

FDA Proposes Rule to Expand Food Facility Registration Exemption

In April 2015, the U.S. Food and Drug Administration (FDA) proposed a rule that would allow roadside stands, farmers' markets and community supported agriculture programs to classify as "retail food establishments" and become exempt from food facility registration.

Food facilities that manufacture, process, pack or hold food for consumption in the U.S. are required to register with the FDA. However, "retail food establishments," defined as establishments that sell food directly to consumers as their primary function, are exempt from registration and therefore do not have to comply with the requirements of the Food Safety Modernization Act (FSMA). An establishment's primary function is to sell food directly to consumers if the monetary value of sales directly to consumers exceeds the monetary value of sales to all other buyers.

The proposed rule would expand the definition of "retail food establishment" by allowing sales made at roadside stands, farmers' markets, community supported agriculture programs and other direct-to-consumer sales establishments (door-to-door sales, mail, catalog and Internet orders, state and local fairs, and religious or other organization bazaars) to be categorized as sales made directly to consumers. The FDA estimates that 71,000 establishments sell food directly to consumers in the ways specified in the proposed rule.

The proposed rule also contains provisions mandating additional registration requirements for nonexempt establishments. These new requirements include the listing of an email contact, biannual registration and an assurance that the FDA can inspect registered food facilities. The FDA is also seeking to improve the usefulness of its food facility registration database by requiring electronic submission of registrations, implementing measures to verify the accuracy of registration information, requiring certain additional data in registration, and giving the FDA authority to cancel a registration in a number of circumstances.

Food establishments need to understand whether they can classify as a retail food establishment under the proposed rule and gain an exemption from the restrictions of the FSMA. Nonexempt establishments, however, need to be prepared to take steps to comply with the new administrative requirements. These businesses must track developments during the rulemaking process to

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understand how the final rule will impact their status as a food facility.

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