure, and the importance of continuous feedback loops and enhanced communication and information sharing among all stakeholders and with the public at large.

Mike Robach, Vice President, Corporate Food Safety & Regulatory Affairs, Cargill, agreed that the most important metric is improved public health, specifically, reductions in foodborne illness. He also emphasized the importance of building and maintaining confidence in the food supply, as well as the need for better alignment with messaging and communications between the public and private sectors on issues such as continuous quality improvement, verification, and validation. Mr. Robach noted the importance of continued dialogue and collaboration throughout the implementation of FSMA, building on the positive outreach and ongoing engagement Mr. Taylor has spearheaded at FDA. He emphasized the need to have a flexible, outcomes-based system that can adapt and change with new technology and strongly supported harmonizing the standards established with global requirements, such as under Codex and the Global Food Safety Initiative, and to make sure domestic U.S. standards are consistent with those around the world.

Bob Ehart, Public Policy Director, National Association of State Departments of Agriculture (NASDA), concurred that public health is the ultimate metric. FDA and states have long been in conversation about building an integrated food safety system, and Mr. Ehart emphasized the importance of all stakeholders rethinking how they do business, as well as the importance of continuous education that will require new and different technical assistance as part of ongoing information exchange and

collaboration. He emphasized the critical importance of educating before regulating and that the states can play a key role.

When discussion was opened up to the larger group, participants continued to focus on metrics for success from several dimensions, including public health, culture change, and overall confidence in the food production and oversight system. Many participants emphasized metrics that reinforce and incentivize continuous improvement, working towards the objective of collaboration, and enhancing the public's health. Highlights of key areas of discussions are summarized below.

Culture Change

Most participants agreed that a culture shift is necessary, both within FDA and among stakeholder organizations for successful implementation of FSMA. Participants suggested that some of the catalyst for passing FSMA was due to recognition that the food oversight system was not working optimally, and now, with improved public health outcomes as the primary goals of FSMA, there will need to be change across all sectors and organizations to achieve these goals. Representatives from FDA also commented on the topic of culture change, noting that any change will also have to increase the understanding of what it means to advance public health within a regulatory context.

Metrics

Participants discussed the need to define a cross section of appropriate metrics for success. While all participants agreed public health indicators are essential, some strongly encouraged additional measures of success, such as rates of achieving compliance, public confidence in the safety of the food supply, a diversity of food production systems, and increased access to safe and nutritious foods. Participants did discuss multiple metrics that, combined, could capture improvements in public health as a result of improvements in food safety driven by implementation and compliance with the public health standards, such as:

- Fewer foodborne illness outbreaks and associated individuals sickened or hospitalized;
- Successful root cause analyses and more rapid interventions or modifications to address root causes;
- Higher compliance rates and verification of compliance;
- Lower numbers of incidences of microbial contamination (from such indicators as testing results, lower number of enforcement actions with same level of effort, etc.);
- Higher consumption of fruits and vegetables (in all forms) and overall improved diet of the American public;
- Robust public confidence in the food production and oversight system; and
- Meeting achievable benchmarks along the way towards full compliance and continuous improvement.

Some participants identified limitations with relying solely on public health metrics, such as direct attribution of improved public health outcomes to compliance with standards, lack of near-term results, and data gaps, such as unreported foodborne illnesses, and felt that considering other measures of success would help round out the overall picture of moving towards overall success. Other participants also suggested that the goal of food safety should also be aligned with broader public health outcomes, rather than in competition with them. For example, access to safe and nutritious food requires compliance with safe food practices, as well as preventing barriers that make food less available.

Participants felt that collaboratively engaging stakeholders on further conversations around metrics is a priority area.

Continuous Learning System

Several participants noted the importance of building a mechanism, or mechanisms, for continuous feedback that can be informed by lessons learned along the way while evolving with advances in technology and knowledge. Aspects such as defining high-risk foods and understanding root cause analyses will need to evolve along with regulatory components and inspections as FSMA is implemented. A risk-based systems review will require deeper understanding of the food safety systems in the context of the diversity of food production and will require a more nimble auditing strategy that moves away from check-list type audits to more scientific, risk-based audits. Several participants emphasized the need to think about establishing metrics that could be easily calibrated against risk profiles. Metrics will need to examine where those high risks are and help inform FDA prioritization.

The idea of joint training programs, inclusive of industry, and state and federal governments emerged as a successful model that has been used in the United States and in other parts of the world. Such training would orient all stakeholders – from regulators to inspectors to industry representatives – towards a food safety management system at the same time and in the same context, with the goal of increasing consistency of approach and implementation.

