

- 2012 - 50-STATE WORKSHOP

August 15-17, 2012
WORKSHOP
Nashville, TN



Food Protection



Local Coll





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MESSAGE FROM THE PFP EXECUTIVE COMMITTEE

On behalf of the PFP Coordinating Committee and the Food and Drug Administration, it is an honor and privilege to provide the report from the 50-State Workshop held on August 15-17, 2012, in Nashville, TN. The Workshop goal was to review accomplishments of the Partnership for Food Protection (PFP) Workgroups and develop implementation plans for critical components of an Integrated Food/Feed Safety System (IFSS).

Over 200 representatives from local, state and federal food regulatory agencies attended the workshop. We appreciate everyone taking time out of their busy schedules to participate and look forward to continuing our work towards implementing an integrated food safety system. The Workshop agenda, presentations and meeting information are available at:

<http://www.fda.gov/ForFederalStateandLocalOfficials/Meetings/50-StateMeeting/default.htm>

Electronic links are also included for documents that are currently available online.

Workshop highlights in the report include:

- Summaries of keynote presentations from local, state and federal food regulatory officials;
- An update from the IFSS Task Force;
- Accomplishments of the PFP Workgroups
- Breakout Sessions Summary Results

Recommendations from the breakout sessions will be reviewed by the PFP Executive Committee. The PFP Executive Committee will identify top priorities and assign them to workgroups. For more information and updates on the Partnership for Food Protection go to:

<http://www.fda.gov/ForFederalStateandLocalOfficials/Meetings/50-StateMeeting/default.htm>

A list of the PFP Coordinating Committee members and their contact information is also on the web site at:

<http://www.fda.gov/downloads/ForFederalStateandLocalOfficials/Meetings/UCM304989.pdf>

...and included in this report.

Thank you for your participation, leadership and commitment to enhance food safety in a globally integrated food safety system through efforts of the PFP.

PFP Executive Committee

Brian Collins (Plano, TX), Jeff Farrar (FDA), Tracey Forfa (FDA), Oscar Garrison (GA), Pat Kennelly (CA), Joseph Reardon (FDA), Robert Waltz (IN)

SPECIAL THANKS TO THE PLANNING TEAM AND SPEAKERS

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EXECUTIVE SUMMARY

The Partnership for Food Protection (PFP) held the 2012 PFP 50 State Workshop from August 15-17, 2012 in Nashville, TN. The Workshop brought together regulators and public health professionals from federal, state, local, and territorial agencies with a wide range of expertise in food, feed, epidemiology, laboratory science, veterinary science, environmental science, and public health. This was the fourth 50-state workshop that the U.S. Food and Drug Administration (FDA) has sponsored since 1998. The 2012 PFP 50-State Workshop was an opportunity for partners from all disciplines of food safety and public health to work towards the implementation of an Integrated Food Safety System (IFSS).



The workshop began with opening remarks from state, local, and federal food regulatory program leaders who provided their perspectives on the history, value, and current status on national and global integration initiatives. Leadership from the Integrated Food Safety System Taskforce described their role as a high level taskforce charged by FDA Commissioner Margaret Hamburg to identify potential solutions FDA can use to improve its business processes for integration. The IFSS Task Force leadership, comprised of local, state and federal officials, provided an overview of a balanced process approach the Task Force used to identify strengths and weaknesses in the current food regulatory system, and outlined five overarching recommendations for FDA to enhance their integration efforts. PFP Work Group leaders, representing the ten PFP workgroups, presented the progress each group had made since the 2010 50-State Workshop.

Project highlights presented on Day One are described below:

- **Information Technology** – Developed the “Business Process Evaluation and Improvement Tool for Inspection Systems”, designed to help state and local programs gain a detailed understanding of their program’s business processes and serve as a mechanism to form requirements for information technology (IT) system improvements or new developments.
- **Laboratory** – Drafted a national standard guidance document to assist state laboratories build quality laboratory programs and leverage resources amongst local, state, and federal laboratory partners.
- **National Standards** – Completed a comparative analysis of current food program standards in the U.S. and recommended areas for harmonization related to outbreak investigation and response, industry and community outreach, and training of inspection personnel.
- **National Work Planning** – Developed a process for FDA, State and local work planning to promote integration and developed an assignment on domestic import sampling of animal feed to facilitate sharing of sample data across regulatory agencies.

- **Oversight** – Drafted a white paper defining the audit processes in the Manufactured Food Regulatory Program Standards (MFRPS) and created a Model Good Manufacturing Practice (GMP) Inspection System Process to assist states with inspection procedures, training and auditing materials.
- **Performance Measures and Outcomes** – Identified several performance and outcome measures to assess progress in an integrated food safety system.
- **PETNet** – Developed PETNet, a secure, web-based network that enhances rapid response to adverse events associated with pet food products by allowing a more efficient exchange of information between federal and state regulatory agencies.
- **Policy & Procedures** – Developed an information sharing procedure for the PFP to use to share information related to integration success stories and the work of the PFP.
- **Response** – Developed a Quick Start Response Guide, a visual tool to enhance rapid response communication and capabilities by food, epidemiology and laboratory programs. The workgroup also drafted a traceback white paper and a tool to facilitate records collection.
- **Training & Certification** – Developed a process to identify and prioritize training and certification needs for inspectors and investigators. Updated the training curriculum framework with competencies linked to FSMA.

On Day Two, participants with varying expertise were separated into six subject specific breakout sessions and charged with creating collaborative operational processes that could be implemented across government agencies. The topics included integrating routine workplanning, formulating a common data set for use in regulatory activities, implementing a joint inspection process, implementing integrated compliance and enforcement processes, generating a cross-jurisdictional after action review (AAR) process, and developing an implementation plan. The sessions produced valuable insights with each breakout session presenting a summary of its recommendations to the larger group on Day Three. The PFP Executive Committee is currently reviewing the recommendations from each breakout session and the recommendations are being considered for implementation.



BACKGROUND ON THE PARTNERSHIP FOR FOOD PROTECTION



Building an integrated national food safety system has long been a foundational element of our nation's strategy for carrying out an effective and efficient food safety program. It is also one of the key mandates of the new FDA Food Safety Modernization Act (FSMA). Such a system is premised on building full strategic and operational partnerships with federal, state, local, tribal, and territorial food safety agencies – an effort in which FDA has been engaged for the last decade through the Partnership for Food Protection (PFP) and other initiatives. While American consumers enjoy one of the safest food supplies in the world, further integration of state, local, and federal food safety efforts along with a greater focus on prevention will be necessary to enhance public health protection in our global food safety system.

