

Amendments to Registration of Food Facilities; Final Rule

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Presentation Objectives

To communicate information regarding food facility registration requirements as amended by the FDA Food Safety Modernization Act including new provisions



Food Facility Registration Background

The owner, operator, or agent in charge of a domestic or foreign facility engaged in manufacturing/processing, packing, or holding food for consumption by humans or animals in the United States is required to register the facility with FDA

- Food facilities must be registered before such operations begin
- The owner, operator, or agent in charge of a facility that is required to register may authorize an individual to register the facility on its behalf
- Food facilities that are required to register with the FDA must renew their registrations every two years, between October 1 and December 31 of each even-numbered year. The next registration renewal period will be October 1 through December 31 of 2016.



Food Facility Registration Background

The following facilities are exempt from Food Facility Registration requirements:

- A foreign facility if food from the facility undergoes further manufacturing/processing (including packaging) by another facility outside the United States. The foreign facility is not exempt from registration if the further manufacturing/processing (including packaging) activities of the subsequent facility are limited to affixing a label to a package or other de minimis activity.
- Farms
- Retail Food Establishments
- Restaurants
- Nonprofit Food Establishments in which food is prepared for, or served directly to, the consumer
- Certain fishing vessels not engaged in processing;
- Facilities regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601, et seq.), the Poultry Products Inspection Act (21 U.S.C. 451, et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031, et seq.).

Food Facility Registration Final Rule

- The final rule codifies FSMA requirements already in effect, implements other FSMA provisions and other amendments necessary to improve the utility of the registration database, allowing the agency to better respond to food-related emergencies and better use its limited inspection resources

FSMA Requirements Already in Effect

- The e-mail address for the contact person of the domestic facility or, in case of a foreign facility, the email address of the U.S. Agent for the facility
- Assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act
- Updated food product category information, as determined appropriate by FDA in already-published guidance
- Biennial Renewal

Provisions to Improve Accuracy of Registration Information

- Unique Facility Identifier(UFI) requirement
 - Will assist FDA in verifying accuracy of site specific address
 - FDA verification of UFI prior to issuance of registration number or confirmation of registration
 - To be implemented October 1, 2020
- US Agent Voluntary Identification System(VIS) and verification procedure
 - US Agent VIS to be implemented via forthcoming guidance
- Requirement for email address of owner, operator, or agent in charge who authorized a third party to act on behalf of the facility and verification procedure
- Some previously optional fields are now mandatory
 - Preferred mailing address, emergency contact email address, type of activity

Other Amendments to Food Facility Registration

- Electronic registration as of January 4, 2020
- Waiver process:
 - For registrants who submit waivers explaining why it's not reasonable to submit registration, registration renewals, updates, or cancellations electronically (e.g., no internet access)
 - Also from the requirement to provide the email address of the owner, operator, or agent in charge of the facility, as well as a waiver from the requirement to provide the email address for the individual who authorized registration submission
- Abbreviated Registration Renewal Process
- Authority to cancel registrations in additional circumstances
 - FDA independently verifying facilities not required to register, facility address not updated in a timely manner, unauthorized registration submissions, registration expiration due to failure to renew
- Require immediate update to incorrect registration information
- Changes to activity types
 - Addition of Ambient human food storage warehouse/holding facility, Refrigerated human food warehouse/holding facility, Frozen human food warehouse/holding facility, Farm Mixed-Type Facility, Animal food warehouse/holding facility



Amendment to Retail Food Establishment Definition

- Clarifies that in determining the primary function of an establishment, establishments located on a farm and “farm-operated businesses” may consider sales directly to consumers at:
 - Roadside stands
 - Farmers’ markets
 - Community Supported Agriculture (CSA) programs
 - Other such direct-to-consumer platforms



