Collaborative Food Safety Forum (CFSF)

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

June 25 - 26, 2015
Washington, D.C.

Background and Overview of Goals and Outcomes

The Collaborative Food Safety Forum (CFSF or Forum) is focused on implementation of the FDA Food Safety Modernization Act (FSMA), and is comprised of industry (e.g., growers, processors, distributors, retailers, accreditors and certifiers), consumer, academia, and federal and state government stakeholders. With funding from The Pew Charitable Trusts (Pew) and the Robert Wood Johnson Foundation (RWJF), the Forum holds workshops that elicit dialogue regarding implementation of FSMA and develop ideas in a creative, constructive, and collaborative manner. On June 25-26, 2015 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, academia, and associations attended a 2-day workshop to discuss and develop potential public health-based metrics for successful implementation of FSMA.

The specified goals of the workshop included:

- Discuss and develop potential public health-based metrics for measuring progress in meeting the goals of FSMA.
- Draw on other regulatory systems' models for evaluating impact on public health.
- Discuss key fundamentals (i.e., the "top tier" metrics) of the draft Preventive Controls Strategic Program Planning framework, as well as the Produce Safety Strategic Program Planning framework.
- Determine possible next steps for developing FSMA metrics.

This summary is intended to provide an overview of the two days of deliberations.

Brief Updates from FDA: Updates on FSMA Implementation, Transition to Phase 2 (i.e., implementation of standards and requirements), and the Importance of Metrics

Mike Taylor, Deputy Commissioner for Foods at FDA, provided an update on the timeline for the finalization of the FSMA rules, noting that the Final Rule for Preventive Controls is expected to be released by August 30, 2015 the Produce Safety Rule, Foreign Supplier Verification Program, and Third-Party Accreditation all by October 30, 2015 and the Intentional Adulteration and Sanitary Transportation Rules in 2016. Deputy Commissioner Taylor also updated the group on FDA's transition to Phase 2: (Implementation of FSMA – relative to Phase 1 which focused on establishing standards and requirements for an effective oversight system). He emphasized FDA's dedication to the success of the process and noted that Roberta Wagner, Deputy Director for Regulatory Affairs, and Joann Givens, Acting Regional Food and Drug Director (Midwest Region), Office of Regulatory Affairs, are leading the internal steering committee for Phase 2 and associated planning efforts.

Taylor noted that internal management at FDA is critical, and attention will be dedicated to looking at whether the regulatory system is working effectively and efficiently, and is prevention focused. He also noted the importance of adequate appropriations to the successful implementation of FSMA. Taylor emphasized the importance of identifying the right metrics to evaluate the successful implementation of FSMA. FDA is shifting to an outcomes-based approach of performance management, and public health metrics are central to measuring progress in reducing foodborne illness. He stressed that measures must be meaningful, measurable, accessible, practical, and cost-effective and dialogues, such as the Collaborative Food Safety Forum, play an important role in determining effective metrics and the overall successful implementation of FSMA.

Public Health Metrics: Some Key Considerations and Criteria

Glen Mays, F. Douglas Scutchfield Endowed Professor, Health Services & Systems Research at the University of Kentucky, presented a session on Public Health Metrics: *Key Considerations and Criteria* which discussed general strategies for developing metrics for public health services and systems and specifically the organization, financing, and delivery of public health services at local, state and national levels, and the impact of these activities on population health (click here to view the presentation). He provided an overview of criteria characterizing "good" health metrics, including the following:

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.

Dr. Mays explained that selecting appropriate and effective metrics begins with a logic model - a framework that depicts an understanding of the relationships between a policy's goal(s), available resources, potential activities to make progress towards the goal(s), and the outcomes sought to be achieved. The model should be grounded in the overall health goals of the regulatory action, such as reduced risk of asthma, heart disease, foodborne illness, etc. Once the goals are clear, then the focus shifts to operationalizing the goals, including identifying processes intended to make progress towards the goals. The processes are then mapped to the outcomes to ensure that they, in fact, accomplish the public health goals. A suite of metrics are then determined to measure and analyze the effect of the chosen activities, processes, and structures for achieving improved health outcomes. The set of metrics often is selected to complement one another, balancing relative strengths and weaknesses of each, for an overall robust set of metrics.

Dr. Mays explained the "weight-of-evidence" or "Value of Information" (VOI), approach to select measures based on expected health impacts. He noted that VOI allows evaluators to determine the expected proportional reduction in a health impact or enhanced outcome that is attributable to improvement in the measured activity. Dr. Mays discussed the importance of re-evaluating selected measures, particularly during the early stages of data collection, as well as over time. Early evaluation is important to determine whether the data collected and the associated analyses are tracking with expectations for an effective measure. Dr. Mays also discussed the use of proximal and distal measures, as well as the retirement of some measures no longer useful or relevant, and the relative challenges associated with them. He noted that some measures can lose value as higher levels of compliance are achieved because the measurable change can decrease to undetectable levels, so it is important to periodically re-evaluate the measure to determine its effectiveness over time. He also suggested that some measures that are retired can be revisited periodically to track whether or not they should be brought out of retirement. When asked a question about incorporating change into an evaluation model for food safety over time, Dr. Mays suggested using appropriate analytic strategies to reduce or partially account for the effects of other confounding factors and better isolate a specific measure to determine its true impact.

Dr. Mays walked through an example of measurement selection that the Public Health Practice-Based Research Networks have developed for several measures of high-value public health services provided by public health departments, such as chronic disease prevention, communicable disease control, and environmental health protection. The example of the Multi-Network Practice and Outcome Variation Examination Study (MPROVE) illustrated how selection of a suite of health metrics can strengthen overall evaluation with inclusion of a variety of individual metrics meeting the different criteria listed above. Dr. Mays mentioned that among the metrics for the MPROVE research effort, six important metrics for food safety are included as one of several metrics evaluating policies and programs of public health departments. (Click here to view, "Final Set of Public Health Delivery Measures Selected for Multi-Network Practice and Outcome Variation Examination (MPROVE) Study," for the six important metrics for food safety on pages 5 – 6 (the enteric disease bundle) and 9 – 10 (the food protection bundle)).