In 1998, FDA hosted the first 50 State Meeting in Kansas City, Missouri bringing together state, local and federal officials to make recommendations for improving the coordination of foodborne outbreak investigations and responses. This group recognized the need for an integrated food safety system (IFSS) encompassing all levels of government, but it was not until 2007, when the nation was facing several major foodborne illness crises, that this initiative received greater attention. These large scale foodborne illness outbreaks also brought greater public awareness of the complexity and ever increasing global nature of the food supply. That same year Congress incorporated specific food safety items into the FDA Amendments Act (FDAAA), and FDA produced the Food Protection Plan (FPP) which focused on prevention, intervention and response. Coordination among state, local and federal officials is essential to protecting consumers in our highly diverse and globalized food system. FDA works closely with state and local food regulatory programs to regulate \$417 billion worth of domestic food and \$49 billion worth of imported food each year — everything Americans eat except for meat, poultry, and some egg products, which are regulated by the U.S. Department of Agriculture (USDA).

At the 2008 50-State Meeting, public health partners were asked to make recommendations on implementing the FPP. Recommendations from the meeting led to the establishment of the Partnership for Food Protection (PFP), a group of dedicated officials from all levels of government who were charged to build the foundation of an IFSS. The PFP includes an Executive Committee, a Coordinating Committee and Workgroups. By September 2009, President Obama had established the Food Safety Working Group (FSWG) to serve as a central coordinating mechanism for the federal government's food safety activities and FDA, with PFP support and considering FSWG findings, drafted a vision for a national IFSS that included strengthening inspection, laboratory, and response capacity. Participants at the 2010 PFP 50-State Workshop built on the progress of the existing PFP workgroups by providing advice and recommendations on various elements of the IFSS vision, including integrating response efforts, conducting joint investigations, and measuring outcomes.



In 2011, President Obama enacted the FDA Food Safety Modernization Act (FSMA), which holds FDA accountable for taking the IFSS vision and creating operational processes that will help bring the vision to reality. FDA acknowledged that it cannot do this alone. The President and agency's commitment towards quality, communication and collaboration with partners in state and local food safety and public health agencies is vital for addressing the challenges arising from federal-state-local integration, supporting the PFP work, and ensuring the success of FSMA.



The focus of the 2012 PFP 50-State Workshop was to move integration from the conceptual development phase to putting these new practices into operation. Everyone readily acknowledged that this cannot be accomplished by FDA alone. These practices will need to be operationalized across all levels of government for an integrated food safety system to truly exist. To ensure that all voices were heard and represented, it was crucial for government officials to be able to come together at this workshop to focus and prepare for the operational phase of the IFSS. Outcomes needed from the workshop included proposed pilot projects to test concepts and recommendations for implementing core processes for joint workplanning, joint inspections, sharing regulatory information, and conducting after action review meetings. The workshop served as a mechanism to ensure that all stakeholders at all levels of government are involved in this development, that the PFP has a clear direction for the next phase of the IFSS, and that the IFSS message reaches the appropriate audiences.



KEYNOTE MESSAGES

Brian Collins (Plano, TX) - This was Brian's third PFP workshop, and he shared his perspective on this Workshop being a turning point in history. He provided a background on the Partnership for Food Protection beginning in 1998, with the first meeting in Kansas City. He acknowledged that preventive controls are still few and that agency staff losses have added an additional burden. Mr. Collins reminded attendees there are still communication problems and insufficient laws that needed to be addressed and asked them to reach into their passion and turn the PFP and FSMA into an integrated food safety system.

Oscar Garrison (GA) - Oscar recalled his first 50-state meeting and noted that we learn from what we do at all levels of government. We roll together to make the operation right for a public health outcome instead of being concerned about who does what. Mr. Garrison asked participants to put their heart and soul into the next few days, and he acknowledged that we need to build a system in which we are preventing, not just reacting, to gain consumer confidence. As we build our food safety system we need to rely on each other as subject matter experts and communicate with each other. He quoted Warren Buffet who said "Risk comes from not knowing what we are doing."

Mike Taylor (FDA) - In his keynote address to the 2012 PFP 50 State Workshop, Mike Taylor, Deputy Commissioner for Foods and Veterinary Medicine, congratulated attendees on their many accomplishments since the group first gathered in 1998 and spoke about the passage of the FDA Food Safety Modernization Act (FSMA) in 2011. "To build a successful food safety system," said Taylor, "we need specific mandates that build accountability into the system." He stated that it was a privilege to work on this challenge and reiterated that this was a turning point meeting. He told attendees that "We need to take the vision and operationalize to fulfill this vision. We need to take a few minutes to celebrate where we are and to feel the motivation needed to carry this work forward." Mr. Taylor referenced the formation of the PFP and acknowledged the dedication and efforts of the ten PFP workgroups. He also referenced the progress made to date on existing collaborative models such as the Rapid Response Teams (RRTs), the Manufactured Food Regulatory Program Standards (MFRPS), and efforts for joint inspection planning by states and FDA Districts. "FSMA challenges us to operationalize the vision going forward." He stated that many challenges still remain to be overcome, thus the reason for this workshop. His final reflection on the process was that working with three thousand food agencies was not easy. "It's a day-by-day and step-by-step process. We're on a long-term pathway. I'm pleased to see our local, state and federal partners meeting. We're all in it together."



