



**WISKERCHEN
CHEESE INC.**

**FDA FOOD SAFETY
MODERNIZATION ACT**



*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 proposed 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



HACCP versus HARPC

SIMILARITIES



Focus on Proactive Food Safety



Identifies Hazards - Biological, Chemical and Physical



Includes Corrective Actions

KEY DIFFERENCES

| | HACCP | HARPC |
|---------------------------------------------------------------------------------------------------------------|-------------------------|-----------------------|
|  Recognized Standard: | Global | US only |
|  Food Products: | FDA & USDA | FDA only |
|  Identify | Critical Control Points | Preventative Controls |
|  Required Support | Internal Team | Qualified Individual |
|  Re-Analysis | Within 1 year | Within 3 years |

Key Requirements of Preventive Controls for Human Food

1. Facilities must establish & implement a food safety system. Requirements for a written food safety plan include:



Management of Preventive Controls

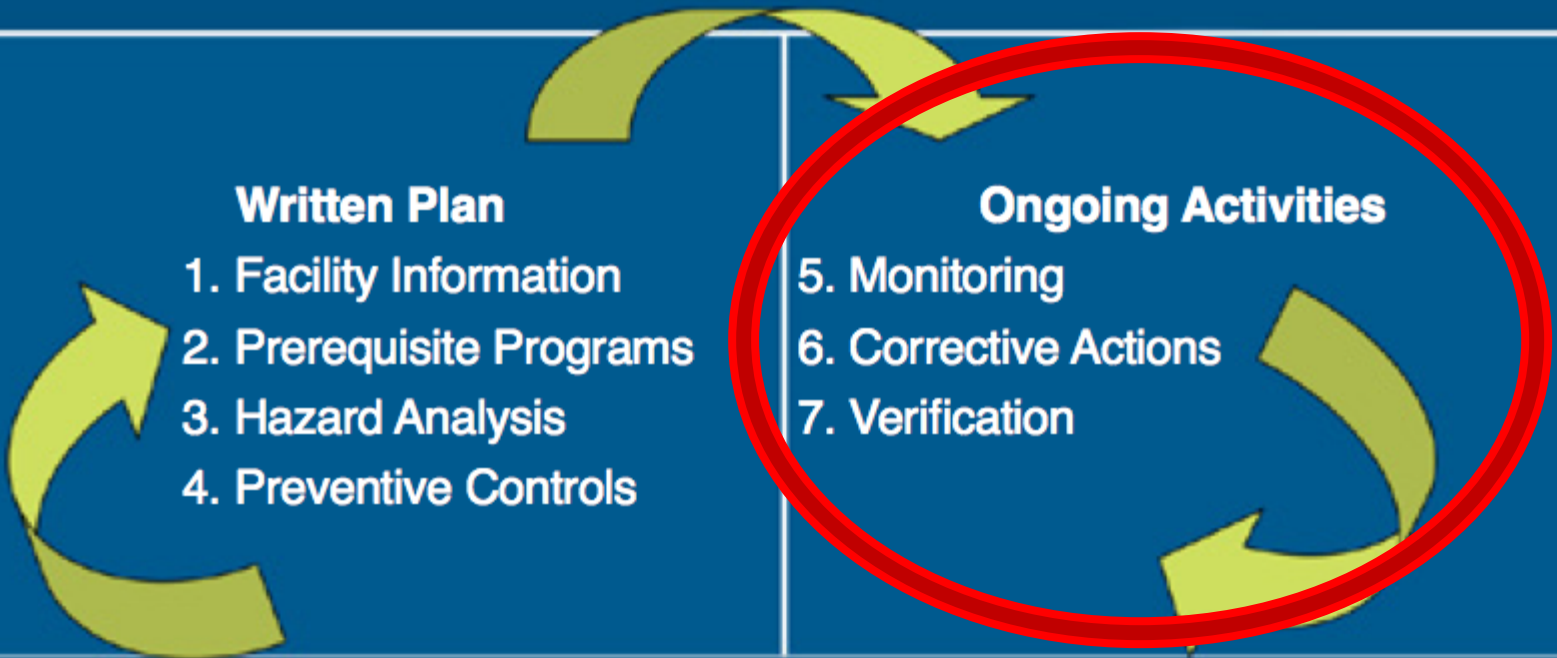
The Food Safety Plan

Written Plan

1. Facility Information
2. Prerequisite Programs
3. Hazard Analysis
4. Preventive Controls

Ongoing Activities

5. Monitoring
6. Corrective Actions
7. Verification



The regulation requires:

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)

Is performed or overseen by a Preventive Control Qualified Individual (PCQI) who has successfully completed training in the development & application of risk-based preventive controls.