Others noted that it will be important to continue such education with consistent messaging and good communications tools such as trainings, webinars, and frequently asked questions (FAQs) documents.

Preparations for and Fostering of Successful FSMA Implementation

In the following session, participants discussed key aspects of FDA's FSMA implementation with the [*Operational Strategy for Implementing the FDA Food Safety Modernization Act: Protecting Public Health by Strategic Implementation of Prevention-Oriented Food Safety Standards*](#). FDA presentations supplemented and provided additional current thinking about how FDA is preparing for successful implementation. Rather than focusing on specific proposed rules, the discussion was broad in nature, including such topics as building capacity, transforming culture, working with other stakeholders and partners, and other activities and efforts to support successful implementation.

Roberta Wagner, Deputy Director of Regulatory Affairs, FDA, presented "FSMA: Where We've Been and Where We're Going," highlighting implementation planning and the FDA "culture change" in particular. As FDA moves towards implementation, operations will differ from those in the past. The Agency, Ms. Wagner stated, will speak with one voice, with investigators and subject matter experts working together to correct problems and ensure compliance. Inspection forces will become more specialized and may include subject matter experts from the Center for Food Safety and Applied Nutrition (CFSAN), the Office of Regulatory Affairs (ORA), and the field, and the notion of "education before regulation" will play an important role in implementation for fostering modern, preventive practices with the shift towards public health metrics. With this approach, there will be a need for robust data integration, analysis, and information sharing.

FDA will also invest in regulator training to promote consistent inspections and decision-making. The agency is actively having conversations with industry around how best to conduct effective training programs and build common understanding about the inspection approach and protocol. For example, FDA created an expanded toolkit for promoting and facilitating compliance that offers commodity and sector-specific guidance, education, outreach, technical assistance, and regulatory incentives for compliance. Risk-based prioritization and planning will be enhanced by better data collection, sharing, and evaluation. Additionally, FDA Workgroups for Preventive Controls, Produce Safety, and Imports will develop multi-year implementation plans for ensuring compliance with regulators. Ms. Wagner's presentation is available [online](#).

Following Ms. Wagner's presentation, the discussion focused around lessons learned from previous food safety models as well as challenges to successful FSMA implementation.

Participants discussed lessons learned from Seafood HACCP and, in particular, the extended timeframe for compliance. Some participants thought the timeline for implementation was too long and that while more outreach is a positive strategy, earlier deadlines need to be established to help promote quicker compliance. The education and training, which included regulators and industry together in the same room, was seen as a model and beneficial to building trust and enhancing learning. Participants stated that hazard analysis and industry guidance will need to be provided early on and shared in advance of inspection and enforcement. Scale is also important and developing a plan for industry groups of all sizes and varieties will be critical for achieving maximum compliance.

A key challenge to implementation will be coordination at, and between, state and federal levels in order to ensure consistency on the front lines of inspection. Because oversight varies across states, i.e. for some states, food safety inspection rests with health departments, while for others, the departments of agriculture, coordination and consistency can be even more challenging.

Preventive Controls

Priya Rathnam, Consumer Safety Officer, Office of Compliance, CFSAN FDA, gave an overview of the work done by the FSMA Preventive Controls Working Group, including creating a detailed, results-oriented framework. The results framework is based on comprehensive, science-based regulation of food and involves written plans for mitigating hazards at facilities. The framework was developed, in part, to understand key results for measuring success and the steps needed to achieve those results. The framework identifies strategic goals such as reduced foodborne illness, reduced contamination from facilities, increased industry implementation preventive controls rules, and more rapid and effective recalls. It also specifies the roles both industry and the regulatory community have in working towards the key results.

Essential components for enabling industry to meet food safety standards include: enhanced learning resources in the form of both internal and external technical assistance networks; the development of a guidance document identifying hazards and preventive control strategies; and training and curriculum development involving Food Safety Preventive Controls Alliance (FSPCA), FDA, and states.

Additionally, FDA is looking to promote and facilitate compliance through non-enforcement incentives as part of the strategy. Ms. Rathnam reiterated that they are working with industry, trade associations, and states, to understand different incentive structures and considering how to best modify inspections based on risk-ranking, compliance, as well as a firm's existing food safety system. She also emphasized the need to highlight situations when firms "do the right thing" to ensure consumer safety.

