



TRAINING THAT DEVELOPS
REAL CAPABILITY



**Food Safety Modernisation Act
(FSMA) FSPCA Preventive Controls
for Human Food (PCQI Qualification
Course) Second Edition**

FS018

Food Safety Modernisation Act (FSMA) FSPCA Preventive Controls for Human Food (PCQI Qualification Course) Second Edition

Under US Code of Federal Regulation CFR 117 each food manufacturer in the US must have a Preventive Controls Qualified Individual (PCQI). This individual must have successfully completed training in the development and application of risk based preventive controls using a standardized curriculum (Version 2.0) recognized by the FDA. 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.” This course, developed by the FSPCA, is the “standardized curriculum” recognized by FDA; successfully completing this course is one way to meet the requirements for a “preventive controls qualified individual”

Under the Preventive Controls for Human Food rule, the responsibilities of a “preventive controls qualified individual” include to oversee or perform

1. Preparation of the Food Safety Plan
2. Validation of the preventive controls
3. Records review
4. Reanalysis of the Food Safety Plan, and other activities as appropriate to the food

The FSMA concept is to move away from a reactive approach towards a preventive system. With FSMA there are seven rules which are specific to different types of foods, elements of the supply chain and stakeholders. With this level of complexity and change, the challenge for Irish indigenous and Irish based multinational food companies is to understand how these rules will affect their current Food Safety Management Systems.

The Food Safety Modernisation Act (FSMA) is the most significant change to US Food Safety legislation in over 70 years. The act was signed into law by President Obama in 2011. FSMA is in response to numerous food poisoning incidents that have occurred in the US over the past ten years. Figures released by the USDA estimate that each year over 48 million Americans become ill from food poisoning, resulting in 50,000 hospitalisations and over 3,000 deaths.

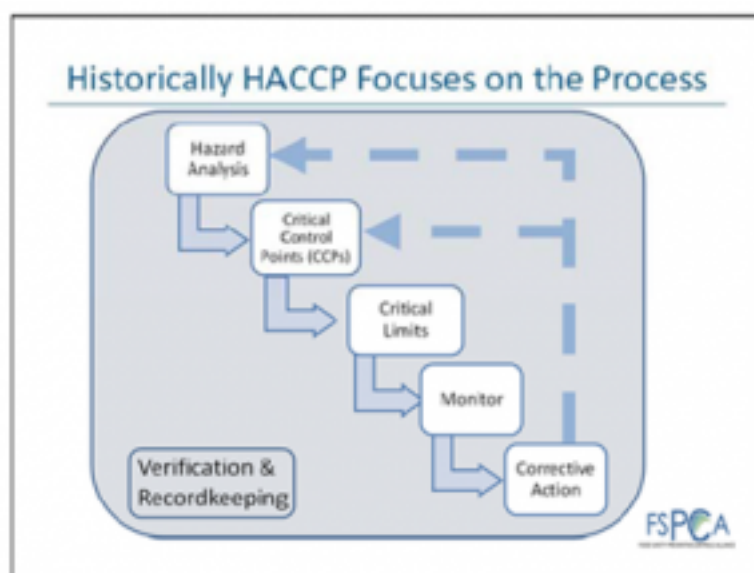


Figure 1



Figure 2

Figure 1 & Figure 2 from the Food Safety Preventive Control Alliance (FSPCA) above show the similarity and difference between HACCP and FSMA. Both employ a similar logic however, FSMA moves away from the traditional HACCP approach of just being focused on the manufacturing process to address the entire supply chain. It also stresses the point that most food poisoning incidents are not due to CCP failures hence the focus on Preventive Control Procedures, PCs.

Figure 3 below of a “preventive food safety system” identifies how FSMA requires four of the traditional GFSI pre-requisites of supply chain programme, allergen control, sanitation control

and recalls plan to be included in the Food Safety Plan. This is in direct response to what was seen as major flaws in recent US food poisoning investigations most noticeably in the salmonella typhimurium contamination of peanut products.

