

Introduction

A documented and implemented SQF System goes a long way in preparing certified sites for enforcement. The FDA Produce Safety Rule (or Rule) has specific requirements that may go beyond what is required by the SQF Code or are otherwise different. This document identifies and describes these requirements organized by where they are likely to correspond to the requirements in the SQF Code.

While comprehensive, this document does not replace a thorough review of the Rule to assure proper compliance.

General

Subpart A – General Provision

§ 112.5 – Eligibility for Exemptions -Based on the averaged dollar (\$US) value of farms sales over a three (3) year period and/or who those products are sold to certain farm operations may be exempt from the Rule.

§ 112.6 – Modified Requirements - Based on the average dollar (\$US) value of farms sales over a three (3) year period and/or who those products are sold to certain farm operations may qualify for modified requirements.

Subpart C – Personnel Qualification and Training

The Rule has similar requirements to the SQF Code with respect to training of employees that handle product and work on product contact surfaces. There is a specific requirement for personnel that are in a supervisory or oversight role in that they will need complete food safety training where the curriculum is recognized as adequate by FDA. The FDA has designated training conducted through the Produce Safety Alliance as the standard curriculum.

Subpart E – Agricultural Water

The Rule establishes definitions for the various types of agricultural water and the testing and sampling requirements to illustrate compliance. The testing and reporting can seem complex, however it is intended to provide flexibility for the farm to adapt their water use to possible changes due to weather, floods and other factors that can affect water quality. The SQF Code provides an excellent framework into which the specific aspects of the Rule can be incorporated into.

Key Terms

Many of the terms used in the Rule have the same meaning as that used in the SQF Code, however in the Rule there are additional terms as well as terms with unique meaning such as those listed below. It is recommended that a review be completed of the definitions for those terms listed below and all terms used in the Rule in Subpart A § 112.30.

Agricultural Water

Covered Activity

Covered Produce

Primary Production Farm

Secondary Activities Farm

Ground Water

Produce

Raw Agricultural Commodity (RAC)

Module 2

2.1 Management Commitment

2.1.2 Management Responsibility

§ 112.22 Qualifications

Responsibility for Produce Rule on the Farm: The Rule stipulates that “At least one supervisor or responsible party on the farm must have successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration.” The FDA has contracted with the Produce Safety Alliance (PSA) to develop a curriculum and trainers who can deliver courses. These course offerings can be found through the PSA website (<https://producesafetyalliance.cornell.edu/>). Qualified SQF practitioners would not be required to take this course since they would have food safety training already as part of their qualification. They would need to upgrade their understanding of the Rule which could be through other course, although they should seek guidance as to its equivalency with PSA courses.

2.2 Document Control and Records

2.2.2 Records

Subpart O - Records

While the SQF Code requires the site to document and implement the methods and responsibility for maintaining document control and verifying, maintaining and retaining records, the Rule has additional, specific and prescriptive requirements for records and record retention. Carefully read Subpart O of the Rule to assure compliance.

Some sections of note include:

§ 112.161 General Requirements

Required information for records: The Rule requires that all records need to include the following information:

- the location of the farm location of growing area;
- the date and the time of the activity documented;
- the signature or initials of the person performing the activity;
- a review, date and signature with reasonable time after the records are created by a supervisor or responsible party; and
- an adequate description (such as the commodity name, or the specific variety or brand name of a commodity, and, when available, any lot number or other identifier) of covered produce applicable to the record.

The details noted above generally are more prescriptive in what FDA is looking for to deem records to be in compliance. Record and recording information is challenging for some farm operations so this additional detail will need to be incorporated in the daily practices of the operation.

§ 112.164 Requirements for record retention.

Record retention requirements: The Rule provides the following information regarding record retention:

- Record keeping is required for at least two (2) years past the date the record was created.
- Records that relate to the general adequacy of the equipment or processes or records that relate to analyses, sampling, or action plans being used by a farm, including the results of scientific studies, tests, and evaluations, must be retained at the farm for at least 2 years after the use of such equipment or processes, or records related to analyses, sampling, or action plans, is discontinued.

The SQF Code does not stipulate how long, how or where records and documents must be kept; however it does require the document control system to state, "Furthermore, under 112.64 records that relate to the general adequacy of the equipment or processes or records that relate to analyses, sampling, or action plans being used by a farm, including the results of scientific studies, tests, and evaluations, must be retained at the farm for at least two (2) years after the use of such equipment or processes, or records related to analyses, sampling, or action plans, is discontinued." And finally, if the site closes, the documented food safety plan "may be transferred to some other reasonably accessible location but must be returned to the plant or facility within twenty-four (24) hours for official review upon request."

2.9 Training

2.9.2 Training Program

§ 112.164 Qualifications

The SQF Code provides a framework for which the Rule requirement for training qualifications can be inserted. The SQF Code is not specific in its applications and requirements to Good Agricultural Practices for employees, whereas the Rule is decidedly more specific in those requirements. Of note is the requirement for "at least annually" in reference to the frequency of training. The SQF Code does not stipulate the frequency; however given the seasonal nature of primary production, it is an industry best practice. Additionally, SQF Code Module 7, element 7.4.3 also provides an opportunity to define employee practices. Specifically, the Rule states:

All of the following requirements apply regarding qualifications and training for personnel who handle (contact) covered produce or food contact surfaces:

- All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, must receive adequate training, as appropriate to the person's duties, upon hiring, and periodically thereafter, at least once annually.

