



FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

## Preventive Controls for Human Food

First Edition - 2016



# Participant Manual

Human-Food-Part-Manual\_V1.2

<https://tinyurl.com/FSPCA-Manual>

# FSMA Preventative Controls for Human Foods FSPCA Objectives Summary (Cheat Sheet)

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*This is not an FSPCA document*

**FSPCA QUOTE:** The information provided by the FSPCA will vary in applicability to each food manufacturer. It is not possible for the FSPCA training curriculum to address every situation. Companies should implement the practices and programs that will function best to produce safe foods based on the nature of their individual operations.

**FSPCA materials do not outline the only approach to developing and implementing a Food Safety Plan. Companies can follow any approach that satisfies the requirements of the applicable statutes and regulations related to FSMA.**

## Additional FSPCA Resources for workshop participant use

Course Text book (manual) FSPCA Manual 524 pages (2016) <https://tinyurl.com/FSPCA-Manual>  
FSPCA Course worksheets (model forms)  
FSPCA Model Completed Food Safety Plans (5)(entrée, peanut butter, pepper, pressed bars, vegetable salad)

**Forward:** The following is a summary or **cheat sheet** for the first 7 chapters of the FSPCA curriculum – considered day 1 of a typical workshop. The FSPCA course or any equivalent is not designed such that it can teach all there is to know. The course (or workshop) will provide a participant with starting knowledge or awareness and a general understanding of how to document and implement a FSMA food safety plan. The FSPCA manual is extensive and has valuable information and resources.

## Chapter 1 Introduction to Course and Preventive Controls

Develop **awareness** of:

- The objectives of the course (this document and at the beginning of each chapter in the FSPCA manual)
- Format of the course (Knowledge + Hands on work designed to get you off to a start on writing and implementing a Human Foods Preventative Controls Plan)
- How preventive controls build on established food safety principles (of HACCP and Prerequisite programs and of GFSI schema)
- Components of a Food Safety Plan (An enhanced Hazard Analysis may indicate the need for preventative control programs including: process, environment, supply, and allergens. A Recall plan is added.)

- The responsibilities of a qualified individual (21 CFR 117.180 (a) and (c))  
A qualified individual 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 (the FSPCA course) or is otherwise qualified through job experience to develop and apply a food safety system.
- Where to find definitions relevant for the course (21 CFR 117.3 Definitions and in the FSPCA manual)

## Chapter 2 Overview of a Food Safety Plan

Learn:

- Understand the benefits of a food safety plan (prevent foodborne illness and recalls – make safer foods)
- The principles applied to build a Food Safety Plan (similar to HACCP – follow systematic steps, all products and processes are controlled, similar processes may be grouped)
- A roadmap for building a Food Safety Plan (this is detailed objective – consult the slides or manual, use the outline, or use the FSPCA template to format your food safety plan),(An enhanced Hazard Analysis is required that **may** indicate the need for preventative control programs including: process, environment, supply, and allergens. A Recall plan is required. Similar to HACCP, the format is flexible.)

## Chapter 3 Good Manufacturing Practices and Prerequisite Programs

Learn (be aware) of:

- The definition of prerequisite programs and their importance in a food safety system (Procedures, including Good Manufacturing Practices (GMPs), that provide the basic environmental and operating conditions necessary to support the Food Safety Plan).
- Basic requirements of GMPs for human food (Required: Personnel, Plant and grounds, Sanitary operations\*, Sanitary facilities and controls, Equipment and utensils, Processes and controls\*, Warehousing and distribution, and Defect action levels), (Training of staff on GMPs is required), (\*=Preventative Control)
- Where to find more information on GMPs (21 CFR 117 Subpart B and in the FSPCA manual – **note there are changes from 21 CFR 110**), (*Author*: It is recommended by some to learn GMPs and other prerequisite programs as a stand-alone topic).

## Chapter 4 Biological Food Safety Hazards

Develop awareness of:

- The term “hazard” (Any biological, chemical (**including radiological**), or physical agent that has the potential to cause illness or injury. See 21 CFR 117.3), (Spoilage, adulteration, or economic fraud are not permitted but these are not strictly termed hazards unless they cause a food safety issue).
- Biological hazards (The FDA reportable food registry indicates biological hazards number one reported followed by allergens), (Biological hazards cause the greatest significance of foodborne illness), (Understand bacteria, viruses, yeast, molds, parasites, and prions), (Understand intoxication and infection), (Understand sporeforming bacteria), (FSPCA has provided a hazards guide to assist in determining food biological hazards).
- Potential controls for these hazards (Kill), (Control growth – acidity, Aw, remove oxygen, temperature, nutrients, and preservatives), (*Author*: since biological hazards are



the greatest concern for foodborne illness it is suggested that stand alone learning in food microbiology would be a tremendous benefit), (Biological hazards not controlled in the food safety plan may lead to foodborne illness).

