

Collaborative Food Safety Forum (CFSF)

Collaborative Implementation of the Food Safety Modernization (FSMA) Act: Workshop #3 Summary: Food Safety Culture and Associated Public-Health Based Metrics

May 20, 2016
Washington, D.C.

Background and Overview of Meeting Goals and Outcomes

On May 20, 2016, the [Collaborative Food Safety Forum](#) (CFSF or Forum), with funding from the Pew Charitable Trusts (Pew) and the Robert Wood Johnson Foundation (RWJF), convened the one-day “Collaborative Implementation of FSMA Workshop #3” on food safety culture and associated public health-based metrics. This meeting brought together representatives from the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the U.S. Department of Agriculture (USDA), industry, consumer advocacy groups, public health associations, and academia to continue discussions on food safety culture and public-health based metrics for evaluating the successful implementation of the Food Safety Modernization Act (FSMA).

The goals of the meeting included:

- Provide an update on and discussion of preventive controls implementation.
- Advance the metrics discussion for promoting and evaluating successful FSMA implementation.
- Explore current food safety culture work to build upon to support successful FSMA implementation.
- Determine any potential next steps for developing short-, mid-term – and long-term FSMA metrics, such as data collection, analysis, and information-sharing.

Proposed Next Steps

Throughout the meeting, participants highlighted several ideas as potential next steps and areas to pursue at future Collaborative Food Safety Forum meeting. The following activities are proposed to continue building on the deliberations and support successful implementation of FSMA:

- 1) Enhancing the use and value of root cause analysis by first looking at other industries that use such an approach to gain valuable information and to incorporate into continuous improvement for advancing safety goals;
- 2) Bring additional clarity around what constitutes “reliable audits,” who is able to conduct them, and how information is collected and used.
- 3) Potentially, additional next steps on “web of metrics” and food safety culture.

The next meeting of the CFSF is targeted for fall of 2016.

Meeting Deliberations

Outlined in the following sections of this summary report are the main themes derived from conversations during the meeting, as well as potential next steps and future topics for the Collaborative Food Safety Forum.

Brief Updates from FDA: Updates on FSMA Implementation, Changes at FDA, and Future Participation in the CFSF

Mike Taylor, Deputy Commissioner for Foods at FDA, kicked-off the morning deliberations thanking The Pew Charitable Trusts (Pew), Robert Wood Johnson Foundation (RWJF), RESOLVE, and all CFSF members for their continued work with FDA on FSMA Implementation both within and outside of the Collaborative Food Safety Forum. In the midst of his departure from FDA, Deputy Commissioner Taylor was glad to see the topic of food safety culture on the agenda for this meeting and encouraged participants to continue working together and with FDA to figure out how food safety culture could be integrated into FSMA implementation. He also shared his gratitude for all those who were and have been involved in developing the final FSMA Rules framework, including the Phase 2 implementation and oversight teams at FDA, partners from USDA, and the many other dedicated stakeholders who provided input into the rule-making process.

Dr. Stephen Ostroff, incoming Deputy Commissioner for Foods at FDA, echoed Deputy Commissioner Taylor in thanking CFSF participants for their continued work with FDA and said that he looked forward to working with the group going forward. He added that the kinds of discussions and partnerships that have been fostered by the CFSF are critical to making Phase 2 of FSMA implementation a success. While much progress has been made, he also reminded the group that there is a tremendous amount of work to be done, including the FSMA Guidance for Industry, which FDA is currently working on, and the education and training of stakeholders. He encouraged participants to remain engaged with FDA and to continue providing their input on any necessary corrections that need to be made so that FSMA is implemented effectively and successfully.

Food Safety Culture: A Proposed Framework and Current Activity

Following the brief updates from FDA, Lone Jespersen, Chair of the Food Safety Culture Technical Working Group of the Global Food Safety Initiative (GFSI), Principal at Cultivate, and PhD candidate from the University of Guelph, presented to CFSF participants a proposed maturity model framework she developed for evaluating food safety culture within organizations – particularly those entities that fall within preventive controls requirements - and provided her reflections and lessons learned to date. CFSF participants then provided feedback on how the maturity model could be used and adapted to support FSMA implementation efforts.