Joan Menke-Schaenzer, Global Chief Quality Officer, ConAgra Foods, discussed some of things she and her colleagues are trying to do in regards to FSMA, such as educating people on what the rules will likely mean and working on better documentation for validation and verification purposes. She spoke about how she's framed FSMA as a positive initiative that the food industry can support. Ms. Menke-Schaenzer said it will take "culture shift" to encourage producers that FSMA is not to be feared, but will ultimately help industry succeed. She suggested creating a food facilities working group to discuss two new processes to improve food safety inspections: (1) a real time escalation process, and (2) an after-the-fact mediation process.

One participant picked up on the theme that compliance with FSMA is generally a smart business move. Further, neither the concept of supporting and facilitating compliance nor industry education or

technical assistance is new. They are both done today, and help create a continuum of expectations that many already hold in various sectors of industry. Other participants supported the proposal to develop a process for real-time deliberation and mediation as part of the inspection effort.

Kathy Gombas, Deputy Director of the Office of Food Defense, Communication and Emergency Response, FDA, gave a brief update on the Food Safety Preventive Controls Alliance (FSPCA). She noted that the Preventive Controls Alliance was one of three such alliances (including the Produce Safety and Sprout Safety Alliances) which includes representatives from FDA, state representatives, academia, and the regulated community. These bodies are tasked with developing standardized training and education programs for food producers and companies, as well as fostering a network for technical assistance to small and very small producers. The FSPCA is modeled after an alliance that came out of the Seafood and Juice HACCP systems. The Alliance recently tested curriculum materials during a two and a half day session involving 40 stakeholders. Currently, materials are being reworked and then will be completed once the final rules are published. Her presentation is available [online](#).

Conversation following Ms. Gombas's presentation centered on the need for consistent and meaningful training, as well as how to best target small and medium-sized producers for education, outreach, and support to achieve compliance.

Produce Safety Rule

Samir Assar, Director, Produce Safety Staff, CFSAN FDA, spoke about FDA's preparations for successful implementation of the Produce Safety Rule with regard to building regulator capacity and reshaping the regulatory approach. FDA is building a workforce with a specialized skill set focused on produce safety and a comprehensive, hands-on approach to regulator training based on the Produce Safety Alliance (PSA) core curriculum, including an on-farm component. A new approach will also allow inspectors real-time access to subject matter experts and other resources through a technical assistance call center. This approach will encourage corrections in the field, routinely sharing preventive measures and practices, and shift away from the current focus on citations. Speaking to a point made earlier in the day about the burden of multiple audits on producers, Dr. Assar also shared that FDA is investigating how to better integrate data from different sources to conduct root cause analyses and direct inspections programs based on risk profiles. Dr. Assar's presentation is available [online](#).

Following Dr. Assar's presentation, there was additional discussion regarding training and the sharing of lessons learned. Some expressed concern with the static nature of regulation and the associated standards, particularly when the science is still evolving. Participants further suggested that policy guides be updated regularly and feedback integrated into training and compliance standards. There also was additional discussion around engaging small producers in building a quality systems approach. One participant suggested a "network" or "cooperative" approach wherein small and medium-sized producers could link together to hire a food safety expert.

Betsy Bihn, Director of the Produce Safety Alliance (PSA), discussed the activities taking place related to shaping PSA curriculum on the Produce Safety Rule. There are 10 working committees from 37 states with 549 members, and they have held 72 calls to develop the curriculum. The PSA has opted to educate regulators and producers together and will do so prior to the finalized rule. The curriculum includes having trainees write a plan (even though the rule does not) in order for them to better understand what may need to change and have them process those variables. PSA will disseminate information about the training through their listserve, as well as their educators and outreach groups. See <http://producesafetyalliance.cornell.edu/> for more information.

Steve Warshawer, Farmer, La Montanita Cooperative, Beneficial Farms CSA, suggested developing food safety co-operatization models to enable small-scale farmers to leverage individual capacity at a group level. For example, 20 farms may be able to pool resources together to hire a food safety expert to help everyone, which would not be affordable on an individual farm basis.

Following the presentation and additional remarks, discussion focused on validation. As was noted, validation of compliance will not predominantly come from FDA. Related questions that were discussed included: who or what entities are providing validation, the standards against which validation is evaluated, and how to ensure consistency of approach with the evaluation. Also tied into this cluster of issues is the additional work that needs to be done around audits and incorporating private inspection organizations. For example, how GFSI standards can be included and aligned with regulatory requirements is of interest and needs clarification. Additionally, the role of USDA's Agricultural Marketing Service (AMS) and other potential regulatory bodies, such as foreign governments, requires additional clarification. One participant also raised the challenge of "audit fatigue," and the need to streamline or combine different checklists for improved compliance and cooperation, particularly by smaller growers.

