

PREVENTIVE CONTROLS FOR HUMAN FOOD GUIDANCE

The FDA Food Safety Modernization Act (FSMA), Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food Rule. (21 CFR 117) has been adopted in Rule 5K-4002, Florida Administrative Code. Your business has been identified as being required to comply with 21 CFR 117 and the following information will help to prepare your business for compliance and inspection. Listed below are a few highlights of the rule as well as some informational links:

You must establish and implement a food safety system that includes an analysis of hazards and risk-based preventive controls. The rule sets requirements for a written food safety plan that includes:

1. **Hazard analysis:** The first step is hazard identification, which must consider known or reasonably foreseeable biological, chemical, and physical hazards. This must be written and if a hazard needing a control is identified then a written preventive control procedure is required.
2. **Preventive controls:** These measures are required to ensure that hazards requiring a preventive control will be minimized or prevented. They include process, allergen, and sanitation controls, as well as supply-chain controls and a recall plan.
3. **Oversight and management of preventive controls.** The rule provides flexibility in the steps needed to ensure that preventive controls are effective and to correct problems that may arise.

Preventive controls qualified individual (PCQI)

A preventive controls qualified individual is someone who has successfully completed certain training in the development and application of risk-based preventive controls or is otherwise qualified through job experience to develop and apply a food safety system. The written food safety plan required of food facilities must be prepared, or its preparation overseen, by one or more preventive controls qualified individuals. And the preventive controls qualified individual is charged with overseeing the validation that preventive controls are capable of controlling identified hazards and the records review. Information and a list of available trainings to become a PCQI can be found at either:

<https://www.ifsh.iit.edu/fspca> or <http://www.crec.ifas.ufl.edu/>

Helpful Links

Preventive Controls for Human Foods Fact Sheet:

<https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM584807.pdf>

Current Good Manufacturing Practices, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; Final Rule: <https://www.govinfo.gov/content/pkg/FR-2015-09-17/pdf/2015-21920.pdf>

FDA Food Safety Modernization Act (FSMA): www.fda.gov/fsma

Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food information:

<https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM517610.pdf>

Draft Guidance Hazards Tables (Appendix 1):

<https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM517402.pdf>

FAQ on FSMA: <https://www.fda.gov/food/food-safety-modernization-act-fsma/frequently-asked-questions-fsma>

Food Safety Plan Builder: <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm539791.htm>

