

## WHO is the FSPCA?

In 2011, the FDA helped to establish a public-private partnership called the Food Safety Preventive Controls Alliance (FSPCA), created to provide Food Safety Modernization Act (FSMA) technical assistance and training programs. The FSPCA is managed by the Illinois Institute of Technology (IIT). IIT partners with the International Food Protection Training Institute (IFPTI) and the Association for Food and Drug Officials (AFDO) for training implementation.

The FSPCA developed core curricula, training, and outreach programs to assist stakeholders to be prepared to adhere to the following FSMA final rules: *Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human and Animal Food; Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals*; and *Mitigation Strategies to Protect Food Against Intentional Adulteration for Human Food*.

- The link to the IIT Alliance homepage is: fspca.net.
- The link to the FSPCA Community, an interactive portal where users can ask questions of Alliance Food Safety Experts (FSEs), find a list of Lead Instructor (LI) trainers, and locate technical resources, is: https://fspca.force.com/FSPCA/s/?language=en\_US.

### WHAT does the FSPCA do?

#### Alliance outreach goals and objectives aim to:

- increase industry awareness about the education, outreach, and technical assistance programs;
- identify and develop relevant technical information and educational resources useful especially for the small food companies. For example, the FSPCA Preventive Controls course curricula contains a chapter (Chapter 7 in the PCHF Curriculum) that provides a list of technical resources to assist in the development and modification of a food safety plan. This chapter contains a list of publications such as the FDA draft hazard guides, peer reviewed literature, and trade association publications and links to numerous credible websites that contain technical information;
- establish a network of FSPCA FSEs that would be available to assist the industry with technical and scientific questions that they may have subsequent to the training; and
- ensure opportunities and educational materials are available to international audiences in a manner that is appropriate and sensitive to various cultures, religions, political situations, languages, and development levels.

# **WHY** seek this training?

The two Preventive Controls rules require registered facilities that manufacture, process, pack or hold human or animal food have one or more "Preventive Controls Qualified Individuals(PCQI)".

Both domestic facilities and foreign food processors exporting food intended for sale in the U.S. must comply with the Preventive Controls regulations unless an exemption applies. Each facility, unless covered under an exemption or modified requirement, will be required to implement a written food safety plan that focuses on preventing hazards in the food. The "PCQI" will be responsible for performing or overseeing the implementation of the facility's food safety plan, namely: preparation of the food safety plan, validation of the preventive controls, review of records and reanalysis of the food safety plan. The Preventive Controls rules require that a "PCQI" must have either 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.

In contrast to the Preventive Controls (PC) rules for human or animal food, the FSVP rule does not require an FSVP "qualified individual" to attend a training program following a "standardized curriculum" recognized by FDA. The FSPCA has developed an FSVP curriculum which was designed by regulatory, academia, and industry professionals and developed with funding from FDA as part of the FSPCA. While FDA assisted in the preparation of the FSVP course materials, the materials have been written and produced by the Alliance and are not official FDA materials. Completing the FSVP participants course is not mandatory. Attending the FSVP course, however, will help course participants understand the FSVP requirements and how those requirements can be met in their circumstance.

### WHERE, WHEN, & HOW can the public access FSPCA training and resources?

Links to available Preventive Controls for Human and Animal Food, Foreign Supplier Verification Programs, and Intentional Adulteration information and courses can be found below. Participation in Alliance courses is self-funded, save for certain opportunities which may be available through USAID or USDA programs. FDA does not have the capacity to sponsor participation at this time.

Technical and scientific questions can be submitted to the FSPCA Technical Assistance Network (TAN) through the FSPCA Community directly or via IIT's FSPCA pages (<a href="https://www.ifsh.iit.edu/fspca/fspca-technical-assistance-network">https://www.ifsh.iit.edu/fspca/fspca-technical-assistance-network</a>). Note that FSMA rule interpretation questions must be submitted to FDA's TAN (<a href="https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm">https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm</a>).