Examples of cultural failures leading to food safety outbreaks and recalls

Ms. Jespersen began her presentation with describing examples of cultural failures organizations often experience, which can lead to food safety outbreaks and recalls. She categorized the failures into vision and mission failures, people systems failures, consistency failures, adaptability failures, and risk failures. Common examples were pulled from investigation reports that she reviewed during her research and are described in the table below.

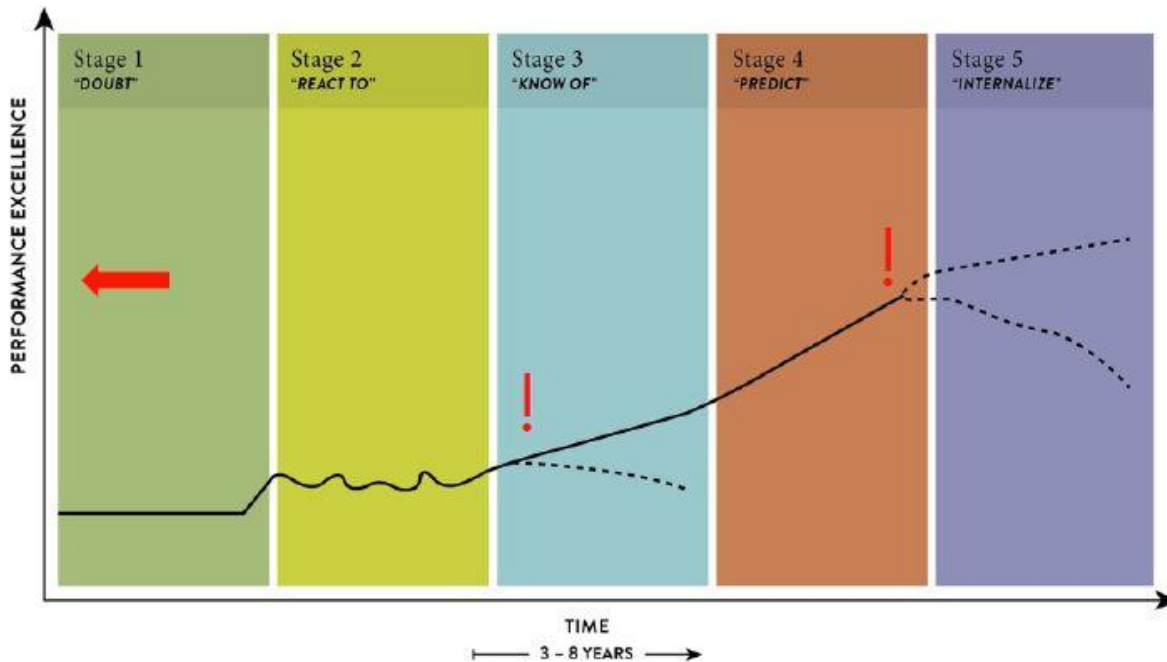
Cultural Failure Category	Example
Vision and Mission	Senior levels of management, such as a CEO, were not made aware of the environmental testing results.
People Systems	It was found that departments and functions were working in silos.
Consistency	The plant did not follow its own written programs and inspectors did not call this out. Written procedures were bypassed to ensure product was shipped. This was noted as common and accepted practices.
Adaptability	The plants and its inspectors did not conduct analysis of root-causes on high-level days.
Risk	Findings were not analyzed by the plant or head-office to detect trends over time.

Food safety culture and maturity profiling

Having identified common cultural failures within organizations which could be linked to, or at least contributed to conditions for, food safety outbreaks, Ms. Jespersen then worked with an expert panel to develop a maturity profile that would allow companies to evaluate, measure, and improve their food safety culture performance. The team determined a five stage maturity profile that evaluates a company's behaviors and performance over a period of time, including:

1. "Doubt"- characterized by employees behaving as though they only need to comply with company regulations;
2. "React to" – characterized by employees initiating food safety actions or projects;
3. "Know of" – characterized by an increase in employee performance relative to food safety, but in moments of other crises or complacency, employee attention is diverted away from food safety culture and performance falls;
4. "Predict" – characterized by employees being able to understand the root cause of problems and predict when problems may occur; and
5. "Internalize" – characterized by employees having a mindset of food safety culture and where spending on food safety culture initiatives are internalized in the performance and evaluation process.