Deborah Autor (FDA) - In her keynote address, Deborah Autor, Deputy Commissioner for Global Regulatory Operations and Policy thanked the planning team, the PFP Executive Committee and the IFSS Task Force for the workshop and stated that it was an honor and privilege to attend. She acknowledged that much has changed since 2010 because of FSMA. FDA has a new structure for global food safety. Much of the food consumed in our country is imported. In the last 10 years, imported food has increased significantly. She stated that collaboration is key to food safety. The building block, harmonization of standards, is the blueprint. It's a shared responsibility between agencies and the private sector. She told the PFP audience to rely on each other and use short - and long-term tools such as state enforcement procedures to embargo food. We need to use and leverage epidemiology, laboratory, and technical and scientific resources. Our ultimate goal is public health. Preventive controls are one proactive tool given to us by FSMA. Warning letters and education are long-term tools. Collaborative efforts need to be rewarded and Federal-state cooperation requires broad coalitions. She asked everyone to remember that food safety is not just domestic, it is global. "We have to leverage resources and collaborate with each other - there is more to be accomplished. "



REPORT AND DISCUSSION ON THE FINDINGS OF THE INTEGRATED FOOD SAFETY SYSTEM (IFSS) TASK FORCE

Presented by Jeff Farrar, Joe Reardon, Melinda Plaisier, Robert Waltz, Pat Kennelly, Roberta Wagner

Jeff Farrar (FDA) - In September 2011, Commissioner Margaret Hamburg charged Mike Taylor, then Deputy Commissioner for Foods and Deborah Autor, the Deputy Commissioner for Global Regulatory Operations and Policy, with establishing a high-level IFSS Task Force (ITF) to develop and implement new strategies and action plans to achieve full partnership with state and local agencies. The task force they developed included senior officials from FDA's Office of Regulatory Affairs, Center for Food Safety and Applied Nutrition, and Center for Veterinary Medicine, and state and local agencies involved in the PFP.

The ITF was charged with identifying the strengths and weaknesses of the current federal-state partnership, taking into account the perspectives of officials from FDA and state and local agencies. In addition, the Task Force was charged to identify current federal policies and practices that are fostering and impeding development of full partnerships; identify specific actions FDA leadership can take to institutionalize the communication and operational practices required to achieve full partnerships; and develop an agenda for taking full advantage of FSMA's mandate for an IFSS that



strengthens the role of the states and local agencies to build a full partnership. The ITF used open-ended feedback and face-to-face interviews with a representative sample of state and FDA district officials from across the United States to collect the necessary data. Based on their initial findings, the ITF presented the following recommendations. One caveat to the presented recommendations was that both information technology needs and the integration of critical and numerous laboratory data will require long-term strategies for prioritization of efforts.

Melinda Plaisier (FDA) provided an overview of the ITF recommendations:

1. Clarify the public health mission of the FDA Foods Program

The ITF process validated the need to shift the primary driver for FDA from compliance to public health outcomes. A change management plan with metrics is needed to clarify FDA's mission, operationalize the transition, and evaluate the progress.

2. Reaffirm and act upon FDA's commitment to the IFSS

The ITF acknowledged the need to continue its discussions with senior level management about how to best incorporate integration goals and measures in management performance contracts, including the dedication of staff and resources to support the PFP process and the implementation of food regulatory program standards.

3. Build the operational infrastructure needed for a true IFSS

The ITF needs to make information sharing between agencies more permanent by assessing existing information sharing mechanisms and addressing gaps. This requires reaching out to state leaders to engage in more information sharing and streamlining the process for efficiency.



4. Strengthen training through improved coordination, priority setting, and use of modern delivery methods

The ITF recognized the need to further enhance the work of FDA's Office of Regulatory Affairs' Division of Human Resource Development (ORA-U) by moving to a new model that involves cross-cutting groups conducting training needs assessments, developing training alliances, and ensuring that funding for training is aligned with program goals.

5. Provide strong technical support to investigators

The ITF also validated the need to leverage FDA knowledge internally, as well as with other federal agencies. One recommendation is to develop a strategic plan to build a full-time technical support center similar to other federal agencies that will be staffed with subject matter experts to provide technical support to field staff in real-time.

Joe Reardon (FDA) also presented an overview of FDA accomplishments to date, including:

- A successful initiative to increase the use of the more efficient 20.88 Confidentiality Agreements for sharing confidential commercial information among state and local food regulatory program managers,
- New cooperative agreements and grants that enhance state and local programs,
- The formation of a Development and Integration Branch to assist with implementation of the MFRPS,
- The issuance of awards to states for ISO laboratory accreditation to enhance sharing and use of laboratory data between agencies, and
- Since 2009, FDA has doubled the Federal funding awarded to state and local programs for manufactured food, feed, laboratory and retail cooperative programs.



The panel representing state, local and federal partners on the ITF reflected on their mission and also took questions from the audience.

Bob Waltz (IN) – “As a state regulatory agency we have a number of challenges including the ability to cooperate across agency lines on food and feed safety. It will be important for states to incorporate new laws into our systems and food and feed standards. Animal feed laboratories are a critical part of our system. This is a new partnership with food folks. There is a diversity of programs within states, different priorities; we are going to have to address different needs.”

Pat Kennelly (CA) – “The process was designed to get to the root of what worked and could be done better. This was an opportunity to talk about successes. The process gave us an opportunity to share information and come up with solutions. A balanced approach was used.”

Roberta Wagner (FDA) – “We needed to focus on internal FDA communication first. The task force was eye-opening. Horizontal communication breakdowns were often the issue. Communication needs to be top down and bottom up. Good communication needs to be a habit.”



ACCOMPLISHMENTS OF THE PARTNERSHIP FOR FOOD PROTECTION WORKGROUPS (2010-2012)

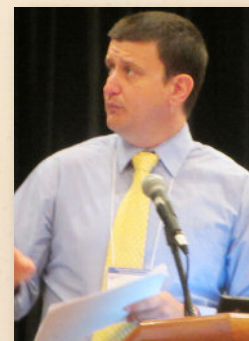


The PFP is a group of dedicated officials from federal, state, and local governments with roles in protecting the food supply and public health. The PFP was originally established to work on projects recommended during the 2008 FDA-hosted 50-state workshop. Since 2008, the PFP has been responsible for building the foundation for an IFSS. Ten workgroups were established in 2010 to work on foundational pieces of an IFSS. The following summaries of their accomplishments from 2010-2012 were reported during the workshop.

For more information, see:

<http://www.fda.gov/ForFederalStateandLocalOfficials/Meetings/50-StateMeeting/default.htm>

The **PFP Information Technology (IT) Workgroup** was charged with defining and understanding the requirements for developing an integrated electronic information management backbone, and undertaking technical projects to create an interoperable and integrated national food safety system. This group began to tackle their charge by identifying business needs from the bottom up. Instead of focusing on how the information would be used, the group focused on what data was needed and why. In response to their charge (and FSMA Sec 205(c)2C), this workgroup developed a Business Process Evaluation and Improvement Tool for Inspection Systems, that was designed to help state and local programs gain a detailed understanding of their program’s business processes and serve as a mechanism to form requirements for IT system improvements or new developments. They also began identifying common data elements in a food Good Manufacturing Practice (GMP) inspection program to support integration efficiency, and did so by soliciting feedback from FDA and 33 participating state programs. The group recommends evaluating the public health benefits of the data fields to determine their value.