- All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, must have a combination of education, training, and experience necessary to perform the person's assigned duties in a manner that ensures compliance with this part.

§ 112.22 Personal Training for Covered Activities

The SQF Code provides a framework for inclusion of the Rule requirements for specific training for employees who handle produce. The Rule labels this “covered activities” at term that was included in the definition section above. The specifics for harvesting and requirements for employees are covered in the SQF Code, Module 7, element 7.4.3. Similar to SQF Code requirements, sites will need to have records and materials that can illustrate the content of what they train employees to understand.

Specifically the Rule states:

“At a minimum, all personnel who handle (contact) covered produce during covered activities or supervise the conduct of such activities must receive training that includes all of the following:

- Principles of food hygiene and food safety;
- The importance of health and personal hygiene for all personnel and visitors, including recognizing symptoms of a health condition that is reasonably likely to result in contamination of covered produce or food contact surfaces with microorganisms of public health significance.”

Persons who conduct harvest activities for covered produce must also receive training that includes all of the following:

- Recognizing covered produce that must not be harvested, including covered produce that may be contaminated with known or reasonably foreseeable hazards;
- Inspecting harvest containers and equipment to ensure that they are functioning properly, clean, and maintained so as not to become a source of contamination of covered produce with known or reasonably foreseeable hazards; 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.

Module 7

7.3.2 Sanitary Facilities and Hand Washing

§ 112.130 Hand Washing

The SQF Code requirements for handwashing are very specific and do not provide a substitute for this important health and hygiene activity. The Rule very specifically indicates what is not allowed as a substitute for handwashing, therefore the site will need to indicate how employees are required to perform handwashing.

Specifically the Rule states:

- The use antiseptic hand rubs as a substitute for soap (or other effective surfactant) and water is not allowed.

§ 112.44 Hand Washing

The SQF Code requirements for hand washing are similar to the Rule but worded a bit differently. The intent and expectations are similar other than the Rule does stipulate requirements when sites might include animal husbandry activities.

Specifically, the Rule states:

Hands shall be washed by all personnel

- Before starting work;
- Before putting on gloves;
- After using the toilet;
- Upon return to the work station after any break or other absence from the work station;
- As soon as practical after touching animals (including livestock and working animals), or any waste of animal origin; and
- At any other time when the hands may have become contaminated in a manner that is reasonably likely to lead to contamination of covered produce with known or reasonably foreseeable hazards.

7.5.1 – Water System Description

§ 112.42 Agricultural Water Sources

The SQF Code provides a framework for which a site can insert the more prescriptive nature of the Rule requirements for many of the water requirements. Since the Rule emphasizes microbiological control factors and water is one of those major factors to assess and control it is imperative that the sites address the specific requirements of the Rule. Part 112.42 contains extensive information on the sources and it is aligned with the SQF Code in several areas.

Below are the Rule requirements for the general description of the water system:

Inspection all of agricultural water systems, to the extent they are under farm control (including water sources, water distribution systems, facilities, and equipment) is required at the start of the growing season and on an annual basis. The inspection will identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces in light of covered produce, practices, and conditions, including consideration of the following:

- The nature of each agricultural water source (for example, ground water or surface water);
- The extent of your control over each agricultural water source;
- The degree of protection of each agricultural water source;
- Use of adjacent and nearby land; and
- The likelihood of introduction of known or reasonably foreseeable hazards to agricultural water by another user of agricultural water before the water reaches your covered farm.

7.5.5 Water Management Plan

§ 112.42 Agriculture Water Sources and Distribution Systems

The SQF Code provides the frameworks for sites to include the Rule requirements regarding the types of activities that are required to minimize the risk to contamination of site water sources. It includes planned maintenance and provides good examples of the types of risks to look for and maintain.

Specifically the Rule states:

- All agricultural water distribution systems to the extent they are under your control, must be maintained as necessary and appropriate to prevent the water distribution system from being a source of contamination to covered produce, food contact surfaces, areas used for a covered activity, or water sources, including by regularly inspecting and adequately storing all equipment used in the system.
- All agricultural water sources to the extent they are under your control (such as wells) must be adequately maintained. Such maintenance includes regularly inspecting each source to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces; correcting any significant deficiencies (e.g., repairs to well cap, well casing, sanitary seals, piping tanks and treatment equipment, and control of cross-connections); and keeping the source free of debris, trash, domesticated animals, and other possible sources of contamination of covered produce to the extent practicable and appropriate under the circumstances.
- As necessary and appropriate, measures reasonably necessary to reduce the potential for contamination of covered produce with known or reasonably foreseeable hazards as a result of contact of covered produce with pooled water must be implemented. For example, such measures may include using protective barriers or staking to keep covered produce from touching the ground or using an alternative irrigation method.

