

# Collaborative Food Safety Forum (CFSF)

## Collaborative Implementation of the Food Safety Modernization (FSMA) Act: *Workshop #2 Summary: Public Health-Based Metrics*

December 3, 2015  
Washington, D.C.

### Background and Overview of Meeting Goals and Outcomes

On December 3, 2015, 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 #2” on 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, and associations to continue discussions and further develop potential public health-based metrics that could be used to measure the successful implementation of the Food Safety Modernization Act (FSMA).

The goals of the meeting included:

- Advance the discussion of metrics for measuring progress in meeting the public health goals of FSMA and associated enhancement of food safety culture.
- 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

At the conclusion of the meeting, several ideas discussed during the deliberations were highlighted as potential areas for additional, productive activity for the Collaborative Food Safety Forum. We are proposing the following activities to continue building on the deliberations regarding development of public health-related metrics and incentivizing the development of a food safety culture:

#### Near-Term Next Steps

- Identify factors that demonstrate the development of a food safety culture.
  - Adapt the [Walmart Food Safety Culture survey](#) provided by Frank Yiannas to be relevant for a cross section of organizations and/or sectors.
    - RESOLVE will reach out to participants to create a small group to take the lead on this task.
    - RESOLVE will then organize a call among those who develop tailored surveys to review the compiled adapted surveys to identify a set of possible uniform metrics that could be used to assess whether preventive practices are being implemented across the food industry to improve food safety and their relevance to preventing foodborne illnesses.

- RESOLVE will bring the resulting ideas to the full group for additional discussion and consideration of next steps for using the identified factors to foster and evaluate progress in developing food safety culture.
- Identify incentives that promote data and information sharing between industry, CDC, FDA, and other stakeholders (i.e., other state and federal government agencies, NGO's, academia, etc.), particularly those related to potentially powerful but complex factors such as "near misses."
- Develop a straw proposal for an initial web of metrics for evaluating successful FSMA implementation. As acknowledged by the CFSF participants, an initial framework will need to be deployed at some point and include a web of metrics for evaluating successful FSMA implementation, including some of the following attributes:
  - Variables that will evolve over time,
  - Metrics that span across programs, as well as some more relevant to one or a subset of programs,
  - Metrics tracked by FDA to determine their role in FSMA success, and metrics tracked and spearheaded by others,
  - Metrics that will drive and be driven by continuous improvement, and CFSF participants, with possible input from external experts, (such as Glen Mays from University of Kentucky) will work together to develop a straw proposal to discuss with the group.

#### Mid-Term Next Steps

- Develop a collaborative process to guide root cause analysis of foodborne illness outbreaks, which:
  - Might use an approach similar to the development of the CFSF Supply Chain Consultation Process.
  - Leverages the academic community to provide reliable methodologies.
  - Facilitates the development and continuous improvement of root cause analysis studies.
  - As part of this collaborative process, CFSF members could explore topics including:
    - Barriers preventing the regular practice of conducting root cause analyses and the dissemination of information from those that have been completed, and developing recommendations mitigating these barriers;
    - Reinvigorating the Food Protection Task Forces already in existence in 25 states to partner with public universities to act as research hubs for providing root cause analyses and evaluating FSMA; and,
    - Developing a Food Safety Progress Committee, which would follow up on root causes of multi-state outbreaks as part of contributing information and data for FSMA implementation analysis.

### Longer-Term Next Steps

- Explore vehicles, such as the Farm Bill, which could include measures to increase incentives for adopting a food safety culture and complying with FSMA, as well as near-term incentives for data collection and sharing. Potential incentives include:
  - Providing loan guarantees for qualified enterprises and farms working to gain compliance with FSMA, and
  - Providing crop insurance incentives, such as reduced premiums, to farms that, according to FSMA metrics, receive “high-performance” ratings.

We will continue to reach out to CFSF participants to shape future deliberations and schedule additional dialogues and workshops.

### Meeting Deliberations

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

### Brief Updates from FDA: Completion of the FSMA Rules and the Importance of Metrics

Mike Taylor, Deputy Commissioner for Foods at FDA, reminded CFSF members that the Final Rules on Accredited Third-Party Certification, Preventive Controls for Human Food, Produce Safety, and the Foreign Supplier Verification Programs were released and that FDA has a goal of achieving high rates of compliance based on the expectation that complying with FSMA regulations will result in reduced public health risk. To accomplish this goal, he emphasized the importance of this and past Collaborative Food Safety Forum deliberations that seek to identify the right metrics for not only evaluating the successful implementation of FSMA, but that also act as drivers of progress for food safety and enhance food safety culture. He noted that instilling a food safety culture within companies is critical to reducing risk and so FDA is happy to use information garnered from the December 3<sup>rd</sup> CFSF meeting, and other deliberations, to guide FDA’s future actions. Taylor also noted that figuring out the right metrics and how best to evaluate progress is a complicated and long-term process. So, FDA continues to encourage information sharing on metrics between the food industry and its regulators and plans to work with the industry and CDC to illustrate to the public FSMA’s success in reducing the number of incidents that put people at risk.