The graph below is an illustration of the maturity profile and performance journey.



Methods and behavior measurements

Next, Ms. Jespersen used a triangulation of methods (a common methodological approach in social science research) to identify and validate 200 specific behaviors used in the measurement system. The triangulation of methods used a compilation of points of information, including behavior based self-assessments (i.e. surveys), performance assessments (i.e. meeting minutes, organizational documents, etc.), and on-site confirmations (i.e. in-person interviews with 2-3 per plant), and behavioral observations). The behavior measures identified are role or job specific and include behaviors for roles such as senior executive, manufacturing functional leader, manufacturing leader, manufacturing supervisor, food safety and quality functional leader, food safety and quality leader, food safety and quality supervisor, etc. This categorization of behaviors for specific roles is useful because it encourages individuals to identify the specific behaviors that should be exhibited in each role. Ms. Jespersen also defines “measurable behaviors” as those that are action-oriented, context specific, targeted to a particular audience, and offer a specific timing for when the action should be completed. An example of a measurable behavior is: “schedules and leads production morning meeting attended by associates every day at 8:30 a.m.”

Food safety maturity model

With the maturity profile developed and behavior measurements defined, Ms. Jespersen then worked with an expert panel to define broad capability areas that could be used to measure the overall food safety culture of plants. These capability areas include:

1. people systems (to evaluate the communication systems in place);

2. process thinking (to evaluate whether the organizational cultural is task vs. process-oriented and to evaluate the responsiveness of the organization to safety situations);
3. perceived value (to evaluate the importance placed on food safety within a company);
4. technology (to evaluate how well data is being collected and whether decisions are data driven); and,
5. tools and infrastructure (to evaluate whether a company has the necessary tools and infrastructure in place).

These capability areas were then plugged in to the maturity model and used to calculate and plot the minimum, maximum, and mean scores of performance for each capability area, indicating where a company’s food safety culture fits within the maturity profile, what progress is still needed, and where a company should dedicate future effort and resources (see illustration below).