The workgroup closed their presentation by highlighting the seven challenges of a globally integrated IT system, including heterogeneous structures, unifying data structure, information ownership, information privacy and security, standardized structural metadata, systems operation and maintenance, and mutual and individual benefits.

The **PFP Laboratory Workgroup** was charged with developing and implementing national standard laboratory practices and procedures, in an effort to promote consistent and meaningful laboratory data (from environmental, food, and feed samples) for compliance and surveillance to support uniform acceptance of food and feed regulatory data. To tackle this charge, the group was broken into eight subcommittees to work on individual projects, including the development of an action plan for creating and implementing a management system that meets the management and technical requirements of ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories (laboratory standards that are accepted worldwide). Also, the workgroup was charged with the development of a comprehensive comparison document that incorporates ISO/IEC 17025, the Analytical Laboratory Accreditation Criteria Committee (ALACC) guidelines and the regulatory annex requirements, the development of a catalogue of existing proficiency testing programs or series that could be used by laboratories to demonstrate competency, the identification of critical elements for food and feed sampling intended for regulatory evaluation and laboratory testing, the identification of model standards for selecting methodology based on the concept of "fit for use," the identification of a list of elements that should be contained in raw data worksheets to meet the national standards, and the creation of a catalogue of IT systems commonly receiving laboratory data. This workgroup has drafted a National Standards Guidance Document, with the intent to help facilitate harmonization, reduce redundancy and promote leveraging partnerships. The workgroup's next step is to finalize the document.



The **PFP National Standards Workgroup** was charged with developing recommendations for improving how the different national program standards are maintained and implemented, promoting an understanding of the common elements of existing U.S. program standards, and providing a forum to consider harmonization of national standards and to address challenges facing users of national program standards. In response to these charges, the group made recommendations for a MFRPS maintenance process and made the following proposals to the PFP Executive Committee: establish an alliance to solicit input from all state manufactured food regulatory programs, establish an alliance board to define by-laws and provide direction, and establish sub-committees to deliberate on standard changes. At the time of the presentation, the workgroup was waiting feedback on the scope and structure of their proposals from the PFP Executive Committee.




The group also developed documents that summarize what “standards” exist for key elements in four different regulatory programs and established a crosswalk document to assist in recognizing how the expectations for different programs are similar and how they are different. The workgroup will be considering how feed regulatory program standards, standards that were under development at the time of the workshop, will fit into the workgroup actions.

The **PFP National Workplanning Workgroup** was charged with developing a process by which FDA, state, local, territorial and tribal entities can move toward an integrated food safety system by developing a “framework” for workplanning. In response to this charge, the workgroup reviewed and commented on a draft workplanning concept paper, which reflects a model currently being used by FDA and the state of California. This concept paper could provide a “framework” to assist those government agencies that do not already have procedures in place for joint workplanning. The group is also working on two separate projects related to animal feed: the development of a domestic import feed sampling assignment designed to facilitate the sharing of sample data and developing guidance on retail food salvage for animal feed in an effort to help prevent food and feed safety issues. The group intends to continue working to finalize a workplanning “framework” document and plans to assess the practicality of its use.



The **PFP Oversight Workgroup’s** sub-workgroup for Audits was charged with supporting the Food Safety Modernization Act’s (FSMA) requirement for an objective and uniform means of verifying functional equivalency between inspection programs by defining processes that verify the performance of federal, state, and local food regulatory agencies against regulatory standards such as the MFRPS. An audit system consists of defined processes that will systematically, independently, and objectively evaluate the extent to which organizations and individuals conform to pre-established criteria (e.g., MFRPS)

in the performance of required inspections, investigations, compliance actions, foodborne illness outbreaks, emergencies, and outreach. In response to their charge, the group defined the inspectional process by adopting a Model GMP Inspection Process Procedure, created a GMP inspection process training PowerPoint, and implemented an audit tool to verify that the GMP inspection process is being performed per the inspection procedure. The workgroup recommends integrating the Model GMP Inspection Process System into another PFP Workgroup or organization.



The **PFPP Performance Measures and Outcomes Workgroup** was charged with creating a “Goals and Metrics” workgroup that includes representatives from federal, state, local, tribal, and territorial governments, as well as industry and public policy makers to provide metric recommendations and a strategy for measuring successful integration. Over fifty measures were identified as potentially valuable in reporting on improvements to an IFSS. The group was able to develop eight of the original fifty metrics given available resources:

- Number of confidentiality agreements in place per state,
- Number of districts with FDA district/state-specific regulatory partner communication standard operating procedures (SOPs) in place,
- Number of states with FDA contracts (44) for which contractually required information exchanges have been accomplished annually by FDA and state partners,
- Conformance with national standards,
- Median number of days from submission of stool specimen/food sample to report the final result,
- Medicated feed compliance,
- Inspection assessment for high-risk food manufacturing facilities, and
- Percent of retail and foodservice establishments successfully implementing controls for key foodborne illness indicators.

The workgroup recommends the next iteration of performance measures workgroup collaborate with all other PFPP workgroups to develop group specific measures.



The **Pet Event Tracking Network (PETNet) Workgroup** was charged with providing a platform for securely exchanging information about pet-food related incidents, such as illness associated with the consumption of adulterated pet food or pet food product defects, between FDA, the states and other federal government agencies charged with protecting animals and public health. In response to this charge, the group

launched PETNet on August 1, 2011, which is a secure, web-based network used by government employees (members) to freely and efficiently exchange information associated with pet food products.

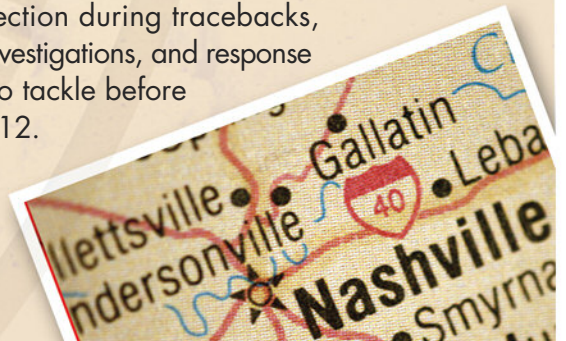
Information is entered into the system via an electronic reporting form, and the data from this form is entered into a searchable database assessable to all members. The system is currently active, and the workgroup plans on expanding the PETNet system to include food-producing animals. A team will be assembled for this next phase with the expectation to complete the development phase by September 2013.



