

<b>Training Manual</b>	
<b>Subject: Food Safety Plan</b>	<b>Number:</b> 5.029

### **Food Safety Plan/Training**

\*US Food and Drug Administration (FDA) is a federal-level food safety regulatory agency.

\*The Food Safety Modernization Act (FSMA) is a preventive, proactive approach to food safety.

#### **Background**

Congress passed FSMA in 2010 and the President signed it in 2011, significantly overhauling the United States food law. Since then, FDA has proposed, revised then revised again the rules that determine how FSMA affects farmers and food processors. In all, FSMA includes seven rules:

1. Produce Safety
2. Preventive Controls for Human Food
3. Preventive Controls for Animal Food
4. Sanitary Transportation of Foods
5. Foreign Supplier Verification Programs
6. Accredited Third-Party Certification
7. Protect Food against Intentional Adulteration

The Preventive Controls for Human Food is the specific component of FSMA that affects food processors. FDA finalized the Preventive Controls Rule in September 2015.

#### **The Difference Between HACCP and HARPC**

Hazard Analysis and Critical Control Points (HACCP) is a specific food safety management system required for facilities that process juice and seafood.

Hazard Analysis and Risk-Based Preventive Controls (HARPC) is a food safety management system introduced by FSMA. It has some similarities to HACCP and applies to virtually all food processing facilities.

#### **Key Requirements of Preventive Controls for Human Food**

1. Facilities must establish and implement a food safety system that includes an analysis of hazards and risk-based preventive controls. Requirements for a written food safety plan include:

Hazard Analysis – This is the first step where you must consider known or reasonably foreseeable biological, chemical (which include radiological) and physical hazards. These hazards could be present because they: 1) Occur naturally, 2) Are Unintentionally introduced or 3) Are Intentionally introduced.

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Preventive Controls – These are measures taken to ensure that hazards requiring a preventive control are minimized or prevented.

2. Good Manufacturing Practices (GMPs) are updated and clarified.

Management is required to ensure that all employees who manufacture, process, pack or hold food are qualified to perform their assigned duties. Employees must have the combination of education, training and/or experience necessary to complete their assigned duties. Employees must receive training in the principles of food hygiene and food safety, including the importance of employee health and hygiene.

**Oversight and Management of Preventive Controls Include**

1. Monitoring – these are designed to provide assurance that preventive controls are consistently performed. For example, monitoring of a heat process to kill pathogens (HTST) would include actual temperature values and be more frequent than monitoring preventive maintenance (PM) activities used to minimize metal hazards, which could be a simple record of the date on which the PM took place.

2. Corrective Actions and Corrections – are steps taken to identify and correct a minor isolated problem that occurs during food production. Corrective actions include the actions taken to 1) Identify a problem 2) Reduce the likelihood of the problem reoccurring 3) Evaluate the affected food for safety and prevent it from entering commerce. Corrective actions must be documented with records.

3. Verification – these activities are required to ensure that preventive controls are consistently implemented and effective. They include validating (with scientific evidence) that a preventive control is capable of effectively controlling an identified hazard.

The regulation requires that certain activities must be completed by a Preventive Control Qualified Individual (PCQI) who has successfully completed training in the development and application of risk-based preventive controls. This person performs or oversees:

1. The preparation of the Food Safety Plan
2. Validation of the preventive controls
3. Records review
4. Reanalysis of the Food Safety Plan (Every 3 years or when there is a process change.)

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