

purpose of The FDA's Food Safety Modernization ACT (FSMA) is to protect public health through adopting a preventive, risk-based approach to food safety regulation. FSMA represents a monumental shift in regulations from how to respond to contamination to developing appropriate controls designed to prevent them.

The compliance date for FSMA Preventive Controls for registered companies having more than 500 employees was September 17, 2016. To meet compliance regulations for FSMA, registered companies subject to this rule must focus first on developing an updated food safety system, which requires a written food safety plan. Your written **Food Safety Plan (FSP)** must include documentation of the following HACCP principles:

## 1. HAZARD ANALYSIS

A food safety hazard is any biological, chemical or physical property that could cause a food to be unsafe for human consumption. This first important step involves identifying which of these food safety hazards may be present at any point along your food production processes, from purchasing and transportation to handling and serving. All known hazards to be present must be documented. Once the hazards are identified, the next step is to document whether these hazards are "significant." In HACCP terms, significant means the hazard is "reasonably likely to occur." How can you know this? Doing a little research may provide the answers. For instance, does your facility already have existing measures in place to control the hazard? If so, it could mean this hazard is known to be a problem. Other ways to identify a hazard as significant include if you're able to find any documentation of previous customer complaints relevant to the hazard, or if there are any documented outbreaks or recalls relevant to the hazard.

According to the FDA, there are 5 primary risk factors that contribute to the most foodborne illnesses in the United States:

- Food from an unsafe source
- Inadequate cooking
- Improper holding temperatures
- Contaminated processing equipment
- and Poor personal hygiene.

Identifying where there is potential for these common risks along your manufacturing processes is a good starting point.

## 2. UPDATED PREVENTIVE CONTROLS FOR HAZARDS

If it is determined that a hazard qualifies as significant, that hazard will require a preventive control if one is not already in place. Any hazards not determined to be significant will also require documentation. This just means documenting the steps you took to determine which hazards require preventive controls and which (if any) do not. If any new hazards are uncovered in this process, then you will need to update your preventive controls for that hazard and document the updates. According to the FDA, Preventive Controls (PCs) are defined as "measures required to ensure that hazards requiring a preventive control will be minimized or prevented."<sup>1</sup>

In the article "[Top 10 Grainger Solutions for Preventive Controls](#)," you can read about common examples of hazards and their respective preventive controls.

### 3. EFFECTIVE MONITORING PROCEDURES

Monitoring procedures, according to the FDA, are put in place to ensure that preventive controls are consistently performed. One example of this, as given by the FDA, might be if a heat process is needed to kill pathogens, proper monitoring could include frequent checking of actual temperature values at critical points, and then recording the date and time the monitoring activity took place.

### 4. CORRECTIVE ACTION PROCEDURES

If while monitoring the food production process, a problem with a preventive control is identified, corrective actions must be taken to fix the problem. Corrections are steps taken to identify and correct a minor, isolated problem in a timely fashion. As stated by the FDA: "Corrective actions are put in place to reduce the likelihood the problem will recur, evaluate affected food for safety, and prevent it from entering commerce. Corrective actions must be documented with records."<sup>2</sup>

### 5. VERIFICATION PROCEDURES

Verification activities are required to ensure that preventive controls are consistent and effective. For verification to be effective, it has to include scientific evidence that a preventive control can prevent a potential hazard. Using measurement, such as thermometers and calibration instruments qualify as scientific evidence.

Product testing and environmental monitoring also can qualify as verification activities depending on the nature of the preventive control, and the role it plays in the food safety plan. For example, environmental monitoring would be required if there's a preventive control in place for an environmental pathogen contamination hazard.

Your Food Safety System will include documentation of many other elements, but you can start with an updated Food Safety Plan to include these 5 HAACP principles with a renewed perspective on hazard identification and prevention. Download [this helpful checklist](#) to get started on your new Food Safety Plan.

#### SOURCE

1., 2. United States Food and Drug Association FDA. "[Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.](#)"

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