

Food Safety Modernization Act - Food Safety Plan Requirements

Domestic and foreign food facilities are required to register with the FDA under the Food, Drug, & Cosmetic Act and must comply with the FDA Food Safety Modernization Act (FSMA) which requires food facilities to have and implement a written food safety plan, commonly called a Hazard Analysis and Risk-Based Preventative Controls Food Safety Plan (HARPC) that includes:

Hazard analysis: The first step is hazard identification, which must consider known or reasonably foreseeable biological, chemical, and physical hazards. These hazards could be present because they occur naturally, are unintentionally introduced, or are intentionally introduced for economic gain (if they affect the safety of the food).

If the hazard analysis reveals one or more hazards that require a preventive control, the facility must have and implement written preventive controls for the identified hazards.

Preventive controls: Facilities have the flexibility to tailor preventive controls to address hazards that occur in the products they manufacture. The preventive controls, which must be written, must be implemented to ensure that any hazards requiring a preventive control will be significantly minimized or prevented and help ensure that the food is not adulterated. The rule includes the following preventive controls:

1. **Process controls** include procedures that ensure the control parameters are met. Process controls can include operations such as cooking, refrigerating, and acidifying foods. They must include parameters and values (e.g., critical limits), as appropriate to the nature of the applicable control and its role in the facility's food safety system.
2. **Food allergen controls** are written procedures the facility must have and implement to control allergen cross-contact and ensure allergens are appropriately listed on the labels of packaged food products.
3. **Sanitation controls** are procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition to minimize or prevent hazards such as environmental pathogens, hazards from employees handling food, and food allergen hazards.
4. **Other Controls** are controls that are not described above but are necessary to ensure that a hazard requiring a preventive control will be significantly minimized or prevented.

Oversight and management of preventive controls: Once a facility has identified a preventive control for a hazard, the facility must make sure that the controls are being met.

- **Monitoring:** These procedures are designed to provide assurance that preventive controls are consistently performed. Monitoring is conducted as appropriate to the preventive control. For example, monitoring of a heat process to kill pathogens would include recording temperature values. Monitoring must be documented.
- **Corrections:** These are steps taken, in a timely manner, to identify and correct a minor, isolated problem that occurs during food production.

- **Corrective actions:** These include actions to identify and correct a problem implementing a preventive control, reduce the likelihood the problem will recur, evaluate affected food for safety, and prevent that food from entering commerce if you cannot ensure that the affected food is not adulterated. Corrective actions must be documented with records.
- **Verification:** These activities are required to ensure that preventive controls are consistently implemented and effective in minimizing hazards. Examples of verification activities include scientifically validating process preventive controls to ensure that the control measure is capable of effectively controlling an identified hazard and calibrating (or checking the accuracy of) process monitoring and verification instruments such as thermometers. Verification activities also include reviewing records to ensure that monitoring and corrective actions (if necessary) are being conducted. Verification activities must be documented.
- Product testing and environmental monitoring are also possible verification activities, required as appropriate to the food, facility, nature of the preventive control, and the role of that control in the facility's food safety system. Environmental monitoring is required if the contamination of a ready-to-eat food with an environmental pathogen is a hazard the facility identified as requiring a preventive control.

Supply chain program: Manufacturers must have and implement a risk-based supply chain program if the hazard analysis identifies a hazard that (1) requires a preventive control and (2) the control will be applied in the facility's supply chain.

- Facilities do not need to have a supply-chain program if they control the hazard in their own facility, or if a subsequent entity (such as another processor) will control the hazard, and the facility follows applicable requirements.
- Manufacturers are responsible for ensuring that raw materials and other ingredients requiring a supply-chain-applied control are received only from approved suppliers, or on a temporary basis from unapproved suppliers whose materials are subject to verification activities before being accepted for use. (Suppliers are approved by the facility after the facility considers several factors, such as a hazard analysis of the food, the entity that will be controlling that hazard, and supplier performance.)
- Another entity in the supply chain, such as a broker or distributor, can conduct supplier verification activities, but the receiving facility must review and assess that entity's documentation that they verified the supplier's control of the hazard.

Recall plan: If the hazard analysis identifies a hazard requiring a preventive control, the facility must have a written recall plan that describes the procedures to perform a recall of the product. The recall plan must include procedures to notify consignees, to notify the public when necessary, to conduct effectiveness checks and to appropriately dispose of recalled product.