In addressing questions regarding how to determine feasibility and whether a cost analysis or subjective analysis is more useful, Dr. Mays responded that he and his team used input from relevant stakeholders to determine how feasible it was to report data on certain measures. When responding to questions on the reliability of foodborne illness data and considering there is little consistency among how and when data are captured by states, Dr. Mays acknowledged the importance of being aware of the bias in surveillance measures and to anticipate biases at the front end to help determine which measures may be more vulnerable and to factor into projections or modeling accordingly. Additionally, when examining the weight of the evidence, Dr. Mays suggested that an expert panel could be used to help identify metrics criteria, determine the relative importance of the criteria, and then rank scores across the criteria to determine a proposed suite of metrics.

Dr. Mays also discussed unintended consequences of metrics and gave an example of New York State identifying the unintended, negative consequence of hospitals only conducting heart surgeries on patients in better condition versus those in more critical need because the survival rates were posted publicly and this biased patient selection and access to care for less-healthy patients negatively. To their credit, New York State identified this consequence and addressed it in their approach. Dr. Mays encouraged the use of reporting initiatives as a way to evaluate the unintended consequences associated with regulatory reporting measures. He also suggested that unintended consequences should

be considered in the early stages of metric development and near-term evaluation included as part of the design so that identification and associated remedies can be conducted in a timely fashion.

Learning from Other Prevention or Risk-Reduction Oversight Models

Following Dr. Mays' broad overview of public health metrics, the next series of presentations were designed to examine prevention and risk-reduction regulatory oversight programs. While all of the programs are relevant to food safety, they were selected to encourage participants to think broadly and creatively about public health objectives and measures for evaluating progress.

Environmental Protection Agency (EPA)'s Office of Pesticide Programs: Performance Measurement

Bill Jordan, Deputy Director of Programs from the EPA's Office of Pesticide Programs, presented performance measurements used by EPA to evaluate the effectiveness of regulatory programs focused on pesticide oversight (click here to view the presentation). Authority for pesticide oversight includes the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Food Quality Protection Act (FQPA), the Pesticide Registration Improvement Act (PRIA), and the Endangered Species Act (ESA). FIFRA regulates the sale and use of pesticide distribution by requiring the licensing and registration of all pesticides distributed or sold in the U.S. Performance measures included in the oversight program range from the reduction of pesticide exposures in the general population to EPA's ability to meet specific strategic targets, such as efficiency in issuing risk assessments. FIFRA uses a hierarchy of measures based on environmental indicators (including health impact and exposure uptake) and administrative indicators which include government's regulations and activities, some of which are outlined in the above mentioned legislation, but also include consideration of broader governmental oversight requirements contained in such laws as the Government Performance and Results Act (GPRA).

Deputy Director Jordan emphasized the importance of establishing measures that are data driven. Such measures can help the Agency understand how well the regulatory program is being implemented and whether it is achieving the public health outcomes, as well as other priorities, such as environmental goals. Jordan provided a summary of targets and benchmarks achieved over time, including such high priority targets as the significant reduction in exposure of children to rodenticides, less pesticide residues in watersheds, and reduced impact on non-target species. In addition to cumulative targets, such as overall reduction of residues, Jordan also gave examples of targeted, non-formal measures, used to evaluate whether Agency actions have had the intended affect. The reduced use of methomyl in strawberries, directly tracking with EPA action, has led to a reduction in pesticide exposure. This example emphasized the value of both formal and non-formal measures to evaluate progress of a regulatory program.

Deputy Director Jordan noted that feedback loops, or mechanisms for evaluation and integration of information for continuance improvement and adjustment, should be established to improve the effectiveness of the overall system and address any problems, unexpected impacts, or other concerns. Jordan ended by stressing the importance of reporting data to the general public that tells a story and is therefore understandable.

Centers for Disease Control and Prevention (CDC) Vessel Sanitation Program (VSP):

Captain Charles Otto, Deputy Chief, Vessel Sanitation Program, Centers for Disease Control and Prevention, provided an overview of the CDC's Vessel Sanitation Program (VSP) and the performance measures used to evaluate the program (click here to view the presentation). The VSP was established according to a 1988 Congressional Directive to prevent the introduction, transmission, and/or spread of

communicable diseases into the United States, and to assist the cruise ship industry in developing and implementing a comprehensive sanitation program. Included areas of evaluation are knowledge of best practices, disease reporting, potable water, pools and spas, food safety and environmental health. A key element of the program design is the inspection and consultation process. A scored evaluation is coupled with time spent on a ship consulting on how to improve safety practices implemented by the crew and thereby reduce potential areas of risk. VSP is also involved in the development of new vessels to ensure innovative ship designs improve workflows and reduces the potential for risk of illness. In addition to periodic, planned inspections, the VSP staff conducts outbreak investigations. Additional surveillance and reporting measures are expected. The VSP program evaluates all of the data from inspections and outbreak investigations to identify additional trends and interventions to improve safety, including better ship design and construction.

A critical aspect of the VSP is transparency, including posting the scores of inspections on the publicly-accessible website: http://wwwn.cdc.gov/inspectionquerytool/InspectionSearch.aspx. The program is fully funded by user fees, approximately $.02 per passenger.

In response to questions, Otto noted that in addition to the public's ability to access inspection data, the industry also uses the data to monitor and benchmark their own fleets against competitors. Additional questions examined whether VSP inspectors are certified and how CDC ensures consistency across inspections. CDC ensures consistency by requiring inspectors to have a strong background in environmental health and participate in a two-month orientation. Each inspector is part of a peer-review team and every inspection is peer-reviewed before being released online. The information that is posted publically includes summaries, narrative reports, and corrective action statements. Captain Otto also noted that if there is a disagreement between what the VSP staff reports and the inspected stakeholder, there is an appeals process that includes supervisor and/ or manager reviews.

