# Partnership for Food Protection
# Progress Reports from the Workgroups



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## PFP WG: Information Technology

**Vision for the WG:**

Define and understand the requirements of developing an integrated electronic information management backbone, and undertake technical projects that align with findings and contribute to the creation of an interoperable and integrated national food safety system.

Description of Current PFP WG Projects

**Project #1: Tool for Evaluating and Improving State and Local IT Systems**

*Description*:

Develop a tool that state, local, and tribal programs can utilize to assess and evaluate their current IT systems. The tool will walk program managers and IT staff through several areas of their inspection program: inventory, assignment, field work, recording findings, issuance, review/approval, data storage, and data management. It will help state programs evaluate specific job and program functions in each area from an IT perspective, and serve as a mechanism to gather requirements for future IT system developments or improvements. This project will also work to share specific steps state programs can take to ensure future compatibility with the MARCS system. In addition, a template will be included to help direct states in the development of Requests for Proposals (RFP) for IT systems.

*Status:*

The group has completed an outline of the initial factors in each area of the inspection program that should be considered when conducting an evaluation. The group is proceeding to further evaluate each factor and develop specific questions as well as specific tips that will help the state program evaluate the factor. The group has begun exploring ways to present the tool publically.

*Estimated Timeframe for Completion*: The group is aiming for a completion date of August 2012.

**Project #2: Identifying Common Data Elements to Support Integration**

*Description:*

Form a landscape view of data elements currently being collected and stored by state food programs and the FDA. Determine the commonalities amongst these data elements in order to make recommendations on how state programs and FDA can construct a data library. These recommendations will include a presentation of the data elements most "integration-friendly", as well as suggested changes to state and FDA business processes that would facilitate a larger degree of data integration. A statistically sound sampling of food programs will be evaluated. In the future, this project will expand to include local jurisdictions and feed programs.

*Status*:

This group has assembled a listing of states that it wants to collect inspection forms and screen shots from. It plans to meet shortly to discuss how to collect this data. It has received data from a handful of states to date.

*Estimated Timeframe for Completion*: The WG expects this project to extent past August 2012.

**Project #3: Seamless Data Transfer between State and FDA Systems**

*Description:*

Work directly with 1 or 2 state programs to facilitate a seamless data transfer of inspection information between state systems and FDA systems. One area that is being considered for transfer is BSE inspections, but additional inspection types as well as laboratory information will be considered. This project will seek to complete the transfer directly between systems, as well as include a Strengths, Weaknesses, Opportunities, and Threats (SWOT) evaluation for expanding the scope of this methodology.

*Status*:

Currently a detailed project plan is being worked on to present to FDA.

*Estimated Timeframe for Completion*: The estimated timeline to completion is resource dependent and resources have not been allocated to date.

**PFP WG: Laboratory Workgroup**

**Vision for the WG:**

The Laboratory Workgroup utilized local, state, and federal laboratory expertise to develop national standards for food regulatory laboratories to follow to produce consistent and meaningful analytical results sufficient for regulatory actions. These standards should facilitate the rapid acceptance of such analytical results for all regulatory agencies that might utilize the data. Laboratories adopting these standards should form the analytical foundation of any national surveillance program, national inspectional work plan, or emergency outbreak response.

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Description of Current PFP WG Projects

**Introduction**

The Partnership for Food Protection (PFP) initiative was established to provide guidance on implementing the necessary infrastructure and food safety strategies essential to building a national integrated food safety system. One of the Workgroups established to accomplish this goal is the Laboratory Workgroup which has been charged to develop and implement standard laboratory practices and procedures to promote consistent and meaningful data for compliance, surveillance and environmental samples. Within the PFP Laboratory Workgroup, there are seven Subcommittees: Accreditation, Methods, Proficiency Testing, Regulatory Requirements, Reporting, Standardized Worksheets and Sampling. Each group has defined charge documents and deliverables.

**Project #1: Accreditation Subcommittee**

*Description*: The Accreditation Subcommittee has been charged with defining what a laboratory quality management system entails, and how FDA will support and guide food/feed testing laboratories to obtain such a quality system. Specific deliverables are:

- To develop an action plan to help laboratories obtain ISO/IEC 17025 accreditation, by creating and implementing a quality management system that meets the management and technical requirements of ISO/IEC 17025.
- To compare and contrast the specifics of other quality accreditation programs and determine correspondence with the management and technical requirements of the ISO/IEC 17025:2005 international standard.
- To develop an estimated accreditation cost analysis, based on estimates from laboratories that are already accredited to ISO 17025:2005, of the time and expenses necessary to implement and maintain a new quality system, including accreditation fees.

*Estimated Timeframe for Completion*: Complete.

