KEY REQUIREMENTS:
Final Rule on Produce Safety

The FDA Food Safety Modernization Act (FSMA) Produce Safety rule is now final, and the earliest compliance dates for some farms begin one year after the effective date of the final rule (see "Compliance Dates" below). The rule establishes, for the first time, science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption.

This rule was first proposed in January 2013. In response to input received during the comment period and during numerous public engagements that included public meetings, webinars, listening sessions, and visits to farms across the country, the FDA issued a supplemental notice of proposed rulemaking in September 2014. The proposed revisions were designed to make the originally proposed rule more practical, flexible, and effective.

The final rule is a combination of the original proposal and revisions outlined in the supplemental proposal, with additional changes as appropriate. The definition of "farm" and related terms were revised in the final Preventive Controls for Human Food rule, and the same definitions of those terms are used in this rule to establish produce safety standards. Operations whose only activities are within the farm definition are not required to register with FDA as food facilities and thus are not subject to the preventive controls regulations.

Below are summaries of some key requirements, compliance dates, and other information.

1. AGRICULTURAL WATER:

- **Water quality:** The final rule adopts the general approach to water quality proposed in the supplemental rule, with some changes. The final rule establishes two sets of criteria for microbial water quality, both of which are based on the presence of generic *E. coli*, which can indicate the presence of fecal contamination.
  - No detectable generic *E. coli* are allowed for certain uses of agricultural water in which it is reasonably likely that potentially dangerous microbes, if present, would be transferred to produce through direct or indirect contact. Examples include water used for washing hands during and after harvest, water used on food-contact surfaces, water used to directly contact produce (including to make ice) during or after harvest, and water used for sprout irrigation. The rule establishes that such water use must be immediately discontinued and corrective actions taken before re-use for any of these purposes if generic *E. coli* is detected. The rule prohibits use of untreated surface water for any of these purposes.
  - The second set of numerical criteria is for agricultural water that is directly applied to growing produce (other than sprouts). The criteria are based on two values, the geometric mean (GM) and the statistical threshold (STV). The GM of samples is 126 or less CFU of generic *E.coli* per 100 mL of water and the STV of samples is 410 CFU or less of generic *E.coli* in 100 mL of water.
    - The GM is an average, and therefore represents what is called the central tendency of the water quality (essentially, the average amount of generic *E. coli* in a water source).
    - STV reflects the amount of variability in the water quality (indicating *E. coli* levels when adverse conditions come into play—like rainfall or a high river stage that can wash waste into rivers and canals). Although this is an over simplification, it can be described as the level at which 90 percent of the samples are below the value.

- The FDA is exploring the development of an online tool that farms can use to input their water sample data and calculate these values.
- These criteria account for variability in the data and allow for occasional high readings of generic *E.coli* in appropriate context, making it much less likely (as compared to the originally proposed criteria for this water use) that a farm will have to discontinue use of its water source due to small fluctuations in water quality.
- These criteria are intended as a water management tool for use in understanding the microbial quality of agricultural water over time and determining a long-term strategy for use of water sources during growing produce other than sprouts.

- If the water does not meet these criteria, corrective actions are required as soon as is practicable, but no later than the following year. Farmers with agricultural water that does not initially meet the microbial criteria have additional flexibility by which they can meet the criteria and then be able to use the water on their crops. These options include, for example:
  - Allowing time for potentially dangerous microbes to die off on the field by using a certain time interval between last irrigation and harvest, but no more than four consecutive days.
  - Allowing time for potentially dangerous microbes to die off between harvest and end of storage, or to be removed during commercial activities such as washing, within appropriate limits.
  - Treating the water.

■ **Testing:** The final rule adopts the general approach to testing untreated water used for certain purposes proposed in the supplemental notice, with some changes. The rule still bases testing frequency on the type of water source (i.e. surface or ground water).

- 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.
- There is no requirement to test agricultural water that is received from public water systems or supplies that meet requirements

established in the rule (provided that the farm has Public Water System results or certificates of compliance demonstrating that the water meets relevant requirements), or if the water is treated in compliance with the rule's treatment requirements.

2. BIOLOGICAL SOIL AMENDMENTS:

- **Raw Manure:** The FDA is conducting a risk assessment and extensive research on the number of days needed between the applications of raw manure as a soil amendment and harvesting to minimize the risk of contamination. (A soil amendment is a material, including manure, that is intentionally added to the soil to improve its chemical or physical condition for growing plants or to improve its capacity to hold water.)
  - At this time, the FDA does not object to farmers complying with the USDA's National Organic Program standards, which call for a 120-day interval between the application of raw manure for crops in contact with the soil and 90 days for crops not in contact with the soil. The agency considers adherence to these standards a prudent step toward minimizing the likelihood of contamination while its risk assessment and research is ongoing.
  - The final rule requires that untreated biological soil amendments of animal origin, such as raw manure, must be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered prdouce after application.
- **Stabilized Compost:** Microbial standards that set limits on detectable amounts of bacteria (including *Listeria monocytogenes*, *Salmonella* spp., fecal coliforms, and *E. coli* 0157:H7) have been established for processes used to treat biological soil amendments, including manure. The rule includes two examples of scientifically valid composting methods that meet those standards. Stabilized compost prepared using either of these methods must be applied in a manner that minimizes the potential for contact with produce during and after application.

3. SPROUTS

- The final rule includes new requirements to help prevent the contamination of sprouts, which have been frequently associated with foodborne illness outbreaks. Sprouts are especially vulnerable to dangerous microbes because of the warm, moist and nutrient-rich conditions needed to grow them.
  - Between 1996 and 2014, there were 43 outbreaks, 2,405 illnesses, and 171 hospitalizations, and 3 deaths associated with sprouts, including the first documented outbreak of Listeria monocytogenes associated with sprouts in the United States.
- Requirements specific to sprouts include, for example:
  - Taking measures to prevent the introduction of dangerous microbes into or onto seeds or beans used for sprouting, in addition to treating seeds or beans that will be used for sprouting (or relying on prior treatment by the seed/bean grower, distributor, or supplier with appropriate documentation).
  - Testing of spent sprout irrigation water from each production batch of sprouts, or in-process sprouts from each production batch, for certain pathogens. Sprouts cannot be allowed to enter commerce until it is ascertained that these required pathogen test results are negative.
  - Testing the growing, harvesting, packing and holding environment for the presence of *Listeria* species or *Listeria monocytogenes*.
  - Taking corrective actions if spent sprout irrigation water, sprouts, and/or an environmental sample tests positive.
- Sprout operations will have less time to come into compliance with the rule than farms growing other produce. They will have one to three years to comply based on the size of their operation, with no additional time to meet the water requirements.

