

Frequently Asked Questions for the FSPCA Preventive Controls for Human Food Course

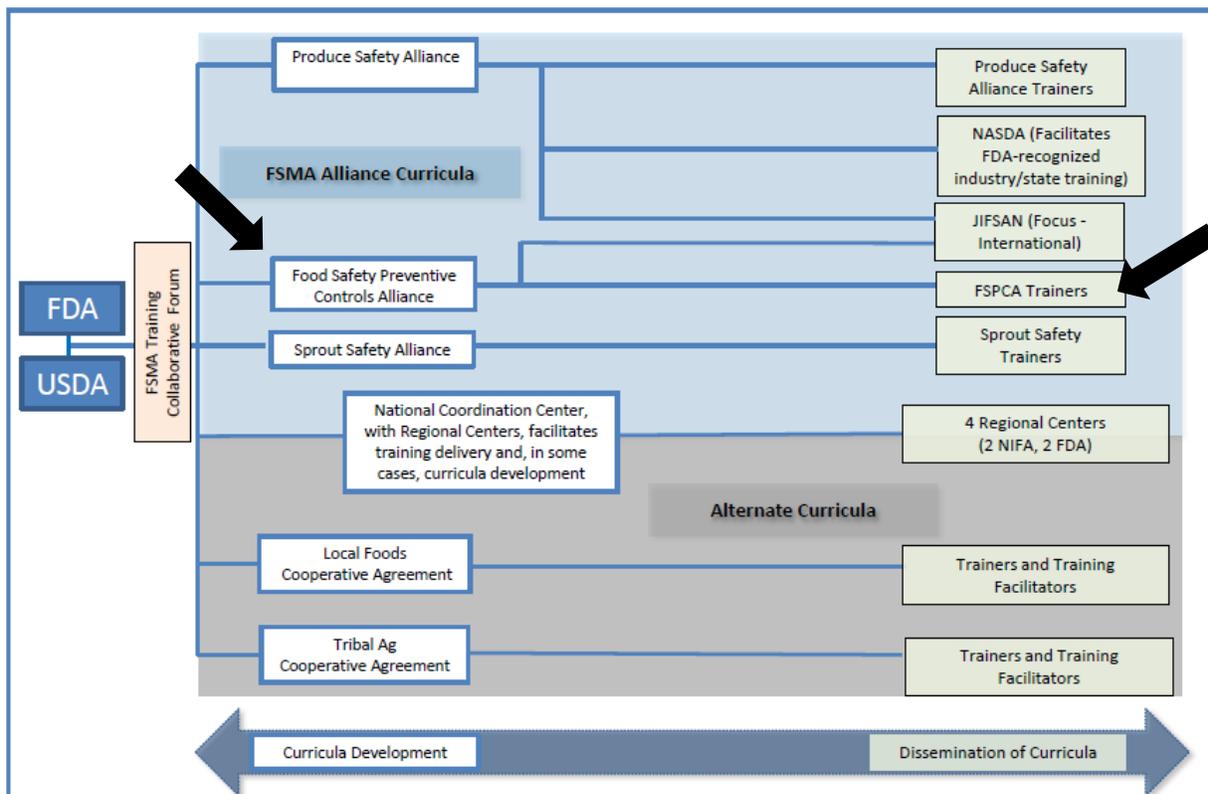
What is The Food Safety Preventive Controls Alliance (FSPCA) and how does it fit into FSMA training?

The Food Safety Preventive Controls Alliance (FSPCA) is a broad-based public-private alliance of key industry, academia and government stakeholders. It was established in late 2011 by a grant from the FDA to Illinois Institute of Technology's Institute for Food Safety and Health. The mission of FSPCA is to support safe food production by developing and delivering educational programs that assist the food industry in complying with the preventive controls regulations that are part of the Food Safety Modernization Act (FSMA).

The FSPCA developed the curriculum for the Preventive Controls for Human Food course and trained lead instructors. Cherney's lead instructors are Preventive Controls Qualified Individuals (PCQI) and have successfully completed FSPCA lead instructor training. This is the only FDA-recognized PCQI training for industry and is one way for someone to be a PCQI.

FSMA Framework for Industry Curriculum Development and Dissemination

October 2015



This is not an all-inclusive list of entities that will be developing training curricula and delivery for domestic and foreign food businesses. Image from FDA

Who is a Preventive Controls Qualified Individual?

A PCQI is an employee or consultant who successfully completed specific 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. (21 CFR 117.180)



What are the responsibilities of a Preventive Controls Qualified Individual?

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

Below are the requirements from the regulation.

§117.180 Requirements applicable to a preventive controls qualified individual and a qualified auditor.

(a) One or more preventive controls qualified individuals must do or oversee the following:

(1) Preparation of the food safety plan (§117.126(a)(2));

(2) Validation of the preventive controls (§117.160(b)(1));

(3) Written justification for validation to be performed in a timeframe that exceeds the first 90 calendar days of production of the applicable food;

(4) Determination that validation is not required (§117.160(c)(5));

(5) Review of records (§117.165(a)(4));

(6) Written justification for review of records of monitoring and corrective actions within a timeframe that exceeds 7 working days;

(7) Reanalysis of the food safety plan (§117.170(d)); and

(8) Determination that reanalysis can be completed, and additional preventive controls validated, as appropriate to the nature of the preventive control and its role in the facility's food safety system, in a timeframe that exceeds the first 90 calendar days of production of the applicable food.

(c)(1) To be a preventive controls qualified individual, the individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum. This individual may be, but is not required to be, an employee of the facility.

(d) All applicable training in the development and application of risk-based preventive controls must be documented in records, including the date of the training, the type of training, and the person(s) trained.

How can I become a Preventive Controls Qualified Individual?

You can become a PCQI by attending our 2.5 day training course that teaches the FDA-recognized FSPCA curriculum. Other options are available to be a PCQI; however, feedback from industry indicates that even those with decades of food safety experience are taking the course to ensure their PCQI status is easily recognized by FDA during an inspection.

What will I receive from attending?

The course includes the official FSPCA course materials, including a participant guide, exercise workbook and examples. Activities during the course provide an opportunity to apply concepts and discuss best practices. Upon successful completion of the course, you will receive an official FSPCA certificate, showing that you successfully completed training.