Otto stated that each industry fleet has a public health manager with whom the VSP program communicates to share data from previous years' cumulative results and challenges. The VSP program staff uses the information from industry, along with inspection and investigation results, to conduct program reviews and revisions every 5 years.

Captain Otto mentioned that a series of Congressional hearings were held and a number of studies were conducted on the failings of the pre 1998 voluntary system and that subsequently, the CDC's VSP was established. This information also reinforced the design and value of training programs and putting the inspector in the position of educator and enforcer. Training classes are not only conducted for inspectors, but also are offered to industry managers. During these classes, feedback from industry participants has been used to improve VSP staff knowledge, as well as enhanced the overall program.

U.S. Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS): Protecting Public Health and Preventing Foodborne Illness

Dr. Michelle Catlin, Office of Public Health Science, and Dr. Joanna Zablotsky Kufel, Office of Data Integration and Food Protection at the U.S. Department of Agriculture discussed the development and use of performance measures at the Food Safety and Inspection Service (FSIS) at USDA (click here to view the presentation). Specifically they discussed the development of the *All-Illness Measure*, the concept of measuring progress in terms of reduction in total foodborne illnesses associated with FSIS-regulated products (meat, poultry, and processed egg products), and use of the Healthy People 2020 as the public health goal to set food safety performance measures. Accordingly, the *All-Illness Measure* is a summary of all *Salmonella*, *E.coli* 0157:H7, and *Listeria monocytogenes (Lm)* food-borne illnesses

attributed to FSIS-regulated products. Data to develop this measure are collected from within USDA, CDC's surveillance (e.g., FoodNet and FDOSS), other stakeholders in the field, and associations such as the chicken and turkey councils.

The *All-Illness Measure* established baseline measures by examining the case rate for each pathogen (illnesses per 100,000 people per pathogen), attribution fraction (proportion of illnesses attributed to products by pathogen), population estimate (based on 2009 Census), and a fixed scaling factor (pathogen-specific scaling factor adjusted for under-reporting of illnesses). Targets are then calculated per year as well as anticipated progress towards the Healthy People 2020 goals of a 25% reduction in *Salmonella* illnesses, a 25% reduction of *Lm*, and a 50% reduction of illnesses attributed *to E. coli* O157:H7.

Benchmarks are evaluated for years and quarters between the baseline measure and the Healthy People 2020 goals using a linear extrapolation. The total number of illnesses is summed by pathogen to determine the total illness target for each year by pathogen. To develop performance standards, FSIS compares the targeted numbers with actual illness data. In addition to the *All Illness Measure*, the data can be analyzed for particular pathogens and specific product types. This kind of analysis highlights where additional effort needs to be focused.

The FSIS *Salmonella* Action Plan (SAP) resulted from data indicating targeted reductions of *Salmonella* were not occurring fast enough to achieve the Healthy People 2020 Goals. Further analyses of the data also highlighted which product types had higher percentages of prevalence and therefore required more concentrated attention. The risk assessment output measures calculate options for performance standards based on assumptions of industry compliance rates and "allowable positives."

Dr. Glenn Morris provided additional background on the FSIS performance standards, explaining that it started as a technology metric, not a public health metric. It was anticipated that the measure would be adjusted annually; however, annual review and adjustment language was not written into the regulation and therefore became more permanent than anticipated. Dr. Morris further commented that a key lesson learned – and which should be heeded in developing FSMA metrics - was that the regulation should be written in a way that includes the ability to more easily adjust and modify the standards, based on data and an established feedback loop for continuous improvement. Without such language, a a lengthy regulatory modification process is required and stifles necessary updating.

Source Attribution Models for Salmonella serotype Enteritidis (SE) Infections and the Health and Human Services Priority Goals for SE in Shell Eggs

Patricia Griffin, MD, Chief, Enteric Diseases Epidemiology Branch Division of Foodborne, Waterborne, and Environmental Diseases, at the Centers for Disease Control and Prevention, presented on developing attribution models for foodborne illnesses, and specifically for the Department of Health and Human Services *Salmonella* serotype Enteritidis (SE) Priority Goal for shell eggs (click here to view the presentation). She highlighted the challenges of identifying attribution because it can be difficult to detect with full certainty, the source of a pathogen. To improve coordination of federal food safety analytic efforts the CDC, the FDA, and the USDA-FSIS partnered in forming the Interagency Food Safety Analytics Consortium (IFSAC) the focus of which is estimating sources of specific foodborne illnesses. For the SE in shell egg attribution project, IFSAC provided input on data, methods, and time period of analysis. Two models were evaluated, a food contamination model and an exposure model.

Dr. Griffin explained that IFSAC attempted to use the Hald model, which was developed in Denmark by Tine Hald and colleagues, to examine sources of food contamination and design intervention strategies accordingly. Their results have been significant in Denmark and there is interest in applying this model to address SE in the U.S. The goal of using this model has been to effectively attribute *Salmonella* infections to food sources and detect changes in food sources over time. To be successful, the model requires contamination data, data on Salmonella subtypes and food consumption data. IFSAC ultimately did not have the data necessary (contamination and subtype data) to use the Hald model and, instead, used an exposure model, based on food consumption data from NHANES, along with illness outbreaks from FoodNet. This analysis led to an estimated percent of illnesses attributed by food category, and consequently, resulted in a focus on shell eggs as a priority. Griffin stated she continues to believe the Hald model could be very valuable in refining analyses and associated actions if and when the right data are available.