4. DOMESTICATED AND WILD ANIMALS

- The rule addresses concerns about the feasibility of compliance for farms that rely on grazing animals (such as livestock) or working animals for various purposes. It establishes the same standards for these animals as it does for intrusion by wild animals (such as deer or feral swine). Farmers are required to take all measures reasonably necessary to identify and not harvest produce that is likely to be contaminated.
  - At a minimum, this requires all covered farms to visually examine the growing area and all covered produce to be harvested, regardless of the harvest method used.
  - In addition, under certain circumstances the rule requires farms to do additional assessment during the growing season, and if significant evidence of potential contamination by animals is found, to take measures reasonably necessary to assist later during harvest. Such measures might include, for example, placing flags outlining the affected area.
- Although the final rule does not require establishing waiting periods between grazing and harvest, the FDA encourages farmers to voluntarily consider applying such intervals as appropriate for the farm's commodities and practices. The agency will consider providing guidance on this practice in the future, as needed.
- As was stated in the supplemental notice, farms are not required to exclude animals from outdoor growing areas, destroy animal habitat, or clear borders around growing or drainage areas. Nothing in the rule should be interpreted as requiring or encouraging such actions.

5. WORKER TRAINING AND HEALTH AND HYGIENE

- Requirements for health and hygiene include:
  - Taking measures to prevent contamination of produce and food-contact surfaces by ill or infected persons, for example, instructing personnel to notify their supervisors if they may have a health condition that may result in contamination of covered produce or food contact surfaces.
  - Using hygienic practices when handling (contacting) covered produce or food-contact surfaces, for example, washing and drying hands thoroughly at certain times such as after using the toilet.
  - Taking measures to prevent visitors from contaminating covered produce and/or food-contact surfaces, for example, by making toilet and hand-washing facilities accessible to visitors.
- Farm workers who handle covered produce and/or food-contact surfaces, and their supervisors, must be trained on certain topics, including the importance of health and hygiene.
- Farm workers who handle covered produce and/or food contact surfaces, and their supervisors, are also required to have a combination of training, education and experience necessary to perform their assigned responsibilities. This could include training (such as training provided on the job), in combination with education, or experience (e.g., work experience related to current assigned duties).

6. EQUIPMENT, TOOLS AND BUILDINGS

- The rule establishes standards related to equipment, tools and buildings to prevent these sources, and inadequate sanitation, from contaminating produce. This section of the rule covers, for example, greenhouses, germination chambers, and other such structures, as well as toilet and hand-washing facilities.
  - Required measures to prevent contamination of covered produce and food contact surfaces include, for example, appropriate storage, maintenance and cleaning of equipment and tools.

EXEMPTIONS

The rule does not apply to:

- Produce that is not a raw agricultural commodity. (A raw agricultural commodity is any food in its raw or natural state)
- The following produce commodities that FDA has identified as rarely consumed raw: asparagus; black beans, great Northern beans, kidney beans, lima beans, navy beans, and pinto beans; garden beets

(roots and tops) and sugar beets; cashews; sour cherries; chickpeas; cocoa beans; coffee beans; collards; sweet corn; cranberries; dates; dill (seeds and weed); eggplants; figs; horseradish; hazelnuts; lentils; okra; peanuts; pecans; peppermint;potatoes; pumpkins; winter squash; sweet potatoes; and water chestnuts

- Food grains, including barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (e.g. cotton seed, flax seed, rapeseed, soybean, and sunflower seed)
- Produce that is used for personal or on-farm consumption.
- Farms that have an average annual value of produce sold during the previous three-year period of $25,000 or less.

The rule provides an exemption for produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, under certain conditions.

The rule also provides a qualified exemption and modified requirements for certain farms.

- To be eligible for a qualified exemption, the farm must meet two requirements:
  - The farm must have food sales averaging less than $500,000 per year during the previous three years; and
  - The farm's sales to qualified end-users must exceed sales to all others combined during the previous three years. A qualified end-user is either (a) the consumer of the food or (b) a restaurant or retail food establishment that is located in the same state or the same Indian reservation as the farm or not more than 275 miles away.
- A farm with the qualified exemption must still meet certain modified requirements, including disclosing the name and the complete business address of the farm where the produce was grown either on the label of the produce or at the point of purchase. These farms are also required to establish and keep certain documentation.
- A farm's qualified exemption may be withdrawn as follows:
  - If there is an active investigation of an outbreak of foodborne illness that is directly linked to the farm, or
  - If FDA determines it is necessary to protect the public health and prevent or mitigate an outbreak based on conduct or conditions associated with the farm that are material to the safety of the farm's produce that would be covered by the rule.
- Before FDA issues an order to withdraw a qualified exemption, the agency:
  - May consider one or more other actions to protect public health, including a warning letter, recall, administrative detention, refusal of food offered for import, seizure and injunction.
  - Must notify the owner, operator, or agent in charge of the farm, in writing, of the circumstances that may lead FDA to withdraw the exemption, provide an opportunity for response within 15 calendar days of receipt of the notification, and consider actions taken by the farm to address the issues raised by the agency.
- A withdrawn exemption may be reinstated if (as applicable):
  - The FDA determines that the outbreak was not directly linked to the farm, and/or
  - The FDA determines that the problems with conduct or conditions material to the safety of the food produced or harvested at the farm have been adequately resolved, and continued withdrawal of the exemption is not necessary to protect public health or prevent or mitigate an outbreak of foodborne illness.

VARIANCES

The rule also permits states, tribes, or foreign countries from which food is imported into the U.S. to submit a petition, along with supporting information, to FDA requesting a variance(s) from one or more of the requirements of this rule.

- The rule enables a state, tribe, or country, if it concludes that meeting one or more of the rule's requirements would be problematic in light of local growing conditions, to request variances to those

requirements. The state, tribe, or foreign country must demonstrate that the requested variance is reasonably likely to ensure that the produce is not adulterated and provides the same level of public health protection as the corresponding requirement(s) in the rule.