**Project #2: Regulatory Annex Subcommittee**

*Description:* A set of regulatory standards (also called the Regulatory Annex) to supplement ISO 17025 and AOAC laboratory food analyses guidelines are needed to address specific federal and state regulatory requirements to support confidence in the integrity and scientific validity of data, and to facilitate acceptance of data for other sources by federal and state agencies for

regulatory action. Documents and references used by FDA for regulatory and enforcement actions and decisions include, but are not limited to:

1. Investigations Operations Manual
2. ORA Laboratory Manual
3. The U.S. Food Safety and Modernization Act
4. 111th Congress Public Law 353

The Regulatory Annex Subcommittee has engaged federal and state stakeholders to address the development of a Regulatory Annex that will define those regulatory components needed to supplement ISO 17025 and AOAC elements. These national standards are written primarily to supplement or to provide further explanation of ISO 17025 requirements in regulatory laboratories. They are intended for those laboratories that will submit analytical data to the FDA or states for use in regulatory or enforcement actions or decisions.
*Estimated Timeframe for Completion*: Complete.

**Project #3: Standardized Worksheets Subcommittee**
*Description:* The Standardized Worksheet Subcommittee (SWS) is tasked with providing uniform standards for recording raw analytical food testing data. These national standards will provide laboratorians with a list of critical information required in their raw data worksheets to properly document the processes. Additionally, the SWS began development of standardized static worksheets to be used in various food testing laboratories, to demonstrate practical applications of the uniform standards. Standardized worksheets can be used by any food regulatory laboratory that follows the documented analytical pathway and will assist regulatory agencies, state and federal, with the reviewing of laboratory data by ensuring that all quality control elements are contained in the worksheets and are easy to locate. Standardized worksheets also provide assurance to the laboratory using them that they are meeting the national standards.
*Estimated Timeframe for Completion*: Complete

**Project #4: Proficiency Testing Subcommittee**
*Description*: The Proficiency Testing (PT) subcommittee is tasked with developing national standards and guidance for laboratories with respect to proficiency testing requirements. The PT Subcommittee also assessed the current state of food/feed PT relevant to the Partnership for Food Protection (food/feed analytical data, food safety and defense) and developed recommendations for future needs with respect to national proficiency testing. This group focused on currently available PT series/programs (including federal, state and private assets), leveraging existing proficiency testing series/programs and identifying potential enhancements.

In addition to the above minimum requirements, the PT Subcommittee has begun developing a catalog of existing PT Programs/Series that could be used to support laboratories in demonstrating competency for tests/methods/technologies/techniques. The Subcommittee will then develop a document providing cost estimates for maintaining a comprehensive PT Program both at the laboratory and PT Provider level.

Based on these deliverables, the Subcommittee will generate an evaluation of the state of existing PT Programs/Series and PT Participation Requirements, providing recommendations,

where possible, for minimizing redundancies and reducing the burden on laboratories while maintaining adequate proof of competency and laboratory accreditation status.
*Estimated Timeframe for Completion*: Complete.

**Project #5: Reporting Subcommittee**
*Description*: The Reporting Subcommittee is tasked with developing national standards for reporting of analytical data as well as recommendations with respect to electronic data capture and future national Information Technology (IT) development. Historically, while several laboratories have a working laboratory information management system (LIMS), there is no universal, mandatory national IT system for food testing laboratories, and few laboratories are truly 'paperless.' With the advent of initiatives like the FSMA for the electronic transmission and acceptance of state data, secure and comprehensive IT systems incorporating national reporting standards will need to be in place to handle the large volume of data in an efficient and effective manner to suit the needs of both state and federal partners and this issue is being addressed by several IT subcommittees and workgroups within PFP and FSMA.

In addition to the list of requirements devised by this committee, The PFP Reporting Subcommittee created a catalog of IT systems commonly receiving laboratory data, based on the experience of our subcommittee members. We also solicited input from the PFP Laboratory Workgroup as a whole. The purpose of this catalog was to inform the PFP Lab Workgroup of the current state of electronic data reporting mechanisms in use by food testing laboratories. The PFP Reporting Subcommittee reviewed this catalog to inform its recommendations for national IT in support of analytical data reporting standards and requirements, as established by the PFP Laboratory Workgroup. Specifically, the PFP Reporting Subcommittee was looking to see what existing systems could be used or enhanced to meet the electronic data reporting needs of the PFP.

Further, the subcommittee proposed recommendations with respect to electronic data capture and future national IT development. The recommendations have been shared with relevant PFP and FSMA National IT subcommittees and workgroups.
*Estimated Timeframe for Completion*: Complete.

**Project #6: Methods Subcommittee**
*Description*: The Method Subcommittee has the responsibility of identifying national standards and providing food testing laboratories with a catalog of compendia of analytical methods so that laboratories can quickly respond to foodborne outbreaks in a unified manner to prevent and reduce illnesses. Additionally this group will define parameters for selection of methods including validation information and fit for purpose definitions etc.
*Estimated Timeframe for Completion*: The draft of the PFP National Methods Guidelines was presented to the full laboratory workgroup on 7 February 2012.