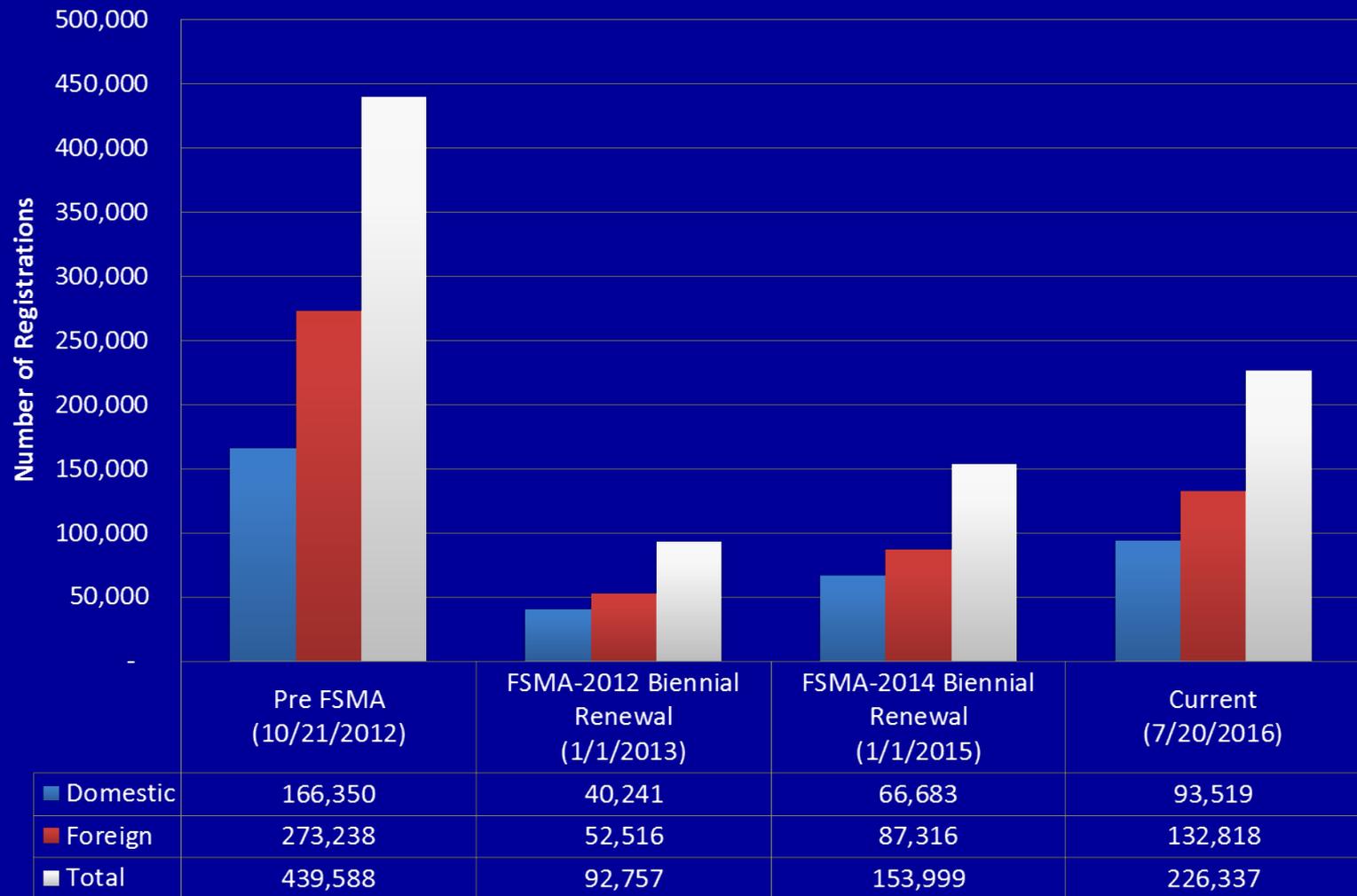
Preventive Controls and Food Facility Registration: On-Farm Activities

- Section 103(c)(1)(A) of FSMA, regarding Hazard Analysis and Risk-Based Preventive Controls, required that the Secretary publish a notice of proposed rulemaking in the Federal Register to issue regulations with respect to "activities that constitute on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership" and "activities that constitute on-farm manufacturing or processing of food that is not consumed on that farm or on another farm under common ownership" within the context of section 415 of the FD&C Act. We finalized the rulemaking on September 17, 2015. See Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, 80 FR 55908. That rule is a separate rulemaking and not the subject of this registration rulemaking.

Other FSMA Amendments Involving Food Facilities Required to Register

- FSMA also amended the FD&C Act such that section 415 functions in connection with other food safety provisions
 - Section 418 of the FD&C Act (21 U.S.C. 350g) establishes certain preventive control requirements for food facilities that are required to register under section 415
 - Section 201(a) of FSMA created section 421 of the FD&C Act (21 U.S.C. 350j) requires the Agency to identify high-risk "facilities" and mandates more frequent inspections for domestic high-risk "facilities" than for domestic non-high-risk facilities and also includes an inspection mandate for foreign facilities
 - Section 423 of the FD&C Act (21 U.S.C. 350l), which provides a "responsible party" an opportunity to voluntarily cease distribution and recall a food under specified circumstances and also provides FDA with authority to mandate a recall under specified circumstances.

Food Facility Registration Inventory Through July 20, 2016



For More Information

- Visit www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration
- Email FURLS@fda.gov
- Call 1-800-216-7331 or 301-575-0156

The screenshot shows the FDA website's 'Registration of Food Facilities' page. At the top, it features the FDA logo and the text 'U.S. Food and Drug Administration Protecting and Promoting Your Health'. A navigation bar includes links for Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco Products. The main content area is titled 'Registration of Food Facilities' and includes a 'Food Facility Registration' sidebar with links to 'Online Registration of Food Facilities', 'Acidified & Low-Acid Canned Foods (LACF) Registration', 'New Dietary Ingredients Notifications (NDI)', 'Qualified Facility Attestation', 'Shell Egg Producer Registration', and 'Structure/Function Claims Process'. The central text area contains a 'FDA Industry Systems' box with a 'Login / Create Account' link, OMB Approval Number: 0910-0502, OMB Expiration Date: 08/31/2016, and a link to the 'OMB Burden Statement'. Below this, it explains the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and lists regulations requiring food facilities to register with FDA and provide advance notice on imported food shipments. It also provides contact information for FDA, including the phone number 1-800-216-7331 and the email FURLS@fda.gov. A 'Help Desk' section is also visible, providing technical and computer-related assistance.