

ALERTS

Food, Drug & Device Law Alert - FDA Issues Proposed Rule On Produce Safety To Implement Parts Of Food Safety Modernization Act

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On the two year anniversary of the adoption of the Food Safety Modernization Act (FSMA or Act), the FDA recently issued a lengthy proposed rule covering standards for produce safety. At the same time, the FDA issued a separate proposed rule to update its existing rules on current Good Manufacturing Practices for food (which is the subject of a contemporaneous Alert) and stated that it expects to soon release rules on foreign supplier verification required by the FSMA.

The standards for produce safety focus on microbiological hazards. FDA recognizes the potential for chemical, physical, or radiological contamination of produce, but left for another day rules addressing those potential hazards. The proposed produce rule covers all fruits and vegetables except those rarely consumed raw, produced for personal consumption, or destined for commercial processing that will reduce microorganisms of public health concern.

The rule proposes minimum standards for the safe growing, harvesting, packing and holding of produce on farms in several areas:

- Worker training and health hygiene – this portion establishes qualification and training requirements for all workers who handle produce, requires documentation of training, and establishes hygiene practices to prevent contamination of produce
- Agricultural water – this portion includes a several provisions directed to water quality, including general and specific standards, inspection and maintenance of water, water sources, and water systems, treatment of water of suspect quality, and documentation
- Biological soil amendments – this refers to practices such as spreading manure in the soil and the proposed rule includes, among other things, requirements for treating such soil amendments to satisfy specific microbial standards and prohibiting the use of human waste for such purposes except in compliance with EPA or comparable regulations
- Domesticated and wild animals – this portion applies if animals graze or work in fields where produce is grown and there is a reasonable probability they may contaminate the produce. The rule requires at least an adequate waiting period between any such grazing or work and harvest and also monitoring of the area for intrusion
- Equipment, tools and buildings – this portion establishes requirements for several matters related to the general description,

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such as hand-washing and toilet facilities, pest control, sewage, trash, and plumbing, and documentation requirements for cleaning and sanitizing certain equipment

- Sprouts – this portion imposes several requirements specifically for the growing and handling of sprouts, including requirements to test for several pathogens and documentation requirements

The proposed rule also includes several exemptions. The FDA provided a 120 day period for the public to comment on the rule, and will adopt a final version at some point thereafter. Although the rule will be effective 60 days after the FDA adopts the final version, the FDA will generally give farms two years from the effective date to comply, small businesses three years, and very small businesses four years.

A copy of the FDA's proposed rule on produce safety can be [found here](#).

For more information, please contact the Barnes & Thornburg LLP attorney with whom you work or one of the following attorneys in the firm's Food, Drug & Device group: Lynn Tyler at (317) 231-7392 or lynn.tyler@btlaw.com; and Hae Park-Suk at (202) 408-6919 or hae.park.suk@btlaw.com.

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