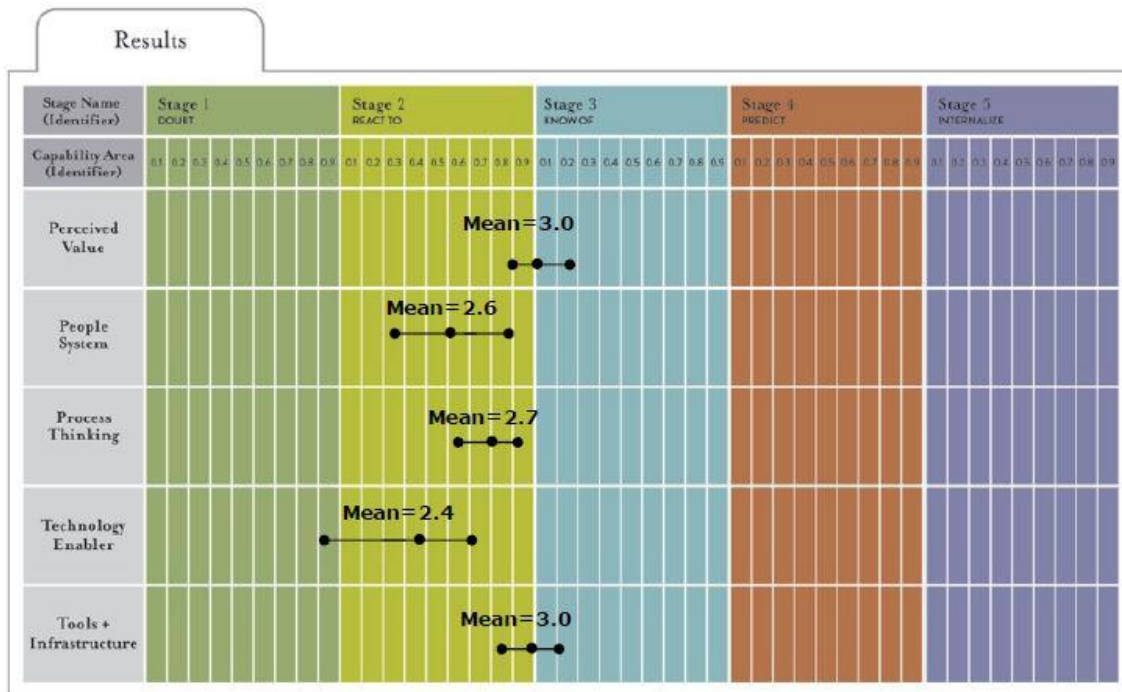


Table legend: Maturity measures across five capability areas. Mean score (●) and plant average minimum and (●—●) maximum. All plant data.

Lessons learned

Ms. Jespersen identified two major lessons learned in developing the first version of the food safety maturity model. The first lesson is to make sure that the methods used are valid and practical. If a method’s validity is not ensured, then the results will likely be inaccurate. To account for this challenge, Ms. Jespersen used a triangulation of methods to validate her results. Practicality is also important because if a method is too costly or too cumbersome, then it will likely not be implemented. The second lesson she identified was to ensure that future versions of the model account for differences in leader mindset (i.e. there are differences between senior leaders who recently joined a company and those who have worked

in the company for several years), the size of a company (i.e. there are differences between very large companies with a tall hierarchy and small companies with a flatter hierarchy), and the types of technologies used by companies (i.e. differences between companies with more automated processes and companies with more human-driven processes). She plans to incorporate these lessons in future versions of the food safety maturity model.

Discussion

Following Ms. Jespersen's presentation, CFSF participants discussed how the maturity model could be used or adapted for FSMA implementation efforts. Below are key questions or suggestions posed by participants accompanied with Ms. Jespersen's responses:

- **Participants wondered how the maturity model could help companies identify specifically where improvements in food safety culture are needed and at what level in the company hierarchy.** Ms. Jespersen responded that to make improvements and move on to the next stage of maturity, a company would need to identify the most important behaviors that define that next stage and implement tools and incentives that drive those behaviors and improvements at each level of the hierarchy within the company.
- **Participants also wondered what could be done to inspire companies and their employees to begin taking steps to focus on food safety culture aside from a food safety outbreak or crisis.** Ms. Jespersen responded that in her research experience, aside from a crisis, food safety culture is also inspired by a leader who thinks it is important and is willing to listen to consumer's personal stories of food safety issues. It can also be inspired from a business perspective in terms of positively impacting the company's bottom line. In her research, some companies have found a correlation between improvements in food safety culture maturity and decreases in production costs as a result of more controlled and consistent processes, so the business case can inspire companies to focus on food safety culture
- **Participants asked Ms. Jespersen to share the self-assessment behavioral questionnaire she used to evaluate the food safety culture of seventeen plants.**
- **Participants also wondered if the maturity model measures how well a company's food safety culture protects consumers, not just the brand of the company.** Ms. Jespersen responded that this could be better incorporated into the model by perhaps measuring behaviors that have an impact on the company's social responsibility.
- **Another participant wondered how the maturity model could be applied to other sectors such as a farm where there are many other factors to consider associated with the outdoor environment.** This participant suggested that a farm's food safety culture maturity could be assessed based on the amount of time employees spend on chores – the less time spent on chores and the more time spent on projects could be an indicator for a higher stage of food safety culture maturity. Ms. Jespersen responded that to apply the maturity model to a farm, key experts within the sector should be convened to adapt the definitions of the behaviors and capability areas to fit the farm sector and to identify the key leadership roles on a farm to construct the key behaviors. She also suggested thinking not about how much time a farm is spending on projects, but rather

how to better control farm processes that lead to improvements in food safety culture and prevent practices that produce foodborne outbreaks.

