



New Rules for Produce Safety Its All About the Water

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Are You a Farm, a Processor, or Both?

- Do you make “processed food” (Part 117) or
- Do you make a “raw agricultural product” that is commonly eaten raw? (Part 112)
- Manufacturing/processing now includes **packing, and holding**



Major Changes Under FSMA for Producers of Raw Agricultural Products

- Must have plan for controlling microbes of public health significance
 - know and document who in the value chain controls a hazard if it is not you
- Must be able to show staff is trained
 - training documented, annual training required
- Environmental testing– agricultural water
- Records – lots of records



Major Changes Under FSMA for Processors

- Processors must take **condition of facility** into account as part of hazard analysis (this will determine whether product is high risk)
- Control programs for **allergens** (allergen cross contact)
- Control programs for **undesirable** (not just pathogenic) microorganisms, radiological hazards, unapproved additives, color additives, economic adulteration for **processed food**
- **Everyone will need a preventive controls based food safety plan and a recall program**



Major Changes Under FSMA for Processors

- All facilities must have a **Preventive Controls Qualified Individual** on staff to manage aspects of the Food Protection Plan
- Approval process for **suppliers** is now required
 - Suppliers must have traceability programs



Key Provisions for Produce Eaten Raw (Covered Produce)

1. Agricultural Water
2. Biological Soil Amendments
3. Sprouts
4. Domesticated and Wild Animals
5. Worker Training and Health and Hygiene
6. Equipment Tools and Buildings
7. Records
8. Exemptions



Produce

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.



Produce Safety Rule – “Covered Produce”

§ 112.1 Raw agricultural commodity (RAC)
grown domestically or imported



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8. **Exemptions**



Subpart E--Agricultural Water

- § 112.41 What requirements apply to the quality of agricultural water?

All agricultural water must be safe and of adequate sanitary quality for its intended use.



Agricultural Water

- Agricultural water means water used in covered activities on covered produce where:
- Water is intended to, or is likely to, **contact covered produce** or food contact surfaces, including
- Water used in **growing activities** (including irrigation water applied using direct water application methods)
- Water used for **preparing crop sprays**
- Water used for growing sprouts
- **Harvesting, packing, and holding activities** (including water used for washing or cooling) harvested produce
- Water used to **prevent dehydration** of covered produce



Adequate

Adequate means that which is needed to accomplish the intended purpose in keeping with:

- Good public health practice.
- Adequately reduce microorganisms of public health significance means reduce the presence of such microorganisms to an extent sufficient to prevent illness.



Direct Water Application

Direct water application method means using agricultural water in a manner whereby the water is intended to, or is likely to, contact covered produce or food contact surfaces during use of the water.



Ground and Surface Water

- **Ground water** means the supply of fresh water found beneath the Earth's surface, usually in aquifers, which supply wells and springs.
- **Surface water** refers to water as found in "streams," "oceans," "rivers," "lakes," and "bodies" of water "forming geographical features." All of these terms connote continuously present, fixed bodies of water, not ordinarily dry channels through which water occasionally or intermittently flows.



Requirements for Agricultural Water

§ 112.42 What requirements apply to my agricultural water sources, water distribution system, and pooling of water?

- (a) At the beginning of a growing season, as appropriate, but at least once annually, you **must inspect all of your agricultural water systems**, to the extent they are under your control
- Including: water sources, water distribution systems, facilities, and equipment,

Then 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 your covered produce, practices, and
- conditions, including consideration of the following:



Agricultural Water – Water Quality

- 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.
- Depends on whether water is likely to come in contact with raw produce item or food contact surface or not.



Agricultural Water Quality for Direct Product Contact

- **No detectable generic *E. coli*** are allowed for certain uses of agricultural water if it is reasonably likely 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.
- Water use must be immediately discontinued and corrective actions taken before re-use for any of these purposes if generic *E. coli* is detected
- Untreated surface water for any of these purposes is prohibited



Agricultural Water Quality – Water Used During Growing Activities

- Numerical criteria 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). Roughly the level at which 90% of the samples are below the value.



Agricultural Water- Water Management

- Goal is to understand microbial quality of agricultural water over time and determine long-term strategy for use of water sources

Here is a site for calculating these values:

ucfoodsafety.ucdavis.edu/files/229168.xlsx

- GM and STV account for variability in the data and allow for occasional high readings of generic *E. coli*, making it much less likely that a farm will have to discontinue use of its water source due to small fluctuations in water quality.



Agricultural Water Quality – Die Off Provisions

If the water does not meet 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 to meet the criteria and be able to use the water on their crops.

