

COLLABORATIVE FOOD SAFETY FORUM

Domestic Facility Inspection Workshop

April 12, 2012

Washington, DC

Workshop Summary

The Pew Charitable Trusts (Pew) and the Robert Wood Johnson Foundation (RWJF) are co-sponsors of the Collaborative Food Safety Forum (Forum). On April 12, 2012, they invited representatives from industry, consumer advocacy groups, academia, state regulatory bodies, and other key stakeholders to Washington, D.C. to engage in a workshop focused on the domestic facility inspection provisions of the Food Safety Modernization Act (FSMA). In addition to the stakeholder groups, individuals from the U.S. Food and Drug Administration (FDA) were invited to observe the workshop and the discussions. The following goals and outcomes were proposed for this session.

Goals:

- *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 some of the key aspects of an inspection program, including:*
 - *Establishing priorities for inspection, including:*
 - *Defining "high risk" and "non-high risk"*
 - *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*

Outcomes:

- *Through dialogue and exchange of ideas among stakeholders and policymakers, an exploration of:*
 - *Opportunities and challenges posed by developing the inspection program under FSMA*
 - *Ideas for establishing an effective inspection program*
- *A summary of the deliberations, key themes and any identified next steps*

Copies of the background materials and presentation slides are available on the Forum website at <http://www.resolv.org/site-foodsafety/inspections-forum/inspections-workshop/>.

I. Welcome and Introductions

Two representatives of the organizations hosting the meeting greeted the group. Angela McGowan, a Senior Program Officer for the Robert Wood Johnson Foundation (RWJF), and Erik Olson, the Director of Food Programs at the Pew Charitable Trusts, welcomed the workshop attendees and thanked them for their participation.

Dara Corrigan, the Associate Commissioner for Regulatory Affairs at FDA, extended her appreciation to the meeting participants and acknowledged the opportunities the workshop presented: for FDA to hear from different voices, and for different stakeholders to pose questions of the agency. She noted one of the challenges that FDA faces is the imperative of responding quickly despite imperfect information. Working with partners can help the agency fulfill its mandates.

Abby Dilley, the meeting facilitator from RESOLVE, provided a brief overview of the Forum, which is convened by Pew and RWJF with the purpose of creating dialogue around specific issues that would be helpful to FDA and other federal agencies as they think about implementation of the FDA Food Safety Modernization Act (FSMA). As part of the planning process, RESOLVE spoke with a number of stakeholders to identify topics the Forum could focus on. Based on those interviews, the meeting planners to date have developed the Forum around three sets of issues: imports, surveillance, and inspections. This workshop is the fifth in the series, and the first to focus on inspections.

Ms. Dilley noted that a pre-workshop webinar was held with the purpose of helping participants learn background information about domestic facility inspection.¹ She acknowledged the three presenters who helped with the webinar: Neal Fortin of the Institute for Food Laws and Regulation at Michigan State University, Melanie Mayor of the FDA Office of Regulatory Affairs, and Karyn Campbell of the FDA Philadelphia District Office.

II. Overview of FSMA Requirements and the Role of Inspection in Implementation

Howard Sklamberg, the Deputy Associate Commissioner for Regulatory Affairs at FDA, summarized the various FSMA mandates related to inspections. These include:

- 1) FDA must designate high- and low-risk food and feed facilities. These designations will help determine the inspection frequency of those facilities.
- 2) Companies are required to conduct a hazard analysis and then develop preventive-control plans. FDA, as part of its inspection responsibilities, must review these plans and their implementation.
- 3) FDA is moving to a preventive- controls model. This requires thinking on how to develop a preventive- controls framework and how inspections would change. This will also require training inspectors in a new approach to food safety.

Mr. Sklamberg acknowledged that this expansion in responsibility is happening in a time of limited budgets. He noted that partnerships with the states were vitally important to carrying out inspection responsibilities effectively and efficiently.

¹ A recording of the webinar and copies of the presentations are available online at <http://www.resolv.org/site-foodsafety/inspections-forum/inspections-workshop/>.