- The final rule makes it clear that federally recognized tribes may submit a variance petition.
- The request for a variance must be submitted by a competent authority, meaning a person or organization that is the regulatory authority for food safety for the state, tribe, or foreign country.
- A foreign government does not need to have a systems recognition arrangement or equivalence agreement with the FDA to obtain a variance.
- The variance request must include relevant and scientifically valid information specific to the produce or activity. Information could relate to crops, climate, soil, geography or environment, as well as the practices of that particular region.
- Examples of types of variances that may be granted include a variance from the agricultural water microbial quality criteria for water used during growing covered produce (other than sprouts) using a direct water application method, a variance from the microbial die-off rate used to determine the time interval between the last irrigation and harvest and/or the accompanying maximum time interval; and a variance from the approach or frequency for water testing for water uses subject to the rule's microbial quality criteria.

COMPLIANCE DATES

Compliance dates for covered activities, except for those involving sprouts, after the effective date of the final rule are:

- Very small businesses, those with more than $25,000 but no more than $250,000 in average annual produce sales during the previous three year period: four years.
- Small businesses, those with more than $250,000 but no more than $500,000 in average annual produce sales during the previous three year period: three years.
- All other farms: two years.
- The compliance dates for certain aspects of the water quality standards, and related testing and recordkeeping provisions, allow an additional two years beyond each of these compliance dates for the rest of the final rule.

Compliance dates for modified requirements for farms eligible for a qualified exemption are:

- For labeling requirement (if applicable): January 1, 2020.
- For retention of records supporting eligibility for a qualified exemption: Effective date of the final rule.
- For all other modified requirements:
  - Very small businesses, four years after the effective date of the final rule.
  - Small businesses, three years after the effective date of the final rule.

Compliance dates for covered activities involving sprouts after the effective date of the final rule are:

- Very small businesses: three years
- Small businesses: two years
- All other farms: one year

ENVIRONMENTAL IMPACT STATEMENT

The FDA has also released the Final Environmental Impact Statement (EIS), which places the Produce Safety rule in the context of its likely impact on the environment, including human health and socioeconomic effects. The Draft EIS was published in January 2015. The FDA considered public comments submitted in the two months that followed in drafting the Final EIS. The FDA considered the findings of the Final EIS in finalizing the produce rule.

- The EIS evaluated actions that FDA proposed in the original and supplemental rules, as well as a number of alternative actions for each of the provisions identified as having the potential to result in significant environmental impacts. The provisions of the final rule represent FDA's preferred alternatives, which are detailed in a Record of Decision (ROD). The ROD addresses how the EIS findings were incorporated into decisions about the final rule. The agency's preferred alternatives are those that the FDA believes best fulfill the agency's statutory mission and responsibility, giving consideration to economic, environmental, technical and other factors.

- A significant beneficial impact on public health is expected due to the anticipated decrease in the number of illnesses tied to produce contamination.

- As in the Draft EIS, the Final EIS notes that any produce regulation that causes a farmer to use ground water instead of surface water could exacerbate existing groundwater shortages, although added flexibility in the water provisions make such a management decision unlikely.

- The Final EIS also concludes that Native American farmers may be disproportionately affected by any increases in operating costs necessitated by the produce rule since their average income is 30 percent less than that of other farmers.

ASSISTANCE TO INDUSTRY

The FDA is developing several guidance documents on subjects that include:

- General guidance on implementation and compliance

- A Small Entity Compliance Guide that explains the actions a small or very small business must take to comply with the rule.

- Other documents, including guidance on sprouts, are being considered and prioritized.

Plans for training and technical assistance are well under way. They include:

- Establishing the FDA FSMA Food Safety Technical Assistance Network, already operational, to provide a central source of information to support industry understanding and implementation of FSMA.

- The FDA is developing a comprehensive training strategy that includes collaboration with:
  - The Produce Safety Alliance;
  - The Sprout Safety Alliance;
  - The National Institute of Food and Agriculture in the U.S. Department of Agriculture (to administer a grant program to provide food safety training, education and technical assistance to small and mid-size farms and small food processors, beginning farmers, socially disadvantaged farmers, and small produce merchant wholesalers); and
  - Cooperative agreement partners (to develop training programs for sustainable agriculture and tribal operations).

- The FDA also plans to work with cooperative extension units, land grant universities, trade associations, foreign partners, the Joint Institute for Food Safety and Applied Nutrition (JIFSAN), and other stakeholders to develop a network of institutions that can provide technical assistance to the farming community, especially small and very small farms.

- FDA has entered into a cooperative agreement with National Association of State Departments of Agriculture (NASDA) to help with the implementation of the produce safety regulations.

MORE INFORMATION

Visit http://www.regulations.gov/

FDA's Food Safety Modernization Act page at www.fda.gov/FSMA

Business Size	 Compliance Dates for Sprouts	 Compliance Dates For Most Produce	 Water Related Compliance Dates[1,2]	Compliance Date for Qualified Exemption Labeling Requirement [3]	Compliance Date for Retention of Records Supporting a Qualified Exemption
All other businesses (>$500K)	1/26/17	1/26/18	1/27/20	1/1/2020	1/26/16
Small businesses (>$250K-500K)[4]	1/26/18	1/28/19	1/26/21		
Very small businesses (>$25K-250K)[5]	1/28/19	1/27/20	1/26/22		

[1]Compliance dates for certain aspects of the agricultural water requirements allow an additional two years. Provisions with extended compliance dates include:

- *The specific microbiological criteria that apply to agricultural water*
- *Corrective measures that must be taken if agricultural water does not meet requirements*
- *The frequency of testing agricultural water*
- *Records associated with data to support a microbial die-off rate, corrective measures, test results from a public water system, or data used to support alternative die-off rates, criteria, or sampling strategies*

[2] Guidance published 8/24/16 indicates that a farm has the option of collecting surface water samples over two to four years. For example, a farm that is not small or very small would begin sampling in 2018 and complete the sampling in 2019, 2020, or 2021.

[3] A farm eligible for a qualified exemption must notify consumers as to the complete business address of the farm where the food is grown, harvested, packed, and held.

[4] A farm is a small business if, on a rolling basis, the average annual monetary value of produce sold during the previous 3-year period is no more than $500,000.

[5] A farm is a very small business if, on a rolling basis, the average annual monetary value of produce sold during the previous 3-year period is no more than $250,000.

