

FDA Food Safety Modernization Act (FSMA) FAQs

1) What is a Preventive Controls Qualified Individual (PCQI)?

According to the definitions in the FDA Preventive Controls for Human Food Rule, a PCQI is a qualified individual (QI) 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 otherwise qualified through job experience to develop and apply a food safety system.

The responsibilities of a PCQI include the following activities, according to section 117.180 of the Rule:

- Develop or oversee preparation of the food safety plan - 117.126(a)(2)
- Validation of the preventive controls - 117.160(b)(1)
- Review records - 117.165(a)(4)
- Reanalysis of the food safety plan - 117.170(d)

2) Where can I take a PCQI training class?

The following SQFI Training Centers offer the FSPCA Preventive Controls for Human Food Qualified Individual training, including:

ACET Global Consulting - <http://www.acetglobalconsultingllc.com/index.html>
Alchemy Systems - <http://www.alchemysystems.com/>
American Food Safety Services - <http://www.sqftrainingcenter.com/>
Center for Food Safety and Regulatory Solutions - <http://www.cfsrs.com/>
Cert-ID Solutions - <http://certidsolutions.com/>
Comprehensive Food Safety, LLC - <http://cfsfoodsafety.com/>
College of Southern Idaho - <http://agriculture.csi.edu/food-processing/>
Cornell University - <http://dairyextension.foodscience.cornell.edu/>
DFA of California - <https://dfaofca.com/>
DNV-GL - <https://www.dnvgl.us/>
Ecolab, Inc. - <http://www.ecolab.com/innovation/resources/training-for-food-processors>
Eurofins - <http://www.eurofinsus.com/food-safety>
Food Safety and Quality Systems - <http://sqf.fsnqs.com/>
Food Safety Institute of the Americas (University of Puerto Rico) - <http://www.uprm.edu/portada/>
HACCP Consulting Group - <http://haccpcg.com/>
Merieux NutriSciences - <http://www.merieuxnutrisciences.com>
Northwest Food Processors Association
NSF - <http://www.nsf.org/>
Perry Johnson Registrars - <http://www.pjr.com/>
SAI Global - <https://www.saiglobal.com/>
SCS Global Services - <https://www.scsglobalservices.com/>
SGS Academy - learning.sgs.com/
Superior Food Safety - <http://www.superiorfoodsafety.com/>
UL Registrar, LLC - <http://services.ul.com/service/training/>

Please contact the training center directly for class details and dates.

3) Will SQFI change their Code based on the Rule?

Maybe. SQFI intends to retain the global accessibility of the SQF Code. However certain technical aspects of the Rule may be of benefit to all. SQFI will review the Rule and make changes supported by stakeholder feedback and comments.

4) Will the FSMA food safety plan be accepted instead of HACCP?

It depends. A key foundation of the SQFI certification process is the benchmarking of the SQF Code to the GFSI Requirements Document; if this document provides the latitude to make this differentiation, SQFI will consider this change.

5) What tools does SQFI have available for SQF suppliers, certification bodies and auditors?

SQFI and its partners have completed comparisons of the SQF Code to the Preventive Controls for Human Food Rule, the Produce Safety Rule, and the Sanitary Transportation of Human and Animal Food Rule to better understand where the Rules and the SQF Code overlap and diverge.

SQFI and its parent company, the Food Marketing Institute (FMI) plan to host several train-the-trainer courses for the PCQI for Human Food Rule. Additionally, SQFI will be considered a trainer of trainers for the PCQI for Human Food course.

6) What role will the Global Food Safety Initiative (GFSI) will play within FSMA?

That has not been completely defined. GFSI will more than likely play a role for foreign food facilities and the foods they produce.

7) Where can I find the link to the Preventive Controls for Human Food Rule?

The Rule and supporting materials can be found at:

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

8) Are dietary supplements included in the PC Rule?

Dietary supplements are exempted in the Preventive Controls for Human Foods Rule. However dietary ingredients would be addressed by the Rule.

9) What are some additional resources to help understand and implement the Preventive Controls Rule as it applies to my facility?

