



FAQ: Preventive Controls Qualified Individual (PCQI)

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What is a PCQI: PCQI (Preventive Control Qualified Individual) is an individual(s) on your staff whom you've designated to be responsible for the preventive control food safety plan and its implementation. It's a requirement of the Food Safety Modernization Act (FSMA). A PCQI 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 as otherwise qualified.

What is Preventative Controls for Human Foods: Preventive Controls for Human Foods is one of seven provisions of FSMA and the key to a new generation of food Good Manufacturing Practices (GMPs), based on the HACCP (Hazard Analysis Critical Control Point) principles of "anticipate, prevent, validate."

What is FSMA: FSMA ([Food Safety Modernization Act](#)) is the most sweeping reform of the nation's food safety laws in more than 70 years and was signed into law by President Obama on January 4, 2011. It aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it, based on HACCP (Hazard Analysis Critical Control Point). The origins of HACCP go back to World War II as a solution to a big problem: defective artillery shell firing pins that were blowing up our own soldiers or just not exploding. This problem was solved by carefully examining each possible failure (CP = critical point) and fixing it, until system integrity was confirmed. NASA adopted HACCP to make sure astronauts' food in space was absolutely safe. Salmonella in a space suit = Houston, we have a problem.

What are Preventive Controls: The Preventive Controls (PC) is the process, and Preventive Control Qualified Individual (PCQI) is the person trained to implement the preventive controls developed through a food safety plan.

Who or what falls under the PCQI requirement: All food products, wherever they are from, that are consumed in the U.S. *Note: Some companies are exempt (seafood, juice, low-acid canned food, and Section 111-compliant dietary supplements).*

Who is required to have a PCQI on staff: A food company, brand holder or contract manufacturer that manufactures, packages, holds, or distributes a food product using a Nutrition Facts panel is required to have a PCQI. This includes manufacturers of natural food products and functional foods, such as protein shakes and 'power' bars.



Dietary Ingredient (raw material) suppliers are classified as a food and therefore are subject to the full requirements. These suppliers include companies providing botanical powders used in dietary supplements, such as echinacea, ginkgo, and others. Any company distributing a dietary supplement would be expected to qualify their supplier of these ingredients to ensure they are compliant with the new regulation.

Companies and products using the Supplement Facts panel are required to ensure that all of their ingredient suppliers—including all foreign suppliers—have at least one PCQI on staff. Therefore, it is highly recommended that each finished supplement manufacturer or distributor be fully educated about PCQI so that they can qualify their entire supply chain as required by FSMA to eliminate or prevent hazards from being introduced into the food supply.

Does every manufacturing facility need to have a PCQI: Yes, each facility (not company) must have at least one PCQI. It's important to note that each product must have its own Food Safety Plan in place.

What is a Food Safety Plan: A Food Safety Plan (FSP) is specific to each product type, and it is not uncommon for one facility to have multiple food safety plans. The PCQI is now responsible to create, implement, and maintain compliance through the food safety plan that begins with PCQI training.

When do you need to have a PCQI (Preventive Control Qualified Individual) on staff:

The compliance date for PCQI implementation is dependent on the company size:

- Large (>500 employees): **September 2016**
- Small (<500 employees): **September 2017**
- Very small (<\$1 million in annual sales -- but this includes inventory): **September 2018**

When is the next PCQI training offered by UNPA: Please visit the UNPA [Events](#) page for more information on when and where the next PCQI training classes will be held. Additionally, UNPA is now offering [onsite corporate PCQI training](#), which offers an efficient and cost-effective means for companies to get their staff and even their supply chain in compliance.

Are there addition required trainings to meet the compliance standards: Yes, there are other parts of FSMA that require a qualified individual with separate training, such as the Foreign Supplier Verification Program (FSVP). UNPA will be offering FSVP training, as well.



Is the PCQI Training standardized: Yes, the coursework is standardized and approved by an independent body, the Food Safety Preventive Controls Alliance (FSPCA), recognized by FDA to oversee PCQI training. See FSPCA background and copy of the participant manual [here](#).

Helpful Links & Resources

Where can I find more information regarding PCQI compliance: Here is a link to FDA's [FAQ on the Food Safety Modernization Act](#).

Where can I find more information regarding FSMA: You can find in-depth information at FDA's website [FSMA Laws, Rules & Guidance](#) page.

Where can I learn more about Foreign Supplier Verification Programs (FSVP): You can find information regarding the [Final Rule on Foreign Supplier Verification Programs \(FSVP\) for Importers of Food for Humans and Animals](#) on FDA's website.

Where can I find more information regarding Food Safety Preventive Controls Alliance (FSPCA): You can find information regarding the [Food Safety Preventive Controls Alliance \(FSPCA\)](#) on FDA's website.

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