Before the compliance date, every covered farm that does not qualify for an exemption must have a supervisor (such as a farm owner/operator) complete a standardized food safety training program. You can find out more about food safety training from the Produce Safety Alliance. https://producesafetyalliance.cornell.edu/training

U.S. FOOD & DRUG ADMINISTRATION

FDA FOOD SAFETY MODERNIZATION ACT
THE FUTURE IS NOW

STANDARDS FOR PRODUCE SAFETY
Coverage and Exemptions/Exclusions for 21 PART 112

The Preventive Controls for Human Food rule clarified the definition of a farm to cover two types of farm operations, primary production farms and secondary activities farms. The same definition is used in the Produce Safety rule (section 112.3(c)). Below are basic criteria that determine whether an operation that meets the definition of "farm" is subject to the produce rule.

Does your farm grow, harvest, pack or hold produce?
Sections 112.1 and 112.3(c)
We define "produce" in section 112.3(c).

- NO → Your farm is NOT covered by this rule.
- YES ↓

Does your farm on average (in the previous three years) have $25k or less in annual produce sales?
Section 112.4(a)

- YES → Your farm is NOT covered by this rule.
- NO ↓

Is your produce one of the commodities that FDA has identified as rarely consumed raw?
Section 112.2(a)(1)

If you grow, harvest, pack or hold more than one produce commodity, you must ask this question separately for each one to determine whether that particular produce commodity is covered by this rule.

- YES → This product is NOT covered by this rule.
- NO ↓

Is your produce for personal/on-farm consumption?
Section 112.2(a)(2)

- YES → This produce is NOT covered by this rule.
- NO ↓

Is your produce intended for commercial processing that adequately reduces pathogens (for example, commercial processing with a "kill step")?

- YES → This produce is eligible for exemption from the rule, provided you make certain statements in documents accompanying the produce, obtain certain written assurances, and keep certain documentation, as per Sections 112.2(b)(2) through (b)(6).
- NO ↓

Does your farm on average (in the previous three years) as per Section 112.5:

have < $500k annual food sales,

AND

a majority of the food (by value) sold directly to "qualified end-users"?
Section 112.3(c)

"Qualified End-User" as defined in Section 112.3(c) means:

- the consumer of the food OR
- a restaurant or retail food establishment that is located—
  - (i) in the same State or the same Indian reservation as the farm that produced the food; OR
  - (ii) not more than 275 miles from such farm.

(The term "consumer" does not include a business.)

- YES → Your farm is eligible for a qualified exemption from this rule, which means that you must comply with certain modified requirements and keep certain documentation, as per Sections 112.6 and 112.7.
- NO ↓

YOU ARE COVERED BY THIS RULE.

Produce Safety ALLIANCE

FSMA: Are you in or are you out?

PSA Supplemental Activity

Exclusions & Exemptions

- Some growers may be **excluded** based on:
  - Commodities grown (e.g., rarely consumed raw)
  - Average annual produce sales
  - Personal/on-farm consumption
- Some growers may be **exempt** based on:
  - Processing activities that include a 'kill step'
  - Average annual food sales and to 'qualified end users'
- Ultimately, all growers should understand and take action to reduce food safety risks on the farm

Produce Safety ALLIANCE

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Navigating the Produce Safety Rule Exemptions and Exclusions

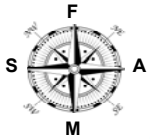
§ 112.1: Definition of what food is covered produce

§ 112.2: Definition of what food is not covered produce

- **§ 112.2(a)(1):** Produce that is rarely consumed raw (exhaustive)
- **§ 112.2(a)(2):** Produced for personal or on farm consumption
- **§ 112.2(a)(3):** Produce that is not a raw agricultural commodity
- **§ 112.2(b)(1):** Produce destined for commercial processing

§ 112.4: Rule applies to farms selling more than $25K produce, unless § 112.5 applies

§ 112.5: Eligibility for a qualified exemption



Produce Safety ALLIANCE

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Exclusions: Average Annual Produce Sales & Produce Definition

- Farms with average annual value of produce sold during the previous 3-year period <$25,000 are excluded
- *Produce* means any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs

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Covered Produce


- Food that is produce and that is a raw agricultural commodity (RAC) is covered by the Produce Safety Rule. This includes a produce RAC that is grown domestically and a produce RAC that will be imported or offered for import in any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.
- Covered produce includes all of the following:

(1) Fruits and vegetables. The Rule includes a list of 98 specific (e.g., carrots) and categorical (e.g., citrus) examples

(2) Mixes of intact fruits and vegetables (such as fruit baskets)

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Exclusions: 'Rarely Consumed Raw'

- Produce that is rarely consumed raw, specifically the produce on this exhaustive list (34 items) are not covered.

asparagus	chickpeas	hazelnuts
black beans	cocoa beans	horseradish
Great Northern beans	coffee beans	lentils
kidney beans	collards	okra
lima beans	sweet corn	peanuts
navy beans	cranberries	pecans
pinto beans	dates	peppermint
garden beets	dill	potatoes
(roots and tops)	(seeds and weed)	pumpkins
sugar beets	eggplants	winter squash
cashews	figs	sweet potatoes
sour cherries	ginger	water chestnuts

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Exclusions: Personal/On Farm Consumption

- Produce that is produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same management <u>is not covered</u>.


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Exclusions: Raw Agricultural Commodities (RAC)

- Produce that is not a RAC is not covered
  - Definition of a RAC is in Section 201(r) of the FD&C Act
  - The term "raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing

RACs	Not RACs
  	  

Produce Safety ALLIANCE

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Covered Activities: Harvest

- Includes cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (*e.g.,* foliage, husks, roots or stems).

Removing stems and husks **Cooling** ***Field Coring*** **Washing**

Shelling **Trimming outer leaves** ***Gathering***

Threshing

Filtering **Hulling**

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Covered Activities: Other Farm Activities

Dehydrating/ drying

Treatment for ripening

Packaging & labeling

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Exemptions: Commercial Processing

- The produce receives commercial processing that adequately reduces the presence of microorganisms of public health significance (e.g., validated canning processes, process such as distilling or winemaking)
- **Specific documentation and written assurances required annually**

Produce Safety ALLIANCE

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safe food ALLIANCE

COMMERCIAL PROCESSING EXEMPTION

1. You must disclose in documents accompanying the produce* that the food is “not processed to adequately reduce the presence of microorganisms of public health significance;” and
2. Written assurance from the processor is required to be obtained annually.