§ 112.44 Agricultural Water Quality

The SQF Code provides framework for sites to include very specific Rule requirements on the quality of the water. The SQF Code requirement makes frequent reference to meeting regulatory requirements for the quality of the water, since potable water criteria vary by different regulatory authorities. The specificity provided by the Rule is very clear however it does appear to be very technically based. There are varying resources to assist in understanding this as well as how to sample properly. The following site provides just one example: <http://agwater.arizona.edu/onlinecalc/> .

Specifically, the Rule states:

Agricultural water must have no detectable generic *Escherichia coli* (*E. coli*) in 100 milliliters (mL) per sample. Untreated surface water must not be used for any of the following purposes:

- Applied in any manner that directly contacts covered produce during or after harvest activities (for example, water that is applied to covered produce for washing or cooling activities, and water that is applied to harvested crops to prevent dehydration before cooling), including when used to make ice that directly contacts covered produce during or after harvest activities;
- Used to contact food contact surfaces, or to make ice that will contact food contact surfaces; and
- Used for washing hands during and after harvest activities.

Agricultural water used during growing activities for covered produce (other than sprouts) using a direct water application method, shall have the following criteria apply:

- A geometric mean (GM) of the agricultural water samples of 126 or less colony forming units (CFU) of generic *E. coli* per 100 mL of water (GM is a measure of the central tendency of your water quality distribution); and
- A statistical threshold value (STV) of your agricultural water samples of 410 or less CFU of generic *E. coli* per 100 mL of water (STV is a measure of variability of your water quality distribution, derived as a model-based calculation approximating the 90th percentile using the lognormal distribution).

7.5.5 Water Quality

§ 112.46 Agricultural Water Testing and Sampling

The SQF Code provides a framework for which a site can define how water quality is maintained and sampled to meet regulatory requirements. Within that framework, sites would need to determine from the Rule which situation best applies to them and set up their sampling and testing accordingly. The link provide above from the University of Arizona is a good reference to assist in this evaluation.

The Rule guidance below stipulates the exact requirements to consider:

Water not received from a Public Water System, as defined under the Safe Drinking Water Act (SDWA) regulations or meets the microbial quality requirement described in § 112.44 must have the following analysis and testing completed:

- In testing untreated surface water—considered the most vulnerable to external influences—that is directly applied to growing produce (other than sprouts), the FDA requires farms to do an initial survey, using a minimum of 20 samples, collected as close as is practicable to harvest over the course of two to four years. The initial survey findings are used to calculate the GM and STV (these two figures are referred to as the “microbial water quality profile”) and determine if the water meets the required microbial quality criteria.
 - After the initial survey has been conducted, an annual survey of a minimum of five samples per year is required to update the calculations of GM and STV.
 - The five new samples, plus the previous most recent 15 samples, create a rolling dataset of 20 samples for use in confirming that that the water is still used appropriately by recalculating the GM and STV.
- For untreated ground water that is directly applied to growing produce (other than sprouts), the FDA requires farms to do an initial survey, using a minimum of four samples, collected as close as is practicable to harvest, during the growing season or over a period of one year. The initial survey findings are used to calculate the GM and STV and determine if the water meets the required microbial quality criteria.
 - After the initial survey has been conducted, an annual survey of a minimum of one sample per year is required to update the calculations of GM and STV.
 - The new sample, plus the previous most recent three samples, create a rolling dataset of four samples for use in confirming that that the water is still used appropriately by recalculating the GM and STV.
- For untreated ground water that is used for the purposes for which no detectable generic *E. coli* is allowed, the FDA requires farms to initially test the untreated ground water at least four times during the growing season or over a period of one year. Farms must determine whether the water can be used for that purpose based on these results.
 - If the four initial sample results meet the no detectable generic *E. coli* criterion, testing can be done once annually thereafter, using a minimum of one sample. Farms must resume testing at least four times per growing season or year if any annual test fails to meet the microbial quality criterion.

7.5.6 Corrective Actions

§ 112.45 Agricultural Water Corrective Actions

The SQF Code requires corrective action protocols when water quality does not conform to regulation or customer requirements. The SQF Code does not specifically indicate what activities should be considered, but does require all activities and results to be documented. The Rule is more prescriptive regarding types of activities and inspections that would conform to the Rule. If agricultural water does not meet the microbial quality criteria (or any alternative microbial quality criteria, if applicable) required under § 112.44(b), as soon

as practicable and no later than the following year, its use must be discontinued, unless any of the following alternatives are used:

- Apply a time interval(s) (in days) and/or a (calculated) log reduction by applying a time interval between last irrigation and harvest or by applying a time interval between harvest and end of storage using an appropriate microbial die-off rate between harvest and end of storage, and/or applying a (calculated) log reduction using appropriate microbial removal rates during activities.
- Re-inspect the entire affected agricultural water system to the extent it is under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, make necessary changes, and take adequate measures to determine if your changes were effective and adequately ensure that your agricultural water meets the microbial quality criteria in § 112.44(b) (or any alternative microbial criteria, if applicable); or
- Treat the water in accordance with the requirements of § 112.43