The **PFP Policy & Procedures Workgroup** was charged with helping to operationalize policy and procedures that support an IFSS. The Workgroup attempted to work within the parameters of current policy development within FDA and communicate with all partners in the IFSS. In response to this charge, the group has been working on the following projects: a draft implementation strategy for sharing integrated food safety accomplishments (under review with the PFP Executive Committee at the time of the workshop); a draft Partnership for Food Protection (PFP) Report, which will include the accomplishments of the PFP workgroups reported at this meeting and scheduled to be finalized in October 2012; developing recommendations for leveraging and enhancing state and local capacities to share information within a timely and effective way as part of a broader FSMA Implementation workgroup; working in concert with the Rapid Response Teams and the Association of Food and Drug Officials (AFDO) to create a directory of state and local emergency responders, which has resulted in an updated directory. It supported a food and feed inspection violation pilot project, simulating real time collaboration, which was initiated in January 2012 and ran for 180 days. The workgroup will continue to support FSMA implementation, but most members agree that this workgroup could be recast to capture and memorialize the work of other workgroups.



The **PFP Response Workgroup** was charged in 2010 with identifying recommendations for improving response and recovery efforts in an integrated system. To meet this charge, the Workgroup identified five projects related to rapid response, after action reviews (AARs), records collection during tracebacks, traceback investigations, and response resources to tackle before August 2012.



The Workgroup developed a Quick Start Response Guide that visually summarizes initial communication steps in an investigation once an outbreak is suspected in an effort to enhance rapid response and communication between epidemiology, environmental and laboratory programs. They also developed an "After Action Initiative" document that identifies current national after action initiatives and includes stakeholder contact information. The group recommends this document be distributed to all After Action (AA) stakeholders to facilitate communication, collaboration and planning of a stakeholder AA meeting to jointly develop a strategy for institutionalizing after actions. The Workgroup's other projects were a checklist to facilitate the collection of records and data most relevant in a multi-state traceback investigation, the finalization of a traceback whitepaper, and a draft index of response resources to promote uniform response. A proposal was also submitted by leadership to review the charge of the PFP Response workgroup moving forward in 2012.

The **PFP Training and Certification Workgroup** was charged with assisting the PFP with the development and implementation of uniform, national standards for training and certification of regulators working in feed, retail foods, manufactured foods, and raw or unprocessed foods. They maintain that a competent regulatory workforce doing comparable work at the international, federal, state, local, tribal and territorial levels is critical to the successful implementation of a fully integrated national food safety system. In response to their charge, the workgroup developed a vision document, began constructing entry level competencies and certifications using the vision as a roadmap and created the first edition of a course catalog. Since then, the group has linked sections of FSMA to the International Food Protection Training Institute (IFPTI) curriculum framework, and developed a process to identify and prioritize training and certification needs, which was piloted in June 2012 at the National Environmental Health Association (NEHA) meeting. In 2011, FDA awarded seven grants (cooperative agreements) for projects that support the IFSS and the curriculum framework. The grants, while subject to the availability of FY funding, were planned for a five-year period of performance. There are over 70 projects that the grantees have been working on. The projects are in various stages of development and will be completed by the end of the fifth and final year of the performance period. Currently, the grants are in year "two." It is anticipated that additional projects will be added as the grants proceed. The Training and Certification workgroup plans to continue to work with the IFPTI to develop and implement a course review process in the future.

"Our journey has started. It's a collaboration of local, state, federal and tribal territories to protect public health. There are no silent partners. You were chosen because of your subject matter expertise. Now is the time to contribute and stay involved."

Davene Sarrocco-Smith – at the closing of Day One of the PFP 50-State Workshop.

BREAKOUT SESSION OUTCOMES AND RECOMMENDATIONS

Day Two of the workshop was designated for breakout working sessions. Each participant was assigned to one of the six breakout sessions listed below.

Session 1: Implementing Routine Workplanning at the FDA District, State & Local levels

Session 2: Implementing Integrated Compliance and Enforcement Processes

Session 3: Generating a Cross-Jurisdictional After Action Review (AAR) Process

Session 4: Implementing a Joint Inspection Process & Protocol for Joint Investigations

Session 5: Formulating a Common Data Set to Exchange Information in Support of Regulatory Functions

Session 6: Developing an Implementation Plan to Facilitate the Use of IFSS Best Practices Across Federal, State, Local, Tribal, and Territorial Governments



Of the six breakout sessions on Day Two, three of those sessions (Breakout sessions 1, 3 and 5) were built off of work currently being conducted by three PFP WGs (National Workplanning, Response, and IT respectively). FDA and state facilitator teams for each session, led by Chief Facilitator Janet Williams (FDA), used a strategic planning scheme as the format for facilitating these sessions. The goal was to leave the workshop with a concrete framework, protocol, or process from each breakout session that could be implemented quickly. A summary of each session and recommendation presented on Day Three is below.

BREAKOUT SESSION 1:

IMPLEMENTING ROUTINE WORKPLANNING AT THE FDA DISTRICT, STATE & LOCAL LEVELS



The FDA and their state and local counterparts with overlapping jurisdiction need workplanning and effective communication to successfully implement an IFSS. This breakout group was charged with identifying specific steps and processes that would help develop, implement, and monitor the implementation of basic, integrated workplanning at the district, state, and local levels in FY 2013.

The group began their session reviewing and commenting on the PFP National Workplanning Workgroup's draft concept paper, a "Practical Model for FDA District Workplanning with State/Local Programs with Overlapping Jurisdiction." This document was designed to serve as a "framework" to assist in joint workplanning efforts at the FDA district, state and local levels, especially for those who do not already have procedures in place. The concept paper was the starting point for the group discussion. The participants identified prerequisites for optimal workplanning, developed broad categories of jurisdictional overlap for workplanning discussion, and prioritized which categories should be tackled in FY 2013.

Prerequisites included:

- Mission goals, objectives and scope: What are we doing and why?
- Stakeholder identification and analysis: Who's in charge?
- Resource analysis and prioritization: What resources are available?
- Communication Strategy: Who else needs to know about this?
- Commissioning Discussion: What can/can't we share?
- Strengths, Weaknesses, Opportunities, Threats (SWOT) Analysis



After thinking critically about the prerequisites, the group agreed that all of their recommendations would assume that the prerequisites were met before workplanning would begin. They identified the three elements of joint workplanning that should be incorporated in the next fiscal year.



