

**COLLABORATIVE FOOD SAFETY FORUM
Domestic Facility Inspections Workshop**

**April 12, 2012
Washington, DC**

Workshop Highlights

The Pew Charitable Trusts (Pew) and the Robert Wood Johnson Foundation (RWJF) are co-sponsors of the Collaborative Food Safety Forum (Forum). The Forum aims to engage key stakeholders in collaborative and creative problem-solving dialogue and to serve as a platform for thinking through ideas for implementing the Food Safety Modernization Act (FSMA) efficiently and effectively. On April 12, 2012, the Forum convened approximately 35 representatives from the food industry; consumer advocacy groups; academia; state regulatory bodies; federal agencies, including the Food and Drug Administration (FDA); and other stakeholders in Washington, DC for a workshop on the domestic facility inspections program, particularly as it relates to FSMA.

The goals of the Forum workshop were to:

- Explore FDA's plans to meet the Food Safety Modernization Act's (FSMA) requirements for inspection of domestic facilities as part of overall FSMA implementation
- Discuss the following key aspects of an inspection program:
 - Establishing priorities for inspection, including:
 - Defining "high risk" and "non-high risk" criteria
 - Determining which facilities are placed into these categories
 - Determining a process by which facilities move from one category to another
 - Determining what is inspected (e.g., records, food products, environment)
 - Determining the frequency of inspection (consistent with FSMA requirements)
 - Deciding who is conducting the inspection, what training they need, and what type of oversight and assessment should occur
 - Ensuring transparency and accountability in the inspection process
 - Considering what metrics should be used in assessing the effectiveness of the inspection process in protecting public health
- Determine any next steps

The following are the main themes emerging from the workshop:

- FDA's move towards a *preventive-controls framework* for its inspections program constitutes a shift in focus. Accordingly, the agency is interested in hearing from stakeholders about their interests, concerns, and ideas for addressing concerns.
- FDA's proposed *criteria for determining high-risk facilities* include:
 - Known safety risks of the food;
 - Compliance history of the facility;
 - The facility's hazard analysis and risk-based preventive controls;

- Certifications for imported foods;
 - Length of time from last inspection; and
 - Any other criteria deemed necessary.
- One suggestion for an *additional high-risk criterion* was the facility's role in the food system (i.e., is it central to the system? Does it supply ingredients for a large number of products?).
- *Registration of all facilities required.*
 - Facilities must register by the end of 2012 and must re-register every two years.
 - A facility must notify FDA of any changes to its production or facility.
- It is important for stakeholders to know and understand *what to expect from inspections.*
 - Small companies do not have the same access or resources for challenging inspection findings as larger companies do. They are also less likely to have trained *all* their employees on how to handle inspections when they occur, which could lead to having to challenge such findings.
 - Other stakeholders want to understand what is involved in an inspection in order to evaluate the effectiveness of this aspect of FSMA and assess whether it is serving its purpose to improve food safety.
- Participants raised the following *questions about the inspections program:*
 - How will inspectors evaluate the food safety plans that are developed and ensure that they are implemented correctly?
 - How will FDA address small producers' facilities?
 - How will FDA know if there has been a change at a facility that would call for a reevaluation? What is the best way to gather this information from industry?
 - A participant suggested that the agency proactively email the registration list to request product updates.
 - How much does an individual inspection cost?
 - How will FDA handle the self-executing, preventative-controls requirements of FSMA if the regulations are not finalized by the July 2012 deadline?
- Information on the current and future FDA *inspector training program* included the following:
 - In most cases, FDA inspectors currently complete two years of training before performing inspections on their own. They are trained to inspect a variety of facilities over which FDA has oversight. This approach may change.
 - Inspectors will be required to go through new FSMA-specific training.
 - It is important to develop an integrated state and federal training program.
 - An industry participant suggested that FDA use industry facilities for hands-on inspection training.
 - Inspectors need to appreciate that there are different ways of getting to the same food safety end point.
- FDA is about to deploy a proof-of-concept *pilot for component inspections.*
 - FDA is conducting a pilot study designed to focus on particular aspects or "components" of a facility's food safety plans, actions, and products.