- The 2016 SQF International Conference - www.sqfconference.com
- Trade associations, including the Food Marketing Institute - www.fmi.org
- SQF registered consultants, SQF licensed certification bodies and training centers – www.sqfi.com
- SQFI – www.sqfi.com/supplier/fsma-resource-page
- FDA Technical Assistance Network (TAN) - <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>
- FDA FSMA email updates - https://public.govdelivery.com/accounts/USFDA/subscriber/new?topic_id=USFDA_206
- Repositrak - <http://repositrak.com>
- University of Minnesota Food Protection and Defense Institute – <http://foodprotection.umn.edu/>

- FDA Food Defense Mitigation Strategies Database - <http://www.accessdata.fda.gov/scripts/foodefensemitigationstrategies>

10) What are the key differences between the SQF Code, the FDA Preventive Controls Rule for Human Food and GFSI?

Requirement	Comparison	Comments
Written food safety plan	Different	<p>FDA: Written food safety plan must address preventive controls (If there are no identified PCs, then recall plan is not needed.). Approved suppliers and EMP have additional requirements. Hazard analysis to include intentional contamination for economic gain.</p> <p>SQF: HACCP following CODEX required. Recall plan required.</p> <p>GFSI: HACCP following CODEX required. Recall plan required.</p>
Food safety-knowledgeable individual in charge	Different	<p>FDA: PCQI to have specific training or demonstration of knowledge.</p> <p>SQF: Designated SQF practitioner with HACCP training.</p> <p>GFSI: No requirement.</p>
Food safety trained staff	Comparable	<p>FDA: PCQI and QI required.</p> <p>SQF: Training required for HACCP-related and food safety duties.</p> <p>GFSI: Employees are to be adequately trained, instructed and supervised in food safety principles and practices, commensurate with their activity.</p>
Validation of controls	Comparable	<p>FDA: Conducted within 90 days of production or when process changes. There are specific exemptions.</p> <p>SQF: Required for HACCP and other programs. Reviewed annually or with process change.</p> <p>GFSI: As part of HACCP.</p>

Requirement	Comparison	Comments
Corrective actions	Comparable	<p>FDA: Correction is allowed without corrective action. Corrective action required for any PC violation.</p> <p>SQFI: Required for all identified non-conformities.</p> <p>GFSI: Procedures for the determination and implementation of corrective action in the event of any significant non-conformity relating to food safety.</p>
Record retention	Comparable	<p>FDA Records must be retained for two years. Exception records allowed but must be validated. Implementation records are to be kept as part of the food safety plan. Records to include product and lot code.</p> <p>SQF: Available, legible, and stored according to company, customer or regulatory requirement.</p> <p>GFSI: Available, legible, and stored according to company, customer or regulatory requirement.</p>
Food defense	TBD	<p>FDA: Vulnerability assessment and actionable process steps and mitigation strategies are to be identified.</p> <p>SQF: Food defense plan is required. Edition 8 will include economic adulteration following GFSI requirements.</p> <p>GFSI Version 7 to require food fraud vulnerability assessment procedure must be in place to identify potential vulnerability and prioritize food fraud mitigation measures.</p>
Product release	Comparable	<p>FDA: All monitoring and corrective action records must be reviewed within seven working days from the time they were created.</p> <p>SQF: Product release procedure in place and executed before shipment.</p> <p>GFSI: Product release procedure in place before shipment.</p>

Requirement	Comparison	Comments
Rework	Comparable	<p>FDA: Rework must be held at temperatures and humidity to prevent adulteration.</p> <p>SQFI: Proper storage of all food, ingredients and food contact packaging to prevent contamination.</p> <p>GFSI: Adequate storage of food.</p>
Outdoor bulk vessels	Comparable	<p>FDA: Adequate precautions to protect food in installed bulk vessels.</p> <p>SQF: General statement for protecting food and storage areas.</p> <p>GFSI: General statement on protecting food.</p>
Gases	Comparable	<p>FDA: Gases mechanically introduced into food must be treated to prevent the contamination of food with unlawful indirect food additives.</p> <p>SQF: Food and food additives are to be safe for use in a food establishment.</p> <p>GFSI: Food and food additives are to be safe for use in a food establishment</p>
By-products for use as animal food	Different	<p>FDA: If applicable, hold human food by-products for use as animal food under conditions that will prevent contamination.</p> <p>SQF: Requirements included in a separate code for feed, FSC 32.</p> <p>GFSI: Requirements included in a separate industry scope: Feed, F1.</p>
Recall program	Comparable	<p>FDA: Recall plan required if a PC has been identified. Effectiveness checks are required to verify that the recall is carried out.</p> <p>SQF: Recall plan required for all facilities. Effectiveness checks are not required.</p> <p>GFSI: An effective incident management procedure shall be established, implemented and maintained and regularly tested.</p>

