

Food safety modernization act and the preventive control qualified individual

Editorial

In response to the Food Safety Modernization Act Preventive Controls for Human Food Rule promulgated by the Food and Drug Administration (FDA), i.e., Current Good Manufacturing Practices, Hazard Analysis, and Risk-based Preventive Controls for Human Food (21 CFR 117, Preventive Control Rule), food companies under FDA regulatory oversight in the United States and those that export to the United States must meet new requirements and develop what is termed a food safety plan. These requirements are an extension of existing regulatory requirements and include elements such as conducting a hazard analysis to consider known or reasonably foreseeable biological, chemical, and physical hazards. These hazards could be present because they occur naturally, are unintentionally introduced, or are intentionally introduced for economic gain, if they affect the safety of the food. Companies are required to have preventive controls to ensure that the identified hazards will be minimized or prevented. Such preventive controls include process, food allergen, and sanitation controls, as well as supply chain controls and a recall plan.

The Preventive Control Rule, or Rule, provides flexibility in the procedures needed to ensure that preventive controls are effective and to correct problems that may arise. The most definitive steps and procedures include monitoring, corrections and corrective action, and verification. In addition, the company shall implement a risk-based supply chain program, good manufacturing procedures, an allergen control program, and a management-led education and training program on food safety policies, programs and procedures.

The Rule states that the food safety plan shall be prepared by a company employee trained as a Preventive Control Qualified Individual (PCQI), or by an employee in collaboration with an external PCQI. Following promulgation of the Rule, the Food Safety Preventive Controls Alliance (FSPCA) was established to develop curriculum in food safety preventive controls. The training ultimately comprised 16 chapters with appendices as a Participant Manual. All individuals that want to become a PCQI need to go through this structured, multi-day class, taught by a trained instructor. There is no deviation from the material being taught. The course material covers all of the requirements associated with the Rule, from an overview of a food safety plan to all of its components such as hazard analysis, food allergen controls and sanitation preventive controls. The Participant Manual is textbook style, and by design, is delivered page by page to ensure uniformity in its delivery.

Anyone can take this course and leave with a PCQI label. There are no tests to assess qualifications. Someone with no practical industry experience can become a PCQI. Someone with no academic competencies in microbiology, chemistry or statistical sampling can

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become a PCQI. A CEO or line employee can become a PCQI. A journalist can become a PCQI. The only qualification to become a PCQI is to attend the course and pay the entrance fee.

It is perplexing that FDA and the FSPCA allows any of these attendees to be labeled as a PCQI. It is perplexing because the Rule is designed to help ensure the safety of the food supply, yet literally anyone can attempt to identify hazards and the associated preventive controls to ensure food safety. The knowledge to appropriately identify microbiological, chemical and physical hazards associated with all raw materials and finished food products, as well as the validated preventive controls cannot be acquired in a few days in a classroom. Experience and knowing one's limitations are critical in developing a food safety plan to protect public health and the health of a food company. As time progresses, it will be interesting to learn the level of adequacy of the food safety plans designed by individuals with a PCQI label, but without the fundamental competencies in food microbiology, food science, statistics and other areas of expertise and experience.

Conflicts of interest

There is no conflict of interest.

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