FDA's Risk-Based Model for Prioritizing Inspections of Domestic Food Establishments At-a-Glance

Food safety is an important priority for the Food and Drug Administration (FDA). The nature of the U.S. food supply is rapidly changing because of complex food supply chains, increasing globalization, changes in the U.S. population, and new and diverse dietary patterns. These changes present new challenges to our food safety system, prompting FDA to find new ways to strengthen its inspection and enforcement program. In 2011, FDA will use an enhanced risk-based model for prioritizing domestic food establishments to be inspected.

One critically important step toward enhanced consumer protection is the Agency's development of a risk-based model to establish consistent, agency-wide priorities when developing annual domestic foods work plans for field activities. For fiscal year 2011 (FY 2011), FDA is focusing and prioritizing its inspectional activities by applying both qualitative and quantitative analyses to traditionally available information.

What factors will be considered in this enhanced risk-based model?

FDA's domestic risk-based model for FY 2011 is based on inherent risk factors at the industry wide level and on compliance history that is firm specific. The inherent risk factors at the industry wide level include foodborne outbreaks, recalls, and reports of adverse events associated with a specific industry or category of food, e.g., produce, seafood, and cheeses. The firm specific factor includes the compliance history, based on FDA inspection results for a firm for the previous five full fiscal years.

FDA's Domestic Risk-Based Model FY 2011 Factors

- Inherent Risk (industry wide)
  - Outbreaks
  - Class 1 Recalls
  - Adverse events
- Compliance History of Facility (firm specific)
  - Inspection results/classifications
  - Five fiscal years

How is it different than past models used by FDA?

In the FY 2011 model, FDA will for the first time use a weighted matrix, with numerical values for each factor, to assign relative risk to specific industries and to firms within the industry. Firms that are new, have never been inspected by FDA, or that have not been inspected by FDA in the previous five fiscal years (i.e., FY 2005 – FY 2009) will be assigned a relatively higher numerical value.

What are the benefits of employing this model?

This enhanced risk-based model will help assure that such firms, particularly those associated with industries with inherent risks, will receive a relatively high risk ranking within the Agency's food establishment inventory. The relative risk ranking process will be used to determine Agency resource allocations. Firms relatively ranked with higher numerical scores will be assigned to appropriate FDA field offices for inspection. The model provides FDA flexibility to adjust priorities as necessary, based on introduction of new factors or by changing relative weights assigned to the factors.

Why is FDA revising its approach?

Traditionally, FDA's food safety activities focused on food facility sanitation, product contamination, and development of evidence to support enforcement actions for regulatory violations. Although this traditional approach provided decades of assurance of food safety and consumer protection, the increasing complexities of the food supply, combined with resource constraints, require FDA to better utilize available information to improve its operational efficiency. Thus, FDA has taken steps to focus its traditional activities to better target firms and foods that present the highest potential risk.

Will this model be updated?

FDA plans to annually review and refine the risk-based model. FDA will improve the model to incorporate new indicators or to adjust the scoring to address new and emerging threats to the safety of foods.