### Public Health Outcomes and FSMA Success: Insights Gathered to Date and Areas for Additional Development

#### *Insights gathered to date*

Following the June 25-26, 2015, “Collaborative Implementation of the Food Safety Modernization (FSMA) Act Workshop,” the first session on public health-based metrics, RESOLVE held several conference calls to advance discussions on identifying potential measures for evaluating the success of FSMA, particularly focusing on achieving improvements in public

health outcomes. These discussions included topics such as what to measure, how to determine whether public health outcomes are improving, and promotion of and indicators for progress in developing or improving a food safety culture. Many CFSF participants supported the concept that these two objectives (improvements in public health outcomes and enhanced food safety culture) are completely integrated and involve a web of metrics.

During these conference calls, several themes and questions emerged. First, participants determined that FSMA's "Web of Metrics," which describes the interconnected relationship between public health-related measures and other measures (i.e., rates of illness and compliance rates), should meet the criteria for "good" health metrics. These "good" health metrics, described by Glen Mays, F. Douglass Scutchfield Endowed Professor, Health Services & Systems Research at the University of Kentucky, and embraced by the CFSF participants include:

1. **Relevance** to the specific policy goal.
2. **Health impact:** reduction of the prevalence and/or severity of the negative health effect.
3. **Economic impact:** costs, resource use, and opportunity costs.
4. **Distributional Impact:** addressing inequities and disparities among populations disproportionately affected, as well as consideration of the impact from the implementation of required measures evenly across relevant actors.
5. **Tractable:** able to be influenced or changed by relevant actors and their respective actions.
6. **Degree and Velocity of Change:** the degree or extent of change one is likely to observe over shorter (proximal) and longer (distal) time periods, as well as the relative speed and degree of change (i.e., more rapid and higher degree of change might be observed early on, but decrease in speed and magnitude of change over time).
7. **Vulnerability:** degree to which other, confounding factors are relevant in determining and influencing health impacts.
8. **Measurement Quality:** validity, reliability, sensitivity, specificity of data and data sources.
9. **Feasibility:** data availability, collection/reporting burden and cost.
10. **Public Values/Preferences:** capturing and evaluating what matters most to the public.

Second, participants acknowledged that multiple metrics will need to be analyzed to understand and evaluate the success of FSMA in achieving its public health goals, and these will vary in scope and dimension. Some metrics need to be high-level enough to span across the various programs of FSMA, while others may be more program specific. In addition, some metrics will be lagging or retrospective measures, such as recalls or "near miss" results, while others will be leading measures of performance, such as training in food safety or deployment of preventive programs, like supplier qualification. Also, metrics will likely vary in importance or impact over time. Therefore, some metrics will be perpetual metrics while others will be phased in and out as they become more or less important or relevant.

Third, participants noted that improved public health outcomes are the overarching goal of FSMA and progress in developing or improving food safety culture is considered a key

component of and metric for achieving improved public health outcomes. Participants also agreed that further exploration is needed into how food safety culture can be measured and how it can be integrated into other prioritized metrics for evaluating FSMA success. What is measured drives priorities for action and this fact must be aligned with promoting a food safety culture across all stakeholders and sectors (from facilities to farms to consumers to regulators) to maximize improved public health outcomes.

Fourth, participants concurred that metrics will be developed, used, and the primary responsibility of different stakeholders, including but not limited to FDA. It will take a collective effort, including information sharing and collaborative analysis and communication, to establish, effectively use, and refine metrics for successful implementation of FSMA.

Finally, participants expressed the point that while different stakeholders will take the lead in collecting data and evaluating and sharing information on different metrics, incentives are essential and should be provided to enhance these efforts around data collection, evaluation and sharing. Incentives include resources, information exchange, and other positive benefits that offset the potential burden of collecting and providing information.

#### **Areas for additional development**

Meeting participants determined that root cause analysis is critical to contributing to and evaluating FSMA success. Determining root cause of foodborne illnesses is vital for developing a continuous improvement process that works to prevent repeated mistakes and provides insights for better practices. It allows food industries and regulators to determine the root causes of outbreaks and foodborne illnesses so that the correct preventive actions can be implemented to ensure food safety across the system. However, participants also acknowledged the need for further exploration into the best methodologies for determining root cause, identifying elements of a “good” root cause analysis, examining supply chain complexity as part of root cause analysis, and involving academics in this process in order to cultivate widespread understanding and legitimacy of, as well as development of corrective actions based on its results.

#### **Measuring Food Safety Culture: What to measure, how, and who?**

Multiple ideas emerged during the June 25-26, 2015 meeting and the successive conference calls for possible metrics to evaluate progress in developing food safety culture as well as what and how to measure progress and the use of different tools. During the December 3<sup>rd</sup> meeting, participants explored this topic of measuring food safety culture further, identifying potential priority metrics, key challenges associated with measuring food safety culture, and additional ideas to explore.