Workshop attendees engaged in a short discussion following Mr. Sklamberg's overview. In response to participant questions, Mr. Sklamberg and other FDA representatives made the following points:

- Most of FDA's inspectors are specialized to some degree, and food products are typically only inspected by personnel who predominantly inspect food. There are also inspectors who specialize in a particular type of food. At the same time, there is enough flexibility and oversight built into the system that inspectors could be reassigned if there was a pressing need.
- FDA is aware of the additional burden that inspections and record-keeping can place on both the industry and the agency and is thinking about how to best balance the needs of public health with ensuring that compliance is not onerous.
- The new inspections framework will include stronger partnerships between the federal government and the states. FDA will be providing training and expertise to support state investigators, and all parties will share data to help inform inspection activities.

One participant suggested that FDA learn from the US Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) as the agency moves forward with a preventive- controls framework.

III. Expectations for the Inspection Program in the Implementation of FSMA

To inform the discussion, meeting participants heard four different perspectives on the role inspections should play under FSMA, including thoughts on key indicators of a successful inspection program and ideas for solutions to some of the challenges in the program's implementation.

Neal Fortin, Director of the Institute for Food Laws & Regulations, Michigan State University College of Agriculture and Natural Resources

Mr. Fortin pointed to the fiscal climate in which FSMA is being implemented. Public health funding has been decreasing at all levels of government, and agencies are being asked to take on more duties without additional funding. Mr. Fortin identified possible efficiencies that FDA could adopt in order to lower the costs of inspections. He commended the agency for its very high standards for inspections, but suggested that lowering standards slightly could result in cost savings with minimal impact to public health. He also suggested that FDA adopt metrics that would measure reduction to overall risk in food production, and measure employee and industry perception of effectiveness. Lastly, Mr. Fortin noted that with states performing inspections, state inspectors will need comparable training to that received by FDA inspectors.

Joan Menke-Schaenzer, Global Chief Quality Officer, ConAgra Foods

Ms. Menke-Schaenzer explained ConAgra's approach to inspections. She noted that large companies strive to always be "inspection-ready." In addition to FDA and state inspections, their facilities are also subject to a number of different inspections and audits, including internal audits, corporate audits, and third-party audits, customer audits of their commercial plants, and certification audits for organic or kosher products. ConAgra's facility training emphasizes being prepared for inspections, with the end goal of food safety.

Ms. Menke-Schaenzer then expressed the aspiration that inspections and audits be risk-, system-, and science-based, and be carried out by individuals who understand the hazards and risks based on the foods being produced in the facility. She also pointed to redundancy in inspections performed by different parties and noted that communication, collaboration, and sharing information among the inspecting bodies could increase efficiency and conserve resources for both the company and the inspectors.

In response to a question, Ms. Menke-Schaenzer explained that ConAgra determines risk using the same variables defined by FDA and USDA, while acknowledging that risk is not static. She noted that the company keeps abreast of the latest science related to food safety so it can take proactive measures to reduce risk before a problem is detected. One participant explained that many in the industry consider food safety to be non-competitive and will share information and best practices to improve safety across the industry.

Following Ms. Menke-Schaenzer's presentation, several participants made additional points. One participant encouraged industry to integrate the newest science and findings on potential hazards in developing preventive controls. This individual also noted that large companies have the resources to undertake comprehensive training of employees, and to provide support during an inspection to a degree that is difficult or impossible for smaller companies. FDA will need to think about how to provide training and encouragement to companies of all sizes in order to protect both the food supply and the company's financial bottom line.

Bob Bauer, President of the Association of Food Industries and Executive Director, the National Association of Flavors and Food-Ingredient Systems

Mr. Bauer informed the group of some of the thoughts from small business members of his associations. He related the following concerns that he heard:

- FDA should be transparent about what inspectors are looking for, how data should be presented, and what the facility should expect during an inspection.
- Facilities should have the ability to appeal the decision of an inspector on the ground, and receive a response in a timely manner.
- There needs to be increased timeliness and efficiencies in inspections, to minimize delays in meeting deadlines.
- Inspector training should be certified and overseen by FDA, whether the inspector is an FDA employee or not.
- Risk of the food should be a factor when determining the outcomes of an inspection (e.g., recalls).
- Inspections should be performed with the goal of ensuring preventive controls are in place and that necessary corrections are implemented.
- The inspector should engage the facility or company being inspected in a dialogue so that inspections could be learning opportunities for both parties.

Donna Garren, the Vice President of Regulatory and Technical Affairs at the American Frozen Food Institute, provided some additional thoughts. She explained her association has been developing a set of tools to help smaller businesses be "inspection-ready." She encouraged FDA to train its

inspectors to be flexible and to focus on the endpoint of whether food safety objectives are achieved or not.