These options include:

- 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. (0.5 log per day – every day after you irrigate, roughly 67% of the microbes in the water would die on the surface of the produce from exposure to sunlight, dehydration). You do not need to test the produce to show that die off rate is accurate, estimation of the die off is enough, but you will need to get below the cut off and keep records of your calculation and length of time you waited between irrigation and harvest.
- You must be able to meet the criteria for die off **within 4 days**
- Allow 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.
- Treat the water.



Treating Agricultural Water

- (1) Any method you use to treat agricultural water (such as with physical treatment, including using a pesticide device as defined by the U.S. Environmental Protection Agency (EPA); **EPA-registered antimicrobial pesticide product**; or **other suitable method**) must be effective to make the water safe and of adequate sanitary quality for its intended use and/or meet the relevant microbial quality (§ 112.440)
- (2) Treatment of agricultural water (delivery system) must ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use.

You must monitor any treatment of agricultural water at adequate frequency to ensure it is consistently safe and of adequate sanitary quality for its intended use.



If You Suspect Water Quality Has Dropped

Re-inspect the entire affected agricultural water system to the extent it is under your control

- Identify any conditions reasonably likely to introduce hazards into or onto covered produce or food contact surfaces
- Make necessary changes, and take adequate measures to determine if your changes were effective
- Ensure that your agricultural water meets the microbial quality criteria in § 112.44(b) (or any alternative microbial criteria, if applicable)
- Resample water and update water quality profile (GM and STV)



Agricultural Water Testing

- **Testing:** Testing frequency depends on 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)
- FDA requires farms to do an initial survey, with at least 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 (the “microbial water quality profile”) and determine if the water meets the required microbial quality criteria.
- After the initial survey, an **annual survey** of at least 5 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** to confirm that the water is safe



Agricultural Water Testing- Untreated Ground Water

- For **untreated ground water** directly applied to growing produce (other than sprouts)
- FDA requires farms to do an **initial survey, with at least 4 samples**, collected as close as is practicable to harvest, during the growing season or over a period of one year.
- Calculate the GM and STV and determine if the water meets the required microbial quality criteria.
- Annual survey of a **at least 1 sample** per year is required to update the calculations of GM and STV.
- The new sample, plus the previous most recent 3 samples, create a rolling dataset of 4 samples to confirm that the water is still used appropriately by recalculating the GM and STV.



Agricultural Water Testing

- If the 4 initial sample results show no detectable generic *E. coli* , testing can be done once annually thereafter, using a minimum of one sample.
- If any annual test fails, farms must resume testing at least 4 times per growing season or year



Agricultural Water Testing – Municipal Supplies

- No requirement to test agricultural water from public water systems
- Must have Public Water System results or certificates of compliance demonstrating that the water meets relevant requirements)
- Or that the water is treated in compliance with the rule's treatment requirements.



Who Does Water Testing?

- You can perform tests (§ 112.46)
- A person or entity acting on your behalf
- Data collected by a third party or parties, provided the water source(s) sampled by the third party or parties adequately represent your agricultural water source(s)
- Agricultural water samples must be aseptically collected and tested using an approved (§ 112.151).



Water Quality During Processing and Handling

- You must manage the water as necessary
- Establish and follow water-change schedules for re-circulated water (to avoid contamination from soil etc)
- You must **visually monitor** the quality of water that you use during harvest, packing, and holding activities for covered produce (for example, water used for washing covered produce in dump tanks, flumes, or wash tanks, and water used for cooling covered produce in hydrocoolers) for **buildup of organic material** (such as soil and plant debris)
- You must **maintain and monitor the temperature** of water at a temperature appropriate for the commodity and operation (considering the time and depth of submersion) - adequate to minimize the potential for infiltration of microorganisms of public health significance into covered produce



Alternate to Water Standards and Testing Requirements

If you can meet the water safety requirements (§ 112.12), you may use one or more of the following alternatives:

- (a) An alternative microbial quality criterion (or criteria) using an appropriate indicator of fecal contamination, instead of *E. coli* § 112.44(b);
- (b) An alternative microbial die-off rate and an accompanying maximum time interval, in place of the microbial die-off rate and maximum time interval set in § 112.45(b)(1)(i);
- (c) An alternative minimum number of samples used in the initial survey for an untreated surface water source, in lieu of the minimum number of samples required under § 112.46(b)(1)(i)(A);
- (d) An alternative minimum number of samples used in the annual survey for an untreated surface water source, instead of the minimum number specified (§ 112.46(b)(2)(i)(A)).