The concept of technical assistance was also raised again, and similarly, how significant a challenge it will be to bring small vendors into compliance.

Imports Operational Plan

Sharon Mayl, Senior Advisor for Policy, FDA, gave an overview of the FSMA Imports Operational Plan. Programs within the Imports FSMA Operations Teams include: Foreign Supplier Verification Program (FSVP), Voluntary Qualified Importers Program (VQIP), Accredited 3rd Party Program, Import Certification, Lab Accreditation Program, and Systems Recognition. The overarching goal for the imports plan is to reduce the risk of illness and injury from imported foods with results oriented particularly toward reducing food safety problems in the foreign supply, more effective interdiction of unsafe food at ports of entry, and more rapid and effective post-entry response in domestic commerce. The team is exploring critical operational considerations and challenges ranging from where to best deploy resources, both internally and in educating external stakeholders; to ensuring a well-trained and sufficient workforce; to how to best leverage and align IT systems; and where and how opportunities to integrate third-party auditing systems for imports exist. The group is also carefully considering how the plan will address and align with the international trade context and trade agreements. For more information, Ms. Mayl's presentation is available [online](#).

Mike Robach, Vice President, Corporate Food Safety & Regulatory Affairs, Cargill, gave an industry perspective on preparations for the Foreign Supplier Verification Program (FSVP) rule. He noted that large multi-national companies do significant amounts of work outside the U.S. and are accustomed to building capacity among their suppliers through food safety systems based on Codex and other international safety standards. They have also worked with the Global Food Safety Initiative (GFSI), specifically the global markets program, which works with producers to meet GFSI requirements. Mr. Robach emphasized that a large component of the program seeks to build capacity to bring producers into compliance and that more work will need to be done particularly with regard to the role of brokers and traders. Ideally, he said, these systems will be harmonized with FSMA standards.

Following the presentation and remarks, there was much discussion on systems recognition or other countries (formerly known as "comparability"). For example, one participant asked about status of systems recognition assessments with other governments. FDA noted that they have completed this assessment with New Zealand and are in progress with the Canada, Australia, and the European Union.

Participants also raised the importance of consistent outreach and messaging, suggesting that additional work will need to be done around how to import products in a compliant way and that resources, such as FAQs, may be a helpful.

Moving Forward: Developing a Mechanism for Ongoing Stakeholder Engagement to Develop a Successful Implementation Strategy

Participants' discussion examined the goals and objectives of ongoing dialogue, design considerations, and the variability in different models to consider in determining key attributes of a multi-sector effort to effectively implement FSMA. There was general agreement around the need for continued engagement on a number of issues, including developing a common vision for successful implementation, along with associated metrics, as well as more specifically targeted problem solving for implementation challenges, some of which are outlined below.

Diversity of People at the Table

Participants noted one of the advantages and benefits of the CFSF has been the diversity of stakeholders actively engaged in the deliberations, including informal input of FDA participants. Having acknowledged this track record, participants also concurred that going forward, additional participation and representation from other stakeholders will also be needed to ensure a good cross-section of viewpoints. Participants identified several additional groups of people that should be brought into the discussion.

- **Increased Participation of Buyers**

Throughout the discussion, participants noted the importance of involving buyers in dialogue and decision-making. As buyers increasingly engage with smaller scale producers (growers and processing facilities), they play an important role in FSMA implementation considerations. Having their voices represented in the cross-section of participants will be important.

- **Engaging and Educating Small and Mid-sized Operations**

Learning lessons from Seafood HACCP, it will be important to include all parts of the supply chain in subsequent discussions. Engaging small and mid-sized operations will be challenging, though critical, as they will have different perspectives and ideas for what technical assistance is needed and what strategies best support compliance. Additionally, the alliances will continue to be an important mechanism for gathering and providing information, and other methods for messaging, communication, and outreach will need to be refined and developed as well.

A Culture Shift is Needed

Many participants noted the desire to shift the culture of FSMA implementation away from the traditional regulatory approaches and towards a risk-based, problem-solving food safety orientation. Participants spoke of the need for culture change among all stakeholders, including within FDA, and among those who also are involved in oversight and compliance, to work towards successful FSMA Implementation.