Following Mr. Bauer's and Ms. Garren's presentations, there was a brief discussion on the support smaller companies receive from a number of sources. Ms. Garren explained smaller companies do rely on their associations to inform them of how to comply with new rules and regulations, best management practices, and to provide them with information they need. In addition, the larger companies also mentor the smaller companies within the association. Mr. Bauer also noted that many small companies supply larger companies, and therefore are subject to the customer's requirements for food safety and quality assurance. If a company is not a member of an association, they often approach an expert for assistance.

Chris Waldrop, Director, Food Policy Institute at the Consumer Federation of America

Mr. Waldrop gave the perspective of a consumer advocacy group on the implementation of the FSMA inspections provisions. He noted that consumers expect the government to ensure a safe food supply, and that inspections are the tool by which to do so. Opinion polls illustrate that consumers expect the federal government to be carrying out the inspections of food facilities. Mr. Waldrop identified a number of concerns with states carrying out inspections: (1) diverting resources away from other vital food safety activities, such as outbreak investigations; (2) variability between states regarding inspector requirements, resources, and other food safety activities; (3) budget constraints at the state level; and (4) limited resources at the federal level to help the states perform food safety activities. Acknowledging that states will be performing inspections for FDA, he asked for transparency as the different levels are integrated into an inspection system, specifically the expectations for the state and the results of state audits.

Another workshop participant requested that FDA provide clarity in two additional areas: (1) the costs of inspections, both in terms of labor hours and dollars; and (2) how FDA would handle inspections for larger companies that may be subject to self-executed preventive controls requirements if the regulations are not finalized by July 2012.

IV. Determination of High Risk and Non-High Risk Facilities for Inspection

The group then heard a presentation from Melanie Mayor from the FDA Office of Compliance, who provided an overview of how the agency plans to determine which facilities are high risk and how it will prioritize inspections accordingly. She listed the following categorization factors that FDA plans to use to identify high-risk facilities:²

- known safety risks of the food;
- the compliance history of a facility;
- the facility's hazard analysis and risk-based preventive controls;
- certifications for imported foods; and
- any other criteria deemed necessary.

She noted that the length of time since a facility's last inspection will also be a criterion in prioritizing inspections.

² Please see Ms. Mayor's presentation for a flow chart demonstrating how these factors will be used to determine high-risk and non-high-risk facilities.

One participant suggested that the facility's role in the food system (i.e., does it supply other facilities?) should be another criterion to consider in determining a high-risk facility.

Ms. Mayor reviewed the current timeline to conduct inspections, the challenges to carrying out the timeline, and FDA's next steps in the process. She explained that the FDA FSMA workgroup tasked with developing the criteria for high-risk categorization is waiting for deliverables from other workgroups before proceeding.

Discussion

Following Ms. Mayor's presentation, participants were given the opportunity to ask questions. The majority of the discussion focused on the registration process for food and feed facilities. Ms. Mayor explained that the Registration Work Group is expected to issue guidance documents in the summer of 2012, which will be coupled with an aggressive outreach campaign. The new registration system is designed to also collect information about risk. Facilities will be required to update their registrations periodically and notify FDA of any changes to their facility. If a facility does not do so, that constitutes a violation, though FDA may not necessarily be aware of any changes until the next inspection or if a problem arises.

Ms. Mayor also made the following additional points in response to questions:

- FDA is still determining many of the specifics of the inspection program, including determining a compliance baseline, how to revisit high-risk plants in a timely manner, and finalizing the criteria for a high-risk facility.
- FDA is working closely with CDC and FSIS on improving foodborne illness surveillance. These efforts will include more laboratory surveillance and moving to pulsed field gel electrophoresis (PFGE) to map the full genome of the pathogen.

V. Key Aspects of Inspections for Domestic Facilities

Karyn Campbell, the Director of Investigations at the FDA Philadelphia Region Office, explained how FDA defines inspections, outlined different types of inspections, and described how the agency will be changing its training program in order to move to a preventive- controls framework. She noted that FDA is planning on two different types of inspections: comprehensive inspections and component inspections, which would focus the inspection on a specific area (plan adequacy, plan implementation, or sanitation). The agency is currently undertaking a proof-of-concept pilot to determine the effectiveness of component inspections and whether they will produce savings in terms of cost and labor hours while still being protective of public health. The pilot is being conducted in seafood and juice facilities, as they are considered high risk and would therefore better demonstrate whether the component inspections are effective.

