

FAQ – FSPCA PC Rules for Human Food

What is FSPCA (Food Safety Preventive Controls Alliance)?

The Food Safety Preventive Controls Alliance was established in 2011 as part of the grant from FDA to the Illinois Institute of Technology's Institute of Food Safety and Health (IFSH) to develop and maintain a cost-effective education and training program to assist the food industry with understanding and achieving compliance with the Preventive Controls regulations applicable to their facilities.

What is FSPCA's Preventive Controls for Human Food Regulation Training Course?

This course developed by FSPCA is the 'standardized curriculum' recognized by FDA; successfully completing the course is one way to meet the requirements for a "preventive controls qualified individual".

Who is a "preventive controls qualified individual"?

As per 21 CRR 117.3, "a qualified individual is one who has 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 is qualified through job experience to develop and apply a food safety system".

What are the responsibilities of a "preventive controls qualified individual"?

The responsibilities include:

- Preparation of a food safety plan
- Validation of preventive controls
- Records review, and
- Reanalysis of the food safety plan

Should the "preventive controls qualified individual" be an employee of the facility?

The preventive controls qualified individual may be an employee of the facility but can also use outside assistance in developing the plan. In some situations, more than one preventive controls qualified individual may be needed to effectively develop and implement a food safety plan.

Who is covered by the Preventive Controls for Human Food Rule?

- Facilities that manufacture, process, pack or hold human food (21 CFR 117.1)
- Facilities required to register with FDA under section 415 of the FD&C Act (no farms or retail establishments)
- Applies to domestic and imported food

There are some exemptions and modified requirements.

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Who are exempted from the Preventive Controls for Human Food Rule?

- “Qualified” facilities- small businesses with less than \$1 Mio in total annual sales of human food OR food sales averaging less than \$500,000 per year during the last 3 years
- Foods subjected to HACCP regulations (seafood CFR Part 123 and juice CFR Part 120).
- Foods subjected to low-acid canned foods regulations
- Dietary supplements
- Alcoholic beverages
- Raw agricultural commodities
- Facilities, such as warehouses that only store unexposed packaged foods
- Certain storage facilities such as grain elevators and warehouses that only store raw agricultural commodities

Are the Preventive Controls for Human Food Rules applicable to food processing facilities or to companies?

Preventive control rules are applicable to each site processing or manufacturing food products or storage facilities where food is exposed.

Disclaimer:

The information provided above is for the general understanding of the requirements of readers. PJRFSI is not responsible for any omissions or errors on the part of individuals in implementing FDA's Preventive control for Human Food rules in their facilities. Individuals should refer to the specific Preventive control for Human Food rules for additional information.

Links:

PJRFSI Training:

<http://www.pjrfsi.com/training-courses/fspca>

FDA Preventive Controls for Human Food At-A-Glance Fact Sheet

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm>

The FINAL FDA Food Safety Modernization Act (FSMA) Preventive Controls for Human Food:

<http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0920-1979>

FDA Questions & Answers on the Food Safety Modernization Act:

http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm#Lab_Accreditation