

FDA issues Laboratory Accreditation Proposed Rule required under FSMA

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The U.S. Food and Drug Administration (“FDA”) recently issued a proposed rule entitled “Laboratory Accreditation for Analyses of Foods” (“Proposed Rule”), which was mandated by the FDA Food Safety Modernization Act (FSMA). The Proposed Rule establishes a new program whereby certain food testing must be performed by laboratories accredited by an FDA-recognized accreditation body. The accredited laboratories would be required to send the results of testing conducted under this rule directly to FDA.

FDA proposes that use of an accredited laboratory would be required: (1) for nine specific existing regulatory testing requirements that apply to bottled water, shell eggs, and sprouts; (2) if the agency issues a “food testing order;” (3) for certain test results presented to FDA in connection with certain serious agency enforcement actions (e.g., mandatory food recalls); and (4) for certain testing involving imports. A food testing order would be a new regulatory tool whereby FDA would have broad authority to require an owner or consignee of food to perform food product or environmental testing in response to an identified or suspected food safety problem.

This memorandum summarizes the key aspects of the Proposed Rule, with a focus on the impacts on food manufacturers and importers. Note that the preamble includes a number of tentative conclusions and questions for comment that warrant careful review, but which are beyond the scope of this memorandum. Comments on the Proposed Rule are due March 3, 2020.

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