**Project #7: Sampling Subcommittee**
*Description*: The Sampling Subcommittee is tasked with assessing the current state of food/feed sampling relevant to the PFP and developing recommended uniform sampling requirements/guidelines that will enable data generated from collected samples to be useful in regulatory analysis. This group will focus on current guidelines and potential enhancements as

well as the creation of a guidance document listing sample sizes of the major federal, state and local sampling programs. This deliverable aims to identify sampling requirements for laboratories to support submission of data to food regulatory agencies for regulatory action. To accomplish this, the subcommittee turned to established standards and requirements for sampling and specifically mined out any language that would apply to sampling requirements.
*Estimated Timeframe for Completion*: The draft of the national sampling standards was presented to the full laboratory workgroup on 23 February 2012.

**Project #8: Develop eLEXNET into the National Food Safety Testing database**
*Description:* The Electronic Laboratory Exchange Network (eLEXNET) is an integrated, secure network that allows multiple government agencies engaged in food safety activities to compare, communicate, and coordinate findings of laboratory analyses. As part of the FDA Food Safety Modernization Act (FSMA), signed by President Obama on January 4th, 2011, FDA's approach to food-borne illness is shifting from post-outbreak reaction, to early detection and prevention of contamination. As part of this new effort eLEXNET provides a central food testing repository that will allow for the sharing of food testing data among various government agencies (Federal, State and Local) in a timely manner. eLEXNET currently allows food safety laboratories at all levels of government to share real-time food safety sample and analysis data on specific microbiological, chemical and radiological analytes. eLEXNET is a program funded by the United States Food and Drug Administration (FDA) and supported by the U.S. Department of Agriculture (USDA) and the Department of Defense (DoD). Specific goals for this project include:

- *Change the data management interface to make it more user friendly.*
- *Re-establish the data exchange between eLEXNET and USDA.*
- *Increase the number of users of eLexnet. This will allow for an increased sharing of analytical data amongst local, state and Federal food safety partners.*
- *eLEXNET should become **the** NATIONAL Food Safety Testing database.*
- *Add international regulatory labs to the eLEXNET data exchange.*

*Estimated Timeframe for Completion*: This project was assigned to the Laboratory Workgroup on February 23, 2012. Timeframes for completion are being developed, however, due to the large scope of this project it is estimated that full completion will require a very extensive amount of time.

.**Project #9: Develop National Laboratory Practices and Procedures**
*Description:* The ultimate charge of the Laboratory Workgroup is to develop and implement standard laboratory practices and procedures to promote consistent and meaningful data for compliance, surveillance and environmental samples. Within the PFP Laboratory Workgroup, the seven subcommittees including Accreditation, Methods, Proficiency Testing, Regulatory Requirements, Reporting, Standardized Worksheets and Sampling were established to accomplish this charge.

*Estimated Timeframe for Completion*: The first draft of the *National Standards for Food/Feed Testing Laboratories: Guidance Document for Food/Feed Testing Laboratories*

*Performing Analysis in Support of Regulatory Action* was presented to the full laboratory workgroup on 16 February 2012**.** This document incorporates the work of the seven subcommittees. The document is being reviewed by all members of the PFP Laboratory Workgroup. Comments will be collected by the individual subcommittees for incorporation into the document. Tentative timeframe for completion of this review and issuing a final document is 30 June 2012.

**Project #10: Operationalizaton of National Laboratory Practices And Procedures**
*Description:* The goal of this project is to implement the national laboratory practices and procedures into full operational status nationally among all food regulatory laboratories.

**Estimated Timeframe for Completion:** Initial discussions on how to bring these national standards and practices into full national operational status have only recently been started. The estimated timeframe for completion has not been established. However it is expected that the implementation of these standards will be tied very closely with the initiatives mandated by the Food Safety Modernization Act.

**PFP WG: National Standards**

**Vision for the WG:**

Program standards that define what constitutes an effective food safety regulatory program and that promote continuous improvement among such programs are important to creating a fully integrated food safety system. The PFP National Standards Workgroup will assist FDA and its regulatory partners by:

- developing recommendations for improving how the different national program standards are maintained and implemented;
- promoting an understanding of the common elements of program standards that exist in the US for various program areas; and
- providing a forum to consider opportunities for harmonization of national standards and to address challenges facing users of the Standards.

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Description of Current PFP WG Projects

**Project #1: Develop recommendations for the establishment of a process for the maintenance and vetting of the Manufactured Food Regulatory Program Standards.**
*Description*: The NSWG will develop recommendations for consideration by FDA Senior Leadership and the PFP Executive Committee. These recommendations will describe what processes should be established for the revision and maintenance of the MFRPS and related documents that support their implementation. This will include recommendations on the structure and make-up of key deliberating bodies and the procedures for deliberation and approval of changes to the Standards. The document is currently in draft form and the workgroup has been addressing questions raised by Workgroup members and others from FDA. The recommendations are being enhanced to ensure they are clear with respect to how changes to the MFRPS are expected flow through a structure of multiple committees, how those committees will be established and the process for committee voting. Before being shared broadly with the Partnership for Food Protection, the Workgroup's recommendations will first be sent to FDA senior leadership and general counsel for review and comment.
*Estimated Timeframe for Completion*: 4 months

