

Registration of Food Facilities: A Key Link in the Safety Chain

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The FDA's mission to protect consumers from unsafe food follows different paths. The seven rules that have been finalized since last fall to implement the 2011 FDA Food Safety Modernization Act (FSMA) will require food producers, importers, and transporters to take science- and risk-based actions to help prevent the contamination that leads to foodborne illness.



Today, the agency finalizes another rule to implement FSMA, one that updates the [requirements for the registration of domestic and foreign food facilities](#) that manufacture, process, pack, or hold food for consumption in the United States, whether for people or for animals. Under the final rule, additional information will be required that will ultimately support the FDA's ability to respond quickly to food-related emergencies and that will also help the agency more efficiently use the resources it has for inspections.

The registration rule also will affect establishments located on farms and "farm-operated businesses" by expanding the definition of a "retail food establishment," which is not required to register as a food facility. The expansion of this definition would allow the inclusion of sales directly to consumers at roadside stands, farmers markets,

Community Supported Agriculture (CSA) programs and other such direct-to-consumer platforms in determining an establishment's primary function and thus whether it meets the definition of a retail food establishment. Congress, through FSMA, directed FDA to amend this definition. (Under the final rule, a farm-operated business is a business managed by one or more farms and that conducts manufacturing/processing not on the farm.)

The registration of food facilities has long been considered a key component of food safety. The September 2001 terrorist attacks highlighted the need to enhance the security of the infrastructure of the United States, including the food supply. Congress responded by enacting the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (called the Bioterrorism Act). This law directed the FDA to require food facilities that manufacture, process, pack, or hold food for consumption in the United States to register with the agency.

Nine years later, FSMA required that facilities renew their registrations biennially, among other new registration requirements. The biennial renewal requirement was effective upon enactment of FSMA, and the final rule codifies

this and other registration requirements. The final registration rule also requires some new information, including the type of activity conducted for each category of food product and certain email address information to help expedite communication between the facilities and the agency. In addition, the final rule establishes mandatory electronic registration (with the availability of a waiver process) beginning January 4, 2020.

Facilities also will be required to provide a unique facility identifier (UFI) number as part of the registration process. This will allow the FDA to verify the facility-specific address associated with the UFI and help the agency ensure the accuracy of the registration database in a way that has not been possible under the current system. FDA plans to issue a guidance document to support compliance with the UFI requirement. Food facilities will be required to provide a UFI beginning October 1, 2020.

Together, the requirements in the final rule will be invaluable in providing the FDA with more accurate information about facility locations and information about the activities within facilities—thus aiding investigators in responding to foodborne illness outbreaks or earthquakes, floods, or other disasters. The final rule will also help the agency identify high-risk facilities and ensure that personnel with the proper training are dispatched to conduct an inspection.

While there is no fee for registration, some in the food industry submitted comments stating that certain aspects of the proposed rule would be too burdensome. In response to these comments, the agency has postponed the requirement for mandatory electronic registrations and the submission of a UFI to 2020 to ensure that facilities have ample time to comply.

The next biennial registration period will be October 1 through December 31, 2016. The FDA is committed to working with the food industry to facilitate implementation of this rule and address any questions that arise.

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