FoodNet was further described as a surveillance system that estimates the number of foodborne illnesses, monitors trends in incidence of specific foodborne illnesses over time, attributes illnesses to specific foods and settings, and disseminates this information. It was suggested that technology can address concerns regarding the lack of attribution data, but it comes at a cost and FoodNet has been impacted by budget reduction issues. Griffin further explained that researchers need more sophisticated models and epidemiological research to be prioritized, continued and improved in order to be effective. Additional input from and comparisons with clinical illness data from state health departments would also be useful.

Public Health Outcome Measures for FSMA

The meeting discussion then shifted from other models and some of their key attributes to a focused discussion of possible public health-related outcome measures for FSMA. To help frame this discussion, comments from a variety of stakeholders' perspectives were given, overviews of which are provided below.

- ***Glenn Morris, Ph.D., Director of Emerging Pathogens Institute, University of Florida*** began with an overview of the elements outlined in the Institute of Medicine's National Academy of Sciences report, *Enhancing Food Safety: The Role of the Food and Drug Administration.* He emphasized the need to identify public health objectives in the strategic planning phase and encouraged FDA to use the Healthy People 2020 goals to inform these objectives. He also emphasized the importance of determining whether public health objectives are being met in the monitoring and review phase of the risk-based approach. He highlighted the importance of creating regulations that provide enough flexibility to permit updates over time without the need to redo the regulation. He also noted the importance of setting up continuous feedback loops and cautioned against relying solely on inspections. (Click here to view the presentation).

- ***Joe Scimeca, Ph.D., Vice President of Global Regulatory & Scientific Affairs at Cargill*** emphasized the need for more research on the casualty of foodborne illnesses in order to better understand which metrics should be established under FSMA, particularly to avoid negative unintended consequences resulting from the publication of the metrics. He described several key insights and lessons learned from the establishment of Cargill's own food safety gap assessment system which has been in place for over 5 years. As part of Cargill's initial effort, a one-year pilot program was launched to evaluate the validity of the preliminary metrics. This pilot helped confirm the value and usefulness of some metrics, based on a number of criteria, as

well as identified some less valuable metrics leading to unintended consequences. As a result of the pilot, some metrics were modified before launching the program. Additionally, Cargill updates and changes their metrics over time based on new technology and information, evolution of their business, and development of enhanced practices. Scimeca also noted there is no "magic-bullet" single metric, and thus Cargill moved to using a suite of a dozen or different metrics, some of which are lagging or retrospective, while others are leading measure of performance. For example, lagging indicators include recalls or "near miss" results, while leading indicators include metrics such as training in food safety, or deployment of preventive programs, like supplier qualification. Cargill also uses objective and subjective information in combination to establish trends and identify areas needing more attention and intervention. One important measure, Scimeca highlighted, is organizational food safety behavior and culture. Inputs to evaluate this can include management commitment as determined by involvement of top management in food safety meetings at plant sites, as well as the kind of communications used by managers with regard to the nature and importance of improvements in food safety.

- ***Jim Gorny, Ph.D., Vice President, Food Safety & Technology, Produce Marketing Association*** pondered what the targets for FSMA implementation should be that are most meaningful, appropriate, and can encourage progress, including whether the measures should be similar to what FSIS uses – the Healthy People 2020 Goals –and which are already established, or something more FSMA-specific that would be developed. He emphasized the importance of determining baselines for key metrics in order to track progress and that performance measures should evaluate and track behavior changes, as well as specific outcomes. He emphasized that metrics do matter, so choosing them carefully is critical, and cautioned that motion does not equal progress.. In establishing behavior change metrics, FDA should think about what really drives food safety improvements and where most important (the market place, compliance with regulatory requirements, lawsuits, consumer confidence). Challenges Gorny highlighted, include evaluating how effective metrics are over time and being able to modify accordingly if they are over or under protective; how component inspections will be developed; what data will support which metrics (i.e., reduced morbidity and mortality from foodborne illness – how can change be attributed to FSMA-related actions?); how evolution of new technologies will be incorporated; and how all of this information is communicated to the public and its impact on their view of the safety of their food. Additionally, Gorny noted that the models for determining attribution are only for one agent and one food – indicating just how complex metrics for FSMA will be to determine given the broad variety of food products the law covers.

- ***Karin Hoelzer, DVM, Officer, Safe Food Project at The Pew Charitable Trusts*** acknowledged the challenge faced in establishing public health metrics initially, particularly given limited accessible data. She suggested a tiered strategy could help alleviate this challenge. In the near-term, measures of reductions in product contamination could be used, and in the medium-term, metrics drawing on data collected during inspection (to assess industry's level of food safety control) could provide key information. For example, industry performance on recalls could be used as surrogate measures while more specific metrics are established and data collected. According to Dr. Hoelzer, product contamination measures are available more immediately than outbreak or recall data and are directly relevant to stakeholders, while the challenges include the need for baseline and historical data to measure trends and data sharing across the public and private sectors. Longer-term metrics could include root cause analyses of 'near misses' along with other aspects of industry performance assessed during inspections. In developing FSMA metrics, Dr. Hoelzer stated there are opportunities to learn from other industries with

similar challenges regarding high impact, rare events including airline, nuclear, and auto industries, or from other areas such as hospitals that have been trying for some time to learn from these industries. (Click here to view the presentation).

- ***Suzanne Thornsbury, Ph.D., Economist, Economic Research Service at the U.S. Department of Agriculture*** discussed a pending project of the Economic Research Service (ERS) and the National Agricultural Statistics Service (NASS) that will survey approximately 12,000 growers in order to update and document current food safety practices in the U.S. produce industry, including grower and post-harvest information. This project will update information gathered from a 1999 survey, is pending final budget approvals, and the results are anticipated to be released in summer 2016 (fruit) and 2017 (vegetables). Dr. Thornsbury noted that the survey results will provide a pre-FSMA look at produce food safety practices, including those that may exceed FSMA requirements, as well as provide a baseline for an assessment of FSMA implementation. Information will be collected on water use, soil amendments, food safety training of staff, staff size, and other information. Survey results will include comparisons of food safety practices for different size farms and post-harvest operations.