*As appropriate based on industry practices

Qualified Exemption

1. During the previous 3-year period, more than half of the average annual monetary value of the **food** the farm sold was directly to qualified end-users
   a) The consumer of the food (consumer does not include a business); or
   b) A restaurant or retail food establishment that is located:
      i. In the same State or the same Indian reservation as the farm that produced the food; or
      ii. Not more than 275 miles from such farm

AND

2. The average annual value of all food the farm sold during the 3-year period preceding the applicable calendar year was less than $500,000

Produce Safety ALLIANCE

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Quiz 1

A farm sells $19,000 in produce average over a 3 year period at a local farmer's market and through a CSA.

Is this farm covered by the FSMA Produce Safety Rule?

A.) Yes
B.) No
C.) I'm not sure

Produce Safety ALLIANCE

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Quiz 2

A farm sells $35,600 in produce, and also sells $650,000 in other food products, including sauerkraut and jam (3-year rolling average).

Do they satisfy the 'qualified exemption' requirements?

A.) Yes
B.) No
C.) I'm not sure

Produce Safety ALLIANCE

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Quiz 3

A farm sells $475,000 in produce (3-year rolling avg)

- $200,000 wholesaler out-of-state/more than 275 miles,
- $200,000 to a local restaurant, and
- $75,000 to a local grocery store.

Do they satisfy the requirements for a qualified exemption?

A.) Yes
B.) No
C.) I'm not sure

Produce Safety ALLIANCE

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Quiz 4

- A farm sells all of their $27,000 in produce annually to a distributor located more than 275 miles away and not in the same state of where the produce was grown. The farm grows potatoes, pumpkins, sweet corn, winter squash, and has a 1 acre of raspberries and strawberries.
- Is this farm covered by the Produce Safety Rule?
  A.) Yes
  B.) No
  C.) I'm not sure

Produce Safety ALLIANCE

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Qualified Exemption: Modified Requirements

- If your farm is eligible for the qualified exemption, you must follow modified requirements:
  - When a food packaging label is required, you must prominently and conspicuously display **on the food packaging label** the name and the complete business address of the farm where the produce was grown; or
  - When a food packaging label is not required on food you must prominently and conspicuously display, **at the point of purchase**, the name and complete business address of the farm where the produce was grown, on a label, poster, sign, placard (internet sales: e-notice)
- The complete business must include the street address or post office box, city, state, and zip code for domestic farms, and comparable full address information for foreign farms.

Produce Safety ALLIANCE

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FINAL EXAM QUESTION

- A grower is eligible for a qualified exemption and therefore is only subject to modified FSMA requirements. Their buyer requires a food safety audit in order to accept them as a supplier. Does this grower need to comply with the buyer's requirements?

  A.) Yes, if they want to sell their produce to that buyer
  B.) No, because FSMA exempts them, so they are exempt from buyer requirements too
  C.) I don't know

Produce Safety ALLIANCE

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Recap

- There are several ways the farm or operation may be excluded or exempt from the FSMA Produce Safety Rule
- Exclusions and exemptions are largely based on the types of commodities grown, total sales of produce annually, and where and to whom the food is sold
- Definitions play a key role in understanding if a farm is subject to the FSMA Produce Safety Rule or not

Produce Safety ALLIANCE

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Evolution of the Farm Definition

- The final Preventive Controls for Human Food rule clarifies the definition and expands it further to cover two kinds of farming operations:
  - Primary production farm
  - Secondary activities farm

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Primary Production Farm

- An operation under one management in one general, but not necessarily contiguous, location
- Devoted to the growing of crops, the harvesting of crops, the raising of animals, or any combination of these activities
  - The definition has been expanded to include operations that just grow crops and operations that just harvest crops.

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Primary Production Farm

- In addition to these activities, a primary production farm can:
  - Pack or hold RACs (regardless of who grew or raised them)
  - Manufacture/process, pack, or hold processed foods so long as:
    - all such food is consumed on that farm or another under the same management; or
    - the manufacturing/processing falls into limited categories

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Manufacturing/Processing within the Farm Definition

- Drying/dehydrating RACs to create a distinct commodity (e.g., drying grapes to produce raisins)
- Treatment to manipulate the ripening of RACs (e.g., treating produce with ethylene gas)
- Packaging and labeling RACs

FDA 25

Secondary Activities Farm

- An operation not located on a primary production farm that is also devoted to farming activities, like harvesting, packing and/or holding RACs.
- The primary production farm(s) that grow, harvest, and/or raise the majority of those RACs must own or jointly own a majority interest in the secondary activities farm.

FDA 26

Secondary Activities Farm

- The definition also allows certain, limited additional manufacturing/processing, packing, and holding
  - Same as those for a primary production farm

FDA 27

Activities That Do Not Fall Under Farm Definition

- Activities that do not fall within the farm definition include manufacturing/ processing that goes beyond what falls within the farm definition. As examples:
  - Pitting dried plums, chopping herbs
  - Making snack chips or flours from legumes
  - Roasting peanuts, tree nuts, or seeds (e.g., pumpkin, sunflower, or flax seeds)

FDA 28

Produce Packing Houses

- Produce packing houses that fall under the new farm definition → produce safety rule
- Produce packing houses that do not fall under the new farm definition → PCHF
- Specific steps necessary to ensure the safety of produce would generally be the same

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Off-farm Produce Packing House

- CGMP requirements have analogues in produce safety rule (new PCHF provision allows packing house to choose)
- We expect off-farm packing houses subject to PCHF to look to the produce safety rule in developing food safety plans and establish preventive control management components

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Off-farm Produce Packing House

- Food safety plan would focus on a few key preventive controls, generally with counterparts in the produce safety rule
  - Maintaining and monitoring water temperature
  - Sanitation controls
- PC management components
  - Product testing: unlikely
  - Environmental monitoring: some facilities may choose as a verification activity

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Geometric Means, Statistical Threshold Values, and Microbial Die-Off Rates

This document outlines how to perform key mathematical steps necessary to develop a microbial water quality profile (MWQP) and then calculate microbial die-off if the MWQP values exceed numerical Geometric Mean (GM) and Statistical Threshold Value (STV) criteria outlined in the Food Safety Modernization Act (FSMA) Produce Safety Rule. There are tools to make the calculations easier, but for those who want to know how to do the math, it is covered here.

The first VERY IMPORTANT POINT!

Here are several web-based and Excel tools that can do the calculations once water samples have been analyzed and test results are in hand. If these tools meet your needs, there may be no need to do the math the long way.