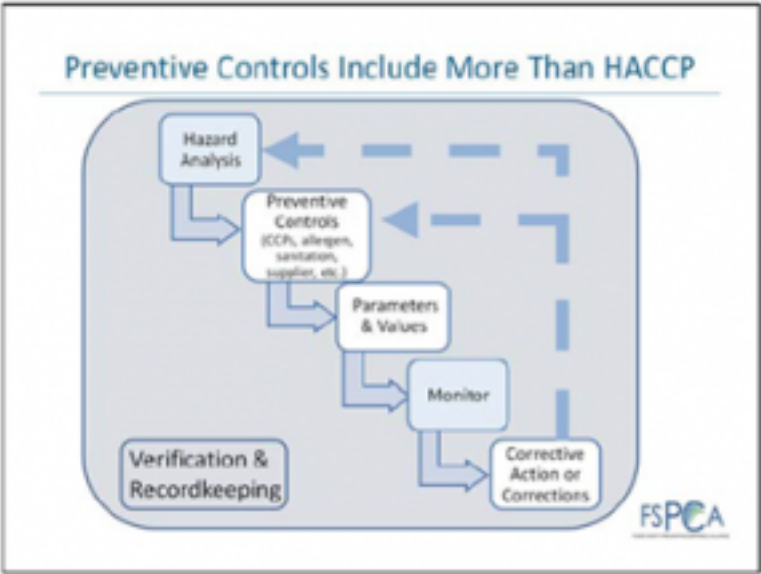


Figure 3

Duration & Price

Duration: 3 days
Public Virtual Training: £1,065 + £80 fees
Delivery mode: This programme is available In-Company, and via Public Virtual Training

Dates & Locations

Date	Venue	
23 - 25 Sep 2025	Virtual	Book Date
09 - 11 Dec 2025	Virtual	Book Date

In-Company Training

Please [contact us](#) for more information on our In-Company training options

What's covered?

Day One

Chapter 0 Preface – Overview

Chapter 1 Food Safety Plan Overview

Chapter 2 Good Manufacturing Practices and Other Prerequisite Programs

Chapter 3 Biological Food Safety Hazards

Chapter 4 Chemical, Physical and Economically Motivated Food Safety Hazards

Chapter 5 Preliminary Steps in Developing a Food Safety Plan

Day Two

Review and Questions

Chapter 6 Hazard Analysis for Human Food

Chapter 7 Preventive Controls Determination for Human Food

Chapter 8 Process Preventive Controls – Parameters & Values

Chapter 9 Process Preventive Controls – Monitoring & Corrective Action

Chapter 10 Process Preventive Controls – Verification & Records Keeping

Chapter 11 Food Allergen Preventive Controls

Chapter 12 Sanitation Preventive Controls

Chapter 13 Supply Chain Preventive Controls

Day Three

Review and Questions

Chapter 13 Verification and Validation Procedures

Chapter 14 Record keeping Procedures

Chapter 15 Recall Plan for Human Foods

Chapter 16 Regulation Overview – cGMP, Hazard Analysis, and Risk Based Preventive Controls for Human Food

Who should participate?

- Quality / Technical Managers
- Food Safety Team Leaders
- Food Safety Team Members
- Purchasing / Supply Chain Personnel
- Internal Audit Personnel
- Compliance Personnel
- 2nd Party Supplier Auditors

What will I learn?

Participants achieve the following learning outcomes from the programme;

- Understand why there is an enhanced focus on sanitation, allergen management, supplier controls and product recall
- Understand Hazard Analysis & Risk Based Preventive Control (HARPC)
- Understand the role of a PCQI
- Understand the structure of the regulation (CFR Part 117) and the sub parts
- Understand the structure and contents of the Food Safety Plan
- Know the cGMP as per sub part B of the regulation
- Understand how to make an Irish / European HACCP system FSMA compliant

How do we train and support you?

In-House Courses

For In-House courses, the tutor will contact you in advance to discuss the course programme in more detail.

Course Manual

Delegates will receive a comprehensive course manual (FSPCA Participant Manual) as well as exercise Workbook and teaching examples.

Programme accreditation

The certificate is issued by the [International Food Protection Training Institute \(IFPTI\)](#). The IFPTI serves food protection professionals in the United States and the rest of the world, improves public health through competency-based learning solutions while cultivating strong leadership in the global food protection community.

The [Food Safety Preventive Controls Alliance \(FSPCA\)](#) is a broad-based public private alliance consisting of key industry, academic and government stakeholders whose mission is to support safe food production. The FSPCA has developed a nationwide core curriculum, training and outreach programs to assist companies producing human and animal food in complying with the preventive controls regulations that will be part of the Food Safety Modernization Act (FSMA).

Delegates who attend will become qualified PCQIs and will be able to download their PCQI certificate on course completion. Mandatory attendance for the entire programme is required to achieve certification.

Tutors



Denis Kiely

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What Our Learners Say

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