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

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

Focus: Overview of compliance rules including facility registration, attestation, food defense, and small entity guidance.

Compliance Rules for Commercial Food Processing Facilities

Compliance rules exist for every commercial food processing facility and include the following:

- Food Facility Registration under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.
- Very Small Firm Attestation as outlined in in 21 CFR 117.201.
- Food Defense strategies 21 CFR 121.126.
- Small Firm Entity guidance outlined in Subparts A, B, and F.

With the new FSMA 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.

Food Facility Registration

The FDA Food Safety Modernization Act (FSMA) enacted on January 4, 2011 amended section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Facilities engaged in manufacturing, processing, packing, or holding food for consumption in the United States must submit additional registration information to FDA. This includes an assurance that FDA will be permitted to inspect the facility at the times, and in the manner, permitted by the FD&C Act, Section 415.

- Unless a firm is exempt from Bioterrorism Act registration, all food facilities must register upon start of operation and keep their registration current. At registration, firms provide FDA with firm profile information and scope of activities. Only domestic kitchens and firms with retail sales over 51% are exempt.
- The Food Facility Registration FDA Portal is part of a directive from the Public Health and Security and Bioterrorism Preparedness and Response Act of 2002. It was created to allow the FDA to take steps to protect the public from a threatened or actual terrorism attack on the U.S. food supply and other food-related emergencies.

Food Facility Registration

- All firms food facilities must renew their registration with the FDA at the Food Facility Registration Portal every even numbered year between the months of October and December. During renewal, firms will update their profile of ownership, contact information, and activities conducted.
- The Bioterrorism Act also requires firms to give the FDA advance notice on shipments of imported food. It also provides FDA authority to suspend the registration if the food is determined to have a reasonable probability of causing serious adverse health consequences or death to humans or animals.
  - For more information on facility registration visit: https://oda.fyi/FDAregistration
    This website provides guidance for food facility account management, user guides for online registration, guides for the biennial registration renewal, cancellation by mail, and system status.
    FDA help desk phone: 1-800-216-7331 and email: furls@fda.gov

Attestation for Qualified Firms and Very Small Firms

- *Qualified facility (CFR 117.3):* A firm that has less than $500,000 in gross sale average over three years where product is sold directly to a qualified end user. A qualified end user is a direct consumer of the food located in the same state, or within 275 miles from the facility, or is purchasing product/ingredients for sale directly to a consumer at a restaurant or retail food establishment such as a grocery store.
- *Very small business or firm (CFR 117.3):* A business that has a market sales value average of less than $1 million (for the prior three years) of all human food that is manufactured, processed, packed, or product that is consider finished product but not yet sold. The Oregon Department of Agriculture (ODA) recommends the use of the $1 million, 3-year gross sales average of the small firm definition for all attestations.

A very small firm in Oregon cannot file an attestation if:

- It has a parent company, or is part of a subsidiary or an affiliate,
  that individually or in any combination has over $1 million is gross sales over a 3-year average, for human food that is manufactured, processed, packed or held without sale.
- The firm will be subject to the full requirements of Subpart C: Preventive Controls and Subpart G: Supply-Chain Program.

If you have determined you qualify for the Preventive Controls exemption after reviewing the requirements, the next step is to read 21 CFR 117 Subpart D.
View the attestation guidance: https://oda.fyi/QualifiedFacilityDefined

When you are filing an attestation form, you are stating you are a very small firm and that you are meeting state and local licensing food safety laws.

Food Defense

Food defense is part of the FDA Mitigation of Intentional Adulteration final rule that requires firms to learn awareness of food defense strategies.

FDA provides a Food Defense Awareness for Front-Line Employees course which includes:

- Training modules,
- tools and resources regarding vulnerabilities,
- how to recognize intentional contamination,
- how to build a food defense plan, and
- how to understand intentional contamination and the impact on the global food supply.

The food defense plan provides basic preventive measures, action plans, and strategies on how to conduct vulnerability assessments of food processes, and how to address identified issues.
For more information visit: https://oda.fyi/FoodDefense101

Small Entity Industry Guidance

Small entity industry guidance explains who must comply, definitions of terms, who is exempt, foods covered by 21 CFR 117, what is a hazard analysis, what are preventive controls, what is a supply-chain program, education and training, information on qualified facilities, on-farm activities, the updated and clarified cGMPs, and includes the updated regulations.

The FDA guidance document provides details on most components that pertain to small entities. New topics include items such as training records, warehouses, defect levels, and terms such as allergen cross contact. To see the guide visit: https://oda.fyi/SmallEntityGuidance

Implementation and Inspection of the New Rules

A cGMP inspection will be conducted using 21 CFR 117 Subpart B. The inspector will be looking at training records for food safety and employee hygiene, hazards, sanitation, building and equipment construction, sanitary operations, controls, food contact surfaces and equipment, and adequate processes and controls for microbial growth in the food.

A preventive controls inspection using 21 CFR 117 Subpart C will, as with an cGMP inspection, look at training records for food safety and employee hygiene, reporting of employee illnesses, and proper hand washing. The food safety plan component will review the hazard analysis, implemented preventive controls, monitoring of the controls, corrective actions developed and taken, verification and validation of processes, the recall plan, and the supply-chain program.

These inspections will be a systems approach following the flow of incoming ingredients, through the processing of the product, to the storage of the finished product. ODA will look for routes of potential contamination of a product, insanitary processing conditions, and allergen cross-contact.