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food industry lawflash

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FDA Releases Major New Food Safety Proposals

Affected parties should familiarize themselves with proposed rules for safe food processing and handling and on-farm produce safety; comments to FDA are due by May 16.

On January 4—the second anniversary of the enactment of the Food Safety Modernization Act (FSMA)—the U.S. Food and Drug Administration (FDA) announced the upcoming publication of proposed rules establishing two of the major elements of the modernized system of food safety control contemplated by the FSMA.[1] The first rule, "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food" (Preventive Control Rule), would mandate the adoption, implementation, and ongoing documentation of the operation of a science-based preventive food safety system for most processing, handling, and warehousing operations.[2] The second rule, "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" (Produce Rule), would focus on produce safety and mandate the on-farm adoption of various risk-prevention measures by growers, farms, and mixed-type facilities.[3]

FDA contemplates official publication of the proposed rules in the January 16, 2013, edition of the *Federal Register*. Comments on the official record associated with the rules can be submitted for a period of 120 days until May 16, 2013.

All interested parties should consider active participation in the rulemaking process since FDA is required to carefully evaluate all public input before issuing any final regulations. It should also be noted that, even after any such rules are ultimately finalized, FDA contemplates a phase-in period that will take several years to complete. At the same time, however, the food and farm industries should also recognize that these proposed rules—as well as other companion proposals on issues such as foreign supplier verification, which should be issued by FDA shortly—include extensive discussions of what FDA now considers to be food safety control measures that are both feasible and effective. As such, these documents will unavoidably have an immediate impact upon the commercial, legal, and regulatory environment in which all food and food-related businesses presently function.

Background

Through the enactment of the FSMA, Congress directed FDA to issue regulations and take various additional measures designed to enhance food safety, thereby minimizing the risk of foodborne illnesses to the American consumer. In broad terms, the FSMA shifts the focus of both the regulator and the regulated toward prevention of, as opposed to reaction to, food safety problems. FDA, again in broad terms, is responding to the mandate by proposing the establishment of a system that, to the fullest extent possible, would guarantee that any food reaching the consumer has been properly filtered through such a preventive system.

A more detailed discussion of the Preventive Control Rule is available at https://www.morganlewis.com/pubs/FDA_LF_PreventiveControlRuleAnalysis_09jan13.pdf. In general, the rule would require all "facilities" that

1. View FDA's announcement at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm334156.htm.

2. Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (proposed Jan. 4, 2013) (to be codified at 21 C.F.R. pts. 1, 16, 106, 110, 114, 117, 120, 123, 129, 179, 211), *available at* http://www.ofr.gov/OFRUpload/OFRData/2013-00125_PI.pdf.

3. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (proposed Jan. 4, 2013) (to be codified at 21 C.F.R. pts. 16, 112), *available at* http://www.ofr.gov/OFRUpload/OFRData/2013-00123_PI.pdf.

manufacture, process, pack, or store human food to design and implement effective preventive food safety systems. Various exemptions from this extremely broad category of affected businesses, including those accommodating some small businesses as well as other types of operations, are proposed. Traditional farming operations are also not directly covered by the proposal. For operations that are covered, the proposed rule generally recognizes the need for flexibility as it attempts to capture an enormous range of products, processes, and methods of storage and distribution within its scope. At the same time, however, it also specifies an extensive list of items, such as supplier verification, establishment of a recall plan, allergen controls, sanitation, and many other components of what it presumes should be included in any such food safety plans.

A more extensive discussion of the Produce Rule is available at https://www.morganlewis.com/pubs/FDA_LF_ProduceRuleAnalysis_09jan13.pdf. While the proposed rule's details are obviously of greatest interest to growers and handlers of fruits and vegetables, it also should be read within the context of both the Preventive Control Rule and FDA's overall efforts to implement the FSMA. FDA proposes an alternative scheme to address issues associated with those food products that are generally transmitted from the farm directly to the consumer without being captured by any preventive food safety plan (i.e., from further commercial processing that adequately reduces the presence of microorganisms of public health concern). Under these circumstances, FDA shifts the focus to mandatory on-farm control measures. In doing so, it proposes the establishment of a number of standards generally associated with the mitigation of the risk posed by microbiological contaminants involving (1) agricultural water; (2) biological soil; (3) health and hygiene; (4) animals in the growing area; and (5) equipment, tools, and buildings.

Contacts

Morgan Lewis will provide further information and analysis of the FSMA initiative and its current and future impacts over the coming weeks. If you have any questions or would like more information on the issues discussed in this LawFlash, please contact any of the following Morgan Lewis attorneys:

Washington, D.C.

Kathleen M. Sanzo	202.739.5209	ksanzo@morganlewis.com
Robert G. Hibbert	202.739.5611	rhibbert@morganlewis.com
Anthony "Tony" Pavel	202.739.5612	apavel@morganlewis.com
Gary L. Yingling	202.739.5610	gyingling@morganlewis.com
Jonathan A. Havens	202.739.5952	jhavens@morganlewis.com
Zachary A. Rothstein	202.739.5618	zrothstein@morganlewis.com

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