- An Excel spreadsheet, created by the Western Center for Food Safety at UC Davis, can be accessed at wcfs.ucdavis.edu/
- An Ag Water App and an Online Calculator, created by University of Arizona, can be accessed at agwater.arizona.edu/ and agwater.arizona.edu/onlinecalc/ (respectively)

Some more VERY IMPORTANT POINTS!

This is not a standalone document, it is a supplement to the Produce Safety Alliance (PSA) Grower Training curriculum and information presented in **Module 5: Agricultural Water**. This document simply serves as an example of how to do the math. The full requirements of how the MWQP is developed and used can be found in the FSMA Produce Safety Rule and the PSA Grower Training curriculum.

The MWQP consists of two calculated values: the geometric mean (GM) and the statistical threshold value (STV). This document describes how to calculate the GM and STV using quantified generic *E. coli* water test results. For agricultural water intended to or likely to contact covered produce (other than sprouts) during growing activities, the numerical criteria are:

a. Geometric Mean of 126 or less CFU generic *E. coli* per 100 mL water **AND**
b. Statistical Threshold Value of 410 or less CFU generic *E. coli* per 100 mL water

The initial MWQP described in the FSMA Produce Safety Rule for untreated surface water is based on at least 20 water samples taken over a minimum of 2 years and a maximum of 4 years or, for untreated ground water, at least 4 samples taken over 1 year. The initial MWQP is then updated annually. See **Module 5: Agricultural Water** or § 112.46 in the FSMA Produce Safety Rule for the detailed requirements.

The FSMA Produce Safety Rule also includes several corrective measures that can be taken if the water source does not meet the numerical GM and STV criteria. One of the corrective measures is to apply a time interval from the last water application to harvest to allow microbial die-off. This corrective measure uses a die-off rate of 0.5 log/day (for no more than 4 days) to achieve a calculated reduction of the GM and STV to meet the numerical criteria. This document also provides an example of how to calculate the die-off time interval.

The Fun Begins!

An untreated surface water MWQP of 20 sample test results is included in this factsheet. Growers can follow the steps shown in these example calculations using their own results to get the GM and the STV. These are the calculations behind the MWQP that is calculated for some uses of agricultural water, described above.

E.A. Bihn, B.J. Fick, D.M. Pahl, D.M. Stoeckel, K.L. Woods, G.L. Wall

Step 1: Collect water samples from the agricultural water source.

Follow laboratory instructions and the requirements of the FSMA Produce Safety Rule to collect water samples from the agricultural water that needs to be tested. This example is based on water samples collected from untreated surface water used as agricultural water. Have the laboratory analyze the sample for the concentration of (e.g., quantified) generic *E. coli* as CFU/100 mL of water.

Step 2: Gather together the sample results.

The example data set includes 20 test results that would be the minimum number of results for the MWQP of an untreated surface water source.

Year 1		Year 2		Year 3		Year 4	
Sample	Result CFU/100 mL	Sample	Result CFU/100 mL	Sample	Result CFU/100 mL	Sample	Result CFU/100 mL
#1	**73**	#6	**120**	#11	**1,200**	#16	**1,600**
#2	**260**	#7	**2,300**	#12	**110**	#17	**120**
#3	**900**	#8	**180**	#13	**290**	#18	**270**
#4	**140**	#9	**510**	#14	**2,100**	#19	**67**
#5	**5,500**	#10	**210**	#15	**220**	#20	**220**

Step 3: Log transform the sample results

Log transformation is often done with results that cover a wide range of values, such as these results that range from 67 CFU/100 mL water to 5,500 CFU/100 mL water. To do a log transformation on the results, use the log function on a calculator or a spreadsheet such as Microsoft Excel or OpenOffice Calc. Tables of log values are also available on the internet. The example calculations were done using log base 10. If the results you get do not match the results below, check your calculator's manual or spreadsheet's supporting information. Some log tables, calculators, and spreadsheet functions are based on natural log and will not give the same log (base 10) transformed values as below.

The results from the lab usually should have only 2 significant digits (there are only 2 'real' numbers followed by zeroes that show order of magnitude, like in the value 5,500 above; 2 significant digits are underlined). To avoid rounding errors, calculations are done using 1 extra significant digit. In this fact sheet the calculations are done using 3 significant digits. For log-transformed values, the number of significant digits is the number of decimal places, like in 1.863 below (3 significant digits are underlined). Once calculations are complete, the final result is rounded back down to two significant digits (e.g., 354 becomes 350, 356 becomes 360).

Year 1		Year 2		Year 3		Year 4	
Sample	Result (Log CFU/100 mL)	Sample	Result (Log CFU/100 mL)	Sample	Result (Log CFU/100 mL)	Sample	Result (Log CFU/100 mL)
#1	**1.863**	#6	**2.079**	#11	**3.079**	#16	**3.204**
#2	**2.415**	#7	**3.362**	#12	**2.041**	#17	**2.079**
#3	**2.954**	#8	**2.255**	#13	**2.462**	#18	**2.431**
#4	**2.146**	#9	**2.708**	#14	**3.322**	#19	**1.826**
#5	**3.740**	#10	**2.322**	#15	**2.342**	#20	**2.342**

Step 4: Calculate the Geometric Mean (GM)

The GM can be calculated without log transformation. There is a function in some spreadsheets, such as the GEOMEAN function within Excel, that uses regular results. Since the STV has to be calculated, and the STV calculation requires log transformation, the GM calculation here is done using log-transformed results.

The first step in the GM calculation is to take the average of the log results. To get the average, add all the log-transformed results from Step 3 (i.e., 50.972), and then divide by the number of samples (i.e., 20 samples in this example). The average of the 20 log-transformed results in the example data set is 2.549.

Next, convert the average from the log scale to the regular scale. This process is called taking the antilog.

- One way this can be done is to use the antilog function on a calculator to convert the calculated log value (2.549) to a regular scale value.
- Another way to find the regular value is to raise 10 to the power of the log value (the button is labeled 10^y on many calculators. For this example, "y" would be 2.549).
- A third way is to use a spreadsheet function such as the POWER function in Excel. For this example, the formula would be =POWER(10,2.549)

Since the log-transformed value of the GM is 2.5489, the regular value of the GM is the antilog of 2.549 ($10^{2.549}$) or 354 CFU/100 mL.

- When using this as a final result it would be rounded to 2 significant digits, or 350 CFU/100 mL.