#### **Topics identified to date**

During the Produce Safety conference call on November 20<sup>th</sup>, several participants discussed the benefits of using on-site employee surveys to evaluate food safety culture within facilities. Frank Yiannas, Vice President of Food Safety at Walmart shared with CFSF members the, [“Food Safety Culture Survey,”](#) Walmart uses to understand employees perceptions and awareness of

the company's expectations, training and education, communication, goals and measurements, and consequences. This survey was offered as an example of a tool for both evaluating and fostering food safety culture within the workplace.

Participants also encouraged FDA to employ joint inspection trainings and other collaborative activities among regulators, the regulated industry, and other stakeholders to improve communications about progress and challenges related to FSMA, foster shared visions around FSMA success, and reduce variability in the interpretation of FSMA requirements, information and data. Models for these kinds of trainings for produce operations and open facilities could be adapted from the processed foods industry/closed facilities' experiences and models.

Finally, when discussing potential goals and metrics for food safety culture, participants emphasized the need for metrics that improved communications and data sharing, and encouraged continuous improvement of the evaluation system. Potential metrics included: (1) speed with which information is acted upon and interventions are implemented to prevent and contain a problem, (2) the availability of safe opportunities for farmers/growers to talk with one another, gather useful information, and share information, and (3) the number of and/or percentage of farms that complete a root cause analysis and use the results to improve their operations.

#### **What does food safety culture look like?**

Participants emphasized the need to determine what food safety culture really means to all stakeholders and how it should be defined while taking into account the diversity of stakeholders that exist within the food industry. To begin the process of defining food safety culture, participants acknowledged that overall messaging about food safety culture should be about prevention. Then to accomplish the goal of prevention, for larger companies, one participant suggested thinking of food safety culture as the output for good programs that determine the root cause of an issue, identifies existing gaps, and puts corrective actions in place. Alternatively, for small farms/producers, food safety culture is not an output, but rather it is a starting point. Therefore, a customer-centric approach should be established first.

#### **What criteria for measures should be used to evaluate food safety culture?**

Participants agreed that in order to use food safety culture as a way of evaluating FSMA progress, FDA needs specific objectives for assessing it. Therefore as measures are developed, FDA and stakeholders should prioritize the critical few measures that are related to FSMA outputs, so as not to overburden agencies and stakeholders with excessive data collection and analysis efforts. When thinking about proper criteria for food safety culture measures, first, participants suggested designing the measures in a way that balances embracing food safety culture with ensuring production rates remain high and businesses stay economically viable. Therefore, it is important to evaluate the cost burden of measures before employing them. Second, participants believed that measures should evaluate whether employees understand their role in promoting food safety and also encourage industry, regulators, and other stakeholders to identify the reasons behind their behaviors that either encourage or discourage food safety and a food safety culture. Third, participants emphasized that measures should

help industry and regulators identify root causes and encourage communication about failures, mistakes, and near misses. Allowing problems to be identified is a vital component of a food safety culture and so helping industry and regulators understand this will be critical to FSMA's success. To promote this behavior, measures should encourage the sharing of near misses within an industry without prompting punitive actions from regulators. Sharing information such as near misses requires trust between regulators and industry and when information is voluntarily shared, the response should not be negative. In addition, culture evolution should be viewed as a two-way process, occurring within industries and regulatory agencies. Therefore, in both industry and regulatory agencies "bad actors" should be addressed effectively, but should not overly influence the entire system of oversight or dominate the culture causing it to become overly enforcement driven. Measures should also be established and used to identify, acknowledge and communicate positive behaviors.

### **How can food safety culture be measured?**

After discussing potential criteria for food safety culture metrics, participants then discussed the best ways for actually measuring food safety culture. Several participants noted that many approaches for evaluating safety culture already exist in other sectors and it would be useful to apply these to FSMA regulated foods. When doing so it would be important to also explore how other sectors have fit safety culture metrics to smaller businesses and enterprises in order tailor metrics to fit small farmers. Examples of such approaches include worker protections and personal safety in other industries as well as in food production, including on farm practices. Both of these areas of policy could serve as models for how to get entire organizations working together to accomplish a shift in culture. Also, food safety auditors are already beginning to incorporate food safety culture into their evaluations as a way to assess suppliers, but it's important that these metrics are measured consistently across the sector.

Participants also acknowledged several barriers to measuring food safety culture. First, food safety can be very resource intensive, depending upon the requirements and starting points of facilities and farms. Therefore, melding or incorporating food safety into other areas, such as personal safety, conservation practices, tractor safety, well-head protections, etc., which are concepts and practices that are already being conducted by small farm and facility operations, could help reduce operation costs. Second, widespread education, communication, and training are needed especially for small "mom and pop" businesses that are not even aware FSMA has been passed or how it affects their business. To help small establishments prepare for FSMA compliance and to garner their support, they should be educated on what a near miss is as part of building their food safety culture acumen and it should be communicated that the most vulnerable populations are their customer-base.

