

E-ALERT | Food & Drug

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FDA RELEASES PROPOSED RULE FOR PRODUCE SAFETY UNDER FSMA

On January 4, 2013, FDA issued its long-awaited [proposed rule](#) implementing the produce safety provisions of the Food Safety Modernization Act (“FSMA”). The proposal would establish new requirements for domestic and foreign farms that grow, harvest, pack, or hold raw or unprocessed fruits and vegetables for human consumption in the United States. The proposed rule was released on the two-year anniversary of the enactment of FSMA, and will be published in the Federal Register on January 16, 2013. Stakeholders have until May 16, 2013 to submit comments.

This client alert discusses highlights of the proposed rule. Covington also released today our client alert on FDA’s proposed rule to implement the hazard analysis and preventive controls provisions of FSMA, which also provides a brief background summary of the statute.

SCOPE OF THE PROPOSED PRODUCE SAFETY RULE

The produce safety rule proposed by FDA addresses the growing, harvesting, packing, and holding of produce to be used for human consumption. It would subject farms to a new 21 C.F.R. Part 112 that establishes “science-based minimum standards” to target microbiological hazards that arise with fruits and vegetables. “Covered produce” governed by the proposed rule encompasses only fruits and vegetables grown for human consumption in their raw or “natural,” unprocessed state. Foods that are rarely consumed raw, intended for commercial processing, or intended for on-farm consumption would not qualify as “covered produce,” and thus would not be subject to the proposed rule. Given these limitations, FDA proposes that the term “covered produce” excludes grains, which are commercially processed, but includes foods not commonly thought of as fruits or vegetables, such as mushrooms and tree nuts.

FDA emphasized that the proposal addresses only microbiological contamination and does not extend to chemical, physical, or radiological contamination. Although FDA acknowledges that these latter types also pose a risk of foodborne illness, the proposed rule explains that the forms of contamination not covered by the rule are relatively rare and do not fit in with the agency’s risk-based approach to improving produce safety. In contrast, FDA sees the microbiological contamination of produce as a significant public health concern warranting regulations.

Although the agency’s proposal on produce safety applies to only a limited set of foods and operations, other facilities that handle produce but are not covered by this rule likely would be subject to FDA’s proposed rule implementing FSMA’s hazard analysis and preventive controls requirements.

MAJOR PROVISIONS OF THE PRODUCE SAFETY PROPOSED RULE

The bulk of the proposed rule sets out standards for what FDA has identified as the most common routes of microbiological contamination of produce on farms: agricultural water; biological soil

amendments; domesticated and wild animals; equipment, tools, and buildings; and health and hygiene.

- **Agricultural water:** The proposed rule requires that all water intended or likely to come in contact with either the harvestable portion of covered produce or a food-contact surface be of safe and sanitary quality for its intended use. This requirement involves recordkeeping, inspection, maintenance, and follow-up actions for the agricultural water, water sources, and water distribution systems used in growing, harvesting, packing, and holding covered produce.
- **Biological soil amendments:** The proposed rule establishes standards for the use and treatment of animal waste and prohibits the use of human waste in growing covered produce, except when such use is permitted by other regulations.
- **Domesticated and wild animals:** The proposed rule requires that procedures be established for circumstances in which animals are allowed or are reasonably likely to enter areas where covered produce is grown. For example, if animals are allowed to enter the fields where covered produce is grown, then FDA proposes that there be an adequate waiting period between when the animal is in the fields and the produce is harvested, and that other measures be implemented to avoid the introduction of known or reasonably foreseeable hazards into the covered produce.
- **Equipment, tools, and buildings:** The proposed rule establishes requirements for any equipment and tools that are intended or likely to come in contact with covered produce as well as for any facilities involved in growing, harvesting, packing, and holding covered produce.
- **Health and hygiene:** The proposed rule requires that all personnel—or individuals who supervise personnel—coming into contact with covered produce be subject to qualification and training requirements. FDA also requires that sanitation and hygiene procedures be established to prevent people from contaminating covered produce with microorganisms of public health significance.

FDA proposes to allow two years and 60 days after the date of publication of a final rule for most facilities to come into compliance, with later compliance dates for smaller businesses.

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Covington & Burling LLP will continue to monitor FDA's implementation of FSMA and advise clients on developments.

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