- **A participant also suggested adding a stage before Stage 1 to the maturity model, which would be titled, “denial and ignorance.”** This participant suggested that there are people within the food system that do not understand that they are making food that people will eat and could harm consumers if not handled or prepared properly. Ms. Jespersen agreed that this situation does exist within the food safety system and suggested that this situation was captured in Stage 1 “Doubt.” Companies in this stage of maturity often have a designated food safety expert whose job is to ensure the company complies with the minimum regulatory requirements, rather than encouraging all employees to have a food safety mindset.
- **A participant wondered how the maturity model for food safety could be informed by research from the worker safety sector.** Ms. Jespersen said that some worker safety measures used by OSHA could be adapted and included in the maturity model for food safety culture. She also suggested that the food safety sector learn from the worker safety sector and create a burning platform to get employees to care about consumers by putting a face to the consumer that could be harmed if employees are not handling or preparing food safely. As an example, one company asks its employees, “Would you feel comfortable feeding this food to your family members?” By making food safety more personal for the employee it could help inspire employees to care about the impacts of their behaviors on consumers. She also suggested packaging food safety and worker safety together in the company’s communications and messaging about improving culture and performance. Another participant emphasized the significance of helping CEO’s understand the importance of food safety culture and how it impacts the bottom line because culture is defined by leadership.
- **Participants wondered whether the model could be applied to a company of any size.** Ms. Jespersen responded that for the maturity model to produce accurate results, a company must have a minimum of eight employees. Another participant emphasized a need to understand the differences between the customer-facing emphasis of small enterprises vs. large enterprises. This participant suggested that because smaller enterprises have a more direct relationship with their customers, they may have a better understanding of how their production processes and products impact consumer health. In addition, this participant believed that any model applied to smaller enterprises should be affordable, so as not to overburden these smaller franchises.
- **Participants also questioned how the maturity model or other models could be adapted for regulators at FDA.** Participants emphasized the need to ensure that frontline inspectors understand the importance of food safety and that regulating agencies also cultivate a culture of food safety within their organizations. Participants emphasized the need for training that help front line inspectors reimagine their role as educators that help companies improve their food safety culture rather than just enforcers. Some participants feared that if inspectors continue to see their role as only enforcers rather than food safety culture educators, it will cause companies to remain locked in a state of denial for fear of being punished.

FDA Updates on Preventive Controls and Produce Safety Related Activities and Inclusion of Food Safety Culture

After the presentation and discussion on food safety culture, FDA representatives provided an update on recent preventive controls and produce safety related activities, presented FDA's current framework for preventive controls metrics, and discussed ideas for incorporating food safety culture into FSMA implementation efforts. Participants were provided an opportunity to comment on the FDA's activities and metrics and discuss their ideas for next steps.

FDA updates on preventive controls related activities

Scott MacIntire, Director of the Division of Enforcement at the Office of Regulatory Affairs at the Food and Drug Administration, kicked-off the presentation explaining that FDA is currently evaluating a two-tiered inspection approach for evaluating the food safety culture of preventive controls regulated facilities. In this two-tiered approach, inspectors are evaluating large parent companies as well as their subsidiaries and suppliers to ensure they are aware of the FSMA Rules, have a recall plan, etc. FDA is also in the process of ranking the preventive controls infractions according to risk. They are categorizing infractions according to whether they should be considered critical, major, and minor infractions as well as determining whether a particular number of, for example, major citations equals a critical level citation. They will then use these citations to evaluate how well the industry is doing and measure the impact of corrective actions taken by the industry as a result of agency inspections.

Mr. MacIntire also commented that FDA and state inspectors are in the process of being trained and will begin good manufacturing practice (GMP) inspections of facilities producing and handling human food in FY 2017 and GMP inspections of facilities producing and handling animal food in FY 2018. The technical assistance network is also being set-up to provide facilities with information about developing a preventive controls hazard plan, recall plan, applying GMPs, and reducing risks in the food system. Mr. MacIntire emphasized that FDA has been and will continue to work with stakeholders, partners, other governmental agencies, congress and auditors to determine whether and what changes are needed to improve the regulatory system.

Discussion

Participants had several questions regarding FDA's updates. Questions from participants and responses from FDA representatives are outlined below.