Also, when thinking about how food safety culture can be measured, participants stressed the importance of helping companies and their employees understand **why** food safety culture is important to them and their business. Making these connections more explicit, participants suggested, can help move people in the right direction. To accomplish this, participants encouraged investigators to evaluate food safety culture through an interview process, rather than a checklist process. An interview process better assesses the degree to which food safety

culture exists at a farm or facility and whether or not employees understand how to prevent problems. Interviews also encourage conversations between investigators and industry employees about how to build a better food safety culture. Regulators should understand that this approach is about encouraging those conversations, educating before regulating with the goal of preventing and reducing bad or problematic practices, and fostering improved food safety culture. Participants also generated a list of potential interview questions that could be used to evaluate food safety culture, including:

- What issues potentially affecting food safety are employees finding?
- How are they finding them?
- Do employees understand **why** they are looking for particular issues or problems, and if they find problems, what do they do as a result and to fix them?
- Can employees describe a recent food safety problem encountered? How did employees respond and what preventive measures are in place as a result?

### **Who should be involved?**

Participants were also encouraged to think about who should be involved in the process of developing metrics and evaluating food safety culture. Participants agreed that a mixture of industry leaders, academics, FDA and CDC officials, and crop consultants were essential stakeholders who should be engaged. Academics should be involved in helping to determine and evaluate the best qualitative and quantitative metrics and methodologies for evaluating food safety, especially those that would inspire behavior changes. They should also be involved in communicating lessons learned to industry, regulators, and other stakeholders.

To accomplish this goal of promoting continuous improvement, universities should develop a research agenda to identify and support food safety culture metrics and set-up remote trainings or forums for industry leaders. Simultaneously, FDA officials should determine the kinds of recurring practices and problems inspectors are seeing to use as risk factors, while industry leaders should be involved in conducting evaluations of industry food safety culture and share lessons learned from outbreaks, near misses, and recalls. Crop consultants should also help educate farmers on how to prevent problems from occurring, which problems to look for, and what improved practices could help them achieve FSMA compliance.

Finally, several participants suggested developing a Food Safety Progress Committee. CDC has thought about developing this kind of a committee to follow-up after multi-state outbreaks and to help determine the root causes of the outbreaks. As suggested by participants, the group membership could change every year and each year the group would decide what to follow-up on as a result of outbreaks identified in the prior year, address the problem, and determine how to prevent those issues in coming years. This information could then be disseminated to the food industry to incorporate into their evaluations of food safety culture.

### **FSMA-Wide, Cross-Program Metrics**

Following the discussion on better defining, measuring and fostering food safety culture, participants' attention was then directed to a discussion on possible key components of or



frameworks for a mix or web of metrics and their respective advantages and disadvantages. The two frameworks discussed during this meeting included 1) pathogen-specific metrics, or metrics that track overall incidence rates for key (but not all) foodborne pathogens, such as *Salmonella*, *Listeria*, and *E. coli* 0157:H7), and 2) process failures, near misses and root cause analysis metrics, or metrics that track rates of foodborne outbreaks linked to process failures (i.e. inadequate separation of pasteurized and non-pasteurized products) and/or selected root causes (i.e. failure to adequately monitor a process).

**Pathogen-specific metrics:**

Dr. Patricia Griffin, Chief of the Enteric Diseases Epidemiology Branch, CDC introduced the pathogen-specific metrics discussion along with her colleagues Kelly Barrett and Antonio Vieira, who provided a brief overview of CDC data related to produce within the context of discussing possible pathogen-specific metrics.

Participants appreciated the information gathered and thought the logic and criteria used to select the key pathogens were clear. The deliberations highlighted other reactions and ideas on pathogen-specific metrics as well. First, participants emphasized that the outbreak data used for evaluating pathogen-specific metrics should be drawn from those events that could be linked to and are impacted by the FSMA Rules. For example, norovirus, while a significant cause of foodborne illness outbreaks, is predominately caused by sick food workers, which FSMA does not have authority to change. Therefore, it is not a pathogen that should be highlighted for the purposes of evaluating FSMA success. An additional observation related to FSMA relevance was identification of any pathogens that could be linked to specific FSMA programs. For example, as was suggested, cyclospora, and its link to imported foods could provide a metric for evaluating progress with imported foods. Understanding other confounding factors may make pathogen-specific links to program-specific evaluation impossible, but where viable, is worth considering. Second, in evaluating FSMA using pathogen-specific metrics, participants thought there could be value in comparing produce trends to trends in other food groups (i.e., processed foods) in order to better understand the true impact of FSMA in preventing foodborne illnesses and outbreaks within produce. Finally, participants encouraged measuring the accuracy of pathogen-specific metrics overtime to foster continuous improvement of the evaluation system.