Discussion followed the series of opening comments and covered a wide range of considerations for selecting public health-related metrics for FSMA. Beginning with the preceding presentation, the group was very enthusiastic about the survey described and hoped it would move forward to gather information for updated, baseline information on current, pre-FSMA on farm food safety practices is viewed as quite important.

To the broader topic of top tier public health-based metrics, many participants encouraged a focus on the reduction of risk, rather than only the number of illnesses, stating that a prevention focus is best achieved through reducing risk of foodborne illnesses. Others – including those supportive of reducing risk – noted evaluation of risk reduction is challenging, but also suggested predictive modeling could assist in this kind of framework. Participants also noted that as more scrutiny and effort, along with more sophisticated technology, is applied to evaluating risk and risk reduction, most likely and particularly initially, more problems will be identified, and therefore communication to the public is critical so as not to give the impression the food safety system is becoming more unsafe. Some participants also noted that while some technology is being developed that could be very helpful, some key technologies, such as culture diagnostics, are eroding due to lack of resources and a shift to technologies with particular attributes, such as more rapid results.

Some participants encouraged a tiered approach, but had different views of what information would be most relevant to review. Some cautioned against relying on contamination levels for metrics because, in some cases, the low prevalence of detectible pathogens – particularly with produce – could prohibit meaningful data collection. While some thought recalls could be a good metric, including both the number of Class 1 recalls and the scope of such recalls, others cautioned against using recalls as a metric for inspection performance to prevent overly emphasizing number of recalls as a driver of the system. Comments also addressed the interest in providing industry the opportunity to take corrective action in the event of identification of a problem and potential outbreak. Further, information regarding an outbreak should be made available to establish transparency and to encourage broad understanding of root cause analysis, if possible, and translation to better food safety practices in a more rapid cycle.

Participants also discussed tracking progress in overall development of a food safety culture, including building knowledge and uptake of food safety practices. Additional indicators of improved food safety

culture is not only volume of tests conducted for verification, but behavior when tests are positive for a pathogen or a related surrogate, and ability to problem solve and address the issue to reduce risk. A suggestion was made to combine multiple indicators in a "dash board" approach that could include tracking process failures, best practices adoption, high priority or high risk foods, number and severity of foodborne illnesses, increased number of root cause analyses and translation into improved practices. Collectively, the dash board could indicate improvements in food safety culture, including improved development and adoption of best practices, along with concurrent reduction of risk and severity of foodborne illness.

Participants also expressed interest in drawing from other models, such as the one used by the airline industry because they have one body, the Federal Aviation Authority (FAA), to set standards and another, the National Transportation Safety Board (NTSB), to investigate prevention failures or accidents. This model was thought to be a good one in that it focuses attention on rapid investigation and root cause analyses and subsequent implementation of improved safety measures – features participants encouraged FDA to adopt for FSMA oversight.

Other participants noted that changes in behavior and increased food safety culture, should involve more dialogue, information exchange, and problem-solving during inspections. Participants also commented that extensive documentation would create a burden for small businesses with fewer resources and suggested using metrics that encourage participation in the food safety oversight system, such as demonstrating knowledge of food safety requirements and best practices, rather than using requirements that could drive small business to seek exemptions from the rules because of punitive or overly burdensome requirements.

Discussion circled back to the importance of communicating efforts more broadly and to the general public that places food safety efforts into context. A challenge repeatedly highlighted was how to communicate to the public that increases in the number of outbreaks identified may actually be a positive outcome of FSMA and indicative of a critical step in increasing knowledge regarding producing food safely and reducing risk. Ideally, the story to be communicated, is that we collectively (i.e., all stakeholders) are getting smarter about how to produce safer food and are doing so more effectively, and that the metrics will ultimately support and reinforce these conclusions.

FDA Thinking to Date on Public Health Outcome Measures

The afternoon continued with an informational session from FDA on their work to date regarding the development of public health-related outcome measures, with a particular focus on "top tier" metrics. (Click here to view the presentation).

Roberta Wagner, Deputy Director for Regulatory Affairs, FDA, began by underscoring that the ultimate goal of FSMA is to reduce preventable foodborne illness through the development and use of an improved, risk-informed food safety system. She reviewed FDA's vision and action plan for implementing the new risk-informed food safety system, including developing strategic goals, setting priorities, formulating a budget, setting specific risk-informed priorities, executing activities and determining prioritized resource allocations, and measuring progress and activities. Sherri McGarry, Senior Advisor, Office of Foods, FDA, continued with a more detailed overview of the strategic program plan and highlighted its focus on results to better inform planning, management and reporting. As part of this process, outcomes are prioritized with performance indicators of tasks considered critical for

achieving the results. In other word, FDA is using a logic model to shape their performance measures framework.

Ms. McGarry presented FDA's draft results frameworks for Preventive Controls and Produce Safety. Questions focused on understanding how outcomes were presented and integrated into the frameworks and how each step reduces risk of illness attributed to food from facilities subject to the preventive controls or produce rules? While the frameworks indicate that the foods evaluated are those that fall within the scope of FSMA, all acknowledged the challenge of confounding factors, such as not all foods or facilities included under FSMA due to exemptions, and subsequently affecting analysis of attribution of impacts from requirements and improvements in public health-related metrics. Modeling most likely will need to be used, in combination with specific data, to account for some of these variables.

It was suggested that the framework should include, in addition to measuring performance, measuring the impact of FDA's performance on its overarching goal of reducing risk of foodborne illness and to continually evaluate what is being measured and what should be measured. Other comments highlighted the importance of integrating feedback loops and a mechanism into the framework that will allow for updating and changes based on information and analysis. Ms. McGarry responded that the frameworks are anticipated to be re-evaluated every 3-5 years which will include ensuring alignment to the Food and Veterinary Medicine's Strategic Plan, and she encouraged the CFSF group to help FDA generate ideas for how best and how frequently the framework should be reviewed and, if appropriate, updated or modified.