Necessary Records

1. Findings of agricultural water system inspection (§ 112.42(a))
2. Results of all analytical tests conducted on agricultural water
3. Scientific data or information you rely on to support the adequacy of a method (§ 112.43(a)(1)&(2))
4. Documentation of the results of water treatment monitoring (§ 112.43(b))
5. Scientific data to support the microbial die-off or removal rate(s) used to determine the time interval (in days) between harvest and end of storage, including other activities such as commercial washing, as applicable, used to achieve the calculated log reduction of generic *Escherichia coli* (*E. coli*), in accordance with § 112.45(b)(1)(ii);



Necessary Records

6. Documentation of actions (§ 112.45) with respect to time interval or (calculated) log reduction (§ 112.45(b)(1)(i) and/or (ii)). Documentation must include the specific time interval or log reduction applied, how the time interval or log reduction was determined, and the dates of corresponding activities such as the dates of last irrigation and harvest, the dates of harvest and end of storage, and/or the dates of activities such as commercial washing)
7. Annual documentation of the results or certificates of compliance from a public water system required (§ 112.46(a)(1) or (2)) if applicable
8. Scientific data or information you rely on to support any alternative that you establish and use (§ 112.49)
9. Any analytical methods used instead of the one the FDA specifies (§ 112.151(a))



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)



Exemptions

- Produce 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
- Produce that is to be commercially processed to adequately reduces the presence of microorganisms of public health significance (under certain conditions)
- Qualified exemption and modified requirements for certain farms.



Produce Exempt from Produce Safety Rule

The produce receives **commercial processing** that **adequately reduces the presence of microorganisms of public health significance.**

Examples of commercial processing are thermal processing (juice and acidified foods), treating with **a validated process** to eliminate spore-forming microorganisms (such as processing to produce tomato paste or shelf-stable tomatoes),

and processing such as refining, distilling, or otherwise manufacturing/processing produce into products such as sugar, oil, spirits, wine, beer or similar products; and



Products Exempt from Produce Safety Rule

(3) You must either:

- (i) Obtain written assurance annually from the customer that commercially processes produce – that they have established and are following procedures (identified in the written assurance) to adequately reduce the presence of microorganisms of public health significance; or



Products Exempt from Produce Safety Rule – Commercially Processed to Kill Microbes by Your Customer

- (ii) Annually obtain written assurance from your customer that an entity in the distribution chain **subsequent to the customer** will perform commercial processing and that the customer:
- (A) Will disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance”; and



Products Exempt from Produce Safety Rule

(2) You must **disclose in documents accompanying the produce**, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance;” and



Covered Produce

- Covered produce means produce that is subject to the requirements of this part in
- accordance with §§ 112.1 and 112.2. The term “covered produce” refers to the harvestable or
- harvested part of the crop



Covered Activity

Covered activity means growing, harvesting, packing, or holding covered produce on a farm. Covered activity includes manufacturing/processing of covered produce on a farm, but only to the extent that such activities are performed on raw agricultural commodities and only to the extent that such activities are within the meaning of “farm” as defined in this chapter.

Providing, acting consistently with, and documenting actions taken in compliance with written assurances as described in § 112.2(b) are also covered activities. This part does not apply to activities of a facility that are subject to part 110 of this chapter.



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- farm. Covered activity includes manufacturing/processing of covered produce on a farm, but
- only to the extent that such activities are performed on raw agricultural commodities and only to
- the extent that such activities are within the meaning of “farm” as defined in this chapter.
- Providing, acting consistently with, and documenting actions taken in compliance with written
- assurances as described in § 112.2(b) are also covered activities. This part does not apply to
- activities of a facility that are subject to part 110 of this chapter.



Products Exempt from Produce Safety Rule- Commercially Processed to Kill Microbes by Your Customer

(B) Will only sell to another entity that agrees, in writing, it will either:

- (1) **Follow procedures** (identified in a written assurance) that adequately reduces the presence of microorganisms of public health significance; or
- (2) **Obtain a similar written assurance from its customer** that the produce will be commercially processed. A disclosure in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance”; and



Qualified Exemption

- 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.



Loosing Qualified Exemption

- 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.



Qualifications and training for personnel who handle (contact) covered produce or food contact surfaces

(a) 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.**

(b) 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.



Need PCQI Training?

- Next on line class (FSPCA approved) FDA recognized course. University certificate issued and AFDO certificate available.
- Starts every nine weeks – next class is March 20, May 24, August 10, etc
- <https://online.wsu.edu/courses/foodscience/reg.aspx>
- Or email me at rasco@wsu.edu
- We will be offering Produce Safety Training when the curriculum is released this fall.