Participants also identified challenges associated with pathogen-specific metrics that should be addressed before their implementation. First, under FSMA Rules, produce is regulated differently depending on whether it is fresh-cut, processed, etc. and the ever-variable, open environment of a farm can present challenges for pathogen-specific metrics that should be reconciled. Second, reconciliation of data and clarity on definitions of “processed” and “fresh” produce between CDC and FDA is needed. It was stated that such discussions have been initiated, but the group thought it particularly critical to draw on current data, set baselines, and then be able to evaluate against metrics. Third, in determining pathogen-specific metrics, how this information is and can be communicated to the public should be considered. It’s important to consider how media and advocacy groups might communicate information that

comes from these metrics and the consequences industry may face as a result, as well as the potential impact of overall confidence in the safety of food.

Fourth, to show real progress related to FSMA, metrics for compliance should move past attribution or product and pathogen pairings and towards root cause analysis. Root cause analysis should try to determine which practices or systems failures caused the outbreaks, not just determine the source of contamination. However, oversight system improvements are needed before root cause can be determined. Oftentimes in an outbreak event, by the time the inspectors arrive the conditions have changed completely from the time the contamination occurred, making root cause analysis problematic, if not impossible. Root cause can also be especially difficult to determine for imported produce, given the lack of access to and authority over facilities and farms outside of the US.

The final challenge related to pathogen-specific metrics identified by participants is that states have varying capacities for gathering data leading to incomplete national-level data sets, especially for linking outbreaks to process failures. Some states received increased funding for investigations, while others lack full-time staff dedicated to outbreak investigations and data collection. The federal government should consider allocating additional resources and providing incentives to states and localities to improve local and state-level data collection and entry efforts if pathogen-specific metrics are pursued.

**Process failures or root-cause analysis metrics:**

Joe Scimeca, Vice President of Global and Regulatory Affairs at Cargill, Karin Hoelzer, Officer of the Safe Food Project at The Pew Charitable Trusts, and Steve Warshawer, Farmer at La Montanita Cooperative/Beneficial Farms CSA introduced the process failures or root-cause analysis metrics discussion providing a [brief summary](#) of their preliminary thinking and discussion which occurred on November 24, 2015. Mr. Scimeca, Ms. Hoelzer, and Mr. Warshawer identified several root causes that could be considered for evaluating FSMA progress and success, including: inadequate technical expertise; training failures; equipment-related failures or problems; inadequate communication channels; poor food safety culture and associated lack of leadership and/or management support; and, supply chain management issues, such as contaminated ingredients, inadequate implementation of post-harvest interventions, inappropriately determined and/or monitored Critical Control Points, and insufficient surveillance along the supply chain to test, verify, or intervene.

This overview was followed by a discussion among participants on the important considerations for root-cause analysis metrics, data necessary for evaluating near misses, process failures, and root cause analysis, and the challenges associated with these kinds of metrics. First, when considering which metrics to use, participants emphasized the need for metrics that generate the greatest impacts relative to their associated costs. Participants also encouraged incorporating protocols for frequent communication to relevant audiences, such as speed of information gathering and delivery and reporting of information in usable ways, into these metrics to encourage capturing lessons learned and implementing changes effectively and efficiently. Finally, participants continued to emphasize that process failures or root-cause

analysis metrics should encourage industry to get to **why** a failure occurred that caused an outbreak or near miss, so that a corrective action can be instituted.

To effectively evaluate near misses, process failures, and root cause analyses, participants identified important data that would need to be collected and potential incentives that could encourage data sharing. State-level outbreak investigations are critical for identifying root causes, but it is important to ensure the outbreak is attributed to the right factors. To encourage data-sharing between industry and FDA, sharing efforts should be set-up through collaborative, research avenues, rather than regulatory avenues. A collaborative, rather than regulatory, data-sharing system will help to build trust between industry and FDA, making industry more comfortable with providing data. In addition, to support small producers in collecting data and other FSMA-related activities, regulators should consider providing them with incentives. Some examples were suggested as models to incentivize growers, such as the program initiated by the Natural Resource Conservation Service (NRCS) to encourage small farmers through grants to establish wildlife habitats on their farmland to enhance environmental services for the broader community.

Participants also identified challenges associated with process failures or root cause analysis metrics that should be addressed before their implementation. First, it is important to consider the correlation between supply chain complexity and risk (i.e., for some supply chains, the more people or equipment that come in contact with the food, and the greater the length of time in transit, the greater the associated public health risks). How should supply chain complexity be captured in root cause analyses and what are the impacts for data collection? Second, it is important to consider the correlation between the economic impact of root-cause analyses and producer size. If smaller producers are disproportionately burdened, how can this impact be addressed or reduced to encourage full engagement of all facilities, no matter the size of the facility or exemption? Third, legal barriers within FDA present significant challenges for the Agency's ability to report out root cause analysis data. Fourth, cause and effect of food contamination can be very difficult to determine.

