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Identifying hazards & preventing harm: How to apply FSMA preventive controls in your firm

Focus: Brief introduction to the Subparts A through G of 21 CFR 117.

21 Code of Federal Regulations 117 (21 CFR 117) Subparts

Subpart A—General Provisions

- Definitions for terms used through the new rules. Identifies required training and records for individuals regarding equipment, food hygiene, and food safety. Defines requirements for a Preventive Controls Qualified individual. Includes exemptions for applicability for certain foods, activities, and facilities.

Subpart B—Current Good Manufacturing Practices (cGMP's)

- Covers personnel, plant and grounds, sanitary operations, sanitary facilities and controls, equipment, processes, warehouses and animal food. Applies to all foods, activities, and facilities subject to the regulation.
- Addresses the holding and distribution of human food by-products for use as animal food.

Subpart C—Hazard Analysis and Risk Based Preventive Controls

- Addresses the need for food safety plans, conducting a hazard analysis, instituting preventive controls, development of a recall plan, monitoring the preventive controls, establishing corrective actions for when preventive controls are not properly implemented, verification steps to ensure monitoring is being conducted, and validation procedures to ensure the system is working.
- Identifies the roles of PCQI individuals to develop, implement, and monitor the program.

Subpart D—Modified Requirements

- Describes the application for a small firm and how it meets the qualification for exemption from preventive controls. This attestation document will be submitted to FDA.
- Describes a warehouse that requires time and temperature monitoring if a firm is solely engaged in the storage of unexposed packaged food when it holds refrigerated foods to prevent pathogen growth.

Subpart E—Withdrawal of a Qualified Facility

- Overview of circumstances that may lead FDA to withdraw a qualified facility exemption.

Subpart F—Records

- Overview of records that must be established and maintained. Records must be original, accurate, and created concurrently with details, signature or initials and date. Records must be created at the time of activity and all records are required to be made available for an official authorized representative.

Subpart G—Supply Chain Program

- Requires a receiving facility to establish and implement a risk-based supply chain program for raw materials and ingredients identified during the hazards evaluation.

Implementation and Expectations

All routine inspections will be conducted by the Oregon Department of Agriculture (ODA) as Limited Scope cGMP's (Current Good Manufacturing Practices) in the 2018-2019 fiscal year. The approach will be to educate and regulate—working with all levels of business to implement a new system inspection approach, develop food safety plans, and to provide a preventive approach to food safety.

The firm is expected to have a trained Preventive Controls Qualified Individual (PCQI) to develop a food safety plan if a hazard is identified, or submit documentation for exemptions based on ability, training, or using a third-party consultant.

FDA fully implemented all aspects of 21 CFR 117 for federal inspections beginning September 18, 2018.

This includes the Pasteurized Milk Ordinance (PMO) and Appendix T, to include Preventive Controls for FDA Grade A milk products.

Inspection Plans

A systems approach will apply for all inspections following the flow of incoming ingredients, through product processing, to storage of the finished product. This will include examining routes of potential product contamination, insanitary processing conditions, and allergen cross-contact.

Inspections will either be a cGMP Limited Scope or Preventive Controls Full Scope inspection, but not both. The cGMPs establish a base to avoid contamination of food products and the preventive controls take it a step further with a concentration on issues that if not controlled, could be a public health concern.

cGMP Limited Scope Inspection

Conducted using 21 CFR 117 Subparts A, B, F.

Inspection focus areas:

- Training records for food safety & employee hygiene
- Hazards
- Sanitation
- Building & equipment construction
- Sanitary operations
- Controls
- Food contact surfaces & equipment
- Adequate processes & controls for microbial growth in the food

Preventive Controls Full Scope Inspection

Conducted using 21 CFR 117 Subparts C, G. Includes components from cGMP inspection.

Inspection focus areas:

- Training records for food safety & employee hygiene
- Reporting of employee illnesses
- Proper hand washing
- Hazard analysis
- Implemented preventive controls
- Monitoring of the controls
- Corrective actions developed and taken
- Verification and validation of processes
- Recall plan
- Supply-chain program