Step 5: Calculate the Statistical Threshold Value (STV).

Calculate the STV using this formula. Steps 5a through 5d give details of the process.

$$\log(STV) = avg(\log values) + 1.282 * std(\log values)$$

5a) Here is the good news: *avg(log values)* is the log-transformed GM value from Step 4 (i.e., 2.549).

↓

$$\log(STV) = 2.549 + 1.282 * std(\log values)$$

5b) Next, and this may be tricky, calculate the standard deviation of the log-transformed results from Step 3. Use a statistical calculator or a spreadsheet to find the sample standard deviation (the function in Microsoft Excel is STDEV). The process is different for different software and calculators so you may need to look in the instruction manual for the statistical calculator, the help function in the spreadsheet program, or equations from the internet to help. The standard deviation of the log-transformed results from Step 3 is 0.547.

5c) Plug all the values into the log*(STV)* formula. The value 1.282 is a constant that is needed in the calculation (the STV is an estimate of the 90th percentile of the data set). The value 1.282 comes from statistical tables. From here, the math is a little simpler. Do the multiplication and addition, and calculate the value for log(*STV*) of the example data set. It should look like this:

$$\log(STV) = 2.549 + 1.282 * 0.547 = 3.250$$

5d) Using the log value calculated in Step 5c (i.e., 3.250), calculate the regular value using the same process used in Step 4. The STV in the example calculation is the antilog of 3.250, or $10^{3.250}$. The back transformed, or regular, value is calculated to be 1,778 CFU/100 mL.

- When using this as a final result it would be rounded to 2 significant digits, or 1,800 CFU/100 mL

Step 6: Determining if a Corrective Measure is Necessary

Important Note: The next steps use the MWQP that consists of the GM and STV calculated from the full 20 samples. The calculations resulted in a GM of 350 CFU/100 mL and an STV of 1,800 CFU/100 mL.

Comparison of the calculated GM and STV to the numerical criteria shows:

- The GM (350 CFU/ 100 mL water) exceeds the GM criterion (126 or less CFU/100 mL).
- The STV (1,800 CFU/100 mL water) exceeds the STV criterion (410 or less CFU/100 mL).

Step 7: Applying a Time Interval as a Corrective Measure

Several corrective measures are included in the FSMA Produce Safety Rule. One of these is detailed in § 112.45(b)(1)(i)(A), and allows calculation of microbial die-off between the last water application and harvest at a rate of 0.5 log per day, for up to four days. The half-log die-off rate is approximately the same as:

- 68.38% die off over one day (31.62% remains),
- 90.00% over two days (10% remains),
- 96.84% over three days (3.16% remains), and
- 99.00% over four days (1% remains).

Either of the two calculations below results in the same results for the half-log die-off per day adjustment.

1. Multiply the GM by the percent remaining on each day, using the values given above in parentheses
    - For the GM of 354 CFU/100 mL calculated in Step 4 (before rounding to 2 significant digits), the amount remaining after one day is 31.62%
        - **Day 1**: 354 x 0.3162 = 112 (round to 110 CFU/100 mL when used as a final value)
2. For each day of die-off, subtract 0.5 from the log(GM) and log(STV) values that were calculated in Step 3 and Step 5, then back transform the adjusted value. Remember the calculation is antilog(y) = 10^y.
    - For the GM of 354 CFU/100 mL calculated in Step 4, the adjusted value after one day is 0.5 log lower than the original value. The log-transformed value of 354 is 2.549 (from Step 3).
        - **Day 1**: 2.549 – 0.5000 = 2.049 and $10^{2.049}$ = 112 (round to 110 CFU/100 mL)

The same calculations are done for STV in order to know the minimum time interval that would meet the requirements of this corrective measure, since the adjusted GM and the STV both need to meet the criteria.

- **Day 1**: 1,780 x 0.3162 = 563 <u>OR</u> 3.250 – 0.500 = 2.750 and $10^{2.750}$ = 562.
    - Both round to 560 CFU/100 mL when using as the final value
- **Day 2**: 1,780 x 0.1000 = 178 <u>OR</u> 3.250 – 1.000 = 2.250 and $10^{2.250}$ = 178
    - Both round to 180 CFU/100 mL when using as the final value

Since both GM and STV numerical criteria in the Produce Safety Rule must be met, the 1-day time interval is not enough because the adjusted STV is still over the criterion after 1 day (i.e., 560 CFU/100 mL). After a 2-day interval, the adjusted STV and GM both meet the numerical criteria. The water source would meet the numerical requirements of the FSMA Produce Safety Rule, as long as the produce is not harvested for at least 2 days after the last water application.

Remember that the FSMA Produce Safety Rule only allows a maximum 4-day time interval when using the 0.5 log/day microbial die-off rate, so a 2-log reduction (1% remains) is the biggest adjustment that is allowed.

Summary

The mathematical calculations outlined in this document were designed as instructions for how to calculate the GM and STV values that are part of the MWQP. If the GM or STV of the MWQP sample results are higher than the numerical criteria outlined in the FSMA Produce Safety Rule, growers have the option of applying a corrective measure if they want to continue using it as agricultural water. One corrective measure is to use a time interval for die-off between last application and harvest. Calculations supporting the adjustment for die-off interval were also included in this document. All of these calculations can also be done using tools that are available online.

Qualified Exemption Review *Template*

Name and address of farm: _____

Date: _____

Sales receipts or records reflecting **total food** sales over the previous 3 years:

Year 1 (Sales year: _____) $_____

Year 2 (Sales year: _____) $_____

Year 3 (Sales year: _____) $_____

Average total food sales $_____

Total food sales to qualified end users (E.g. consumers, grocery stores, and restaurants) within 275 miles or within the same state or Indian reservation $_____

$_____	÷	$ _____ x 100	=_____%
Sales to qualified end users		Average sales	**Percent sales to qualified end users**

*Sales receipts must also be retained to support this record.

Reviewed by: _____**Title:** _____**Date:** _____

FSMA PSR Reference § 112.7(b) Confidential Record

Worker Training Record *Template*

Name and address of farm: _____ _____ **Date:** _____

Trainer: _____ **Training time:** _____

Topics Covered: _____

Training materials: Please attach any printed materials related to the training. Also reference any relevant SOPs or sections of the farm food safety plan that apply.