“Horizontal,” Rather than “Vertical” Approach

Some participants suggested that traditional implementation approaches have been vertical, linear, and hierarchical, starting with FDA at the top and with small-scale producers at the bottom. Some participants suggested that successful collaborative implementation of FSMA will need to be “turned on its side,” more like a coordinated “web,” with no one at the top or bottom, and all playing critical roles in achieving food safety. Some participants noted that with this approach, there are increased opportunities for fostering trust and enabling shared learning in all parts of the “web” among all stakeholders. In this approach, the food system is more effectively integrated, inherently linked regionally, from state to state, nationally, and globally. In such a system, multiple entities, including AMS and GFSI, are all part of a single, global food system and need to be harmonized accordingly.

Review of Key Themes and Next Steps

The following key themes and next steps were highlighted in a memo sent to participants shortly after the CSFS session, but are included here as well for reference.

What Success Looks Like and How it is Measured

During the discussion, participants identified a number of aspects of successful implementation of FSMA and associated metrics, including the following.

- **Improvement in Public Health Outcomes:** Participants agreed that this should be the overall measure of success and should drive change; they also concurred that this metric (or metrics) is/are difficult to determine as improvements in public health are challenging to attribute to a single factor, such as compliance with specific regulatory standards and policies. Participants did discuss the use of multiple metrics (qualitative and quantitative) that, combined, could indicate improvements in public health as a result of improvements in food safety policies, as well as oversight of and improvements in industry practices. These included:
 - Fewer foodborne illness outbreaks and associated individuals sickened or hospitalized;
 - Successful root cause analyses of foodborne-illness outbreaks and more rapid interventions or modifications to address root causes;
 - Higher compliance rates and verification of compliance with regulatory requirements;
 - Lower incidence of microbial contamination (from such indicators as testing results, lower number of enforcement actions with same level of effort, etc.);
 - A vibrant and diverse food supply that supports small and mid-sized farms and food businesses and sees continued growth in local and regional markets.
 - Higher consumption of fruits and vegetables (in all forms!) and overall improved diet of the American public;
 - Increased public confidence in the food production and oversight system; and
 - High level of success in meeting achievable benchmarks toward full compliance and evidence of continuous improvement.
- **An Integrated and Aligned Food Safety Oversight System:** Participants discussed the hope and expectation that as a result of the FSMA implementation, alignment will be increased among local to global oversight systems. Working toward such a vision includes the following goals:
 - Improving public health outcomes; Minimizing negative impact on different production approaches and recognizing and adapting to the variability of food production (i.e., open/field production versus closed/food facility production systems); and
 - Better alignment of stakeholders and harmonization of systems, including:
 - Global and domestic requirements and oversight;

- Incentives to “do the right thing” (i.e., from education and outreach, adoption and implementation of practices and achieving compliance, to recognition of good practice and compliance, to collaboration for building capacity);
 - Partnership(s) to achieve continuous improvement, including addressing the non-neutrality of implementation (i.e., it is easier for large entities to comply than smaller entities), and build from where we are to where we need to be; and
 - Efficient and effective deployment of resources, in addition to prioritization of effort (which will evolve over time), better alignment will reduce redundancies and keep overall costs lower.
- **A Robust, Diverse Food Production System:** Participants discussed the goal of the oversight system coinciding with a diverse food production sector reflecting the variety of tastes, philosophies, and interests, while also being safe. Support for such a diverse food production system and approaches potentially will require different routes to compliance, necessitating engagement of all stakeholders, sharing information and learning from one another, as well as collaboratively shaping the robust and compliant food production system for future generations.
- **Collaborative Engagement of All Stakeholders:** Participants concurred that successful implementation of FSMA would result in more collaborative effort. Culture change was encouraged by and for all stakeholders and necessitates ongoing dialogue, problem solving, learning, and adjusting to strive for continuous improvement. As an example, FDA indicated that it will rely very heavily on promoting and facilitating compliance in FSMA prior to and in combination with enforcement. Such shifts in (enforcement and other) culture more broadly can be supported by the following:
 - *Education and outreach* (including better language and communication between and among stakeholders – e.g., “soil” and not “dirt”) in advance of, as well as ongoing with, enforcement of FSMA rules;
 - *Establishment and implementation of research priorities* to develop the science base for, or revisions of, requirements;
 - *Development and deployment of tools* to encourage compliance and promote success. Multiple tools were mentioned, some of which were the following:
 - Education and communication – development of a common language among a broad range of stakeholders who speak different languages – (see example above related to “dirt”). Additionally, stakeholders need to be very proactive in providing information and education to their colleagues within their respective sectors – this is a particularly critical role for the private sector, and especially with leadership from the larger companies in working with their medium- and smaller-sized colleague companies.
 - Trial or pilot implementation strategies – joint development of pilots, conducted collaboratively, and lessons learned to increase common understanding and more rapid refinement for effective uptake of practices achieving compliance, or re-design in cases when pilot fails.
 - Inspection
 - Consistency of inspection approach, establishment of mutually understood expectations among inspected and inspectors;
 - Real-time calibration of inspectors review and mediation tools to address different points of view, etc.
- **Validation of compliance:** recognizing achievement of compliance (i.e., reaching benchmark metrics that are clear, measurable, attainable, and publicly reported);

