Guidance Document 2: S 1 2 3 4 5 6 R

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

Focus: Overview of 21 CFR 117 Subparts A (General Provisions), B (current Good Manufacturing Practices, cGMP Limited Scope), and F (Requirement Applying to Records that must be Established and Maintained).

Changes to ODA Food Safety Inspections

Oregon Department of Agriculture (ODA) inspections have always been conducted with a focus on adulteration and misbranding.

» The focus on adulteration determines whether or not the food was made or held under insanitary conditions, contaminated with filth, is putrid, decomposed substance, or if otherwise unfit for consumption.

» Misbranding deals with whether or not a product is labeled correctly or contains misleading or improper statements.

With the new rules (21 CFR 117), the food and the food establishment will continue to be examined for adulteration and misbranding, however the new style inspections will take a systems approach to evaluating potential routes of food contamination. It will also include evaluations of raw ingredients, processing, and finished product.

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.

21 CFR 117 Subpart A—General Provisions

- *117.3 Definitions:* Contains definitions you will need to be familiar with to understand the application and implementation of 21 CFR 117.
- *117.4 Qualifications of individuals who manufacture, process, pack, or hold food:*
  - A cGMP Limited Scope inspection focuses on employee training. Each individual engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) must be trained appropriately for their assigned duties, and in the principles of food safety and personal hygiene. Records for these activities must be retained.
  - The Preventive Controls Full Scope inspection requires that a PCQI (Preventive Controls Qualified Individual) has completed FDA equivalent training course, is able to write a food safety plan, validate the preventive controls, review records, perform reanalysis of the food safety plan, and perform assigned duties related to the plan, which also includes training and records.
- *117.5 Exemptions:* Defines exemptions and identifies which subparts do not apply to certain facilities or activities. See Guidance Document #6 for details on qualification for exemption.

21 CFR 117 Subpart B—Current Good Manufacturing Practice (cGMP)

Most of the old terms from 21 CFR 110 remain. Terms no longer included: "Should" and "Shall" have been replaced by the word "must." New terms include: Audit, Ready-To-Eat, Environmental Pathogen, Allergen, Harvesting, Preventive Controls, Qualified (Auditor, Individual, Facility, User) Supply Chain Control, and Validation.

- *117.10 Personnel:* Directs the firm's management to take reasonable precautions regarding control of illnesses and wounds that may cause microbial contamination and to report health conditions.
  - Requires all workers in direct contact with food, food-contact surfaces, and food-packaging materials to conform to good hygienic practices. Practices include not working when ill, reporting illnesses, hand washing at appropriate times, protecting against allergen cross-contact, and the prevention of contamination of food through other means.
- *117.20 Plant and Grounds:* Requires processors to take precautions against contamination of food by managing grounds around the facility and the construction and design of the building.
  - Requires facility floors, walls and ceilings to be smooth and cleanable. This will also include reducing the potential for allergen cross contact. Facilities need adequate shielded lighting, ventilation to control dust or vapors, and adequate screening to prevent pest entry.
- *117.35 Sanitary Operations:* Requires buildings, fixtures, and other physical facilities maintained in a clean and sanitary manner.
  - Materials used in cleaning and sanitizing be safe and adequate under the conditions of use.
  - Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against allergen cross-contact and contamination of foods.
  - How and when the cleaning and sanitizing of food and non-food contact surfaces must be conducted.
  - Requirements to exclude pests and animals in a food facility (there are limitations for guard and guide dogs) and the use of pesticides to control pests.
- *117.37 Sanitary Facilities and Controls:* Requirements for water supply, plumbing, sewage disposal, hand washing facilities, and toilet facilities.
  - Water supply must be from an approved source, of a safe and sanitary quality, be at a suitable temperature, and have an adequate flow under pressure for processing and cleaning.
  - Plumbing must be of adequate size and design, properly installed to provide adequate supply to all portions of the facility, and convey sewage and liquid disposable waste from the facility. Plumbing must permit floor drainage and have no backflow potential from cross-connections.
  - Readily accessible and clean toilet facilities as well as convenient and accessible hand washing facilities are required.
  - The sanitary facilities include the removal, storage, and disposal of rubbish and offal to minimize pest issues.

