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# FDA Issues Final Rule for Registration of Food Facilities

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Food, Drugs, and Devices

On July 14, 2016, FDA published its amended final regulations for registration of domestic and foreign food facilities under the Food Safety Modernization Act (FSMA).[1] Registration is required for such facilities that manufacture/process, pack, or hold food for human or animal consumption. The final rule codifies a number of provisions that were mandated by FSMA and already in effect under that law, and adds some new requirements.

The final rule is intended to increase the utility and accuracy of the food facility registration database. FDA believes the rule will enhance its efforts to deter and respond to food-related emergencies in light of its limited resources. The rule codifies updates to the form and timing of registration, requires additional information upon registration, and further defines which establishments must register.[2]

## Registration Dates and Method

### Registration Dates

The final rule codifies the FSMA statutory requirement that food facilities must renew their registration with FDA on a biennial basis between October 1 and December 31 of even-numbered years.

### Mandatory Electronic Registration

FDA will require electronic submission of all food facilities registrations—including initial registrations, renewals, updates, or cancellations—beginning January 4, 2020. Food facilities may request a waiver for this requirement by submitting a written request to FDA explaining why electronic submission is not reasonable.

[1] Amendments to Registration of Food Facilities, 81 Fed. Reg. 45912 (July 14, 2016), available here.

[2] Retail food establishments (RFEs) are exempt from FDA food facility registration. The final rule amends the FDA definition of RFEs—found in § 1.227 of title 21—and expands the number of RFEs that are exempt from registration to include: (1) roadside stands or farmers' markets located away from where the food was processed or manufactured; (2) community supported agriculture programs (CSAs); and (3) any other direct sale platforms, as determined by the Secretary.

### Registration Update or Cancellation

Food facilities continue to have 60 days to submit any updates or cancellations to registrations after such changes occur. While FDA had proposed to shorten this time frame to 30 days, the agency reverted to the original 60-day timeframe in response to stakeholder comments opposing the change.

## Additional Registration Requirements

The rule requires food facilities to submit certain additional information with registration, including:

- **Email Address of Contact Person**—To enhance communication between FDA and food facilities, domestic food facilities must provide the email address for the facility contact person, and foreign facilities must provide the email address of the U.S. agent for the facility.
- **Assurance to Allow Inspection**— Registration must contain an assurance that FDA will be permitted to conduct an inspection of the facility at a time and manner authorized by the FDCA.
- **Measures to Improve Database**—The rule contains several changes intended to enhance FDA's ability to utilize up-to-date and accurate identifying information:
  - Registrants must provide the type of activity conducted at the facility for each food product category. This information is required for the upcoming registration renewal period.
  - Beginning October 1, 2020, registrants must provide a unique facility identifier (UFI) recognized as acceptable to FDA. The agency anticipates issuing guidance to specify which UFIs will be recognized as acceptable. FDA did not ultimately require D-U-N-S numbers, as it had proposed to do, though it will accept them as UFIs. FDA noted that Dun and Bradstreet provides D-U-N-S numbers at no cost, and that as of mid-2013, a majority of domestic and foreign facilities required to register with FDA had existing D-U-N-S numbers.
  - FDA will employ verification methods to assure that registration information is accurate. This will include verification of authorization when an individual who is not an owner, operator, or agent in charge of a facility submits registration information. For foreign food facilities, FDA will also verify the U.S. agent and will require an affirmative response from the U.S. agent before it will accept a registration. FDA plans to issue further guidance on how it will conduct certain verification steps.
  - Finally, the rule identifies situations in which FDA is authorized to suspend or cancel registrations to aid its effort to maintain a current database. FDA will cancel a registration when a facility is no longer in business or has changed owners. Cancellation may also occur when facility information has not been updated in a timely manner and when registration has not been renewed in accordance with the rule. FDA will send confirmation of a cancellation to the facility using the contact information required with registration.

## Assistance to Industry

To assist industry in complying with the rule, FDA intends to publish additional guidance documents regarding several requirements discussed above. In addition to various tools offered on the FDA website,[3] the agency is offering a webinar regarding the rule on August 3, 2016.[4]

Covington is experienced in advising clients on legal matters related to conventional foods and dietary supplements and is available to provide individualized compliance counseling concerning these issues. If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food & Drug practice group:


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[3] FDA's website has several tools available to assist industry in understanding the rule. Click here for FDA's FSMA Final Rule webpage. Click here for current registration instructions.

[4] Details on the August 3, 2016, webinar can be found here.