Ms. McGarry next turned to the top tier metrics in the draft Preventive Controls (PC) Framework. When asked what evidence and data FDA used to develop the framework. Ms. McGarry responded that the FDA team that developed the Framework drew from multiple and diverse sources of information, and the team was comprised of representatives with a diverse range of expertise and included state level public health and agricultural experts to develop the Framework. Dr. Wagner also added that the FDA is committed to including the right skills and expertise to further develop the Frameworks. *(Note: a link to the Preventive Controls (PC) Framework will be included in the final summary).*

It was also suggested that FDA consider adding an action plan to the PC Framework to address unexpected outbreaks. For example, FDA could convene a stakeholder advisory group that includes industry and government members to reevaluate the Framework, identify new measures to be included over time and employ a measure of success that includes identification of more outbreaks – indicating a more sophisticated effort and ability to detect and evaluate outbreaks.

FDA noted that this kind of feature is included in the current Framework under the box labeled, "*Increased Transparency/Info Exchange Related to Preventive Controls Rule for Emerging Issues between Regulatory Agencies, Public Health Organizations, and Industry.* "Deputy Director Wagner and others noted that this piece of the Framework should be moved into the foundational section (at the bottom of chart), as it is critical (i.e., "foundational")to overall success.

Ms. McGarry moved to a brief overview of the Produce Safety Rule Draft Strategic Framework, indicating the approach to the Framework is very similar to the PC Framework and noted the opportunity to provide more detailed feedback in the upcoming small group discussions. FDA cautioned that the draft metrics were very early in the development stage relative to the Preventive Controls Framework. She also noted that it was FDA's goal to maintain consistency in the strategic objective of

each rule and would be reflected in the next iteration of the top tier language. *(Note: a link to the Produce Safety Rule Draft Strategic Framework will be included in the final summary).*

Ms. McGarry noted a variety of challenges to establishing effective FSMA metrics and performance measures and encouraged participants to assist FDA in identifying the most meaningful public health measures that indicate progress with FSMA implementation overall, as well as link directly to the individual rules and provide enough flexibility to allow for change. She explained that the challenges inherent in identifying preventive measures include existing data limitations, the fact that measures rarely tell the whole story, that there are differences in each of the four rules i.e., (Preventive Controls, Produce Safety, Imports, and Intentional Adulteration), accounting for exemptions and modified requirements (as well as other confounding factors), and involve different sources of data collection (i.e., federal and state governments, as well as data from the private sector).

Participants first reacted to the different language used for the different strategic objectives across the programs. FDA again emphasized that it is very early in the development of these objectives and the language has not been refined – but will be. Participants identified additional challenges with meeting the draft strategic objectives, including variability in the conduct of inspections. Deputy Director Wagner agreed that moving forward with implementation can provide a significant opportunity for cross training and education of the inspection corps, and that FDA, CDC, and the States need a consistent and clear, compliance and inspection strategy to drive consistency across federal and state governments. It was also noted that a strong data infrastructure that supports adequate sharing is critical. Deputy Director Wagner assured the group that FDA is developing data sharing platforms with the States to build an integrated system.

A challenge raised by participants was whether FDA's goal is to measure the reduction of risk or the reduction in the number of illnesses. Ms. McGarry responded that FDA wants to measure the reduction of risk, but also said that the best way to measure this is unclear. Dr. Wagner commented that she believes FoodNet may be able to provide supportive data, along with other data inputs. Participants cautioned that if predictive modeling is used that appropriate communications ensure consumers do not equate the findings as actual, rather than reduced risk of deaths/ illness/injuries. Ms. McGarry suggested a possible approach could be to release to the public higher level results in context, while maintaining more granular data sets internally that could be used to identify gaps in the existing Frameworks. This information could be shared with academia, industry, and other stakeholders to help identify gaps. Concerns were raised however about only focusing on risk because predictive models are limited by the quality of the assumptions made. It was expressed that there is value in measuring both reducing risk and the reduction of illness.

Resource constraints and limitations for state public health departments in helping FDA and CDC to implement FSMA were identified as critical challenges. State and local health departments are on the front line for outbreak inspections and data collection, but health department budgets have been cut substantially over the past few years.

The morning of the second day of the workshop began with a reassessment of the agenda, which was updated to reflect the progression of the conversation and address questions posed by participants. The first half of the morning was set aside for a continuation of the presentation by FDA, followed by small group discussions of developing metrics on the Preventive Controls and Produce Rules.

Ms. McGarry again encouraged participants to assist FDA with 1) determining prioritized criteria for the "best" measures, 2) identifying the kinds of data needed to support those measures and inform analysis of key indicators, 3) determining evaluation of progress, 4) identifying the biggest areas of concern and how to address them effectively, 5) formulating more positive measures, 6) collecting and providing data supporting key, and 7) highlighting aspects or components of the Preventive Controls and Produce Safety rules (as well as the other rules over time) that are most important for key, meaningful measures.

Comments from participants included cautioning against using zero foodborne illnesses as a metric or goal to determine whether FSMA has been fully implemented or successful. It was noted that costs incurred during an inspection of small businesses can be high and that FDA needs to consider the costs and benefits of each public health measure established. Multiple measures should be determined and should be divided into categories for the near and long term. Examples of long-term measures could include facility hygiene or equipment design.

