Client Alert

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FDA Releases Proposed Food Safety Rules: New Standards Would Address Foodborne Illness and Produce Safety

On January 4, 2013, the U.S. Food and Drug Administration (FDA or Agency) announced the release of two highly anticipated proposed rules affecting the food industry. The first proposed rule is aimed at preventing the spread of foodborne illnesses in the United States, while the second proposed rule seeks to establish science-based standards for the safe growing, harvesting, packing and holding of produce for human consumption.

The proposed rules, scheduled to be published in the Federal Register on January 16, would implement key provisions of the Food Safety Modernization Act (FSMA), bipartisan legislation signed into law in January of 2011. The proposed rules follow almost two years of FDA information gathering from the produce industry, other government agencies, international collaborators and consumers, including five federal public meetings and regional, state and local meetings in 14 states.

FDA is accepting comments on both proposed rules through May 16, 2013.

Proposed Rule: Current Good Manufacturing Practices and Hazard Analysis and Risk-Based Preventative Controls for Human Food

The first proposed rule aims to reduce the prevalence of foodborne disease by amending the Agency's regulations regarding Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (CGMPs). More specifically, the proposed rule would implement the provisions in Section 103 of the FSMA that require human food facilities to adopt preventive controls. Under the proposed rule, the owner, operator or agent in charge of a covered facility would have to develop a written food safety plan for the facility. A "qualified individual," as defined in the proposed rule, would have to prepare and implement the plan. The plan would include:

1) an analysis of known or reasonably foreseeable hazards for each type of food manufactured, processed, packed or held at the facility, including an evaluation of whether a hazard is reasonably likely to occur and an assessment of the severity of the illness or injury that would result if the hazard were to occur;

2) controls for preventing hazards that are reasonably likely to occur;

3) procedures for monitoring the preventive controls to ensure that they are consistently performed, and maintenance of records documenting the implementation of these procedures;

4) procedures for taking corrective actions when needed;

5) verification activities, including verification that monitoring procedures are followed and that preventive controls are consistently implemented and are effective in minimizing or preventing the hazards that are reasonably likely to occur; and

6) a recall plan for hazardous food.

The proposed rule would require facilities to reanalyze their food safety plans at least once every three years, or more often if warranted. The proposed rule would also establish a series of exemptions from the requirements for hazard analysis and preventive controls.

In addition, the proposed rule would update, revise or otherwise clarify certain requirements under the CGMP regulations, which have not been updated in more than 25 years. For example, the word "shall" would be replaced with the word "must" throughout the regulations.

Finally, the proposed rule would revise FDA's current facility registration regulations (21 CFR subpart H) to clarify (1) the types of activities that are included as part of the definition of the term "facility" and (2) the scope of the exemption for "farms" described in Section 415 of the Federal Food, Drug, and Cosmetic Act.

Proposed Rule: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

The second proposed rule seeks to minimize the risk of serious adverse health consequences or death caused by the consumption of contaminated produce. This rule establishes science-based minimum standards for the safe growing, harvesting, packing and holding of produce. The rule defines produce as fruits and vegetables grown both domestically and abroad that are intended for human consumption.

The proposed rule contains provisions that address all aspects of produce handling. It would establish qualification and training requirements for all personnel who come into contact with certain produce or food-contact surfaces, as well as hygienic practices and other measures intended to prevent anyone, including visitors, from contaminating produce with certain microorganisms known to be of public health significance. Once implemented, it would create requirements for the inspection, maintenance and follow-up actions related to the use of agricultural water, water sources and water distribution systems in order to ensure that such water is of safe and sanitary quality for its intended use. It would also prohibit the use of human waste and certain other soil additives for growing covered produce, except in compliance with EPA or equivalent regulations.

The proposed rule contains additional standards that apply to equipment used in the handling of produce, measures to be taken related to seeds and beans used for sprouting, prohibitions and other requirements for the proper treatment and handling of soil used for growing, and guidelines for produce grown on land where animals graze or work. For all provisions, the rule contains detailed recordkeeping requirements to ensure that actions taken to protect the safety and quality of produce are well documented and can be easily monitored.

As currently written, the standards set forth in the proposed rule would not apply to produce that is rarely consumed raw, produce intended for personal or on-farm consumption, or produce that is not a raw agricultural commodity. Additionally, the rule proposes a number of qualified exemptions and modified requirements to its provisions. For instance, produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance would be eligible for an exemption from the requirements of this rule.

FDA seeks comments on all aspects of the proposed rules. Comments must be submitted to the Agency by May 16, 2013. Once the final rules are published, businesses other than small and very small businesses will have one year to come into compliance with the new provisions. Small businesses will be allotted two years to come into compliance, and very small businesses will be given three years.

FDA Requesting Comments

While the proposed rules have not yet been published in the Federal Register, prepublication copies are available at:

- Proposed Rule: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventative Controls for Human Food (http://www.ofr.gov/(X(1)S(v3yf3je4uhgifjgft2sscuim))/OFRUpload/OFRData/2013-00125_PI.pdf)

- Proposed Rule: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (http://www.ofr.gov/(X(1)S(v3yf3je4uhgifjgft2sscuim))/OFRUpload/OFRData/2013-00123_PI.pdf)

In conjunction with the release of the prepublication copies of the proposed rules, FDA stated that additional FSMA proposals would soon follow, including those regarding new responsibility for importers to verify that food products grown or processed overseas are as safe as domestically produced food, accreditation standards for third-party safety audits conducted overseas, and preventative controls for animal food facilities.

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