- **A participant wondered how the idea that high-risk facilities and products would be inspected more frequently (i.e. once per year) would be integrated into the Preventive Controls Rule inspection planning process.** An FDA representative responded that this was being integrated into the planning processes and that the goal is to have these high-risk facilities and products be inspected once per year.
- **A participant wondered when stakeholders would be included in the evaluation process to help FDA answer questions such as how many minor infractions should equal a major infraction, how many major infractions should equal a critical infraction, etc.** An FDA representative responded that they are putting together an outreach

program to help with writing the guidance documents, so stakeholders would be involved at that time.

- **Another participant wondered if the preventive controls trainings, ideas, framework, measures, etc. presented would apply to international facilities.** An FDA representative responded that the outcomes and measures could be slightly different.
- **A participant also wondered if the preventive controls trainings, ideas, framework, measures, etc. would also be applied to facilities that are not parent facilities and that do not have subsidiaries and suppliers.** An FDA representative responded that yes, FDA is trying to build consistency in the process and so the model would also be applied to those facilities.
- **A participant encouraged the FDA Produce Safety Rule team to make the produce framework consistent with the preventive controls framework.** This is because the Preventive Controls Rule will regulate farmers through the supplier verification process and so building consistency between the two rules will generate less of a burden and less confusion for farmers.

FDA's tentative framework for preventive controls metrics

Sherri McGarry, Senior Adviser in the Office of Foods and Veterinary Medicine (FVM) at the Food and Drug Administration, provided CFSF participants with an update on how FDA is integrating the preventive controls draft metrics and measures into a performance management system. She shared the tentative framework FDA created for high-level preventive controls measures which is described below, but noted that the measures are still tentative because they will be working with business owners to refine the measures. She emphasized that not all metrics will be publicly reported due to industry confidentiality and non-disclosure reasons, but FDA will still monitor progress on these measures. She also noted that FDA is continuing to work with the Centers for Disease Control and Prevention (CDC) to identify the important foods, pathogens, and chemicals to monitor. Finally, she emphasized that FDA is continually considering the cost and policy implications of implementing these measures and working to reduce these burdens for all, but particularly small facilities.

CAVEATS: Not all measures will be active at once; they will be staggered based on program and compliance effective dates. These tentative measures will likely be further refined once "business owners" are identified. Some measures will likely remain internal to an office or small group while others will be reported at the FVM program level.

Result SO: Reduced Risk of Illness Attributed to Food from Facilities Subject to the Preventive Controls (PC) Rule. (Note: language will be adjusted for consistency with other FSMA frameworks in near future.)

1. Number of reported illnesses attributed to food produced at facilities subject to the PC rule.
2. Number of reported outbreaks attributed to food produced at facilities subject to the PC rule.

Result 1: More Rapid and Effective Recall Actions by Facilities Subject to the PC Rule. (Note: FDA will rely on states for gathering this information.)

1. Average response time between recognition of food safety concern and when recall is announced by the firm.
 - a. Percent of recalls that remove X% of potentially contaminated product from the market as determined by effectiveness checks.
 - b. Average time from announcement of recall to the public and X% of removal of product from market as determined by effectiveness checks.
2. Number of exposure days to the public.

Result 2: Reduced Contamination of Food from Facilities Subject to the PC Rule. (Note: Most of these can be measured in the near-term.)

1. Number of samples collected by regulatory agencies that test positive for agents that have previously been identified in foodborne outbreaks.
2. Number of contamination events self-reported by firms.
3. Number of foreign firms on import alert as a result of a manufacturing/processing issue or contamination.

Result 3: Increased Compliance by Industry of the PC Rule Requirements (Note: The goal of these measures is to look at the corrective actions being made.)

1. Percent of PC inspections conducted that are NAI, VAI, OAI.
2. Percent of deviations for PC inspections on the FDA 483 that are Critical, Major, and Minor.
3. Percent of intended 483 citations for PC rule inspections where corrections were completed and verified prior to close out of an inspection.
4. Percent of deviations for PC rule cited on an FDA 483 that are Critical or Major, that have been verified corrected by FDA within X calendar day window after inspection, or that an adequate corrective action plan has been implemented.
5. Percent of PC rule inspections in which deficiency letters were issued (if implemented).

