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

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

Focus: Overview of prevention rules including preventive controls, intentional adulteration, sanitary transport, and foreign supplier verification.

Risk-Reducing Strategies

The FSMA rules include risk-reducing strategies, intended to address intentional adulteration, sanitary transport, and foreign supplier verification such as:

- Intentional acts to cause harm by deliberately adding substances to adulterate food.
- How food is required to be transported from processors and distributors to customers using food safety principles.
- The foreign supplier verification program to ensure foreign food processors are qualified to export to the United States.

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 121—Identifying, Mitigating, and Monitoring Vulnerabilities

This rule requires firms to take measures to prevent acts that cause wide-scale harm to public health causing illness, death, or economic disruption due to intentional adulteration. Rather than targeting specific foods or hazards, this rule requires risk-reducing strategies for processes in certain registered food facilities.

This regulation applies to firms that manufacture, process, pack, or hold human food, and that are subject to facility registration as stipulated in 21 CFR 1.225. A covered facility is required to prepare and implement a food defense plan.

Key components are

1) Conducting a vulnerability assessment,

2) developing mitigation strategies, and

3) monitoring the plan.

21 CFR 121—Identifying, Mitigating, and Monitoring Vulnerabilities

1) The identification of vulnerabilities is for each type of food manufactured, processed, packed and/or held at the facility. For each point, step, or procedure in a facility's process, the following must be evaluated:

- The severity and scale of the potential impact on public health.
  - Includes considerations such as; the volume of product, the number of servings, the number of exposures, how fast the food moves through the distribution system, potential agents of concern and the infectious/lethal dose of each, and the possible number of illnesses and deaths.
- The degree of physical access to the product. Access points to be considered may include the presence of physical barriers as gates, railings, doors, lids, seals and shields.
- The ability to successfully contaminate the product.

2) Mitigation strategies must be tailored to the facility and its procedures—identified and implemented at each actionable process step.

3) Monitoring the plan, making and recording corrective actions, verifying that the system is working, and maintaining records are also required steps. A reanalysis is required every three years.

21 CFR 1.500 Subpart L— Foreign Supplier Verification Program

The Foreign Supplier Verification Program is for importers covered by FSMA. Importers must have programs in place to verify that foreign suppliers are producing food in a manner that provides the same level of public health protection as foods prepared in the United States.

- Importers are responsible for
  - Determining known or reasonably foreseeable hazards with each food;
  - Evaluating the risk posed by a food based on a hazard analysis; and
  - A foreign supplier's performance.

This can be accomplished by conducting supplier verification activities, conducting corrective actions, and by establishing & following written procedures for each food from every supplier.

- There are provisions for the use of imported raw materials or ingredients on a temporary basis, from an unapproved supplier, if the foods are subject to adequate verification activities.
  - This provision applies to importers who are manufacturers deemed in compliance through a Supply-Chain Program or who have implemented Preventive Controls for identified hazards. The risk must be reevaluated every three years.
- An importer must establish and follow written procedures for approved supplier verification activities, that may include: an annual on-site audit, sampling and testing, a review of food safety records. Importers may rely on another entity *only* if there is a review of documentation.

Exemptions exist for this requirement. For more information visit: https://oda.fyi/FSMAFSVP

21 CFR 1.900 Subpart O—Sanitary Transportation of Human and Animal Food

This new rule establishes the requirements for sanitary operations involved in transportation of human and animal foods by motor carriers and rail vehicles. This rule also applies to a) firms receiving foods where they are the owner of the foods and b) to carriers that provide a transport service. This does not apply to ship or air transportation.

Key requirements of the rule include:

- Proper design of vehicles and transportation equipment
  - The design and maintenance of vehicles and transportation equipment must ensure that transported food remains safe. Additionally, the vehicles and equipment must be suitable and adequately cleanable for their intended use and be capable of maintaining temperatures necessary for the safe transport of food.
- Transportation operations
  - Measures must be taken during transportation to ensure food safety, such as: adequate temperature controls, preventing contamination of ready to eat food from touching raw food, protection of food from contamination by non-food items in the same load or previous load, and protection of food from cross-contact (i.e. allergen cross-contamination).
- Training
  - Training is required for carrier personnel in sanitary transportation practices and training must be documented. When the carrier and shipper agree that the carrier is responsible for sanitary conditions during transport, carriers are required to provide food safety training to transportation operations personnel.
- Records
  - Records must be retained for all written procedures, agreements, and trainings required of carriers. The required retention time for these records depends upon the type of record and when the covered activity occurred. These records must be retained for a minimum of 12 months.

Third Party Accreditation

This new rule is not specific to food processors. The Third-Party Accreditation rule establishes a voluntary program for the accreditation of third-party certification bodies, which are also known as third party auditors. The rule allows them to conduct food safety audits and issue certifications to foreign entities for the foods they produce.