One priority that emerged early in the day was the importance of **inspection workplanning**. The group agreed on the importance of leveraging resources at all levels and of implementing a risk-based approach to preventing and addressing food associated illnesses. The group recommended developing an overarching list of "to-be inspected" firms, identifying which agency will lead, where there is overlap and which ones are high risk. Geographic Project Targets, for example, would be special sampling inspection projects geared toward high risk products and emerging hazards. Floods or other natural disasters can ruin crops and make a previously "safe" product high risk.

There was a separate breakout session at the 2012 50-State Workshop devoted entirely to implementing **integrated compliance and enforcement processes**, but since there is overlap between workplanning and implementation, this group felt it was important to discuss. They recommend developing a compliance strategy that would identify enforcement triggers and address issues of cross-state violations and chain-wide enforcement. The group agreed that efforts would be well spent in coordinating product removal (recall) activities across jurisdictions, with specific focus on developing standard protocols, effectiveness metrics, and common terminology.

The group also recommended developing an **annual sampling plan**, which would establish chain of custody, identify data requirements and acceptability, and coordinate with laboratory schedules and capabilities. To that end, laboratory staff availability and surge capacity should be taken into consideration. They then discussed developing a comprehensive training plan, which would include program standard (MFRPS and the under-development Animal Feed Regulatory Program Standards), state training for federal workers, and reciprocity.



When faced with emergency preparedness, agencies would benefit from a **Food or Feed Emergency Response Plan (FERP)**, which identifies action standards (When is it an emergency? What does "done" look like?), and MOUs to delegate authority. Legal preparedness was also discussed, with a focus on GAPS and our ability to take action if necessary.

Next Steps: All of the notes and efforts captured from this breakout session will be reflected in the revised framework document for workplanning initially drafted by the PFP Workplanning work group. The revised framework will be submitted to the PFP Executive Committee to review, and if approved, begin steps to implement it.

BREAKOUT SESSION 2:

IMPLEMENTING INTEGRATED COMPLIANCE AND ENFORCEMENT PROCESSES

Leveraging resources at all levels of government will help achieve greater compliance and will result in better public health protection, according to this breakout session. This group was charged with identifying steps for implementing a routine, integrated compliance and enforcement process, and steps for implementing workgroups at the FDA district, state, and local level by the end of FY 2013.



Presentations were made from federal and state public health officials from Georgia and Washington State on the Food and Feed Inspection Violation pilot project. Initiated in January 2012 and running for 180 days, the pilot project was an opportunity for the five states and four FDA Districts who participated to improve communication by identifying approaches to respond to violative inspections in real time. The presentations gave the larger group a starting point for their discussion.

Time was spent establishing the group's definition of compliance and enforcement and discussing the status of current integration efforts. Looking forward, the group would like to see a unified vision for integrated compliance and enforcement that gives each agency an opportunity to decide how it can best utilize its own enforcement capabilities. The group would also like to see a clarification of the FDA state liaison role; they see this position as a tool to enhance the collaboration and communication process, not as a gatekeeper that inhibits the process. The discussion ended with the group identifying additional ideal IFSS elements, for example, eliminating duplicative efforts, proactively identifying training needs and then training across jurisdictional boundaries to help foster relationships.

The group identified a number of **challenges** facing the integration of compliance and enforcement. The challenges include differing enforcement priorities, information sharing across jurisdictions, and the lack of an IT system that can link different programs and databases. In response to these challenges, the group brainstormed potential solutions and recommended short- and long-term goals.

Short-Term Goals

- Implement a new retail (grocery and restaurant) pilot for local officials using a communication model,
- Create a process for real time communication on triggers, and
- Schedule regular inspection, compliance and enforcement meetings

Long-Term Goals

- 100% implementation of compliance and enforcement of the Field Management Directives (FMD) at all levels
- Incorporate domestic imported foods, and
- Joint annual reviews of the overall national compliance and enforcement programs and the FDA District, state and local Standard Operating Procedures (SOPs)

A catalog of enforcement actions, a standardized process for reporting, and phased implementation were among the group's recommendations to achieve some goals.

Next Steps: The framework used for the Food and Feed Inspection Violation pilot will be revised based on information from the pilot and this breakout session and submitted to the PFP Executive Committee for consideration.



BREAKOUT SESSION 3:

GENERATING A CROSS-JURISDICTIONAL AFTER ACTION REVIEW (AAR) PROCESS

This group was charged with identifying steps to implement a cross-jurisdictional after action review process in 2013.



The group kicked off their session by reviewing a draft after action review (AAR) procedure designed for FDA field offices. This AAR is based on the Department of Homeland Security Exercise Evaluation Program (HSEEP), which provides federal grant money to eligible states. Districts and locals can use this draft as a model for developing their own specific procedures. The group

decided they preferred the AAR model in the Rapid Response Team playbook. After reviewing the draft procedure, the group discussed the value of having an after action review or “hot wash.” They agreed that an AAR is an opportunity to identify what went well and what didn’t go well and take steps to improve during the next incident. With the discussion of value, the group raised challenges and triggers associated with conducting an AAR. Some of the challenges were a fear of security issues around vulnerabilities and gaps, a lack of resources (time and personnel), a variance in terminology, and a lack of a single repository for captured information. The triggers, or considerations for conducting an AAR, vary by circumstance. This group’s list of triggers included severity, impact on public health or industry, and significance of an unusual event. The group then recommended several deliverables for consideration by the PFP Executive Committee.



Pilot with FSMA 205c1A Subgroup

- **Who:** (suggested participants): FDA Coordinated Outbreak Response and Evaluation (CORE), Rapid Response Team (RRT), CDC (Food CORE, Centers for Excellence) state health, county health, state & local jurisdictions
- **What:** Use AAR and AA Report SOP in the framework for cross-jurisdictional event pilot being developed by FSMA 205c1A subgroup
- **When:** By December 31, 2012, the FSMA workgroup will have determined the specifics of the pilot (who, what, and duration of pilot)

Beta Testing by PFP Response WG

- **Who:** Beta test at different government levels and collect feedback; start at federal level.
- **What:** PFP Response Workgroup to solicit volunteers for SOP Beta testing from a coordinated event (e.g., recalls); solicit volunteers from groups like AFDO, CIFOR, RNC, AAFCO, and NEHA
- **When:** By January 1, 2013, draft SOP, assessment tool and contact information will be finalized and pushed to groups for a twelve-month evaluation period

The group ended their session by discussing a third deliverable: telling the story. After the participants from the Pilot and Beta Testing report on their outcomes, this breakout group encourages them to tell their stories. The participants could use this opportunity to communicate their accomplishments and lessons learned, potentially improving the process for other district, state and local agencies.