**Project #2: Complete informational documents that characterize the different Standards in place for different program areas.**
*Description:* The NSWG has developed draft documents that characterize current national program "Standards" and a crosswalk document that summarizes the core program requirements that apply to regulatory programs for manufactured foods, retail foods, Grade A milk, molluscan shellfish, and animal feed. These documents will be completed by the end March, along with summary memos that provide context for how they can be most useful to stakeholders, including the other PFP Workgroups that are working on project areas covered by the Standards. This project will inform decision makers of the location and content of the separate "Standards" that apply to different regulatory program areas and how they have evolved over the years. It is important that FDA and State/Local/Tribal regulatory partners have easy access to information

about the expectations placed on each of the partners in an Integrated Food Safety System. This will benefit State agencies that manage multiple programs (such as retail food, manufactured food, shellfish and/or Grade A Milk) as they develop strategies to achieve conformance with each set of "standards" and consider how these strategies can be coordinated. This document should also help FDA and its partners when considering appropriate changes to the criteria in one or more program area. knowing where the similarities and differences are among standards is critical to understanding why states may be challenged in developing one protocol for their staff (who perform retail, manufactured, shellfish and/or Grade A milk work) that would meet each of the standards (if they are different from one another without a good reason).
*Status*: The Workgroup is nearing completion of a document that will provide overview of the standards that exist for Regulatory Programs responsible for oversight in four different program areas: Manufactured Foods, Grade A Milk and Milk Products, Molluscan Shellfish and Retail Food Protection. Shortly after completion of that document the Workgroup will be able to complete a crosswalk document that will provide summary of how each of the key elements of an effective regulatory program is addressed in "standards" documents that apply to each of the four program areas. The Workgroup will complete a more extensive review and comparative analysis of the different approaches to identify where opportunities and challenges exist for integration and to strengthen the requirements that correspond to a particular program element.
*Estimated Timeframe for Completion*: That task is targeted for completion by August 2012.

**Project #3: Complete comparative analysis of different Program Standards**
*Description:* The WG will continue with an analysis of available standards and identify key elements that should be present within all National Standards for food and feed regulatory programs. This will involve describing important overlaps and differences among current program standards, and identifying opportunities for integrating and harmonizing the standards and their implementation conducted by multi-regulatory agencies. The comparison documents make it clear that there are many similarities between the different sets of "standards." An analysis of the similarities and differences will allow FDA and its State/local/tribal partners to determine if and where improvements can be made to one or more sets of the "Standards" and/or the tools that are available to promote their effective implementation. Many of the basic program elements are similar across all program areas, which include:

- Regulatory foundation
- Training/education for staff
- Inspection programs based on risk
- Quality assurance programs to ensure uniformity
- Illness/outbreak response, traceback, product recall
- Collaboration with stakeholders
- Compliance/enforcement
- Laboratory capability
- Program assessment
- Resources

While the individual programs areas may operate differently, analyzing the elements across all program areas will allow FDA and State/Local/Tribal regulatory partners to identify where

opportunities and challenges exist for integration and to strengthen the requirements that correspond to a particular program element.

Recommendations from the NSWG can be forwarded to FDA and the national organizations that are responsible for maintaining the Standards.
*Estimated Timeframe for Completion*: 9 months

**PFP WG: National Workplanning**

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**Vision for the Workgroup:**

FDA has multiple partners outside the agency who have inspectional authorities and responsibilities of food/feed manufacturers and retailers. FDA has relied upon its state partners to conduct more than 10,000 food and feed inspections. Many states have legislative mandates that require annual inspections of firms in the FDA's Official Establishment Inventory. The process by which FDA and States workplan vary from FDA District Office to District Office and State to State. In order to be more efficient and effective in the current times, FDA needs to improve its ability to leverage resources with its external partners. In addition, the passage of the Food Safety Modernization Act (FSMA) into law mandates that the Food and Drug Administration (FDA) ensure food safety from farm to table in an integrated and collaborative manner with state and local partners. To fully leverage resources, the entire inventory must be identified and inspected by officials from FDA, States, localities or jointly. The determination of the coverage should be decided jointly by all entities involved. In order to have a national workplan, the workplanning process must become standardized. To achieve this standardization, the National Workplanning Workgroup has identified a framework to be adopted by FDA offices, State partners and locals. To successfully accomplish a national workplan, at a minimum the following much be implemented:

- FSMA inspection time intervals dictate multi-year workplanning;
- District should share proposed list of firms with States and locals prior to face-to-face meeting;
- District Offices, States and locals should have an annual face-to-face meeting to mutually identify which firms will be inspected by each entity and jointly;
- Quarterly follow-up meetings should occur (option whether face-to-face or by phone);
- As complaints are received requiring immediate follow-up; District/State/locals should discuss who will follow-up;
- At each quarterly meeting, Districts, States and locals should provide feedback to one another to enhance workplanning process;
- Districts, States and locals should discuss firms that are no longer in business so FDA can determine if they meet their Out of Business (OOB) definition;
- District Offices, States and locals should determine if sharing of inspectional information will go beyond the number of firms in contract;
- FDA personnel attending workplanning meeting should include Food/Feed Contract monitor, State Liaison, OEI Coordinator, and Emergency Response Coordinator.
- State and local personnel attending workplanning meeting should include all persons involved in the monitoring and reporting on the contract;
- The workplanning meeting should also include the system by which each entity will share new food/feed registrants;
- Each entity should update firm data in respective databases until universal system is developed.

