

FSMA FACT SHEET

What Training Requirements Does FSMA Have?

Overview

Each of the FSMA regulations includes requirements relating to personnel training and qualifications. This FSMA fact sheet explains the training requirements under the Produce Safety regulations and the Current Good Manufacturing Practices (CGMPs) and Preventive Controls for Human Food regulations.

Produce Safety

The following training requirements apply under the Produce Safety rule:¹

(1) Training requirements for *all personnel* who handle (i.e., contact) produce or foodcontact surfaces, including temporary, part-time, seasonal and contracted personnel, as well as their supervisors:

Such personnel must receive adequate training “as appropriate to the person’s duties,” upon hiring and at least annually thereafter. Additionally, they must have a combination of education, training and experience necessary to perform their assigned duties in a manner that ensures compliance with the Produce Safety rule. Training must be conducted “in a manner that is easily understood by the personnel being trained.” Additionally, training must be repeated as necessary and appropriate in light of observations or information indicating that personnel are not meeting FDA’s standards under the Produce Safety rule.

2) Training requirements for all personnel who handle (i.e., contact) produce during growing, harvesting, packing or holding on a farm,² as well as for their supervisors:

Training must include all of the following:

- Principles of food hygiene and food safety;
- The importance of health and personal hygiene, including recognizing symptoms of health conditions that could result in contamination; and
- The relevant standards under the Produce Safety rule that are applicable to the employee’s job responsibilities.

Additionally, if the personnel conduct harvest activities, their training must address:

- Recognizing produce that must not be harvested, including covered produce that may be contaminated;
- Inspecting harvest containers and equipment to ensure that they are functioning properly, clean, and maintained so as not to become a source of contamination; and
- Correcting problems with harvest containers or equipment, or reporting such problems to the supervisor (or other responsible party), as appropriate to the person’s job responsibilities.

3) Training requirements for supervisors:

- At least one supervisor or responsible party for the farm must have successfully completed food safety training at least equivalent to that provided under the standardized curriculum offered by the Produce Safety Alliance.³
- Appropriate personnel must be assigned to supervise operations to ensure compliance with the Produce Safety rule.

4) For each of the above training requirements, you must establish and keep records that document the date of training, topics covered, and the persons trained. These records must be kept for at least two years after they were created.

CGMPs and Preventive Controls

The following training requirements apply when compliance with the CGMPs and/or Preventive Controls is required:

1) All individuals who manufacture, process, pack, or hold food subject to the CGMPs and/or Preventive Controls must be “qualified to perform their assigned duties.”⁴ This includes temporary and seasonal personnel.

All such personnel must:

- Be a “qualified individual,”⁵ which means they must have the education, training or experience (or a combination thereof) necessary to manufacture, process, pack or hold clean and safe food as appropriate to the individual’s assigned duties; and
- Receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility and the individual’s assigned duties. This training must be documented and corresponding documentation must be maintained for at least two years.

¹21 CFR Part 112, Subpart C.

²These requirements also apply to any manufacturing/processing activities on the farm, to the extent that these activities fall within the scope of the “farm” rule (e.g., on-farm, low-risk manufacturing activities).

³<https://producesafetyalliance.cornell.edu/>

- 2) Responsibility for ensuring compliance with CGMPs and/or Preventive Controls must be clearly assigned to supervisory personnel who have the education, training or experience (or a combination thereof) necessary to supervise the production of clean and safe food.
- 3) When compliance with Preventive Controls is required, certain activities must be performed or overseen by a “Preventive Controls Qualified Individual” (PCQI).⁶ To be a PCQI, the individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under the standardized curriculum offered by the Food Safety Preventive Controls Alliance,⁷ or otherwise be qualified to develop and apply a food safety system through job experience that provides knowledge at least equivalent to that provided through the standardized curriculum. This individual may be, but is not required to be, an employee of the facility. This training must be documented and corresponding documentation must be maintained for at least two years.
- 4) Audits required as part of the supplier verification requirements under the Preventive Controls rule must be conducted by a “qualified auditor.”⁸ To be a qualified auditor, the person must be a “qualified individual” (as defined above) that has technical expertise obtained through education, training or experience (or a combination thereof) necessary to perform the auditing function. This training must be documented and corresponding documentation must be maintained for at least two years.

Other Rules

There also are training requirements under the other FSMA rules — including requirements in the rules on Sanitary Transportation of Food, Foreign Supplier Verification Programs, and Intentional Adulteration. Those requirements are beyond the scope of this FSMA fact sheet.

²21 CFR § 117.4.

³21 CFR § 117.3.

⁴21 CFR § 117.180. The activities that must be performed by a PCQI are: (1) Preparation of the food safety plan; (2) Validation of the preventive controls; (3) Written justification for validation to be performed in a longer timeframe; (4) Determination that validation is not required; (5) Records review; (6) Written justification for records review of monitoring and corrective actions within a timeframe that exceeds seven working days; (7) Re-analysis of the food safety plan; and (8) Determination that re-analysis can be completed, and additional preventive controls validated, in a longer timeframe.

⁷<https://www.ifsh.iit.edu/fspca/fspca-preventive-controls-human-food>

⁸21 CFR § 117.435(a).