- **Continuous improvement:** learning from one another as the challenges evolve, unintended consequences manifest and require adjustment, advancements are accomplished, successes and failures occur, and building a learning system to promote ongoing collaboration to promote continuous improvements;
- **Establishing food safety as “pre-competitive”:** food safety should not be used as a competitive advantage; there is a baseline level of safety that everyone should achieve and that if a producer is meeting this standard, their products should be considered equally safe as others in the market place; and
- **Building and fostering leadership:** a system that taps and leverages diverse strengths and skills of different stakeholders and highlights and supports leadership promoting culture change, collaboration and moving toward a common vision.

The Case for Collaboration Moving Forward

Participants strongly supported establishing an ongoing mechanism for stakeholder engagement and dialogue with FDA as implementation commences. Goals suggested for future collaborative deliberations covered a wide range:

- Accomplishing an essential paradigm shift in the production and oversight of safe food;
- Educating and reaching out to those stakeholders in the food system who are not currently engaged (particularly the small and medium food producers);
- Developing (through idea generation and pilot testing) tools to enable compliance with public health standards and validation of compliance (see above for some of the needed tools identified); and
- Establishing a networked system fostering continuous improvement.

Participants concurred that the overall long-term goal of collaboration is to create a safer food supply, and many believe to accomplish this fundamental goal requires culture change and a different conceptual framework.

Participants proposed the Collaborative Food Safety Forum, has the potential to create, catalyze, and pursue additional collaboration around FSMA implementation because it has the following assets:

- A broad cross-section of stakeholders already engaged in the process (recognizing some supplementation to the roster is needed and desired);
- A close working relationship with FDA;
- A flexible structure that is guided collaboratively; and,
- Access to resources to continue its work in this area.

Proposed Next Steps

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.

Many ideas were proposed, including:

- (1) Development of what was referenced in the discussion as “metrics” for successful FSMA implementation;
- (2) Integrated training for inspectors and various food industry sectors;
- (3) Coordinated communication and outreach (including the development of a common, effective language) to engage all stakeholders;
- (4) Development of tools to support collaborative learning, such as pilot testing implementation strategies, protocols for engagement during inspections, etc.; and,

- (5) Building feedback mechanisms that all stakeholders can contribute to and share in to promote continuous improvement in public health outcomes envisioned by FSMA.

In order to best design a process for effective collaboration, critical preliminary work must be accomplished to set the goals for collaboration. Accordingly, participants agreed to the following next steps.

- (1) Based on the June 18th deliberations, a small working group will be convened to *propose a framework of goals, including metrics for evaluating progress towards the goals, for successful implementation of FSMA*. These goals will provide components for an integrated vision of success, drawing on proposed definitions of success discussed during the meeting.
- (2) The full group will be reconvened to *review and refine the proposed goals framework*, including metrics for measuring progress, and, based on that framework, *determine key challenges to achieving these goals, as well as priorities for collaborative activities*. These priorities will then shape the *organization and design considerations for ongoing collaboration*.
- (3) In the meantime, and as highlighted during the discussion, near-term action is needed, given the impending deadlines around finalization and enforcement of the FSMA rules. *Outreach, education, and engagement are actively underway across and between many stakeholder groups, and must continue to be a priority*. Working through the process outlined above will be on a longer timeframe than the one for shaping essential near-term communication and outreach strategies. However, ideas around developing a common language could be a possible activity for future collaborative efforts.

RESOLVE will convene the working group to develop the goals framework, including metrics, as proposed above in #1, and determine a date for the next full group meeting to accomplish the action steps outlined in #2.

Appendix A: Final Participant List

Participants

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Carolyn Brickey

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