

# **F S M A**

## Food Safety Management Associates

*The new Food and Drug Administration (FDA) Preventive Controls for Human Food regulation, begins implementation this September.*

*The regulation requires that certain activities must be completed by a "Preventive Controls Qualified Individual" (PCQI) who has successfully completed 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.*

### ***FDA Approved Curriculum Training: FSPCA Preventive Controls for Human Food***

This course satisfies the FDA requirement under the Food Safety Modernization Act (FSMA) for a trained Preventive Controls Qualified Individual.

A PCQI is a professional who can manage a Food Safety Plan at a facility in accordance with the FDA's Food Safety Modernization Act (FSMA). This person should have successfully completed training in the development and application of risk-based preventive controls.

This 2.5 day course utilizes the standardized curriculum developed by the Food Safety Preventive Controls Alliance (FSPCA), which is the only curriculum currently recognized by FDA and it is conducted by FSPCA trained Lead Instructor Deborah Shapos.

Dairy food examples will be incorporated to provide added value to participants from the dairy industry

Participants will learn the following:

The requirements of the preventive controls regulation

1. How prerequisite programs and the updated cGMP regulations relate to a food safety plan
2. How to identify hazards requiring preventive controls, then determine and implement the appropriate preventive controls necessary to control those hazards
3. How to monitor preventive controls and apply effective corrective actions to root causes to provide assurances that the controls work properly
4. How verification and validation of preventive controls should be included in a food safety plan
5. Which records must be maintained and included as part of a food safety plan
6. At the completion of this training, participants will have the foundation knowledge to develop, implement and maintain the Food Safety Plan required by the FDA under the new FSMA rule.

***Participants will receive an official FSPCA Preventive Controls Qualified Individual certificate issued by AFDO after attending this training program.***

# REGISTRATION FORM

**Date:** November 2-4, 2016

**Location:** *University of Massachusetts Amherst  
Hotel UMass  
1 Campus Center Way  
Amherst, MA 01003*

**Course Fee**

Cheese Guild Members: **\$650**

Non-Members: **\$895**

To Register:

Return this Registration Form and Payment to:

**FSMA**

**3580 Harlem Road – 2<sup>nd</sup> Floor  
Cheektowaga, New York 14215  
716-208-7770  
716-390-6049  
www.my-fsma.com**

**NAME** \_\_\_\_\_ **TITLE** \_\_\_\_\_

**COMPANY** \_\_\_\_\_

**ADDRESS** \_\_\_\_\_

**City** \_\_\_\_\_ **State** \_\_\_\_\_ **Zip** \_\_\_\_\_

**PHONE** \_\_\_\_\_ **FAX** \_\_\_\_\_

**CELL PHONE** \_\_\_\_\_

**Email** \_\_\_\_\_

**# Participants** \_\_\_\_\_ *(if not listed above. Please include email & contact phone)* **Guild Member?** \_\_\_\_\_

**Name(s)** \_\_\_\_\_

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**Total Registration Fees Enclosed: \$** \_\_\_\_\_

## **Frequently Asked Questions**

### **What is the FSPCA?**

The Food Safety Preventive Controls Alliance (FSPCA) is an FDA-funded Alliance, initiated in September 2011 and composed of members from the FDA, state regulatory agencies, the food industry, and academia. The FSPCA developed the FDA standardized training program for Preventive Controls Qualified Individuals (PCQI) to meet the requirements for the development and implementation of the FSMA Food Safety Plan.

### **What is a preventive controls qualified individual (PCQI)?**

This is a new term in the final rule.

According to the FDA ... *“A preventive controls qualified individual is someone who has successfully completed certain training in the development and application of risk-based preventive controls ...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.”* **FDA 21CFR117.180.**

The course recognized by the FDA as meeting this requirement is the “Preventive Controls for Human Food” course developed by the FSPCA.

### **Why should I become a PCQI?**

Each FDA-registered facility subject to the Preventive Controls for Human Food rule must have at least one PCQI to perform or oversee the preparation of a food safety plan, validate the preventive controls, review records and perform reanalysis of the food safety plan.

### **How can I become a PCQI?**

To become a Preventive Controls Qualified Individual, an interested person must successfully complete training in the development and application of risk-based preventive controls at least equivalent to that received under the FSPCA standardized curriculum recognized by FDA (*requirements of 21CFR117.180.* ) and offered through Lead Trainers of the FSPCA course to develop and apply a food safety system.

