

## Inspection Modernization and Training

### Key Investments for Implementing the FDA Food Safety Modernization Act (FSMA)

*To implement FSMA, FDA will make improvements in six areas with \$109.5 million in new budget authority requested in the President's Budget. One of those areas is Inspection Modernization and Training. To read more about how FDA will be investing funds to implement FSMA, visit [www.fda.gov/fsma](http://www.fda.gov/fsma).*

FDA's FSMA implementation strategy is based on the assumption that most food producers want to comply with food safety standards and that FDA should work to facilitate and verify their compliance, while targeting its more intensive inspection and enforcement efforts on higher-risk situations that need greater FDA oversight to ensure food safety. This means FDA will invest more in guidance, education, and technical assistance, especially for smaller firms. It also means modernizing FDA's approach to inspection and building a workforce that can work in the new ways required by FSMA.

Inspection modernization and training are key components of FDA's budget request for FY 2016. FDA is planning investments to modernize the inspection process and prepare its workforce at all levels to carry out inspection and compliance in the risk-based, prevention-oriented manner envisioned by FSMA.

Inspectors are currently trained to inspect food manufacturers using a compliance model focused on finding evidence of legal violations and bringing enforcement cases. While these tools remain critical, the new inspection paradigm will be focused on whether firms are implementing systems that effectively prevent food contamination, requiring fundamentally different approaches to food safety inspection

and compliance. For example, FDA will deploy specialized inspectors, backed up by technical experts, to assess the soundness and performance of a facility's food safety system, and will use data to guide risk-based inspection priority, frequency, depth, and approach. FDA will also focus on ensuring consistency among inspections.

This new paradigm involves a major reorientation and retraining of more than 2,000 FDA inspectors, compliance officers, and other staff involved in food safety activities, as well as thousands of state, local, and tribal inspectors, including approximately 1,000 in FY 2016. It also requires better data about facilities, new information technology (IT) systems to identify and track risk, and methods for assessing and tracking inspection efficiency and inspector competency.

#### **Requested Increase in FY 2016 Budget**

#### **Authority: \$25 Million**

With the requested increase in funding, FDA's plans include:

- **Designing the new FDA inspection model** and procedures and the internal management system needed to ensure that

FSMA inspections are both effective and efficient.

- **Beginning to implement an inspection approach for larger, multi-facility firms** that involves distinct types of inspections conducted by staff with commensurate levels of expertise and training.
  - FDA will initially inspect such firms, in some cases at the corporate headquarters level, to determine the adequacy of their Food Safety Plan, including hazard analysis and preventive control programs, which will require a high level of technical expertise.
  - FDA will then use other inspection approaches to determine if the firms are implementing their Food Safety Plan and/or complying with current good manufacturing practices (cGMPs).
  - The new inspection model takes into consideration the fact that there may be overarching, corporate-wide programs and policies implemented, in part, at the corporate- or firm-wide level. More specifically, the inspection model is designed to assure corporate-wide programs and policies are consistently implemented by all facilities under a given corporate umbrella.
- **Training FDA inspectors and compliance staff** to ensure uniform application of the new FSMA standards and inspection model. This includes:
  - Delivering training needed to implement preventive controls

(human and animal food) to federal regulatory staff, including inspectors, compliance officers, subject matter experts, managers, and supervisors.

- Delivering a broad curriculum that includes:
    - Introduction to food safety culture and systems thinking to support FDA's new inspection approach;
    - Technical updates on modern approaches to environmental monitoring, supply chain management, and minimizing allergen risks;
    - Practical skills training to support the new inspection approaches, including techniques for assessing food safety systems, negotiation and persuasion skills, and how to conduct cooperative inspections;
    - Specific regulatory prerequisite training, also delivered to industry, in good manufacturing practices, preventive controls, and hazard analysis and critical control points; and
    - Inspectional skills required to ensure FSMA compliance.
  - Leveraging FDA's training capacity by using new training approaches and partnering with academia, industry, and other food safety training organizations to deliver training to federal food safety staff.
- **Improving risk-based inspection work planning and resource allocation** through enhanced, systematic data collection, the

incorporation of dynamic risk algorithms in work planning, and systematic evaluation.

- **Continuing investment in an information technology (IT) framework** that will facilitate consistent and efficient inspection preparation, reporting, and classification, and an IT portal allowing industry submission of corrective action reports and the ability to view inspection reports and sample results.
- **Using facility risk and performance data** to guide the frequency and manner of individual facility inspections.
  - **Fostering an on-site dialogue during inspections** when areas of noncompliance are identified, seeking timely and adequate corrective actions to achieve industry compliance, and, following up with timely re-inspection to verify that compliance has been achieved. When compliance is not achieved in a timely and adequate manner using this approach, FDA will deploy its enforcement tools to protect public health.

### **Accomplishments Achieved with FY 2015 Funds**

The FY 2016 investments will build on progress made and ongoing efforts related to Inspection Modernization and Training in FY 2015, including:

- **Developing and implementing the FY2015 Preventive Controls Rule Readiness Training Plan.**

- **Assessing Preventive Controls rule readiness** during facility inspections and distributing fact sheets on the proposed human and animal food rules in an effort to better define and target future education and outreach activities.
- **Defining the inspection model for large firms** that must comply with the Preventive Controls rules one year after the final rules are published in August 2015.
- **Defining which provisions in the Preventive Controls rules represent critical, major, and minor areas of noncompliance** to assist in developing the compliance strategy.
- **Establishing a phased-in approach and cost analysis for an information technology (IT) framework** that will facilitate consistent and efficient inspection preparation, reporting, and classification, and an IT portal allowing industry submission of corrective action reports and the ability to view inspection reports and sample results.
- **Identifying the inventories of large, small, and very small food and feed facilities**, as defined in the proposed Preventive Controls rules, and mapping these inventories to assist in work planning.
- **Developing and initiating implementation of the multi-year**

- **Preventive Controls Regulator Training Plan.** This includes initiating development of the regulator training curriculum for the Preventive Controls rules.