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Regulatory Alert: FDA Releases Revised Proposed Food Safety Modernization Act (FSMA) Rules

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On September 19, 2014, the Food and Drug Administration released four revised proposed rules to implement the Food Safety Modernization Act (FSMA). The revisions apply to the following rules: Preventive Controls for Human Food, Preventive Controls for Animal Food, Foreign Supplier Verification Program, and Produce Safety. The revisions address some of the key—and most controversial—aspects of the regulations. A brief summary of the major revisions follows.

Summary

Preventive Controls Rule for Human Food

Supplier verification: Supplier verification will be required for raw materials and ingredients if the facility identifies a significant hazard for a raw material or ingredient, and that hazard is controlled before the facility receives the raw material or ingredient. For Class I hazards (serious adverse health consequences or death to humans or animals (SAHCODHA)) an annual onsite audit is required unless the facility can determine (and document) that other verification activities and/or less frequent auditing provide adequate assurances that hazards are controlled. Holding facilities such as warehouses and supermarket distribution centers will not be required to conduct supplier verification on the products they receive. Only facilities that further manufacture/process raw materials or ingredients are required to conduct supplier verification.

Product testing: Product testing will be required as an activity for verification of implementation and effectiveness of preventive controls as appropriate to the facility, the food, and the nature of the preventive control. Facilities must have written testing and corrective action procedures (relating to a positive test result). Product testing records must be maintained.

Environmental monitoring: Environmental monitoring will be required as an activity for verification if contamination of a ready-to eat food with an environmental pathogen is a significant hazard. Written environmental monitoring procedures and corrective action procedures (for the presence of an environmental pathogen or indicator organism) are required. Environmental testing records must be maintained.

Economically motivated hazards: Facilities are required to consider in their hazard analysis, hazards that may be intentionally introduced for economic reasons.

Revision to the definition of farms: The definition of farm is expanded to allow farms that pack and hold the raw agricultural commodities (RACs) of other farms and dry/dehydrate RACs to be exempt from the rule. (Farms were exempt under the old rule as well, but faced regulation if they engaged in these activities.)

Significant hazards: The term "significant hazard" replaces the term "hazard reasonably likely to occur" to avoid the potential for misinterpretation that all necessary preventive controls must be established at critical control points.

Preventive Controls Rule for Animal Food

Human food waste: Human food processors already complying with FDA human food safety requirements would not need to implement additional preventive controls or CGMPs when supplying a by-product for use as animal food other than protecting it against contamination by means such as using appropriate containers, segregating it from sources of contamination such as trash, labeling the containers, and inspecting shipping containers before use.

CGMP revisions: The proposed CGMPs have been made more appropriate for animal food production.

Supplier verification, environmental monitoring, product testing, economically-motivated hazards: Similar requirements for the Preventive Controls for Human Food Rule have been proposed, see above.

Foreign Supplier Verification Program

On-site audits: For Class I hazards (SAHCODHA) an annual onsite audit is required unless the importer can determine (and document) that other verification activities and/or less frequent auditing provide adequate assurances that hazards are controlled.

More comprehensive hazard analysis requirement: Importers are now required to conduct a more comprehensive hazard analysis which examines compliance history of the supplier in the context of the nature of hazards in the food, the entity controlling the hazards (e.g. foreign supplier or foreign supplier's ingredient supplier), the foreign supplier's food safety practices and their performance history. The separate compliance status review requirement in the original rule has been eliminated and folded in to this requirement.

Economically motivated hazards: Importers are required to consider in its hazard analysis, hazards that may be intentionally introduced for economic reasons.

Produce Safety Rule

Water quality standard: The microbial standard for water quality for water that is used during the growing of produce (ex: sprouts) using a direct application way has been loosened to be consistent with EPA's current recreational water standard (statistical threshold value not to exceed 410 CFU of generic *E. coli* v. 235 CFU in previous rule). Increased flexibility is provided to achieve the standard by applying a time interval between last irrigation and harvest, and/or between harvest and end of storage (using microbial die-off rates). Tiered approaches for testing frequency requirements of untreated surface and ground water have been included to reduce the frequency of required testing.

Manure application: The 9-month minimum application interval for use of raw manure has been removed. FDA is deferring its decision on the matter and the agency does not take exception to the National Organic Program standard. If manure has been treated by composting and is applied in a manner that minimizes contact with produce, the minimum application interval has been reduced from 45 days to 0 days.

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