

E-ALERT | Food & Drug

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BIENNIAL REGISTRATION FOR FOOD FACILITIES TO BEGIN SOON, DESPITE UNCERTAINTIES ABOUT REQUIREMENTS

The FDA Food Safety Modernization Act (“FSMA”), enacted in January of 2011, made important changes to the food facility registration system. One such change was a requirement that food facilities re-register during the last quarter of even-numbered years. This period will begin on October 1, 2012, even though certain details of the registration process remain unknown.

Food facilities were first required to register by the Bioterrorism Act of 2002. That Act directed FDA to issue regulations requiring domestic and foreign food facilities – defined as “any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States” – to submit a registration with basic facility information and, when deemed necessary by FDA, the “general food category” of products handled by the facility. The Bioterrorism Act did not impose a registration renewal requirement. FDA’s implementing regulations required facilities to update a registration within 60 days if there was a change in any of the information submitted, but they did not require periodic renewal.

Section 102 of the FSMA specified that a facility’s registration must be renewed biennially during the period of October 1 and December 31 on even-numbered years, presumably under the rationale that this requirement will force facilities on a regular basis to assess whether their registration information is current. FDA is required to provide for an abbreviated process for facilities that do not have any new information to report. In addition to the renewal requirement, the FSMA also specified that facilities must provide the email address for a contact person, and the registration must contain “an assurance that [FDA] will be permitted to inspect such facilities at the times and manner permitted by” the Federal Food, Drug, and Cosmetic Act.

The FSMA also permitted FDA to deem, through a guidance document, “other food categories” that must be listed during registration. As we explained in our August 16, 2012, [client alert](#), FDA recently issued a draft guidance document that specified the “other food categories” that will appear as mandatory fields during the registration process.

The renewal period will begin on October 1, 2012, even though several details remain unknown. FDA’s facility registration information [webpage](#) notes that the registrants must use Form 3537 to renew a registration, and that this form is being updated to meet renewal needs. The new form has not been released, however, and FDA has not released updated online registration instructions on its website. It also is unclear whether the new registration process will involve a request for additional, voluntary information. FDA issued a Federal Register notice in May of 2011 seeking comment on a proposal to request voluntary information from food facilities regarding their operations, which it likely would use for risk-based prioritization of inspections. FDA explained that the information would be collected through a form that would be linked to the online facility registration module. FDA has not stated whether it will collect this voluntary information during the 2012 re-registration period.

FDA indicates on its registration information webpage that it will release a guidance document to clarify the registration and renewal process. Recently, the Grocery Manufacturers Association and 20 trade associations sent a letter to the Office of Management and Budget requesting that this guidance be released in a timely manner.

Covington & Burling LLP has closely monitored FDA's implementation of the FSMA and will continue to apprise clients of important developments.

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