Discussion

Following Ms. Campbell's presentation, meeting participants engaged in a discussion that focused on component inspections and inspector training. Several individuals expressed concern that a component investigation may not be as protective of public health. Ms. Campbell explained that the inspectors will still be looking at the facility within a public- health framework. They are trained to move to a comprehensive inspection if they encounter a significant issue. The pilot project is also

designed to test whether the component inspection provides the same level of confidence in terms of public- health protection as a comprehensive inspection. Participating inspectors are performing both comprehensive and component inspections in order to determine if an individual inspector is capturing the same type of deficiencies in similar facilities. A participant suggested that FDA allow outside experts to peer review the findings of the pilot study.

In response to a question, Ms. Campbell explained that under the component- inspection model, if a facility has detailed inspection history with an evaluation of the three components, then that facility could start off with a component inspection. If there is no history, then the first inspection would be comprehensive in order to establish a compliance baseline.

Many of the workshop participants were interested in how FDA inspectors are trained. Ms. Campbell noted that most inspectors enter the program with a graduate degree and go through about two years of training before performing inspections on their own in the field. Inspectors are given the opportunity periodically to be retrained; in addition, any new regulations and policies require new training. Ms. Campbell explained if the agency adopts component inspections, inspectors will most likely have new training for preventive controls in addition to other training related to FSMA.

During the discussion, participants raised the following questions about the inspections program:

- How will the system evaluate the plans that are developed and ensure that they are implemented correctly?
- How will FDA address small producers?
- 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?
- How much does an individual inspection cost?
- How will FDA handle the self-executing preventive controls provisions of FSMA?

VI. Options for Achieving Greater Capacity

Informed by earlier presentations, the workshop participants discussed options for increasing inspection capacity. Much of the discussion focused on an integrated- inspection system. Several participants raised concerns with integration and having state inspectors carrying out FDA inspections. Some of the concerns included:

- lack of transparency in how state contracts were negotiated;
- whether these inspections would be an additional burden on the states;
- the disparity in the quality of training between the federal level and the various states;
- the lack of consistency in the different state contracts; and
- the level of FDA oversight of state inspectors.

Some of the other participants attempted to address these concerns. One individual informed the group of the Manufactured Food Regulatory Program Standards (MFRPS), which are aimed at establishing equivalency between federal and state “food safety standards, inspection programs, and

enforcement practices.”³ This individual explained that most states already had comparable food safety programs that were well-integrated with FDA and the MFRPS were simply validating and providing support for activities already in place. Eleven states have not yet signed onto the program.

Ms. Corrigan acknowledged that inconsistencies in FDA-state contracts do exist and need to be addressed. While some of the variability can be easily explained (e.g., transportation costs, training requirements for specific inspections), she indicated that FDA will be looking into how the contracts are awarded and negotiated and will seek opportunities to make the process more transparent. She explained that generally, the states inspect facilities that are not high-risk, which requires less formal training. This then allows FDA to focus its inspectors on the higher-risk facilities. Another participant noted that the contracts stipulate the minimum level of training state inspectors must have completed in order to carry out FDA inspections. FDA also has a system to audit the state inspectors.

Several participants also identified potential reasons for why states might be paid differently for performing inspections. One individual noted that in some states, transportation costs would be higher in order to reach the facilities (e.g., driving versus flying). Another participant observed that the lower-risk inspections that are contracted out to the state tend to be easier and faster, reducing the cost of performing those inspections. The higher-risk inspections that are generally performed by FDA inspectors would necessitate more time and training.

One individual informed the group that in many cases, inspections carried out by the state inspectors were counted as both a federal and a state inspection, leveraging resources for both entities. The payment from FDA for that inspection helps bring the cost down for the state.

Several participants raised the question of how to raise minimum standards for inspectors across all states. There have been several previous attempts to establish minimum standards, which, while gaining support from the states, were not adopted at the federal level. Several individuals pointed to the importance of developing an integrated state and federal training program to ensure that state inspectors are consistently trained and qualified to perform FDA inspections. One participant suggested that industry may play a role in helping with this training.

VII. Accountability and Transparency in an Inspection Program

The group then discussed how to increase accountability and transparency in the inspection program. One individual pointed out that transparency facilitates accountability. Much of the discussion focused on data collection on inspections, and how to present this data to the public.