**Total cost metrics:**

Total cost metrics, or metrics that track economic indicators (e.g., disability adjusted life years (DALYs) –which factor in the severity of the illness) to estimate the total cost of foodborne illness linked to FDA-regulated foods, and to track changes in that cost over time, was identified as a topic during the October 7<sup>th</sup> call, but has not been developed further to date. This topic may be discussed in future CFSF deliberations.

**Preventive Controls Specific Metrics**

Roberta Wagner, Deputy Director for Regulatory Affairs, FDA presented the preliminary Preventive Controls Rule Results-Oriented Management (ROM) framework measures to evaluate FSMA success asking CFSF participants for feedback on, “ROM Result #3: Increased implementation by industry of Preventive Controls Rule requirements; widespread industry compliance with FSMA rules” (see below).

**FDA Preventive Controls Rule “ROM Result #3: Increased implementation by industry of PC rule requirements; widespread industry compliance with the FSMA rules proposed” metrics**

- Percentage of firms inspected with an adequate/complete food safety plan.
- Percentage of firms inspected that are fully implementing their food safety plan; no areas of noncompliance noted with food safety plan implementation.
- Percentage of firms inspected that have an adequate supplier management program that is being fully implemented.
- Total number of comprehensive/targeted PC rule inspections conducted.
- Percentage of comprehensive/targeted PC rule inspections conducted that are NAI.
- Percentage of comprehensive/targeted PC rule inspections conducted that are VAI.
- Percentage of comprehensive/targeted PC rule inspections that are OAI.
- Percentage of PC rule inspections that did not result in the issuance of an FDA 483 or did result in the issuance of an FDA 483.
- Percentage of PC rule inspections with one or more critical deviations cited on an FDA 483.
- Percentage of PC rule inspections with one or more major deviations cited on an FDA 483.
- Percentage of PC rule inspections with critical and/or major deviations cited on an FDA 483.
- Percentage of PC rule inspections with only minor deviations captured in OCAR.
- Percentage of PC rule inspections where corrections/corrective actions were completed prior to close out of an inspection.
- Percentage of PC rule re-inspections to verify that critical deviations cited on an FDA 483 have been corrected or that an adequate corrective action plan has been implemented within two weeks? (not sure what the appropriate timeframe will be) of the finding.
- Percentage of PC rule re-inspections to verify that major deviations have been corrected or an adequate corrective action plan has been implemented within 3 months? (not sure what the appropriate timeframe will be) of the finding.
- Percentage of PC rule re-inspections where corrections/corrective actions were found to be complete and compliance achieved.
- Issuance of deficiency letters within 2? days of inspections when warranted; follow-up to deficiency letter within 5 days with admin action if corrections/corrective action plan not implemented.
- Issuance of WLs when warranted within x days.

Participants provided FDA with ideas for additional metrics to consider for ROM Result #3 as well as other considerations to explore as these metrics are developed. Additional metrics proposed by CFSF participants included:

- metric(s) for the results of a negotiated process(es) for achieving compliance. Did it result in compliance or a renegotiation?
- metric(s) for disputes between investigators and industry.

- interim measures for a “percentage of firms inspected with an adequate/complete food safety plan,” metric including whether the plan has been developed, implemented and tested regularly.
- metric(s) for inspector mentoring that fosters consistent and “good practices” across the entire “inspection system,” which includes state and federal personnel. These metrics can help to identify lessons learned and where improvements are needed. FDA has already identified mentors who will supervise trainings and mentor the first cadre of inspectors, which CFSF participants thought was a positive first step.
- metric(s) for inspector calibration to evaluate alignment of, and consistency among inspection protocols.
- metric(s) for state Food Protection Taskforce activities to foster aligned and consistent communications about FSMA-related activities.
- metric(s) that captures near misses, including the identification of and responses to these occurrences.

Participants also suggested implementing these metrics as part of a phase-in program in order to support industry in achieving compliance. Within the first year, industry could ease into compliance with the expectation that they would comply with a set of “easier” metrics and then the second year would be expected to comply with a set of “harder metrics.”

To support the implementation and effective evaluation of these metrics, participants encouraged FDA to design the inspection process in a way that will enhance the efficacy of the FSMA program. First, participants emphasized that inspections training for regulators and industry is critical. Regulators and industry should know what will occur during an inspection, why inspections are being conducted, and how they are being conducted prior to the first inspection. Trainings are particularly important for small farmers because the costs of appeals are insurmountable for small enterprises and can put them out of business. Second, investigators should assume positive intent of employees to build trust between FDA and industry and farmers. In building this trust, reconciliation or negotiation to fix an identified problem is best done on site so inspectors can help employees understand why the problem occurred and help them institute corrective actions to prevent future issues. Third, learnings from each inspection, such as insights regarding design flaws in equipment or systems, should be spread across the industry to alert others to similar problems and spread ideas on interventions to correct them.