Next Steps: The participants recommended the AAR model in the RRT playbook be revised based on comments and suggestions in this session. The revised model will be submitted to the PFP Executive Committee to consider implementing this process by piloting with a FSMA subgroup or beta testing by the PFP Response WG.

BREAKOUT SESSION 4:

IMPLEMENTING A JOINT INSPECTION PROCESS & PROTOCOL FOR JOINT INVESTIGATIONS

The ability to work together across jurisdictions and disciplines is critical to assuring risk-based inspectional coverage that will prevent and address food-associated illness. Building on the efforts of a similar session from the 2010 50 State Workshop and the RRT Joint Inspections chapter of the Best Practices Manual, this group was charged with identifying the steps needed to pilot or implement a joint inspection/investigation process for 2013.

With over 570 years of experience among the breakout session participants, time was needed at the start of this session for the group to establish a mutual understanding of joint inspections, which included such elements as measurable outcomes, overlapping jurisdiction, compliance with applicable laws and regulations, and collaboration. They also acknowledged that long term compliance and the need for an after action review are part of the joint inspection process, but agreed to table the discussion on these topics since they were being addressed by other breakout sessions. The group then assessed the current processes, evaluated their effectiveness, and made recommendations.

The group suggested that a comprehensive **plan** needs to be established before joint inspections occur and agreed that the high level planning needs to be coordinated at the FDA level. This plan could include coordination of legal and jurisdictional issues (e.g. Memoranda of Understanding or Inter Agency Agreements), identification of participants (agencies and jurisdictions), and the establishment of roles and responsibilities. This plan could also be the ideal place to identify resources, establish an inspection approach, address logistical challenges, and incorporate a case review and communication strategy.



An **operational process** is another element that should, according to this group, be incorporated into the planning of a joint investigation. With the right people at the table and with clear roles and responsibilities defined, such a process could identify best practices for establishing inspectional authority, collecting and assessing data, and coordinating the documentation and communication of inspectional observations.

This group also recommended **creating a cohesive inspection report** that clearly communicates the vital statistics of the inspection and firm, corrective actions and timeframes, inspection's impact on public health, and next regulatory steps. The group agreed that the report should include official signatures, and have a standardized format that captures the necessary data elements required for multiple jurisdictions and agencies.



The group acknowledged that the purpose and scope of an inspection would ultimately influence all other aspects of the joint inspection process, and they emphasized that communication and relationship building are a low cost, but highly effective way of improving the current joint inspection process. The session closed by

recommending either a pilot or a limited roll out and emphasized that an assessment and continuous improvement process are necessary steps in either case.

Next Steps: A joint inspection process document will need to be drafted based on the recommendations from this session and submitted to the PFP Executive Committee to review and consider steps to implement nationally.

BREAKOUT SESSION 5:

FORMULATING A COMMON DATA SET TO EXCHANGE INFORMATION IN SUPPORT OF REGULATORY FUNCTIONS

A common data set will increase efficiency and improve public health officials' ability to share information on critical activities that cross jurisdictions. This breakout session was charged with reaching a consensus on a common data set necessary to exchange information in support of regulatory functions, and determine steps to increase usage of that common data set in 2013.



This session began with the PFP Information Technology (IT) Workgroup presenting their progress in identifying common data elements to support integration. After reaching out to all state food programs, 33 states agreed to participate in the project. The Workgroup created a list of common food Good Manufacturing Practice (GMP) inspection data fields and then compared state agencies' incorporation of the common data elements. The breakout session built upon the efforts of the PFP IT Workgroup, and began by discussing the drivers and barriers associated with utilizing a common data set.

Drivers include:

- Improving response time for public health emergencies,
- Helping firms achieve compliance through regulatory uniformity, and
- Using metrics to demonstrate improvement and attract funding

Barriers include:

- Lack of communication,
- Resistance to changing laws, and
- IT availability in the field



The group then focused on developing a uniform data sharing inspection interface. They recommend first assembling a small workgroup that would include representatives from the federal, state, local, tribal, and territorial levels. This workgroup would develop a preliminary data dictionary and work on a data gathering pilot that would start with routine inspections. The next step, this group suggests, is to implement a pilot program to collect the top seven data elements (from limited jurisdictions) using two methods – one electronic and one scantron form for paper-based systems. To accommodate those agencies resistant to change, this group recommends having quarterly meetings to get buy-in, discuss the application of this data and the benefits it will bring to individual agencies. They also suggest evaluating the performance of these common data elements via a breakout scenario (including a recall) to establish benchmarks.

The group recommends using this process to develop a uniform data sharing inspection form with the required data fields and with necessary crosswalks to facilitate data system population (when the system is available). The success of these recommendations is, according to the group, contingent on adequate funding.

Next Steps: There are several recommendations for the PFP Executive Committee to consider: (1) A small Workgroup, possibly the PFP IT Workgroup, to continue work to define key data elements; (2) conduct a Table Top exercise to validate definitions of key data elements; and (3) pilot project, possibly led by the PFP IT Workgroup, to submit data using the defined key elements, mine the data to verify the data element is being used correctly, and once verified, add to the data dictionary.

BREAKOUT SESSION 6:

DEVELOPING AN IMPLEMENTATION PLAN TO FACILITATE THE USE OF IFSS BEST PRACTICES ACROSS FEDERAL, STATE, LOCAL, TRIBAL, AND TERRITORIAL GOVERNMENTS

This group was charged with developing an implementation plan that could be used across federal, state, local, tribal, and territorial governments to assist governments with rapidly implementing programs developed by PFP into routine operations.

This session started by hearing about a draft pilot implementation process from FDA. The group then brainstormed which elements should be included in the implementation plan and identified considerations for implementation. The group believes prioritizing the PFP brand and clearly defining the IFSS mission statement need to be considered



when implementing this plan. They also recommend considering the circumstances surrounding program implementation, for example, whether or not the program should stand alone or be part of a multifaceted initiative. The group defined six **implementation elements** for program's to consider and identified key questions for each element.