A critical understanding of FDA, states, and local authorities is necessary to work towards a national workplan. Key personnel as well as their roles and responsibilities should be identified.

The National Workplan Workgroup has identified three projects/assignments to model the workplanning process above. The projects will include reconciliation of firm inventory, sample collection, laboratories, training, performance measures and IT.

Description of Current PFP WG Projects

**Project #1: Official Establishment Inspection (OEI) Improvement to Target FSMA Establishments**

*Description*: To improve the quality of Official Establishment Inspection data for Bioterrorism Act of 2002 registered facilities resulting in accurate determination of risk of establishments and focused use of resources for states and FDA. The process of this collaborative activity will serve to design the framework for national workplanning and collectively identify the risk of the facilities. The exchange of information will serve as the basis for accurate firm data thereby eliminating FDA assigning firms that are not viable and/or using manpower to visit firms not in business.

*Estimated Timeframe for Completion*: June 1, 2012

**Project #2: Domestic Import Sampling Assignment**

*Description*: An assignment is being created to work with the state on the collection of domestic import samples. This assignment is to share sample results with the states corresponding districts and other states participating in the assignment. The sharing of samples with the not only the states but districts could help in workplanning and avoiding duplication of sample collections. Violative samples results will then be forward up through FDA procedures for consideration of import alerts or bulletins.

*Estimated Timeframe for Completion*: Issuing of assignment targeted for March 2012

**Project #3: (Retail Food Salvage for Animal Feed)**

*Description:* State Veterinarians and State Feed Program Managers have been approached by waste management firms that intend to recycle organic material from large retail and wholesale firms as animal feed.

The scope of this practice is potentially large (national) but unknown at this time. There appear to be potential feed safety concerns with this new practice and this project may help define what risks are associated with such practices.

*Estimated Timeframe for Completion*: July 2012

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**PFP WG: Oversight Workgroup (Audit & Governance Structure Subgroups)**

**Vision for the WG:**

The overall vision of the PFP Oversight Workgroup's Audit sub-group is to provide recommendations on the structure, processes and possible outcomes of an audit function that will validate the processes defined and implemented under any of the National Standard Program. Those National Standards are the core components of the framework of a National Integrated Food Safety System.

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Description of Current PFP WG Projects

**Project #1: MFRPS Audit White Paper**

*Description*: The purpose of the project is to write a white paper that will define the basic components and governance of the MFRPS audit program. The first component is a description of the elements and the processes that are required to perform a system audit of a state's MFRPS programs. The second component will make recommendation of the governance of the audit process under a PFP structure within a National Integrated Food Safety System. The final component will address defining the Findings portions resulting from a MFRPS Audit.
***Estimated Timeframe for Completion***: March 2012

**Project #2: Proposed Governance Structure for Partnership for Food Protection**

*Description:* Create a permanent leadership structure for the PFP project to replace the Coordinating Committee that was established following the 2008 50-state meeting.
*Estimated Timeframe for Completion*: Not Known at this time

**PFP WG: Performance Measures and Outcomes**

**Vision for the WG:**

Develop performance measures to assess progress towards integration. Link these measures to overall public health outcomes. Identify available data and data needs. Propose possible "owners" for each measure.

Description of Current PFP WG Projects

**Project #1: Develop performance measures**

*Description*: The group will develop descriptions of 5-15 performance measures using a standard template to identify data needs. These measures will be in two areas: integration and outcomes. The integration measures are focused on showing changes in the degree to which local, state and federal agencies are working in an integrated way. The outcome measures are indicators of outcomes that are expected to change with changes in integration. For some measures, the group will conduct a proof-of-concept by trying to collect data from a small number of jurisdictions, or by using data already collected by someone else. Potential "owners" of these measures within FDA will be identified, and the group will work to make sure the measures would meet their needs.

| **Integration-Related Measures** |
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| 1. Increase the percentage of regulatory agencies that are covered by a Cooperative agreement or Commissioned status for efficient and secure sharing of information between relevant food and fed safety officials. |
| 2. Number or percent of stakeholders that adopt or adhere to the FDA National standard (Federal, State, and local levels) or Increase in conformance with Standard X (or element) of MFRPS, NRFRPS, or AFRPS |
| 3. Increase in the number or % of FDA districts that have in place and use the FMD-50 form for sharing information, including establishment inventories, workplans and inspection calendars, inspection results, and enforcement actions. |
| 4. Increase the number and percentage of outbreaks that are reported to relevant agencies within a certain time frame (reported by foodborne hazard and food type) |
| 5. Increase number and percentage of recalls that are reported to relevant agencies within a certain time frame (reported by foodborne hazard and food type) |
| 6. Decrease the number and percentage of recalled product available in commerce a specified number of days following recall initiation, depending on recall class |
| 7. Decrease the median time in days to report key foodborne illness data to relevant supporting agencies. |
| 8. Decrease the median number of days to remove implicated product from X% of retail establishments |
| 9. Increased number and percent of compliance and enforcement decisions (domestic and import) made based on state data |
| **Outcomes-related Measures** |
| 1. Percent of retail and foodservice establishments successfully implementing controls for key |