### **Produce Safety Specific Metrics**

Roberta Wagner, Deputy Director for Regulatory Affairs, FDA led CFSF participants in a discussion around generating ideas and considerations for preliminary Produce Safety Rule Results-Oriented Management framework measures, specifically focusing on, “ROM Result #6 Increase incentives for compliance,” and, “ROM Result #16: Encourage more effective engagement between FDA, consumers and trade groups.” These metrics were less developed than the Preventive Controls measures, so CFSF participant input was extremely welcomed.

### **Produce Safety Rule ROM Result #6: Increase incentives to comply with the rule**

For ROM Result #6, participants encouraged FDA to provide incentives for compliance preparation, good performance, and data collection in the form of dollars or the opening of markets. CFSF participants encouraged FDA to work collaboratively with other agencies and the private sector to provide incentives as a way of reducing costs for the single agency. Using FSMA metrics, FDA could determine which metrics not only create improved public health outcomes, but also generate co-benefits in meeting requirements by other policies implemented by other agencies, such as conservation requirements or water quality requirements by the Environmental Protection Agency (EPA). Then, partner with these agencies and the private sector to provide incentives for complying with these metrics.

To encourage and support compliance preparation, participants suggested that FDA offer free or reasonably priced “readiness reviews,” to help farms prepare for inspections and achieve compliance prior to the inspection. This action could be seen as an incentive because it is avoiding a “negative” inspection. Another suggested incentive for compliance preparation was offering start-up grants for initial investments in setting up FSMA compliance programs and continuing grants for gradually improving supply chain systems, including business and financial training for small businesses. Both types of grants are important because startup costs for compliance programs can be quite significant while the costs of maintaining efforts once the program is up and running will likely level off, but could still be burdensome for some enterprises. As a way of improving the cost-effectiveness of these grants, FDA could build partnerships with the Small Business Association or other microenterprises (especially those who are vulnerable) to provide grants for a “bundling” of skills development, not only improving food safety practices, but also other skills, such as management and finance, to improve overall business skills and good practices. Including incentives for FSMA compliance within the USDA Specialty Crop Block Grant Program may also be another avenue.

To encourage good performance related to FSMA, some CFSF members suggested collectively leveraging the 2018 Farm Bill as a way to provide loan guarantees to qualified enterprises and farms working to gain compliance with FSMA and offering crop insurance incentives, such as reduced premiums, to “high-performing” farms (as measured by FSMA metrics). Participants also suggested that FDA begin discussions with private and third-party auditors about developing certifications to reward high-performing small enterprises. Finally, participants encouraged offering revenue support and product liability insurance to high-performers, with the caveat that a recall should not increase premiums or cause coverage to be completely lost and that the successful should not take on the costs or the increased burdens created by those who fail.

To foster and encourage data sharing efforts, participants suggested offering reduced costs on mandatory training to those who provide FDA with sufficient data. FDA could explore USDA’s Food Safety and Inspection Services (FSIS) *Salmonella* Initiative Program as a model for industry data sharing, for those establishments that maintain good performance to provide incentives, such as allowing them to be waived from inspections, allow the frequency of inspections to be reduced, or other kinds of incentives. A challenge with this approach is that FDA works with federal and state level investigators, who have differing frequencies for investigations, some of

which are mandated. This kind of program approach would require alignment across state and federal level investigators. Another approach utilized by FSIS is categorization of establishments based on their performance and employing public web-posting of establishment names.

**Produce Safety Rule ROM Result #16: More effective engagement with consumer and trade groups on produce safety issues**

According to FDA, metrics to improve effective engagement with consumer and trade groups on produce safety issues are important because trade groups serve as a way for FDA to communicate with the private sector about issues or activities related to FSMA and improving the sharing of inspection findings with consumer groups can potentially improve consumers understanding of FSMA successes. Additionally, providing improved root cause analysis information and data to trade groups can allow them to work with their members to facilitate and address identified problems related to food safety practices and compliance with FSMA. However, FDA remains unsure of which trade groups (representatives of domestic and imported produce) to engage for produce sampling and asked CFSF participants for their input on this.

Participants agreed that more effective engagement with trade groups on produce safety issues will be important to FSMA's success. Participants cited better communication and sharing of information between FDA and trade groups as a way to help improve industry attitudes about investigations. To do this, several participants also suggested that FDA and CDC consider, in the event of an outbreak investigation, pulling in key investigators and stakeholders to have a direct and analytical dialogue to get to the root cause of the problem, contamination or outbreak. Participants also believed that more effective engagement with trade groups can improve industry understandings of non-compliance and how to implement corrective and preventive measures. To do this, participants suggested that data sharing among industry, FDA, CDC, and other stakeholders should be encouraged and that FDA and CDC should provide summaries of audits and report back on non-conformance areas across the industry.

Participants also agreed that more effective engagement with consumer groups on produce safety issues is important because consumers would benefit from getting information directly from a credible authority like FDA, rather than second hand or from the media. However they also believed that the timing and focus of interactions between FDA and consumer groups may be different than with trade organizations and so FDA may want to separate this group into another result.

