

Key Statistics Regarding Domestic Food Safety Inspections

Number of Domestic Facilities

- As of January 2011, there were 167,033 active registered domestic facilities.¹
- The total number of FDA-regulated domestic FSMA food processing facilities is approximately 82,300.² Approximately 22,335 of these are high risk facilities and 60,000 are non high risk.³
NOTE: Not all food firms are FSMA firms (e.g. high risk non FSMA firms include egg farms, produce growers, Interstate Travel watering points, etc.).

Number of Inspections

- In FY 2011, FDA completed approximately 11,000 domestic inspections of FSMA high risk facilities and approximately 8,000 domestic inspections of FSMA non high risk facilities. Of these, the *states* inspected approximately 4,500 high risk and 4,800 non-high risk FSMA food facilities.
- In FY 2011, FDA (10,500) and states under contract/partnership (10,000) conducted approximately 20,500 inspections at FSMA and non FSMA food facilities.⁴
- In FY 2012, FDA plans to inspect about 7,400 high risk and 8,600 non high risk facilities.⁵
- FDA currently has 46 contracts in place with state partners (43 states and Puerto Rico) to conduct 10,593 manufactured food inspections. Data are not available on the number of inspectors conducting this work.⁶

Costs of Inspections (pre- FSMA)

- For fiscal year 2010, the appropriations used to inspect facilities registered pursuant to section 415 of the FD&C Act was approximately \$172 million. Of this amount, \$129.6 million was used for FDA inspection of domestic facilities. In addition, of this total, \$16.5 million was provided to the States to perform domestic inspections for FDA. These figures do not include the cost of inspections at the border (i.e., sampling and field examinations) since this function is not performed in registered facilities, nor does it include costs for functions such as laboratory analyses or criminal investigations.⁷

Manufactured Food Regulatory Program (MFRP)

- There are currently 39 state programs enrolled in MFRPS program.⁸
- Currently none of the programs enrolled in the standards have achieved full compliance with all 10 standards. However; with the support of FDA's Office of Regulatory Affairs' Division of Federal-State Relations (DFSR), these programs are receiving the guidance necessary to advance their progress toward full conformance.⁹

- The level of conformance with the standards is largely dependent on when the program enrolled in the MFRPS (from 2008 – 2011).¹⁰
 - The states that enrolled since 2008 have achieved conformance with up to 7 of the 10 standards, whereas newly enrolled states are currently conducting their self-assessment and developing their strategic plans to begin implementation of the 10 standards.¹¹
 - Several standards are easily implemented by the majority of states (e.g., Community and Industry Outreach), whereas other standards require additional time and resources to fully implement (e.g., Audits, and Compliance and Enforcement). These programs are working closely with their FDA District Offices and DFRS to ensure coordination and integration of their efforts toward conformance with the standards.

Risk Factors FDA Uses to Determine High Risk and Non High Risk

FDA is using the following “Primary FSMA Factors for FY 2011-13” to identify a high risk facility.

- Known safety risks of the food;
- Compliance history of a facility;
- Facility’s hazard analysis and risk-based preventive controls;
- Priority under section 801(h)(1);
- Certifications for imported food; and
- Any other criteria deemed necessary.¹²

Note that according to FDA’s website, decision making will be based on the first two factors as well as other criteria identified in the last factor. These other criteria include “establishment type/type of activity conducted at the facility” and “years since last inspection.”¹³

Overlap with FSIS and/or Other Federal Agencies

- The estimated number of food facilities where both FDA and USDA inspect food products is approximately 2,400.¹⁴
- What other federal agencies also inspect facilities under FDA’s bailiwick?¹⁵
 - USDA’s Agricultural Marketing Service (AMS) conducts inspections for grading of food products and for certain contaminants.
 - USDA’s Animal Plant Health Inspection Service (APHIS) inspects plants and animal products for import & export.
 - USDA’s Federal Grain Inspection Service (FGIS) conducts inspections of grain, rice, pulses, and food products.
 - USDA’s Food Safety and Inspection Service (FSIS) inspects food facilities for compliance with FMIA, PPIA, EPIA.
 - The Department of Commerce’s National Marine Fisheries Service (NMFS) conducts fee-for-service seafood inspections and commercial grading inspections for fishery products.
 - The Department of Defense’s Defense Personnel Support Center (DPSC) is associated with large quantities of foods purchased for military personnel both in the continental U.S. and overseas; DOD has food sanitation inspectors that may conduct inspections.

- CDC's Vessel Sanitation Program has jurisdiction for outbreaks on foreign flag vessels or US flagged vessels with international itinerary.
- The Treasury Department's Alcohol and Tobacco Tax and Trade Bureau (TTB) - collects samples and tests alcoholic beverages

¹ Annual Report of Food Facilities, Food Import, and FDA Foreign Offices, accessed April 3, 2012.

<http://www.fda.gov/Food/FoodSafety/FSMA/ucm250569.htm#food_facilities>

² FSMA Domestic Facility Risk Categorization (FY 2012), accessed April 2, 2012.

<<http://www.fda.gov/Food/FoodSafety/FSMA/ucm295345.htm>>

³ Ibid.

⁴ Numbers provided by FDA

⁵ FSMA Domestic Facility Risk Categorization (FY 2012), accessed April 2, 2012.

<<http://www.fda.gov/Food/FoodSafety/FSMA/ucm295345.htm>>

⁶ Information provided by FDA.

⁷ Annual Report of Food Facilities, Food Import, and FDA Foreign Offices, accessed April 2, 2012.

<http://www.fda.gov/Food/FoodSafety/FSMA/ucm250569.htm#food_facilities>

⁸ Information provided by FDA.

⁹ Ibid.

¹⁰ Ibid.

¹¹ Ibid.

¹² Annual Report of Food Facilities, Food Import, and FDA Foreign Offices, accessed April 2, 2012.

<http://www.fda.gov/Food/FoodSafety/FSMA/ucm250569.htm#food_facilities>

¹³ Ibid.

¹⁴ Information provided by FDA

¹⁵ Ibid.