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| foodborne illness factors |
| 2. To measure the inspection authority's efficiency at meeting their target inspection frequencies particularly for high risk firms. Also measure target frequencies against recommended national standards." |
| 3. To measure health –related noncompliance and serious violation rates by industry. Examples of non-compliance includes the following: Adulteration, HACCP deficiencies ( when HACCP is required) and serious misbranding issues, or any issues that result in "official action |
| 4. To measure the changes in the percentage of manufacturing sites HACCP certified regardless of product. |

*Estimated Timeframe for Completion*: June 2012

## **PFP WG: PETNet Workgroup**

Vision for the Workgroup:

The Pet Event Tracking Network (PETNet) is a secure reporting/notification system accessible by state and federal government officials with regulatory authority and responsibility over pet food. PETNet is for government use only and is not open to the public. PETNet facilitates sharing of information about food-borne illness outbreaks in companion animals between Federal and State agencies.

Status: PETNet was launched on August 1, 2011. Additional information about PETNet can be found here.

**PFP WG: Policy & Procedures**

**Vision for the WG:**

This Policy & Procedures Workgroup will help to operationalize policy and procedures that support an integrated food safety system. The work of this group largely depends on the outputs of the other PFP workgroups to identify areas for policy development or clarification. The group will work within the parameters of current policy development within FDA and communicate with all partners in the integrated food safety system.

Description of Current PFP WG Projects

**Project #1: Strategy for Sharing Integrated Food Safety Accomplishments**
*Description*: The objective of this project is to provide recommendations for establishing a process by which FDA can share food safety success stories and other achievements of the overall integrated food safety system effort with policy makers and the public. This information will include: (1) accomplishments and progress in implementing deliverables of the Partnership for Food Protection (PFP) Workgroups; and (2) 'real world' examples of integrated food safety efforts.

The project will outline options and recommendations of the PFP Policy and Procedures Workgroup (PPWG) communications subgroup for communicating progress on PFP deliverables, as well as considerations for an overall communication strategy for promoting and publicizing integrated food safety system activities. A draft document was distributed to the PPWG members on November 21. The PPWG is establishing strategies for communication but will not be in charge of communication moving forward.
*Estimated Timeframe for Completion*: March 31, 2012

**Project #2: PFP Progress Report**
*Description:* Previously, a strategic implementation plan was developed for the integrated food safety system task forces prior to the 2010 50-state workshop. A new report will be created and largely re-tooled into a progress report of the Partnership for Food Protection WG efforts since the last 50-state meeting. The group plans to build from implemented reporting mechanisms for the PFP initiative and will deliver the report in July 2012. Success of the report will depend largely on contributions from the other PFP workgroups.
*Estimated Timeframe for Completion*: July 2012

**Project #3: Information Sharing**
*Description:* The workgroup will continue to support FSMA implementation, specifically participating on FSMA implementation teams associated with information sharing and use of state and federal data to support enforcement actions by FDA and states, respectively.

Additionally, the group will work with the Rapid Response Team (RRT) initiative to explore utilizing the AFDO Directory of State and Local Officials as a starting point in the development of a national contact list for food emergency responders in every state. The goal of this contact

list is to allow any user to contact the most appropriate regulatory or emergency response entity within the state within one or two phone calls.
*Estimated Timeframe for Completion*: August 2012 (for national contact list for food emergency responders)

**NEW Project #4: Food and Feed Inspection Violation Pilot Project**
*Description:* A pilot program has been established to direct FDA district-State discussions when significant objectionable conditions are found during food or feed inspections conducted by FDA or States. The goal is to stimulate real-time collaboration to identify approaches for responding to violative inspections.
*Estimated Timeframe for Completion*: August 2012

## PFP WG: Response Workgroup

Description of Current PFP WG Projects

**Project #1: PFP Quick Start Response Guide**

*Description*: The PFP Response group will develop a quick start multi-jurisdictional response guide that summarizes initial steps in an investigation once an outbreak is suspected and identify mechanisms for distribution to intended users to increase success of operationalizing the tool.

The primary users of a quick start response guide are food emergency response coordinators and response teams including epidemiologists, laboratory and food regulatory officials in local, state and federal agencies who have coordinated public and environmental health authority for food emergency response. Other primary users may include persons with response functions such as local, state and federal law enforcement officials in the event of intentional contamination. Industry is also likely to have an interest in such a guide when training managers about the role of government in response and to help them in preparing their own complimentary response protocols.

The guide will be based on existing response best practices and principles identified by CIFOR, the RRT Project, the IAFP and ICS in their resource documents and toolkits.

The format will be similar to a job action sheet or job aid checklist that serves as a reminder of possible steps to be taken at the onset of a food emergency response.

