Guidance Document 3: 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 C (Hazard Analysis and Risk-Based Preventive Controls) and G (Supply-Chain Program).

Hazard Analysis, Preventive Controls, and Monitoring

The FSMA rules mandate the creation of food safety programs with a focus on preventing contamination, rather than reacting to problems after they happen.

- Every firm is expected to do a hazard analysis to identify hazards associated with ingredients, processing, and the finished product.
- If a hazard is not found, or if it is determined a hazard is not reasonably foreseeable to occur, or a hazard is controlled at a later step through a documented assurance (see written assurances later in this guidance document). The inspection will be a cGMP Limited Scope inspection.
- If the firm identifies a hazard, a food safety plan is required, and a preventive control must be implemented for each hazard. This will require monitoring, corrective actions, records that must be written & maintained, and a recall plan. A Supply Chain Program Control may also be required.
- Preventive Controls for Human Food also requires training to qualify employees for assigned duties, address areas of allergen cross contact, and procedures to handle human food by-products destined for animal feed.

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, and 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 C—Hazard Analysis & Risk-Based Preventive Controls

- *117.126 Food Safety Plan:* Requires written procedures developing a hazard analysis, preventive controls, a supply chain program, recall plan, monitoring, corrective actions, verification activities, and records.
- *117.130 Hazard Analysis:* You must conduct a written hazard analysis to identify, evaluate foreseeable biological, chemical, and physical hazards for each type of food; and to assess the severity of illness or injury in the absence of a preventive control.
  - An evaluation of environmental pathogens must be included if a food is considered ready to eat food and exposed to the environment prior to packaging with no control measures.

21 CFR 117 Subpart C—Hazard Analysis & Risk-Based Preventive Controls

- *117.135 Preventive controls:* If a hazard is identified, preventive controls must be implemented to significantly minimize or prevent food from being adulterated.

The preventive controls must be written and may be:

- Process Control with maximum or minimum values.
- Food Allergen Control to control cross-contamination or allergen labeling issues.
- Sanitation Control to address cleanliness, minimize environmental pathogens and prevent allergen cross contact.
- Supply-Chain Control for receiving ingredients.
- Recall Plan, or other controls the firm may identify.

- *117.136 and 117.137 Written Assurances:* If a firm identifies a hazard and the hazard is controlled at a later step—either by a customer or another entity—a documented assurance/agreement between the two entities is required. This is required if either the supplier or receiver discloses and documents to not control an identified hazard.
- *117.139 Recall Plan:* Requires that a written procedure is in place to assign responsibilities in the event of a recall. The plan will detail how to notify direct consignees and the public, how to conduct effectiveness checks, and how a firm will appropriately dispose of recalled foods.
- *117.145 Monitoring:* Processing activities must have written records to document that processes and controls are being monitored.
  - For example, if a firm has identified that a certain temperature must be obtained, the firm shall record where the temperature was taken, the actual temperature, when it was taken, and who took the temperature. The frequency of temperature readings may also need to be identified.
- *117.150 Corrective Actions and Corrections:* Corrective Actions are recorded written actions that must be taken—if preventive controls are not properly implemented—to identify a problem, reduce the likelihood, correct a problem, and evaluate the food in case of an issue such as a presence of a pathogen or environmental pathogen.
  - Corrections must be done in a timely manner to identify and correct conditions or practices for a minor and isolated problem that does not directly impact product food safety, without citing a violation, and to include a written record of the action.
- *117.155 Verification Activities:* Firms must verify the food safety plan is adequate to control the identified hazards and at a suitable frequency to include corrective action and records.
- *117.160 Validation:* Must ensure the preventive controls have been adequately identified and implemented to control each hazard.
  - To be performed by a preventive controls qualified individual (PCQI) after 90 days from the start of production, whenever a change is made to a control measure, or a reanalysis reveals a need.
  - There is no need to validate a food allergen, sanitation control, a recall plan or for a supply chain supply program.

21 CFR 117 Subpart C—Hazard Analysis & Risk-Based Preventive Controls

- *117.165 Verification of Implementation and Effectiveness:* Firms must verify that preventive controls are consistently implemented, and significantly minimizing or preventing hazards.
  - Verification with written steps would likely include calibration of process instruments and include records regarding product testing, environmental monitoring, and review of records within 7 working days.
- *117.170 Reanalysis:* Firms must conduct a reanalysis of the food safety plan every 3 years, or when any significant changes are made, if new hazards are identified, or if you have unanticipated failure of the food safety plan.
- *117.180 Requirements applicable to a Preventive Controls Individual (PCQI):* A PCQI individual must oversee the preparation of a food safety plan, validate preventive controls, to review all records, perform a reanalysis of the food safety plan.
  - The PCQI must have successfully completed training in the development and application of risk-based controls.
  - All applicable training in development and application of risk-based preventive controls must be documented in records, with date, type and persons trained.
- *117.190 Implementation records required:* If a form does not establish a preventive control, the firm must establish and maintain documents as to why a preventive control was not established.
  - This documentation would require a basis for not developing and maintaining the following records; monitoring, verification, validation, calibration, product testing, environmental testing, records review, reanalysis, supply-chain program, and training.
  - These records will be maintained as stated in Subpart F.

21 CFR 117 Subpart G—Supply-Chain Program

The receiving facility must approve suppliers and determine appropriate supplier verification activities. These procedures will be written showing how to receive raw materials and how to conduct supplier verification activities.

- *117.405 Requirement to Establish and Implement a Supply-Chain Program:* The receiving facility must establish and implement a risk-based supply-chain program for raw materials and other ingredients with an identified hazard, requiring a supply-chain applied control.
- *117.410 General Requirements:* Firms must use approved suppliers, determine verification activities, conduct verification and document verification—using audits, testing, review of records, conduct a hazard analysis, supplier performance, and food safety history.
  - If a supplier is found not controlling hazards, the receiving facility must take prompt action.
- *117.415 Responsibilities of the Receiving Facility*: Firms must conduct verification activities, establish written procedures, and determine that procedures are followed.
  - Firms may not accept a supplier verification audit, a supplier's own review of a food safety plan, or an audit conducted by the supplier.

21 CFR 117 Subpart G—Supply-Chain Program

- *117.420 Using Approved Suppliers:* A receiving facility must use only approved suppliers, document approval before receiving raw materials and other ingredients from those suppliers, and ensure that approval procedures are written and documented.
- *117.430 Conduct Supplier Verification Activities:* Activities such as audits and written assurances must be conducted before receiving and using ingredients on an annual basis.
- *117.435 Onsite Audit*: Onsite audit must be performed by a qualified auditor.
- *117.475 Records Documenting the Supply-Chain Program:* Records are subject to Subpart F and must be written, reviewed with dates showing approvals and procedures, and the results of sampling and testing, plus any results from a third part audit.