### FDA Rule Requirements for Training:

- **PCHF** The Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food regulation (referred to as the Preventive Controls for Human Food regulation) is intended to ensure safe manufacturing/processing, packing and holding of food products for human consumption in the United States. The regulation requires that certain activities must be completed by a "preventive controls qualified individual (PCQI)." This participant course, developed by FSPCA, is the "standardized curriculum" recognized by FDA; successfully completing this course is <u>one</u> way to meet the requirements for a "PCQI." Individuals can also be qualified through job experience.
- PCAF- The Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Animal Food regulation is intended to ensure safe manufacturing/processing, packing and holding of food products for animal consumption in the United States. The regulation requires that certain

- activities must be completed by a "preventive controls qualified individual (PCQI)." The participant course, developed by FSPCA, is the "standardized curriculum" recognized by FDA; successfully completing this course is <u>one</u> way to meet the requirements for a "PCQI." Individuals can also be qualified through job experience.
- FSVP- In contrast to the Preventive Controls (PC) rules for human or animal food, the FSVP rule does not require an FSVP "qualified individual" to attend a training program following a "standardized curriculum" recognized by FDA. The FSPCA has developed an FSVP curriculum which was designed by regulatory, academia, and industry professionals and developed with funding from FDA as part of the FSPCA. While FDA assisted in the preparation of the course materials, the materials have been written and produced by the Alliance and are not official FDA materials. Completing the FSVP participant course is not mandatory. Attending the FSVP course, however, will help course participants understand the FSVP requirements and how those requirements can be met in their circumstance.
- **IA** FDA will be conducting instructor led participant courses. Additionally, web based courses will be offered.

#### **How to find an FSPCA Participant Course:**

https://fspca.force.com/FSPCA/s/courselist?language=en\_US

### How to become an FSPCA Lead Instructor:

- **PCHF** To become a Preventive Controls Lead Instructor (LI), an individual must apply via the FSPCA Community portal (<a href="https://fspca.force.com/FSPCA/s/li-public-guidance?language=en\_US">https://fspca.force.com/FSPCA/s/li-public-guidance?language=en\_US</a>).
  - Applicants must have the adequate education, work experience, and food safety training
    experience detailed on the website. They also need to have successfully completed a PCHF
    participant course before applying to be approved by the FSPCA LI Selection Committee. More
    information on pre-requisites can be found here: <a href="https://www.ifsh.iit.edu/fspca/fspca-preventive-controls-human-food">https://www.ifsh.iit.edu/fspca/fspca-preventive-controls-human-food</a>.
  - o LIs then independently market and offer courses per Alliance administrative requirements.
  - o To register courses after completing the LI course, LIs can log in to their Community account, select the Course Registration tab, and click on "New" to open the registration form.
- **PCAF** In order to become a Preventive Controls LI, an individual must apply via the FSPCA Community portal (https://fspca.force.com/FSPCA/s/li-public-guidance?language=en US).
  - o The process is the same as PCHF, as detailed above.
- FSVP Current LIs or approved candidates for FSPCA's Human or Animal Food courses already meet the criteria to qualify as a candidate to become an FSVP LI. Next steps are:
  - 1. Updating your profile in the FSPCA Community indicating interest (see instructions below), and
  - 2. Completing an FSVP LI course.

#### To update your LI profile:

- 1. Log into your FSPCA Community account at: https://fspca.force.com/FSPCA/s/
- 2. Click on your name to the right of the Search bar and a menu will open
- 3. Select "My Profile" on the menu

- 4. Click the edit button to the right of your name
- 5. Scroll down and check the box "Consider for FSVP LI"
- 6. Scroll down and Save
- o FSVP LIs independently market and offer courses, per Alliance requirements, as well as register courses using the normal FSPCA registration procedures (by logging in to your Community account, selecting the Course Registration tab, and clicking on "New" to open the registration form).
- New LI Applicants Those who are not existing LI must complete a FSVP application, which can be found here: <a href="https://docs.google.com/forms/d/e/1FAlpQLSc6UkW6G-GrTC5yGy88T7qAvQGYdPhoWzZAwk4KLCjV0c-pww/viewform">https://docs.google.com/forms/d/e/1FAlpQLSc6UkW6G-GrTC5yGy88T7qAvQGYdPhoWzZAwk4KLCjV0c-pww/viewform</a>
- For a few months at the beginning of the FSVP rollout, FSPCA will be offering combined courses (a Lead Instructor course coupled with a participant course) since a prerequisite of the Lead Instructor course will be a participant course.
- **IA-** LIs will be sought in the future; a process has yet to be defined.