

Checklist to Meet U.S. Food Safety Modernization Act Requirements

Hazards Analysis and Risk Based Preventative Controls Food Safety Plan

The FDA Food Safety Modernization Act (FSMA) requires domestic and foreign food facilities to register with the FDA and to have and implement a written food safety plan, which is commonly called a Hazard Analysis and Risk-Based Preventative Controls Food Safety Plan (HARPC) that must include the following:

- 1. Hazard analysis:** The food safety plan must include a hazard analysis to ensure the hazards have been properly identified, which must consider known or reasonably foreseeable biological, chemical, and physical hazards that may be present due to natural occurrence or unintentional introduction. If the hazard analysis reveals one or more hazards that require a preventive control, the facility must establish and implement written preventive controls for the identified hazards.
- 2. Preventive Controls:** The food safety plan must include preventive controls to address hazards that occur in the products they manufacture. Preventive controls, which must be written, must be implemented to ensure that any hazards requiring a preventive control will be significantly minimized or prevented to ensure that the food is not adulterated. Preventive controls include process controls, food allergen controls, sanitation controls and other controls necessary to ensure a hazard is minimized or prevented.
- 3. Process Controls:** The food safety plan must include process controls which are written procedures that ensure the control parameters are met. Process controls can include operations such as pasteurization and drying 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.
- 4. Food Allergen Controls:** The food safety plan must include food allergen controls which are written procedures the facility must have documented and implemented to control allergen cross-contact and ensure allergens are appropriately listed on the labels of packaged food products.
- 5. Sanitation Controls:** The food safety plan must include sanitation controls which are written procedures, practices, and processes to ensure 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.
- 6. Monitoring:** The food safety plan must include monitoring, which are documented procedures designed and conducted as appropriate to the preventive control to provide assurance that controls are consistently performed. For example, monitoring of heat processes to kill pathogens would include recording temperature.
- 7. Corrective Actions:** The food safety plan must include documented corrective 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 adulterated food from entering commerce.
- 8. Verification:** The food safety plan must include documented verification activities to ensure preventive controls are consistently implemented and effective in minimizing hazards. Verification activities include scientifically validating process preventive controls to ensure the control measure is capable of effectively controlling a hazard and calibrating process monitoring and verification instruments such as thermometers.
- 9. Recall Plan:** The food safety plan must include 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.