The primary benefit of such a guide when used will be to enhance rapid response capabilities, particularly for agencies whose food emergency response events are less frequent. Secondary benefits include assisting with evaluation of response protocols and procedures during hot washes, development of after action reports and improving planning and preparedness documents.

The guide will not include steps related to planning and preparedness, surveillance and detection and on-going investigation activities. The guide will also not assign roles and responsibilities as that may vary significantly amongst jurisdictions. The guide is not intended as a field guide. Rather its design is to be used by anyone having a leadership role in initiating and planning an investigation of any food emergency event no matter where they are located.

Challenges to the development and operationalization of a quick start guide include keeping the document user friendly. It should be as short as possible and visually appealing. Dissemination to appropriate users before and during emergencies may require multiple mechanisms for distribution to be identified including adding to existing documents and training programs. An owner of the document and a method for storing, receiving feedback and making continuous improvements will also need to be identified.

*Estimated Timeframe for Completion*: July 2012

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**Project #2: Identify Mechanisms to Institutionalize After Actions and Identify Communication Barriers**

*Description:* The goal of this task is to institutionalize the use of after action reviews in multi-jurisdictional food emergency response events and to identify communication barriers based on existing after action reports. These two tasks were combined into one deliverable and the timeframe for completion is expected to be after August 2012.

After action reviews provide valuable lessons learned that can be used to improve an integrated regulatory response system and more importantly identify key strategies to prevent foodborne illness outbreaks. While conducting an after action after a food emergency response event is identified as a best practice in the CIFOR, RRT, IAFP and ICS guidance and resource documents, many local and

state agencies admit to not being able to conduct them as frequently or as comprehensively as they would like. Less have shared lessons learned with programs beyond themselves. FDA is progressing towards including state and local programs into their after action process.
Potential barriers to conducting after actions and sharing critical information include lack of minimum after action performance criteria in the food regulatory program standards, limited resources to sustain after action activities, lack of effective inter and intra-agency communication protocols, legal barriers to sharing of information, and complex after action templates currently in existence. The use of a standardized protocol is not a minimum requirement in the current retail or manufactured food regulatory program standards resulting in a broad array of potential outcomes and lack of quality data.

The PFP Response Group will begin by reaching out to other groups and collecting additional information on ongoing initiatives that relate to after actions in order to ensure that the work of the PFP Response Group is in alignment with those projects and identify tasks that compliment work already in progress. Current efforts underway involve the FDA Florida District, Florida Department of Agriculture, the FDA DFSR RRT Project, FDA CORE and FSMA groups. EHS Net and CIFOR are also likely to have on-going initiatives related to after actions. In addition, the NEHA CIFOR and the FSMA 205 C 2 surveys currently underway and/or scheduled may provide additional information on the status of after actions conducted nationally. Specific tasks based on this outreach will be identified by December 2012. Timeframe for completion and resources for those tasks identified will be completed by January 2013.

The PFP Response Group will also need to communicate with the PFP Performance measures group to assist in identifying performance metrics related to response and after actions and with the PFP National Standards Workgroup to incorporate recommended after action performance measures into the standards, which are updated every 3 years. Timeframe for completion is expected by January 2013.
*Estimated Timeframe for Completion*: Specific tasks will be identified in coordination with other after action stakeholders by December 2012. Timeframe for completion and resources for those tasks will be identified by January 2013. Outreach to PFP Performance Measures and National Standards Workgroup will be completed by January 2013.

**Project #3: (Develop 2-3 page Guide for States on Records Collection for More Successful Tracebacks)**
*Description:* This project concerns the enhancement of records collection by the states in the event of a multi-state (or other) foodborne outbreak that will lead to a traceback of the product. Some smaller states and state and localities with less experience may not know what records to collect or what questions to ask about them. This guide would provide a checklist and some basic description of how to do this.
*Estimated Timeframe for Completion*: 3 months (Project leads: Roberta Hammond and Ben Miller)

**Project #4: Develop index of investigation/response/recovery guidance documents.**
*Description*: Documents may be by pathogen, product, product category, etc. Effort will be to compile existing guidance with links to documents, criteria for inclusion of future documents and will include reviewing documents already created by FDA, CIFOR, states, EHS Net, etc. List can also be used to identify gaps where more documents need to be created. Goal is to promote use of consistent approaches across all agencies and improve the speed and quality of responses.
*Estimated Timeframe for Completion*: July 2012

**Project #5: Complete Whitepaper on Traceback investigations**
*Description*: A draft version of the traceback whitepaper has existed since the first phase of the PFP Response Workgroup. The authors will finalize edits and schedule a conference call to review edits and agree on a final draft.
*Estimated Timeframe for Completion*: March 2012

## PFP WG: Training and Certification

### Vision for the WG:

The training and certification workgroup intends to continue its role as a primary stakeholder providing support for visionary development, best practices, appropriate content and recommendations toward development of an integrated food safety training and certification system. The Workgroup partners with affiliated organizations such as ORAU/DHRD and IFPTI to lend expertise in the process of implementing a plan that will form the foundation for the training and development of all professionals involved in food safety. The Workgroup supports the overall vision plan of the integrated food safety training and certification system and intends to help support the plan internally and by working with other partners.

