

Identifying hazards & preventing harm: How to apply FSMA preventive controls in your firm

- Focus: Overview and summary information for this series of guidance documents on the Food Safety Modernization Act (FSMA) and food safety.

Federal Food Safety Modernization Act (FSMA)

In January 2011, President Obama signed into law the Food Safety Modernization Act (FSMA) and the Federal Food, Drug & Cosmetic Act (FD&C Act) was amended to incorporate sweeping changes to the nation's food safety supply.

Changes were needed to improve the nation's capacity to detect and respond to food safety issues and to prevent foodborne diseases due to an ever-changing global food supply and an increased knowledge of food science.

There are seven major components of FSMA, this series of documents will focus on 'Preventive Controls for Human Food.'

During the rule-making process, FDA took a science and risk approach, listened to industry, and worked with federal and state agencies to develop portions of the Code of Federal Regulations. The result is a code that will allow a systems approach to conducting inspections. It will require that all food processors take a good look at how they conduct business. FSMA focuses on the prevention of food safety problems, rather than being reactive to problems after they occur.

Firms need to:

- Provide and document training of employees.
- Evaluate the hazards that could affect food manufactured or held.
- If necessary, implement preventive controls and monitor those controls to prevent potential for adulteration.

New FSMA Rules Adopted in Oregon

Oregon adopted Title 21 Code of Federal Regulations Part 117 (21 CFR 117) through the Oregon Administrative Rules process.



Guidance Documents: This series will take a brief look at the new FSMA rules, with special attention to 21 CFR 117 and its subparts.

- S_ Summary (this document)
- 1_ Intro to the Subparts A-G of 21 CFR 117
- 2_ Overview of 21 CFR 117 Subparts A, B, and F
- 3_ Overview of 21 CFR 117 Subparts C and G
- 4_ Prevention Rules
- 5_ Compliance Rules
- 6_ Product Exemptions, Training Requirements, Loss of an Exemption
- R_ Resources



Oregon
Department
of Agriculture

Implementation and Expectations

All routine inspections will be conducted by the Oregon Department of Agriculture (ODA) as Limited Scope cGMP's (Current Good Manufacturing Practices) in the 2018-2019 fiscal year. The approach will be to educate and regulate—working with all levels of business to implement a new system inspection approach, develop food safety plans, and to provide a preventive approach to food safety.

The firm is expected to have a trained Preventive Controls Qualified Individual (PCQI) to develop a food safety plan if a hazard is identified, or submit documentation for exemptions based on ability, training, or using a third-party consultant.

FDA fully implemented all aspects of 21 CFR 117 for federal inspections beginning September 18, 2018.

This includes the Pasteurized Milk Ordinance (PMO) and Appendix T, to include Preventive Controls for FDA Grade A milk products.

Inspection Plans

A systems approach will apply for all inspections following the flow of incoming ingredients, through product processing, to storage of the finished product. This will include examining routes of potential product contamination, insanitary processing conditions, and allergen cross-contact.

Inspections will either be a cGMP Limited Scope or Preventive Controls Full Scope inspection, but not both. The cGMPs establish a base to avoid contamination of food products and the preventive controls take it a step further with a concentration on issues that if not controlled, could be a public health concern.

<p>cGMP Limited Scope Inspection Conducted using 21 CFR 117 Subparts A, B, F.</p>	<p>Preventive Controls Full Scope Inspection Conducted using 21 CFR 117 Subparts C, G. Includes components from cGMP inspection.</p>
<p>Inspection focus areas:</p> <ul style="list-style-type: none"> • Training records for food safety & employee hygiene • Hazards • Sanitation • Building & equipment construction • Sanitary operations • Controls • Food contact surfaces & equipment • Adequate processes & controls for microbial growth in the food 	<p>Inspection focus areas:</p> <ul style="list-style-type: none"> • Training records for food safety & employee hygiene • Reporting of employee illnesses • Proper hand washing • Hazard analysis • Implemented preventive controls • Monitoring of the controls • Corrective actions developed and taken • Verification and validation of processes • Recall plan • Supply-chain program