Participants provided FDA with ideas for additional metrics to consider for ROM Result #16 as well as other considerations to explore as these metrics are developed. Additional metrics proposed by CFSF participants included:

- Consumer confidence in food safety as a metric. As a side benefit, increased confidence could lead to an increased consumption of fruits and vegetables and additionally enhance public health outcomes.

- Speed of information sharing with consumers metric. Increasing the speed of information delivery to consumers as well as providing consumers with information in a format that can be readily used and understood can help consumers protect themselves from getting sick by ingesting contaminated produce. It can also help rebuild their confidence in the food safety system following an outbreak, knowing that a problem has been identified and a corrective action has been implemented.
- Post-outbreak recovery response metric and interim measures, including: (1) speed in which an intervention was implemented to correct the problem, (2) speed in which root causes are identified and shared to improve practices throughout the food industry, and (3) speed in which an industry recovers from an outbreak and implements corrective actions to prevent future similar events.
- Market impact following an outbreak metric. FDA could measure how quickly industries recover economically from an outbreak as food safety practices and rapid response mechanisms are improved and new prevention practices are implemented.

### **Potential Next Steps**

Before the close of the meeting, Sandra Eskin thanked participants for attending. Abby Dilley noted that a draft summary will be circulated for review for corrections before being posted to the project website and that next steps for the Collaborative Food Safety Forum will be proposed in the near future. Potential next steps discussed are outlined below (translation of these ideas are in the proposed next steps at the beginning of this summary).

RESOLVE will consult with CFSF members about productive next steps and future topics for the Forum. Topics that garner the most energy and are most relevant to the CFSF principles for successful FSMA implementation will be pursued in future meetings. Suggested next steps and future topics to build on this workshop's discussion include the following:

- Build clarity around potential Food Safety Culture metrics by encouraging CFSF participants to work in groups to adapt the Food Safety Culture survey ([link](#)) provided by Frank Yiannas to fit their organization. This process can help identify a uniform set of metrics that could be used to measure whether preventive practices are being implemented across the food industry to improve food safety and their effectiveness in preventing foodborne illnesses.
- Explore Collaborative Food Safety Forum actions for the 2018 Farm Bill. Potential topics include (1) providing loan guarantees for qualified enterprises and farms working to gain compliance with FSMA, (2) providing crop insurance incentives, such as reduced premiums, to farms that according to FSMA metrics receive "high-performance" ratings, and (3) providing cost-sharing mechanisms for small enterprise certifications and water-testing. The Senate and House Agriculture Committees have already begun stakeholder deliberations on the 2018 Farm Bill, and so this provides the CFSF with an ideal opportunity to pursue Farm Bill reforms NOW.
- Develop a collaborative process for root cause analysis of foodborne illness outbreaks that is similar in approach to the CFSF Supply Chain Consultation Process and that leverages the academic community to provide reliable methodologies. This could help



facilitate the development and continuous improvement of root cause analysis studies by leveraging information and insights gleaned to improve food safety practices. As part of this collaborative process, CFSF members could explore topics including: (1) barriers preventing the regular conduction of root cause analyses and the dissemination of information from those that are conducted and solutions for mitigating these barriers; (2) reinvigorating the Food Protection Task Forces already in existence in 25 states to partner with public universities to act as research hubs for providing root cause analysis and evaluating FSMA implementation; and, (3) developing a Food Safety Progress Committee with following-up on root causes of multi-state outbreaks.

- Determine the components of a “reliable audit” as it relates to Foreign Supplier Verification Programs and complies with produce safety requirements and discuss the value of non-third party audits as compliance indicators.
- Continue deliberations on providing incentives that promote data and information sharing between industry, CDC, FDA, and other stakeholders (i.e., other state and federal government agencies, NGO’s, academia, etc.).

The meeting adjourned at 4:30 p.m.

## Collaborative Food Safety Forum

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### **December 3<sup>rd</sup> Meeting: Successful Implementation of FSMA: Top-Tier Public Health-Related Outcomes and Associated Metrics**

#### **Participants**

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##### **Colin Finan**

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##### **Donna Garren**

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##### **David Gombas**

Senior Vice President of Food Safety  
United Fresh Fruit & Vegetable Association

##### **Jim Gorny** *(by phone)*

Vice President, Food Safety & Technology  
Produce Marketing Association

##### **Craig Hedberg** *(by phone)*

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University of Minnesota

##### **Karin Hoelzer**

Officer, Safe Food Project  
The Pew Charitable Trusts

##### **Sophia Kruszewski**

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National Sustainable Agriculture Coalition

##### **Dara Lieberman**

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Trust for America's Health

##### **Glenn Morris** *(by phone)*

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##### **David Plunkett**

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Center for Science in the Public Interest

##### **Joe Scimeca**

Vice President of Global Regulatory &  
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##### **Kristen Spatz**

Senior Manager, Food Safety and Quality  
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Grocery Manufacturer's Association

##### **Steve Warshawer**

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**Kari Barrett**

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