Health Law Daily Wrap Up, TOP STORY: Farm to fork, food facility registrations clarified, (Apr. 9, 2015)

By Anthony H. Nguyen, J.D.

In order to better utilize limited inspection resources, the FDA would require domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with the agency, importantly exempting certain “retail food establishments” such as farms or restaurants from registration. Under a Proposed rule, food registration regulations would be updated as part of the implementation of the FDA Food Safety Modernization Act (FMSA) (P.L. 111-353). A number of provisions within the FSMA are only applicable to facilities required to register, including hazard analysis and risk-based preventive controls. The FDA’s food safety capabilities in response to food safety issues, such as mandatory recall authority, would be enhanced (Proposed rule, 80 FR 19160, April 9, 2015).

Retail food establishments exempted. As noted, under current regulations, food facilities that manufacture, process, pack, or hold food for consumption in the United States must register with FDA. Notably, establishments that are “retail food establishments,” such as farms, restaurants, and certain other entities are exempt from the requirement to register. The FDA has issued previous guidance on the definition of farms that would not require registration (see Farm definition impacts food facility registration, November 19, 2014).

The Proposed rule would amend the definition of a retail food establishment to expand the number of establishments eligible for registration exemption. Under the FDA’s proposal, the primary function of a retail food establishment would be used to determine exemption. As such a “retail food establishment” would be an entity that: (1) sold food products or food directly to consumers at a roadside stand or farmers' market where such stand or market is located other than where the food was manufactured or processed; (2) sold and distributed food through a community supported agriculture (CSA) program; and (3) sold and distributed food at any other such direct sales platform as determined by the HHS Secretary.

Based on currently available data, the FDA estimated approximately 71,000 farms that only sell food products directly to consumers in ways that include farmers’ markets, roadside stands, and CSA programs. The FDA did not have the data to quantify how many of these farms are currently required to register and would, under the Proposed rule, no longer be required to do so. As part of the rulemaking process, the FDA will seek comments on this issue under the Proposed rule.

Registration provisions. For facilities not exempt from registration, the Proposed rule would add three new provisions to the current regulations to codify certain provisions of FSMA that were self-implementing and effective upon enactment of FSMA. A draft Compliance Policy Guide had detailed some of the provisions as set forth by the FSMA requirements (see Updated food facility registration guidance issued to conform with FSMA requirements, April 4, 2013).

The first new provision, FSMA section 102(a)(1)(A) amending FDC Act section 415, required registrations of domestic food facilities contain the email address for the contact person of the facility, and registrations of foreign food facilities contain the email address of the U.S. agent for the facility. In the second provision, FDC Act section 415 was further amended by FSMA section 102(a)(3) to require that food facilities mandated to register with the FDA renew registrations every two years, between October 1 and December 31 of each even-numbered calendar year. Finally in the third provision, all food facility registrations would be required to contain an assurance that the FDA will be permitted to inspect the facility at the times and in the manner as detailed by the FDC Act.

Registration system. In addition, the Proposed rule would add new requirements to improve the food facility registration system. For instance, all food facility registrations would be required to be submitted to the FDA electronically (effective January 4, 2016) and contain the type of activity conducted at the facility based on
food product categories. The FDA would implement measures to verify the information submitted in these registrations.

**Costs of Proposed rule.** The FDA estimated one-time costs to domestic and foreign facilities at $22 million. Annualized costs were calculated using a discount rate of 7 percent and 3 percent over 20 years. Total annualized costs to food facilities, which would include annualized onetime costs and annualized recurring costs, were estimated to be approximately $5 million and $6 million. Annualized recurring costs to FDA would be approximately $1 million. The FDA noted that the Proposed rule would aid the agency in deterring and limiting the effects of foodborne outbreaks and other food-related emergencies.

MainStory: TopStory FoodSafetyNews FoodNews InspectionNews FDCActNews