Resources was defined as infrastructure support to implement and sustain the project, including capital, human resources, equipment, facilities, information technology, time, and travel. The group recommended a cost benefit analysis and asking key questions, to include:

- What resources are already in place to support the implementation of the project?
- Are additional resources needed for implementation?
- How will the project enhance the efficiency or effectiveness of the food safety program?
- How does the project enhance the development of an IFSS?
- How does the project enhance public health (food and feed safety) outcomes?

Marketing & Communication was defined as the activity, set of institutions and processes for creating, communicating, delivering, engaging, and exchanging offerings that have value for relevant stakeholders. The key questions for this element include:



- Who is the target audience?
- What is the delivery system?
- Who are the partner organizations?
- Is the message consistent, and does it align with the IFSS vision and mission?
- How will you assess the impact of the marketing and communication strategy?

Metrics & Evaluation were defined as the process of measuring the effectiveness, impact, and sustainability of the implementation of the program. Key questions for this element include:

- Is the implementation time sensitive?
- What barriers were identified? Were they overcome?
- How will program effectiveness be measured?
- Was adequate feedback and reporting provided to track the program?
- Were identified resources provided and were they adequate?

Training was defined as the acquisition of Knowledge, Skills, and Abilities (KSAs) as a result of a job task analysis, and taught in a manner capable of being learned by the target audience. The group also agreed that training needs to be sufficient to use for implementation at any level of government. Key questions for this element include:

- Who will need training?
- Does the needed training exist already or does it need to be developed?
- How intensive is the training (online versus face to face)?
- How is uniformity in delivery ensured?
- What is the end result of the training (e.g. Continuing education units, Certification)?

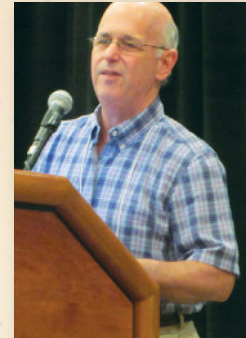
Accountability was defined as an obligation or willingness to accept responsibility for the successful implementation of a program or process. Key questions on accountability include:

- Who is being held accountable?
- What are the expectations for those who are accountable?
- What is the basis for accountability?
- How important to success is accountability at various levels of government?
- What are the mechanisms for holding parties accountable for different components?

Change Management was defined as an approach to transition individuals, teams, or organizations from a current state to a desired future state, with an organizational process aimed at helping stakeholders accept their new business environment. The group identified a number of key questions, including:

- Is the change significant enough to require a formal change management effort?
- Which people and skill sets are needed to champion the change?
- What is the best way to introduce the concepts and address change management?
- How can transparency be ensured?
- How can the change be tied to the project or agency mission?

Next Steps: Recommendations from this session will be submitted to the PFP Executive Committee. A new Workgroup may need to be formed to follow up on the recommendation to develop an implementation process and also to help lead implementation of PFP-related projects.



CLOSING COMMENTS

Closing remarks were provided from federal partners, including Chris Braden, Centers for Disease Control and Prevention (CDC), Wendy Hall, Department of Homeland Security (DHS), Mary Francis Lowe, Environmental Protection Agency (EPA), and David Goldman, U.S. Department of Agriculture (USDA). All expressed gratitude for the opportunity to participate in the 2012 PFP 50 State Workshop and thanked attendees



for all their hard work and dedication to public health. Participants said more emphasis is needed to increase communication at all levels of government and with the public on the goals and accomplishments of the IFSS. Participants from the Association of American Feed Control Officials (AAFCO), the Association of Food and Drug Officials (AFDO), the National Environmental Health Association (NEHA) and the National Association of County and City Health Officials (NACCHO) pledged to increase the visibility of the PFP “brand” and promote a joint integrated food safety system.

Joe Reardon (FDA) stated... “Progressive illumination....just as a mountain becomes clearer, as we build this IFSS we’ll know it when we see it.” He used a puzzle analogy and remarked how the puzzle just got bigger and everyone will have a role in putting those extra pieces together. He stated that in the next six months the PFP will have a clear governance structure, a communication specialist, project managers and full time staff to help PFP groups make sure that these projects become reality.

“At the end of the day it’s about accountability. We need to finish the work that we started years ago. There is nothing that this group cannot accomplish together. There is no greater opportunity to change the quality of life for others. There is nothing in your life that will determine the quality than the food you will consume every day. What a great opportunity and responsibility we all have.”

Oscar Garrison (GA) gave his appreciation to the great work that was done. “Like a rear view mirror, we need to glance to the past but we need to focus on the future, the big picture and what’s in front. We’re all in it together, from federal to state to local – we all have pieces of that puzzle. Don’t glue it down immediately, we may need to reconfigure it, it may change. Flexibility will be key as we build these systems and processes. It’s going to take our knowledge, skills and abilities as subject matter experts to get it right and keep it right.” Mr. Garrison offered one last challenge to the group being that they share the great work that was done. He asked everyone to talk about the projects. “We need a bigger team with more folks involved to get to where we need to go. Continue the great work started here.”

Mike Taylor (FDA) concluded by thanking the planning committee. He thanked the participants again for being there and told the attendees that if anyone had doubts about the success of an IFSS they should have seen the people and the creativity within the groups at this meeting. He stated that being at the PFP was inspiring and invigorating for him and identified the workshop as seamless collaboration and the best use of resources to protect public health. “This is a process of knitting many into one but not losing our identities.” He stated that FDA is fully committed to the PFP and integration including senior leadership from ORA and from the FDA centers. “We are committed to staffing the PFP. We will continue to make funding for PFP a high priority to operationalize full equal partnership.” He reiterated that “governance is needed to make decisions and move this revolution in a transparent way.” Accountability is required by FSMA. The informal accountability among our peers is also critical to make this work. He also commented that the evening meeting with local attendees provided him with some good ideas on how to make local food regulatory agencies become more a part of the PFP. In his ending remark, he used a baseball metaphor – “According to one analysis, a team that has had a winning record will have a high chance of success.” The PFP has wins to celebrate and will be successful by working together.

Pete Salsbury (FDA) officially closed the meeting by thanking everyone for coming.





LINKS TO RELATED DOCUMENTS

[2012 PFP 50-State Workshop Agenda](#)

[2012 PFP Coordinating Committee and Executive Committee](#)

[2012 PFP 50-State Workshop Attendee List](#)

[PFP Workgroup Presentations](#)

[Update from the Integrated Food Safety System Task Force Presentation](#)

[2012 PFP 50-State Workshop – Breakout Session Presentations](#)