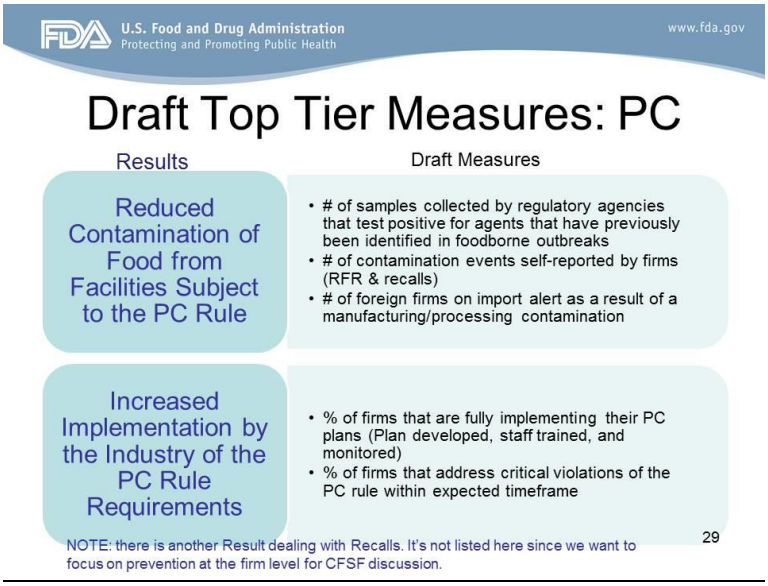
It was also stressed that FDA clarify whether high-risk foods are considered high-risk because of the product itself or because of the type of processing used. Furthermore, developing process measures that would allow high-risk foods to be exempt or have a lower risk profile, if a company could demonstrate satisfactorily that the process includes steps that reduce risk of the food. It was also suggested that mentoring of smaller businesses by larger businesses should be encouraged and evaluated as part of advancing towards an enhanced overall food safety culture.

Work Group Discussions and Reports

Given the fullness of the previous day's agenda, participants did not break into work groups organized around Preventive Controls and Produce Safety until the second day and following a brief re-cap of the previous day's deliberations. Participants then self-selected one of the two small discussion groups and spent around seventy-five minutes in those groups. Key highlights from the two sessions and reported out from each of the groups are below.

Preventive Controls Program Work Group: Metrics, challenges and possible solutions

Participants in the Preventive Controls small group discussion began with a review of the *Draft Top Tier Measures for Preventive Controls*.

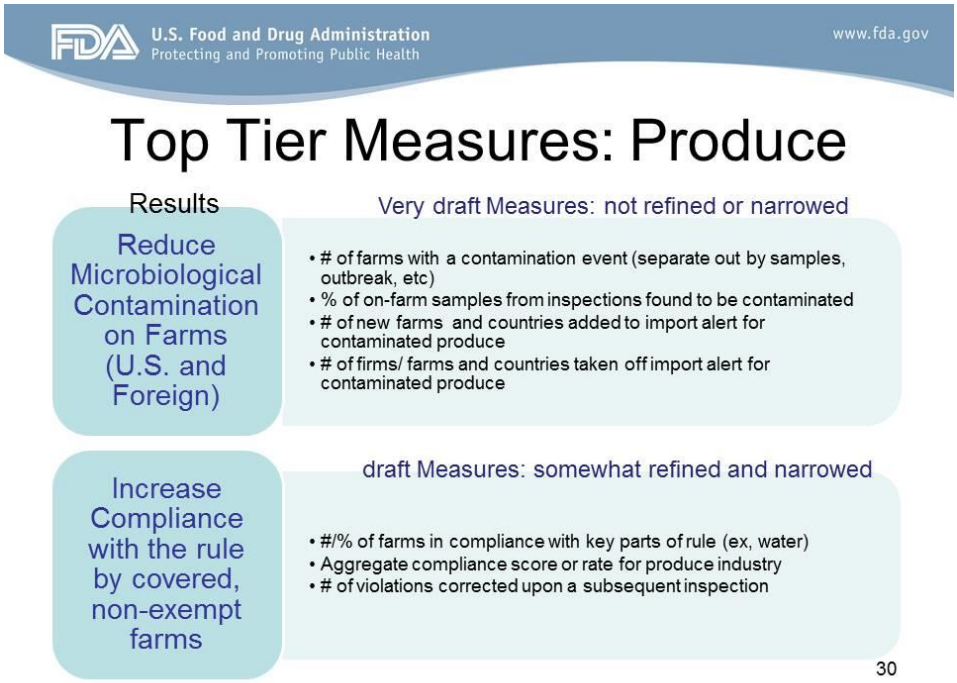


The draft measure of examining the *"number of samples collected by regulatory agencies that test positive for agents that have previously been identified in foodborne outbreaks"* which is proposed to evaluate whether FDA meets the goal of "Reduced contamination of food from Facilities Subject to the PC Rule" raised concern among participants because of the potential for creating unintended consequences from the over emphasis on testing. The group did, however, believe that the proposed measure, "*number of contamination events self-reported by firms (RFR and recalls)"* provided a better measurement of reducing risk of contamination of food from facilities that are subject to the PC Rule. When addressing the" *number of foreign firms on import alert as a result of a manufacturing/processing contamination,"* the group thought it would be better to measure or track the percent of foreign firms on import alert as a result of violations detected by inspections – indicating more foreign firms are on the radar and working towards compliance.

While addressing the second listed result in the slide above, "Increased Implementation by the Industry of the PC Rule Requirements," participants thought measuring the percentage of firms fully implementing their PC plans (i.e., Plan developed, staff trained, and monitored), should be changed to "*percentage of firms (domestic and international) that are fully implementing an adequate PC plan as defined by the regulation*." Additionally, the group identified the need for a second measure to evaluate the "*percentage of firms that address critical violations of the PC Rule within an expected timeframe*."

Produce Safety Program Work Group: Metrics, challenges and possible solutions.

The small group discussion on FDA's preliminary draft metrics for the Produce Safety Rule examined the top tier metrics slide below and provided their observations and ideas to the larger group.