Overall, participants were satisfied with the above listed tentative measures; however, participants did have a few clarifying questions for FDA. These questions are listed below along with responses from FDA representatives.

- **A participant wondered how FDA plans to track “Result 1, #3: Number of exposure days to the public.”** FDA representatives responded that they will begin measuring with the tools and technologies currently available (i.e. whole genome sequencing) and will seek to improve these measures and the measuring tools over time.
- **Another participant wondered what data FDA is using as baseline data.** An FDA representative responded that baselines have not yet been established, but that they are working on this.
- **Another participant suggested including the number of repeat violations by a firm in the measures.**
- **A participant also suggested including under “Result #3: Increased Compliance by Industry of the PC Rule Requirements,”** measures for performing a root cause analysis

and identifying the root cause of an issue, having a food safety plan, and other behavioral measures.

- Another participant suggested including metrics that measure FDA's activities and how well they are influencing behaviors that prevent foodborne outbreaks (i.e. measures similar to, "average time from announcement of recall to the public and X% of removal of product from market as determined by effectiveness checks," listed under Result 1).

FDA updates on produce safety measures development related activities

Ms. McGarry also provided an update on FDA's produce safety related activities. She noted that she is working with the produce safety co-leads to develop the implementation plan for the rule and draft measures. They are working with state agencies to determine how engaged they will be in the inspection process. She emphasized the importance of harmonizing measures across the Preventive Controls, Produce Safety, and Import Rules implementation and encouraged continued stakeholder dialogue around these issues.

FDA updates on food safety culture activities and measures development

Ms. McGarry also discussed FDA's current thinking on how food safety culture can be integrated into FSMA implementation efforts and encouraged further dialogue on this topic. FDA has looked at how food safety culture could be integrated into FSMA trainings for federal and state regulators and facilities and how it can be incorporated into evaluation and inspection processes through the use of survey tools or focus groups (i.e. Ms. Jespersen's food safety maturity model could serve as a model for this goal). In terms of inspections, FDA plans to use certain measures as indicators for food safety culture. Potential measures could explore the following questions:

- What can the adequacy of a food safety plan tell FDA about the culture of the firm?
- What can the corrective action plan implemented by the firm tell FDA about the culture of the firm?
- What can the speed at which the firm implemented a corrective action plan tell FDA about the culture of the firm?

In terms of surveys and focus groups, FDA has thought about partnering with associations to help FDA do this work.

Participants made several suggestions for incorporating food safety culture into FSMA implementation efforts. One participant encouraged FDA to work with Lone Jespersen and the Global Food Safety Initiative (GFSI), DuPont, the British Retail Consortium (BRC) Food Safety Group, Price Waterhouse Coopers (PWC), the United Kingdom's Food Standards Agency (FSA), Campden BRI, and Walmart to identify more research and guidance on this topic. Another participant encouraged FDA to look at guidance from the BRC for how food safety culture can be incorporated into an auditing program.

Building and Expanding on Food Safety Culture Efforts to Date

Updates from FDA were followed by a discussion among CFSF members of how best to draw on the work underway to advance successful implementation of FSMA and to develop food safety culture metrics as part of an envisioned “web of metrics.”

Food safety culture metrics

Some participants strongly support the inclusion of food safety culture metrics in the regulatory framework for FSMA because of its potential to personalize or bring the customer into the equation, create positive public-health outcomes, and reduce stigma around open communication about failures and how to correct them. These participants encouraged FDA and the group to start with a **small** set of metrics that each food safety sector/community (i.e. farming, manufacturing, retail, domestic, international, regulatory, non-regulatory, etc.) is familiar with and **not** create a completely new metrics system. Others thought new metrics would be necessary. Potential metrics identified by participants included:

- Number of employees working on food safety.
- Whether a plant has a food safety assessment plan and the quality/adequacy of the plan.
- How well the farm or facility communicates their food safety plans to their leadership, employees, and the public.
- Ratio of temporary vs. full-time employees.
- Measures associated with proper maintenance and care of equipment.
- Measures associated with proper training of employees (i.e. number of employees trained, the impact of trainings on improved behaviors and reductions in foodborne outbreaks, etc.).
- Measures associated with the motivations behind the owner of a company (i.e. money, improving the health of the immune-compromised or at-risk populations, etc.).