The vision plan supported by the partnership focuses on leveraging the resources of Federal Agencies (FDA, CDC,USDA), State and Local Regulators, Professional Associations (NEHA, AFDO , NACHO, IFPTI and others), Academia (Universities and Colleges), and other parties who have responsibility in Food Safety. These resources in a focused and coordinated effort will identify curriculum framework and provide the required training that meets pre-determined standards for quality and content. As a direct result regulatory officials currently involved in the food safety arena regardless of affiliation will have the knowledge and skills needed to accomplish their regulatory responsibilities. The training will result in competent/qualified investigators/inspectors/ professionals/staff of Federal, State, local and Territorial regulatory authorities conducting comparable work in fulfilling/executing their regulatory responsibilities.

After the specific training is identified it must be provided or made available to the various stakeholders in the Integrated Food Safety System. The plan is to use a variety of approaches or mechanisms to make the training available to the members of the partnership for food protection (PFP). It is anticipated that a number of training centers of excellence will be identified and the training courses/experiences available qualified by an appropriate standard/criteria and centrally catalogued. Specific information detailing how the listed training can be obtained will be provided in the catalogue.

The qualified training listed in the catalogue will be offered through a variety of different mechanisms including Web based on line training/modules, face to face training courses or events etc. The providers of the training will include Grantees, Professional Associations, FDA/DHRD, Academia, State and Local Regulators, and other Federal Agencies (CDC, USDA etc).

All training listed and presented will be based on and address appropriate bodies of knowledge defined through acceptable job or occupational analyses. It is anticipated that in most cases there will be multiple courses (training options) available for each section/box in the agreed upon curriculum framework. The availability of the training as defined by a recognized or agreed upon criteria or standard will be marketed to all stakeholders in the PFP. Successful completion of a catalogued training course or event will be recorded in an appropriate learning management system.

The Training and Certification Workgroup is working on three projects. Each project is being worked on simultaneously by subgroups established by the workgroup. The goal is to complete all three products by August 01, 2012.

Description of Current PFP WG Projects

**Project #1: Link sections of FSMA to IFPTI Curriculum Framework**
The training and certification workgroup will map all sections of FSMA to the International Food Protection Training Institute's (IFPTI's) curriculum framework. The objective is to confirm that all sections of FSMA are covered in the framework. The results of this work will be shared with IFPTI. Any FSMA section(s) that are not covered will be clearly identified. IFPTI will review the specific section(s) in question and modify the existing curriculum framework as needed.

**Extended Goal:** The extended goal is to assure that related Acts and existing food safety regulations are addressed by the IFPTI curriculum framework. The same procedure will be used to map these related Acts and regulations. New regulations will also be mapped to the current curriculum framework once they are approved. For example the new preventive controls regulation and the revised Feed and GMP Food regulations will be mapped once they are approved.
*Status*: A subgroup of the Training and Certification Workgroup began this process in Nashville at the November 2011 PFP meeting. The process was extended to the whole workgroup on December 12, 2011.
*Estimated Timeframe for Completion*: August 01, 2012.

**Project #2: Process for PFP training and certification recommendations**
The training and certification workgroup is developing a process to identify training and certification priorities. The prioritized list of training and certification priorities including certificate programs identified through this process will be shared with the PFP executive leadership team.
**Extended Goal:** The PFP will be able to use the list identified through this process to provide guidance to stakeholders including training and certification centers of excellence regarding priorities for training, certification and certificate programs that support specific subject areas in the curriculum framework.
*Status***:** The Training and Certification Workgroup began work on the development of this process in Nashville at the November 2011 PFP meeting. Input from the workgroup members present led to the identification of a number of specific areas in need of the development of training courses (i.e. traceback, preventive controls). The workgroup also discussed current plans to develop commodity specific certification and certificate programs beginning with GMP food manufacturing. A subgroup was established to continue these discussions and formalize a process for PFP training and certification recommendations.
*Estimated Timeframe for Completion*: August 01, 2012:

**Project #3: Identify and Qualify Existing Job and Occupational Analyses**
The training and certification workgroup is developing a process that will be used to both identify and qualify existing job and/or occupational analyses for specific commodity areas as identified in the IFPTI Curriculum framework. A subgroup has been established to continue these discussions and formalize a process for identifying and qualifying existing job task analyses.

**Extended Goal:** The process could be used by the PFP to encourage other stakeholders to conduct job and / or occupational analyses for specific areas in the curriculum framework that currently are without a qualified analysis.
*Status***:** The Training and Certification Workgroup began work on the development of this process in Nashville at the November 2011 PFP meeting. 7 job task analyses conducted by FDA/DHRD were identified that address specific areas of the curriculum framework. A Subgroup was established to continue work on developing criteria to qualify these 7 job task analyses and other job and occupational analyses identified.
*Estimated Timeframe for Completion*: August 01, 2012