## **Chapter 5** Chemical, Physical and Economically Motivated Hazards

Develop awareness of:

- Chemical (including radiological) food safety hazards (are natural, intentionally added or unintentionally added), (immediate illness for allergens and toxic chemicals), (long term for others that accumulate like lead).
- Physical food safety hazards (hard, sharp, choking hazards - metal, bone, stone, plastic, etc)
- Economically motivated food safety hazards (assess historical events like melamine in milk powder – determine if hazard is possible and then control usually via supplier controls)
- Potential controls for these hazards (Supply-chain, sanitation, allergen and process preventive controls may be required to control hazards identified through hazard analysis).

## **Chapter 6** Preliminary Steps in Developing a Food Safety Plan

Learn:

- Preliminary steps necessary for developing a Food Safety Plan (including: Assemble the food safety team, describe the product and its distribution, describe the intended use and consumers of the food, develop a flow diagram and describe the process, verify the flow diagram on-site), (recall that this is similar/identical to HACCP), (recall that these items are not mandated by FDA in a food safety plan, but are considered useful), (forms are available as templates for these documents).

## **Chapter 7** Resources for Preparing Food Safety Plans

Learn (be aware of):

- Information sources to help identify food safety hazards and establish preventive controls
  - People (subject matter experts, e.g. University Specialists or consultants)
  - Publications (the FSPCA manual and its references, FDA publications, Peer reviewed literature, Trade association publications, References used to develop this curriculum, and FDA guidance documents)
  - Reliable Internet sites (websites from: FSPCA, FDA, CDC, foodsafety.gov, USDA, Canadian Food Inspection Agency, Codex Alimentarius Commission, European Food Safety Authority, Trade association websites e.g. GMA).
  - FSMA Technical Assistance Network (Science and Technical), (Regulatory), (See the manual for details or the FSPCA website).
  - FDA Hazards and Controls Guidance (Seafood and Juice online), (Human Foods Preventative Controls in development)

Participants are encouraged to seek additional topic-specific courses or workshops that provide more comprehensive coverage on issues relevant to their food safety system. Examples are GMPs and prerequisite programs, GFSI schema, Food Microbiology, Sanitation and environmental monitoring. Commodity specific learning is also beneficial focusing efforts on a single food product or category.

# Preventive Controls (SUMMARY)

Process (CCPs), Allergen, Sanitation, and Supplier PC programs. **Need or requirement determined by Hazard Analysis. All PC's require monitoring, corrective actions, and verification. ONLY Process control requires validation.**

## Chapter 9: Process Preventive Controls

**Process preventive controls** is essentially what CCPs are to HACCP.

Learn (be aware of):

- Parameters and values associated with the control (e.g., critical limits)
- Monitoring procedures for process preventive controls, including Critical Control Points (CCPs)
- Corrective actions for process control deviations

## Chapter 10: Food Allergen Preventive Controls

Learn (be aware of):

- Required food allergen preventive controls
- Allergen cross-contact prevention
- Allergen label review
- Allergen preventive controls options

## Chapter 11: Sanitation Preventive Controls

Learn (be aware of):

- Major food safety hazards controlled by sanitation practices (*L. monocytogenes* and *Salmonella*)
- Sanitation preventive controls management components required in a Food Safety Plan
  - Monitoring
  - Corrections
  - Verification (note validation not required)

## Chapter 12: Supply-chain Preventive Controls

Learn (be aware of):

- Definitions of supplier, receiving facility and customer
- Supply-chain program contents
- Supply-chain program records

## Chapter 13: Verification and Validation Procedures

Learn (be aware of):

- The definitions of verification and validation
- Preventive controls qualified individual involvement in validation and verification
- Verification procedure requirements for:
  - Calibration
  - Product sampling and testing
  - Monitoring, corrective actions and record review
- Food Safety Plan reanalysis requirements

## Chapter 14: Record-keeping Procedures

Learn (be aware of):

- What records are required, General information required on records
- Implementation record requirements and examples
- How to conduct a record review
- Record retention (**2 years**) and availability (**made available within 24h**)

## **Chapter 15: Recall Plan**

Learn (be aware of):

- Recall definitions
- Elements of a recall plan
- Who to notify when a recall is necessary
- How to conduct effectiveness checks
- Appropriate disposition of product

**Chapter 16: Regulation Overview – cGMP, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.** The most important part of this material is that regardless of any training material or publication, the FSMA Preventive Controls requirements are specifically outlined in the Code of Federal Regulations 21 CFR 117. **All FDA compliance measurements will be based on that code.**