You can become a PCQI in two and a half days by attending our training course using the FDA-recognized FSPCA curriculum.

### **How are the preventive controls rules different from the Hazard Analysis and Critical Control Points (HACCP) system?**

The Hazard Analysis and Critical Control Points system, **HACCP, is the foundation** of the preventive controls regulations. Although there are similarities between the FSMA preventive controls requirements and the HACCP system,

not every provision is identical. For example, in HACCP systems, controls are applied at critical control points (CCPs), whereas preventive controls include controls at CCPs and controls other than those at CCPs that are appropriate for food safety.

### **What is HARPC?**

This is a misnomer. Prior to the final rule, an association was made between HACCP (Hazard Analysis and Critical Control Point) and the new Risk Based Preventive Controls that would be an extension of the HACCP. Thus, people began referring to this enhanced program as HARPC (Hazard Analysis and Risk-based Preventive Controls). The final rule now refers to the program as the Food Safety Plan.

### **The rule requires food facilities to have a written food safety plan that includes a hazard analysis and preventive controls. How often must that plan be reanalyzed?**

At least once every three years. The facility must also review portions of the food safety plan under certain circumstances, such as when a preventive control is found to be ineffective.

### **Does the preventive controls rule apply to dairy farms?**

Establishments that meet the definition of a farm are not required to register under section 415 of the Food, Drugs, and Cosmetics (FD&C) Act. However, farms, including dairy farms, that conduct manufacturing/processing activities beyond those included in the farm definition in the Preventive Controls rule are subject to registration and would be subject to requirements of the Preventive Controls Rule unless a specific exemption applies. One such activity that would require compliance with the preventive controls rule is cheese making.

### **What are the manufacturing/processing activities allowed under the farm definition?**

Drying/dehydrating raw agricultural commodities that creates a distinct commodity, such as producing raisins and prunes from grapes and plums, and packaging and labeling such commodities, without additional manufacturing/processing are allowed under the farm definition.

Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling raw agricultural commodities, when these activities *do not* involve additional manufacturing/processing, are other examples of manufacturing/processing activities that can be conducted under the farm definition.

### **Do facilities operating under the PMO meet the requirements of the final preventive controls rule?**

The preventive controls provision of FSMA (section 103) **does not exempt dairy facilities** that are required to register with the FDA. The 2013 PMO does not address all of the FSMA requirements, such as a written hazard analysis, those relevant to food allergens, or the potential presence of environmental pathogens in the food processing environment. Such provisions in the Preventive Controls rule could help prevent food safety problems from the consumption of food produced in PMO facilities. At its biennial conference in April 2015, the National Conference on Interstate Milk Shipments (NCIMS) initiated work to modify the PMO; therefore we are extending the compliance date for PMO-regulated facilities to comply with the rule in order to make use of the existing system of state regulatory oversight for Grade "A" milk and milk products provided through the NCIMS and the food safety requirements of the PMO.

**What environmental and product testing for milk and dairy products is required under FSMA and the preventive controls rule?**

The Preventive Controls Rule includes requirements for environmental monitoring and finished product testing as verification activities that would be applied as appropriate to the food, the facility, and the preventive control. Such testing would be appropriate for certain ready-to-eat dairy products, e.g., environmental monitoring for *Listeria* spp. in facilities making soft cheeses that are exposed to the environment.

**What are the Compliance Dates for meeting the FSMA Requirements?**

Compliance dates for businesses are staggered over several years after publication of the final rule.

The final rule was issued September 10, 2015:

**Very small businesses** (averaging less than \$1 million per year (adjusted for inflation) in both annual sales of human food plus the market value of human food manufactured, processed, packed, or held without sale): Three years, except for records to support its status as a very small business (January 2016 for registration as very small business).

**Compliance Deadline: September 2018.**

**Businesses subject to the Pasteurized Milk Ordinance** (compliance dates extended to allow time for changes to the PMO safety standards that incorporate the requirements of this preventive controls rule): Three years

**Compliance Deadline: September 2018.**

**Small businesses** (a business with fewer than 500 full-time equivalent employees): Two years

**Compliance Deadline: September 2017.**

**All other businesses:** One year **Compliance Deadline: September 2016.**