Data Collection

A few participants noted that currently, FDA and the states lack the capacity to collect the information and perform the data analysis required for summary reports. One individual suggested developing a central database to aggregate all data from inspections.

³ The Manufactured Food Regulatory Standards are available online at <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125448.pdf>.

During the discussion, individuals expressed interest in obtaining more detailed data from FDA than summary reports would provide. The following data were specifically mentioned:

- 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 of the inspectors, from both FDA and the states, in order to capture regional variability.

In addition, several participants expressed a desire to better understand the nuances of the inspection program. Stakeholders pointed out that armed with such knowledge, they could in turn help explain FDA funding needs to legislators and policymakers.

Data Reporting

Several individuals pointed to the need for consistency in reporting inspection data over time, in order for the data to be meaningful and useful for analysis. Furthermore, clear, measurable goals for the inspection program are needed in order to gauge progress. One participant noted that when baselines and measurement criteria change, conclusions cannot be drawn from the data.

The group also discussed the format in which data should be presented to the public, emphasizing the importance of accessibility. One individual suggested that FDA produce an annual report similar to the annual report of the European Food Safety Authority (EFSA) and the European Centre for Disease Prevention and Control (ECDC) on zoonoses and foodborne outbreaks in the European Union. The report is a helpful model not only because it presents pathogen data, but also because it contains trend analyses and special reports on outbreaks. Producing an annual report facilitates public awareness and understanding of the information, and enables the various food safety offices and agencies to work together to compile the data and present it in a meaningful way.

In addition to sharing summary information with the public, the federal government, one participant emphasized, needs to share information during an outbreak investigation with the states. Currently, unless a state is actively involved in the investigation, it is not given notice of an outbreak by FDA or CDC.

Grading

The group also briefly discussed the possibility of “grading” the various facilities based on the inspections and publishing the inspection results, in the same way that some state and local health departments “grade” restaurants based on their inspection results. Several individuals expressed openness to the idea, so long as the criteria behind the grades were consistent and transparent. One participant related that the state of Michigan does publish manufacturing sanitary notices and grades. This initiative resulted in increased compliance, as well as highlighted the variability among different facilities.

VIII. Metrics for an Effective Inspection Program

During the discussion on how to increase accountability and transparency in the inspections program, the group underscored the need to identify meaningful metrics. One individual suggested that it is important to define those metrics early in planning the inspections program in order to

determine what risk-related data should be collected. The group agreed that the metrics must be tied to public health. During the discussion, the workshop participants identified the challenge of developing metrics linked to public health outcomes for an inspection program that is focused on compliance.

The effectiveness of the system cannot be measured solely by the number of inspections performed. Several workshop participants touched on the complex nature of food production and how risks enter the system. One individual noted that a facility may be complying with its preventive control plan and still experience negative public- health outcomes, indicating a risk that had not been taken into account. Another individual observed that investigations need to move beyond compliance; rather, the goal should be to identify potential risks, allowing the facility to preemptively address them.

Several participants also pointed to the difficulty in linking the effectiveness of inspections to public- health outcomes. Much of the public-health data is not under FDA control; therefore, the data might not be available in a timely manner and it could be incompatible with FDA systems. In addition, the data on foodborne outbreaks is limited in that it does not capture changes in population, consumption, or diagnostic and surveillance techniques.

During the discussion, several participants identified possible measurable criteria that could be used as metrics. These included:

- improvements in the training pass/fail rate of facility personnel;
- 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.

IX. Assessing Progress and Next Steps

Workshop participants identified the need for more discussion around the following topics:

- **What inspectors are doing and seeing out in the field.** Participants expressed interest in further information from FDA on how inspections are carried out.
- **Helping FDA with inspection pilots.** Several participants indicated a willingness to help FDA with the current pilot. FDA could update an informal group throughout the process or institute a peer review after the pilot is conducted. FDA also requested ideas from stakeholders for additional pilot projects it could plan and implement. **FDA will consider the best way to solicit stakeholder input on the component- inspection pilot and follow up with the workshop participants.**
- **Training.** How can the industry help FDA develop and implement its FSMA-based training program?
- **Metrics.** What are the metrics that are meaningful to public health? What data need to be collected to help inform these metrics?
- **Third-party certifiers.** What role can they play in domestic facility inspections?

- **Data sharing.** The states and industry have information about the facilities that can help inform the inspections. How can these data be shared with the federal government, and with state inspectors?