The work group participants began with an overall grounding of general outbreak data, as well as specific produce-related outbreaks of foodborne illnesses. Dr. Griffin stated that approximately 800 illness outbreaks occur each year, with approximately 50% food-related, many of which are categorized as "complex," meaning the specific vector or food component causing the illness is not known. Dr. Griffin also summarized the range of data tracked, including illnesses confirmed to be attributed to fresh produce; illnesses thought to be, but not confirmed, associated with food; illnesses associated with particular foods; and, risk of illnesses from all of produce. Furthermore, there are about 300 to 350 pathogens that have been found in food. The most significant pathogen carried by contaminated food is norovirus – which is a particularly complicated target to address because it is transmitted by infected humans in close proximity to other humans and not particularly linked with fresh produce or food.

The "hard" numbers, or those that are directly traceable to have caused an outbreak, are too small to detect year-to-year changes. Participants, therefore, suggested that FDA consider looking at outbreak data in five year blocks of time to determine whether reductions have occurred.

The group also concurred that there could be value in measuring both reductions in occurrences of illness as well as reduction in risk, and that risk analysis must be clear about what is meant by "risk." Modeling will require multiple data streams and could enable identification of particular patterns or highlighted problems that need to be addressed and, thereby, reduce risk. Data important to include are consumption patterns of various categories of food, not only for produce generally, but also for categories of fresh produce. Without such data, exposure cannot be calculated accurately and, therefore, risk cannot be quantified effectively.

Result one in the Produce Safety Framework, states, "Reduce Microbiological Contamination on Farms (Foreign and US)," and participants had multiple suggestions for modification. Work group participants discussed what constitutes and how to measure "contamination." It was suggested to change

"contamination" to adulteration, but after some discussion about the benefits and drawbacks, the work group decided not to use "adulterated" and focused on other language or changes. It was suggested that FDA should consider modifying result one from "Reduce Microbiological Contamination on Farms (U.S. and Foreign)" to "Reduce Microbiological Contamination of Fresh Produce that could Pose Risk to the Consumer."

Reducing the risk of microbial contamination that poses risk to consumers is the primary goal. Microbial pathogens known to pose risks include *E. coli*, *Salmonella*, *Campylobacter*, and *Listeria monocytogenes (Lm)*. The work group participants also noted that surveillance should include identification of any emerging pathogens – either those known and becoming an increased risk to consumers, or those previously not known but becoming more prevalent and posing a potential risk.

Measure three evaluates the *"number of firms/farms and countries taken off import alert for contaminated produce."* First, participants thought an important indicator should include finding more contamination on farms and including more farms or countries with farms where problems are detected on alert lists. Including this variable is important because it would indicate that oversight is becoming more thorough, it would encourage proactive identification and transparency of problems, and consequently it would lift up problem areas to be addressed. Participants thought this detection would be done by sampling at sites. It was also noted that FDA should track its success in detecting smaller outbreaks because an increase would indicate growing sophistication in tracing outbreaks to the food source. This increase in detection could serve as a positive measure in FDA's metrics framework for produce.

Draft Measure one which states, "*number of farms with a contamination event (separate out by samples, outbreak, etc.),"* should include an evaluation of the identified pathogens known to pose a risk, as well as allow for inclusion of other pathogens as they emerge.

Result two, "Increase Compliance with the Rule by Covered Farms, non-exempt farms," was identified as needing more and better data. While Good Agricultural Practices (or GAPs) was highlighted as a potential source of this pre-assessment or baseline of information, there currently exists a variability of interpretation of terms associated with GAPs, and therefore, using data is complicated and will require alignment. The National Agricultural Statistics Service (NASS) was identified as a potential source for this information.

Work group participants also discussed how best to collect compliance data and what could constitute a "reliable audit" as part of confirming compliance. Self-audits, second- and third-party audits all have the potential to provide useful information and there needs to be some basic criteria for data from any source to meet that gives the Agency and all stakeholders' confidence in the data. Some of the basic criteria should include achieving standards for quality of information, competency of those conducting the audit, and transparency and reduction of any conflicts of interest. Work group participants suggested that the requirements being put into place for Third-Party Certification might be tailored to establish for audit information gathered domestically for compliance data for farms – exempt and non-exempt. Additionally, participants encouraged mechanisms to foster and incentivize data sharing. Such ideas included receiving some kind of credit, as well as the confidentiality of the data.

Finally, Produce Safety Rule work group participants encouraged FDA and all stakeholders to consider the scope to be all farms, not just those that are not exempt by law. Encouraging good practices and promoting safe food should be of interest to all stakeholders and facilities and growing operations.

Next steps suggested to build on this workshop's discussion included the following:

- Continued deliberations on top tier metrics, including across all of FSMA, as well as for each of the rules. Discussions could include clarifying the priority outcome measures of reduce illness and/or risk of illness, identifying key performance measures that indicate progress toward the health-related outcome metrics, and, in combination, meet a range of criteria for good public health-related measures for evaluating implementation progress of FSMA in achieving improved public health outcomes. Additionally, deliberations would focus on building support for robust metrics, such as collection of and access to data to set baselines and evaluate progress, periodic evaluation of the value and appropriateness of the determined suite of measures, and integrating evaluation results into refined measures and improved food safety practices; and.
- Developing a collaborative process – similar in approach to developing the Supply Chain Consultation Process by the CFSF - for root cause analyses of foodborne illness outbreaks that could help facilitate the root cause analysis process and leverage information and insights gleaned from such analysis to improving food safety practices.

Before the close of the meeting, Sandra Eskin and Pamela Russo thanked participants for attending. Abby Dilley noted a draft summary will be circulated for review for corrections before being posted to the project website. Additionally, next steps for the Collaborative Food Safety Forum to build on this conversation will be proposed in the near future.

The meeting adjourned at 1:00 pm.

Appendix A: Final Participant List

Participants

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*Speaker

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Observer
Jamie Butler

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*Speaker