Component inspection is also intended to target and reduce resources and labor hours compared to comprehensive inspections, while still protecting public health. If component inspection is successful, resources and inspector time and effort will be focused on “high risk” facilities.

- Comprehensive inspection involves reviewing all aspects of a facility.
 - Component inspection focuses on one or more of the following components of a facility’s food production plan and physical plan: plan adequacy, plan implementation, and physical plant, including sanitation and presence of any contaminants.
- The pilot is being conducted in seafood and juice facilities as FDA already inspects these facilities so have comparative data.
- If component inspection is adopted, a facility will only receive such an inspection if there is an inspection history. If there is no inspection history, the first inspection would be comprehensive.
- If an inspector finds a significant deficiency during a component inspection, he or she will shift and undertake a comprehensive inspection.
- It could be useful for FDA to engage stakeholders in evaluating the results of the pilot.
- FDA is interested in stakeholder input on how to make the best use of pilots during the transition from a traditional to a preventative-controls approach to inspections.
- *The role of state inspectors* was discussed.
 - Currently, FDA contracts with state inspectors to perform many FDA inspections.
 - The state inspectors must meet minimum training requirements in order to be eligible to perform inspections on behalf of FDA.
 - Participants were interested in the question of how the standards for inspectors can be raised.
 - The contracted amount FDA pays for each inspection varies from state to state, and is dependent on a number of variables (e.g., differences in travel costs).
 - States are often contracted to perform relatively low-risk facility inspections, freeing FDA staff to conduct the higher-risk facility inspections.
 - FDA is interested in getting input on the best way to measure the quality of the state inspections performed for the agency.
 - Effective FDA oversight of states is important to ensuring accountability.
- *Data collection, reporting, and access* to resulting information are of significant interest.
 - Currently, the states and FDA lack the capacity to collect and analyze inspection data in public summary reports.
 - A data center integrating information across multiple agencies is a clear need as articulated by various stakeholders.
 - Participants expressed interest in more detailed data from FDA, including:
 - The type of facility being inspected (warehouse or food processing plant);
 - Distance of the facility from the home office of the inspector, to ensure that convenience does not determine inspection frequency; and

- Audit results from both FDA and local inspections in order to capture regional variability.
- Participants identified the following needs when reporting data:
 - Consistency in how data are measured and reported;
 - Consistent baselines; and
 - Clear, measurable goals.
- The data should be presented to the public in an accessible and digestible format.
- If facilities are ranked or “graded,” it must be done through a consistent and transparent process.
- *Metrics* are key for evaluating the effectiveness of the inspection program
 - Metrics must be tied to public health outcomes.
 - It is challenging to identify the right set of metrics that have a clear impact on public health.
 - Possible metrics include:
 - Activities that reduce the risk of food contamination;
 - Improvements in the training pass/fail rate of facility personnel;
 - Number of full-time employees (FTEs) and number of inspections per FTE (having this information would help to secure adequate appropriations);
 - A reduction in recalls;
 - Improvements in the specific non-compliance reports that can be linked to a public health impact, similar to a measure used by FSIS; and
 - Microbial limits.
- Possible *future discussion topics* identified include:
 - How inspections are carried out on the ground.
 - More comprehensive discussion of the federal-state inspection plan.
 - Determining evaluation criteria for the effectiveness of the inspections program, including metrics meaningful to public health.
 - Stakeholder assistance to FDA regarding its current components inspection pilot, and with potential future pilots.
 - The potential for public-private partnerships to help FDA transition and improve its training program.
 - The potential role third-party certifiers could play in domestic facility inspections.
 - Information sharing among local, state, and industry representatives with federal representatives.
- *Next steps* following the meeting include:
 - FDA will consider the best way to solicit stakeholder input on the component inspections pilot project and follow up with workshop participants.
 - Distribution, review and comment on the draft summaries (key themes and full summary).
 - Additional consultation will determine any other next steps.