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January 15, 2013

FDA Shifts Focus to Prevention with Publication of Proposed Food Safety Rules

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On January 4th, the U.S. Food and Drug Administration (FDA) published two long-awaited proposed food safety rules aimed at preventing foodborne illness. The proposed rules implement the 2011 Food Safety Modernization Act (FSMA) and are available for public comment over the next four months. The rules have wide-ranging effects on a diverse group of industries, including every link in the global food supply chain.

Preventive Controls for Human Food

The first **rule** would require domestic and foreign food facilities to develop a formal plan for preventing their products from causing foodborne illness. These plans, which are subject to FDA audit, must identify hazards, specify the steps implemented to minimize or prevent those hazards, identify monitoring procedures and record monitoring results, and specify what actions will be taken to correct problems that arise.

Importantly, the preventive controls are both "risk-based" and "flexible." This means that the rule would require controls only where necessary to prevent hazards to public health. Accordingly, the rule would exempt certain facilities from requirements or modify requirements for certain low-risk activities. For example, farms are exempted from this first rule. (The proposed rule would also clarify the definition of "farm" for purposes of exemption from food facility registration, particularly with respect to farms that also engage in food processing activities.) In addition, certain manufacturing operations that are already subject to, and compliant with, specific good manufacturing (GMP) or hazard analysis and critical control point (HACCP) regulations would be exempt from some provisions of the proposed rule, including manufacturers of dietary supplements, acidified and low-acid canned foods, juice products, and seafood.

If and when finalized, most businesses would only have one year to comply with the rule.

Produce Safety Standards

The second proposed **rule** would implement safety standards for the production, harvesting, packing, and holding of produce on farms. This rule proposes science and risk-based minimum standards, focusing on identified routes of microbial contamination of produce. Specifically, the rule:

- Sets standards for equipment, tools, buildings and sanitation used for produce operations on farms;
- Requires workers to use certain hygienic practices (e.g. hand washing);
- Sets criteria for the quality of agricultural water;
- Describes methods to prevent against contamination by domesticated and wild animals; and
- Implements measures to reduce the risk of biological soil amendments of animal origin.

If and when finalized, most businesses would have two years to comply with the rule.

Going Forward

These two proposed rules are the first among five rules that would lay the cornerstone of a prevention-based, modern food safety system. The FDA will soon propose three additional rules: the Foreign Supplier Verification Program, Preventive Controls for Animal Food, and Accredited Third Party Certification. However, funding remains a concern. The Congressional Budget Office estimates that FSMA will cost $1.4 billion to implement, and that funding has not yet been secured.

The new regulations could also be very costly for businesses. FDA estimates the rules could cost large farms $30,000 a year and manufacturers up to $475 million annually. Still, if these proposed rules do become final, businesses will be given time to come into compliance. Depending on the size of the business, the preventive control rule proposes up to a three-year-phase-in from the date the final rule is promulgated, while the produce rule proposes up to a four-year-phase-in.

The proposed rules are expected to be officially published in the January 16th edition of the Federal Register. FDA is currently seeking comments on the rules, with a deadline of May 16, 2013. Interested parties, ranging from both domestic and international farms and other food facilities, consumer groups, grower associations, and importers, are all expected to provide input.

Venable will continue to monitor the progress of the regulations. If you have questions or concerns regarding the comment process or seek further information on how these proposed regulations could affect your business, please contact the authors of this alert or any of the listed Venable FDA Group attorneys.