Client Alert.

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FDA Releases New Food Safety Rules

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The Food and Drug Administration (FDA) recently released drafts of two long-awaited food safety rules as part of the agency's ongoing implementation of the 2011 Food Safety Modernization Act (FSMA). The first proposed rule requires makers of food that is to be sold in the United States to develop written plans to prevent their products from spreading foodborne illnesses. The second proposed rule sets forth food safety standards for the production and harvesting of food.

CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD

The first new rule, in part revising the FDA's existing regulations regarding good manufacturing practice, would apply to facilities that manufacture, process, pack, or hold human food. Some exceptions include facilities engaged in low-risk activities such as making jam and maple syrup, manufacturing dietary supplements, and certain alcoholic beverage operations. Facilities that are covered under the rule would be required to establish and implement a food safety system that incorporates the following components:

- A written food safety plan
- A hazard analysis
- Preventive controls for hazards that are reasonably likely to occur
- Monitoring procedures
- Corrective actions
- Verification
- Record keeping

The hazard analysis and preventative controls components would be similar to the FDA's Hazard Analysis and Critical Control Points (HACCP) systems that are currently required for juice and seafood production operations.

Under the proposed rule, businesses with 500 or more employees would have one year from the date of final publication to develop food safety systems to bring themselves into compliance; companies with fewer than 500 employees would have two years to comply. The FDA also proposes that "very small businesses" grossing less than an as-yet undefined amount in annual food sales would have three years to comply.

STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION

The second new rule would set standards for the safe production and harvesting of fruits and vegetables in their raw or natural, unprocessed states to minimize the risk of foodborne illness. Farms that grow produce for human consumption would be subject to FDA-developed and science-based requirements. However, certain farms that have food sales

averaging less than $500,000 per year and farms that grow very low-risk commodities that are rarely consumed raw, such as potatoes or green beans destined for canning operations, would not be subject to the rule.

The science-based requirements would focus on limiting the potential for microbial contamination of fruits and vegetables that stems from: (1) agricultural water, (2) biological soil amendments of animal origin, (3) health and hygiene of workers, (4) animals within the produce-growing area, and (5) equipment, tools, and buildings. Some of the proposed requirements include annual inspection of water systems for pathogens, constraints on the frequency of use of biological soil amendments, and mandatory periodic sanitation of farm equipment.

Farms covered by the rule would have two years to comply with the new requirements (and four years to comply with some of the water quality standards). Small farms averaging no more than $500,000 in food sales per year would have three years to comply (and five years for the same water quality standards). Very small businesses averaging no more than $250,000 in food sales per year would have four and six years, respectively.

REQUEST FOR COMMENTS

Both proposed rules are to be published in the Federal Register on January 16. Interested parties will have until May 16 to submit written comments. In addition to the general request for comments, the FDA has singled out a number of discrete issues on which the agency seeks input. These issues include:

- The risk-based supplier approval and verification programs
- Review of customer and other complaints as part of the verification program
- The product and environmental testing programs
- Required training for employees and supervisors and documentation of that training
- Required cleaning of non-food contact surfaces
- A draft qualitative risk assessment providing a science-based risk analysis of on-farm activities that would be considered not reasonably likely to introduce serious health hazards

These proposed rules come two years after President Obama signed FSMA into law, a law hailed by the FDA as “the most sweeping reform of our food safety laws in more than 70 years.” The FDA anticipates releasing three additional food safety rules to further implement FSMA mandates in the coming months: a rule requiring foreign food suppliers to verify that their products are as safe as food produced in the United States, a rule to improve the quality of third party food safety audits conducted overseas, and a rule establishing food safety standards for the animal feed industry.

We are prepared to assist you in responding to the FDA’s call for comments about these proposed regulations and we will continue to monitor the FDA’s activities surrounding FSMA and issues regarding food safety. Please do not hesitate to contact us with any questions you may have.

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