

Client Alert

FDA Issues Sweeping New Regulations Targeting Food Manufacturers, Processors, Packers, Holders, and Farms

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On January 4, 2013, the United States Food and Drug Administration (FDA) proposed two new rules implementing key provisions of the 2011 Food Safety Modernization Act (FSMA). The first targets foodborne illnesses generally, while the second proposes specific safety standards for the production and harvesting of produce. Together, these two rules represent the most significant change to U.S. food safety standards in over 50 years. FDA will accept comments on both proposed rules until May 16, 2013.

The first proposed rule, titled "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food," applies broadly to owners, operators, and agents in charge of domestic or foreign facilities that engage in manufacturing, processing, packing, or holding food for consumption in the U.S. It would require such food companies to prepare and implement written food safety plans designed to prevent, monitor, and correct any problems that might arise during food production. Much like hazard analysis and critical control point (HACCP) plans long required of fish, juice, and low-acid canned-food producers, this new rule would require nearly all food producers to have in place written food safety plans that:

- Identify and evaluate known or reasonably foreseeable hazards for each type of food at a facility;
- Identify preventive controls to significantly minimize or prevent the identified hazards;
- Develop a recall plan for foods with the identified hazards;
- Establish monitoring procedures to ensure that preventive controls are performed consistently;
- Establish corrective action procedures if preventive controls are not properly implemented or unanticipated problems occur; and
- Specify verification and validation steps to demonstrate that the plans are implemented properly, including procedures for recordkeeping.

These plans must be developed and overseen by qualified individuals who must be trained pursuant to a standardized curriculum or otherwise qualified through job experience. The proposed rule would require manufacturers to reassess their food safety plans at least once every three years. Additionally, FDA will evaluate the plans and monitor their implementation during future site inspections.

The second proposed rule, titled "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," would apply to farms that harvest or produce certain fruits or vegetables grown for human consumption. Farms covered by the new rule must ensure that:

- Water that touches fruits and vegetables is not contaminated;
- Sanitation facilities, including hand-washing stations, are provided to farm workers;

- Controls for known or reasonably foreseeable microbial hazards are implemented;
- Manure and other material used as fertilizer must be sufficiently composted or treated; and
- Packing equipment must be easy to clean.

Both proposed rules include some important exceptions. Farms, for example, are exempt from the first rule. Fish, juice, and low-acid canned food producers are also largely exempt and instead are subject to current HACCP requirements under existing regulations. FDA also proposed a modified exemption for "qualified facilities," which include very small businesses or facilities whose average annual sales are less than \$500,000, at least half of which are to consumers or local retailers and restaurants. Under the proposed rule, these qualified facilities will be in compliance as long as they either:

- Notify FDA that they are addressing potential hazards through preventive controls and monitoring, or
- Notify FDA that they comply with applicable local regulations and notify consumers of the identity of the facility where the food was manufactured or processed.

FDA suggests a number of exceptions to the second rule as well, most notably to exclude producers of certain enumerated types of produce that are rarely consumed raw.

In releasing these proposed rules, FDA emphasized that its regulatory work under FSMA is far from over: the agency will soon be proposing additional rules on importer foreign supplier verification, preventive controls for animal food, and accreditation of third-party auditors for imported food. It is expected that importers of food will have to certify that imported food was grown and produced under conditions that comport with domestic safety standards.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

John Fuson

Partner – Washington, D.C.
Phone: +1.202.624.2910
Email: jfusion@crowell.com

John B. Brew

Partner – Washington, D.C.
Phone: +1.202.624.2720
Email: jbrew@crowell.com