21 CFR 117 Subpart B—Current Good Manufacturing Practice (cGMP)

- *117.40 Equipment and Utensils:* All plant equipment and utensils used in manufacturing, processing, packing, or holding food must be designed with material and quality be adequately cleanable. It must also be adequately maintained to protect against allergen cross-contact and contamination.
  - Equipment and utensils must be designed, constructed, and used appropriately to avoid the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.
  - Compressed air and gases must not be contaminated with unlawful food additives.
  - Food contact surfaces must be of non-toxic materials and constructed with smooth seams and kept in a clean and sanitary manner. Equipment such as refrigerators, freezers and cold storage warehouses are required to be fitted with a temperature measuring device, and all instruments must be precise, be maintained, and have an adequate number for use by the facility.
- *Section 117.80 Processes and Controls:* Requires a thorough review for all food establishments.
  - Processors are required to demonstrate they are in control of the parameters that make food safe, whether the control is pH, water activity, salt level, temperature, some other control, or a combination of control points. All operations in the manufacturing, processing, packing and holding of food be conducted with adequate sanitation and quality controls. Food processing and storage must be conducted in a manner that prevents allergen cross-contact or contamination.
  - Handle raw materials to ensure they are clean and suitable, that water used is safe and sanitary, frozen materials are kept frozen, foods are held at temperatures and moisture levels to prevent growth of undesirable microorganisms, adequate measures are taken to protect against inclusion of metal, and that ice in contact with food is safe and sanitary.
- *117.93 Warehousing and Distribution:* Looks at storage and transportation of food against allergen cross contact, biological, chemical, radiological, physical contamination, and deterioration of the food and the packaged container.
- *117.95 Holding and Distribution of Human Food By-Products for use as Animal Food:* Requires that human food by-products held for distribution as animal food without additional manufacturing or processing by the human food processor be held under conditions that will protect against contamination.
  - Processors will ensure that containers for the human food by-products are clean, maintained, and protect against contamination and trash. The containers must be examined prior to use, identified, and labeled. This ties in with the Preventive Control for Animal Feed rule (21 CFR 507).
- *117.110 Defect Action Levels:* Requires manufacturers, processors, packers, and holders of food to use strategies to reduce natural and unavoidable defects to the lowest level feasible.
  - You cannot mix adulterated food with another lot of food. If this occurs, the final food is adulterated, regardless of the defect level of the final food.

21 CFR 117 Subpart F—Records that must be Established & Maintained

A new requirement to the new GMP's and Preventive Controls is the requirement to maintain records.

- *117.305 General requirements applying to records:* Records must be kept as either original, true copies (i.e. photocopies), or electronic.
  - Records must contain actual values and observations obtained during monitoring, be accurate, indelible (in ink or pen), legible, and created at the same time as the activity.
  - Records must provide a history of the work performed by identifying the plant and facility name, location, date and time, signature or initials of person performing the activity, and product identification and lot code.
- *117.310 Additional requirements applying to the food safety plan*:
  - Requires the owner, operator or agent in charge to sign and date the food safety plan upon initial completion or any modification.
- *117.315 Record Retention:*
  - Requires all records be retained for at least 2 years.
  - There are special requirements for qualified firms to keep records for 3 years to support its status to be qualified for exemption.
  - Requires records which relate to the adequacy of equipment or process used by a facility be retained for 2 years.
  - Scientific studies and evaluations must be retained for 2 years.
  - Firms are permitted off-site storage if retrieval is within 24 hours.
- *117.320 Requirements for official review:* Records must be made promptly available to a duly authorized representative of the Secretary of Health and Human Services for official review and copying upon oral or written request.