Employee Name (please print)	**Employee Signature**
1. _____	_____
2. _____	_____
3. _____	_____
4. _____	_____
5. _____	_____
6. _____	_____
7. _____	_____
8. _____	_____
9. _____	_____
10. _____	_____
11. _____	_____
12. _____	_____

Reviewed by: _____ **Title:** _____ **Date:** _____

FSMA PSR reference § 112.30(b) Confidential Record

Modified from On-Farm Decision Tree Project: Worker Health, Hygiene, and Training—v14 07/16/14
E.A. Bihn, M.A. Schermann, A.L. Wszelaki, G.L. Wall, and S.K. Amundson, 2014 www.gaps.cornell.edu

Water System Inspection Record *Template*

Name and address of farm: _____

See farm policy for specific water distribution system inspection procedures.

Date	Time	Water Source and/or Distribution System	Observations	Corrective Actions Taken	Initials
4/22/16	*7:00 AM*	*Well 1, north field*	*Well casing in good shape, backflow prevention device in place, no broken pipes*	*None*	*EAB*
4/22/16	*9:00 AM*	*Pond, south field*	*Significant geese presence*	*Introduced swan decoys. Will monitor*	*EAB*

Reviewed by:_____ **Title:** _____**Date:**_____

FSMA PSR reference § 112.50(b)(1) Confidential Record

Modified from On-Farm Decision Tree Project: Agricultural Water for Production—v4 07/17/2014
E.A. Bihn, M.A. Schermann, A.L. Wszelaki, G.L. Wall, and S.K. Amundson, 2014 www.gaps.cornell.edu

Water Treatment Monitoring Record *Template*

Name and address of farm: _____

Please see the food safety plan for overall water treatment procedures.

Date	Time	Water pH	Water Temperature	Turbidity	Sanitizer (name & rate)	Corrective Action Needed (yes or no)	Initials
10/14/16	*8:35 am*	*8.5*	*65° F*	*25 NTU*	*NaOCl 75 ppm*	*Yes - pH was too high, added citric acid; retested –pH 7.0*	*EAB*
10/14/16	*12:00 pm*	*7.0*	*72° F*	*47 NTU*	*NaOCl 55 ppm*	*no*	*EAB*

***Not all of the above factors may need to be recorded. Refer to the product's EPA label for specific use instructions.**

Reviewed by:_____ **Title:** _____ **Date:**_____

FSMA PSR reference § 112.50(b)(4) Confidential Record

Modified from On-Farm Decision Tree Project: Postharvest Water—v7 07/16/2014
E.A. Bihn, M.A. Schermann, A.L. Wszelaki, G.L. Wall, and S.K. Amundson, 2014 www.gaps.cornell.edu

Agricultural Water Die-Off Corrective Measures Record *Template*

Name and address of farm: _____

Water source: _____

Current calculated GM: _____ CFU/100 mL water

Current calculated STV: _____ CFU/100 mL water

Calculated Interval*: _____ Days

Adjusted GM: _____ CFU/100 mL water

Adjusted STV: _____ CFU/100 mL water

EXAMPLE

Water source: *Southwest pond*

Current Calculated GM: *190 CFU/100 mL water*

Current Calculated STV: *690 CFU/100 mL water*

Calculated Interval: *1 days (0.5-log)*

Adjusted GM: *60 CFU/100 mL water*

Adjusted STV: *220 CFU/100 mL water*

Field	Crop	Date and time of beginning of crop harvest	Date and time of end of last water application	Time interval since last water application	Harvest Supervisor Initials
2A	*Cortland Apple*	*9/23/2016, 1:00 PM*	*9/21/2016, 4:00 PM*	*2 days*	*DMP*
2A	*Cortland Apple*	*9/25/2016, 10:00 AM*	*9/21/2016, 4:00 PM*	*4 days*	*DMP*

* Attach documentation to support calculations (e.g. the Ag Water Excel Tool at wcfs.ucdavis.edu). If a die-off rate other than the specified 0.5 log/day in § 112.45(b)(1) is used, include documentation supporting the alternative die-off rate as required by § 112.50(b)(8).

FSMA PSR reference § 112.50(b)(6) Confidential Record

Compost Treatment Record *Template*

Name and address of farm: _____

Type of compost method: *Windrow* **Date piled:** *9-15-2016* **Date finished:** _____ **Row number:** *2*

List all ingredients added to compost: *Poultry litter, kitchen scraps, dried leaves, straw*

Use this record for on farm composting. Record the date piled, turning dates, and the temperatures maintained. Use one sheet for each pile or row.

Date Turned	Temp/Time Test Area 1	Temp/Time Test Area 2	Temp/Time Test Area 3	Temp/Time Test Area 4	Initials
9-25-2016	*135 F/ 2:00 PM*	*138 F/2:01 PM*	*140 F/ 2:03 PM*	*135 F/ 2:04 PM*	*EAB*
9-26-2016	*137 F/ 2:15 PM*	*137 F/2:18 PM*	*138 F/ 2:19 PM*	*137 F/ 2:25 PM*	*EAB*

Proper compost production requires a minimum temperature of 131ºF be maintained for 3 days using an enclosed system OR a temperature of at least 131ºF for 15 days using a windrow system, during which the materials must be turned 5 times (FSMA Produce Rule. 2015. Rule 21 CFR part 112.54(b)).

Reviewed by:_____ **Title:** _____ **Date:**_____

FSMA PSR reference § 112.60(b)(2) Confidential Record

Modified from On-Farm Decision Tree Project: Soil Amendments—v5 7/16/2014
E.A. Bihn, M.A. Schermann, A.L. Wszelaki, G.L. Wall, and S.K. Amundson, 2014 www.gaps.cornell.edu

Cleaning and Sanitizing Record *Template*

Name and address of farm: _____

List the date, time, tool or equipment name, and method for each for each cleaning or sanitizing activity.

Date	Time	List tools/equipment	Cleaned and/or Sanitized?	Method used	Cleaned By (initials)
10/11/16	*10:07 AM*	*Harvest tools*	*cleaned*	*See Cleaning SOP (Removed dirt with brush, washed with detergent, rinsed, air dried)*	*EAB*
10/11/16	*10:30 AM*	*Dump Tank*	*cleaned and sanitized*	*See Dump Tank Cleaning and Sanitizing SOP (drained tank, washed with detergent, rinsed, sanitized with 150 ppm NaOCl)*	*EAB*

Reviewed by:_____ **Title:** _____**Date:**_____

FSMA PSR reference § 112.140(b)(2) Confidential Record