Other participants questioned the necessity of food safety culture metrics and encouraged the group to explore the following questions further before taking any next steps:

- Why should food safety culture be measured?
- What data should be collected to support evaluation of identified measures
- How should the data be collected and used?

Resources and tools for promoting food safety culture

Participants also encouraged FDA and the group to think about the resources and tools (i.e. finances, people, etc.) needed to ensure a healthy food safety culture within a facility or on a farm. For example, participants emphasized the importance of trainings as a tool for promoting food safety culture and ensuring FSMA success. Participants believed that these trainings should help farmers and industry prevent the root causes of food safety outbreaks from occurring by ensuring that employees understand why it is important to follow proper manufacturing procedures and that leaders understand what the proper procedures are and whether employees are following them. A participant encouraged FDA and industry to include in their trainings a depiction of what happens to consumers who fall ill as a result of a food-

borne illness and food-related hospitalization rates. A participant also emphasized the need to reduce the costs associated with FSMA implementation by providing farmers and industry with incentives and/or training tools that are evaluated for effectiveness in preventing outbreaks and improved upon to lessen the system's dependence on food safety inspections. Participants believed that these trainings should incite behavior changes throughout the food system (within leadership on farms and in facilities, within practitioners on the farm and in facilities, within regulatory agencies, etc.).

Participants also made suggestions for how these resources could be provided. A participant suggested targeting resources according to levels of risk and need. Greater attention and resources could be focused on higher-risk foods and poor performing facilities and farms. As a model for this, USDA Food Safety and Inspection Service (FSIS) uses trend-analysis to determine if a cadre of inspectors should be deployed to a farm or facility to conduct a deeper investigation on the root causes of their poor performance trends.

Potential next steps

Participants discussed potential next steps for advancing the activities listed above regarding food safety culture, including:

- Developing a research agenda and gathering additional research and scientific information from food safety culture networks (i.e. Lone Jespersen, GFSI, Grocery Manufacturers Association) to identify common definitions and approaches for the different food sectors (farms, manufacturers, retailers, regulators).
- Developing an expert panel and engagement process for the different sectors.

Data Needs and Incentivizing Collection, Sharing, and Use to Improve Evaluation of Successful FSMA Implementation

Building on the food safety culture discussion, participants next identified priority data needs along with potential incentives for meeting those needs. Participants encouraged further dialogue between FDA and stakeholders about the most appropriate data to share (i.e. lagging and leading indicators, data that exemplifies an impact on public health, a sample of data, etc.), where the data should come from (publicly available sources, industry associations, individual companies, individuals, etc.), who it should be shared with (regulators, other industry members, the public, etc.), and why it should be shared. Participants emphasized the need to build trust between regulators and the regulated community in order to encourage and incentivize data sharing. Some participants wanted to be assured that if farmers and industry were to share their data with FDA that it would not instigate an increase in regulatory investigations, but rather could lead to fewer inspections, particularly for smaller enterprises. In addition, some participants encouraged anonymity or safeguards (such as sharing information about a segment of operations rather than a single operation) in data sharing efforts to ensure the right information and story is shared with the public.

Participants also discussed the importance of reducing the costs of data sharing for smaller enterprises. One participant made the point that for smaller enterprises a third party auditing

system could be too expensive and burdensome. Participants encouraged FDA to provide industry with a benefit for sharing data by looking at existing models for incentivizing data sharing. For example, FSIS has a *Salmonella* inspection program that has incentives for data sharing between industry and USDA by offering waivers to companies for particular activities.

Next Steps on Metrics and/or Other CFSF Topics

In closing the meeting, Sandra Eskin thanked participants for attending. Abby Dilley noted that a draft summary would be circulated for review for corrections before being posted to the project website and that next steps and future topics for the Collaborative Food Safety Forum would be proposed in the near future. Potential future topics are outlined below:

- Root-Cause Analysis
- Drafting a proposal for a “Web of Metrics”
- Reliable Audits”

The meeting adjourned at 3:30pm.