



# FSMA: Are you in or are you out?



**PSA Supplemental  
Activity**



## 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

**X** 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

**X** 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

**X** This product is NOT covered by this rule.

NO

**Is your produce for personal/on-farm consumption?**

Section 112.2(a)(2)

YES

**X** 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")?**

Section 112.2(b)

YES

**C** 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

**C** 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 112.5 and 112.7.

NO

**YOU ARE COVERED BY THIS RULE.**



## 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





## 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 is not covered.





## 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





## 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**





# 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





# 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.



# Common Local Violations or Red Flags

- **Incomplete required documents:** all required documents need farm name, location, date, time, supervisor initials & date – use a template to avoid missing required items
- **Inadequate ability to sanitize:**
  - Strawberry growers: tape on cart handles
  - Raw veggie knife stored in leather sheath
  - Lack of clarity between cleaning and sanitizing
- **Potential for contamination:** putting harvest cart on top of bed - boots and equipment that have been in furrow may be contaminated – this same soil will be on cart wheels
- **Inadequate hand washing:** not a common violation, but when found, it is a big deal
- Harvesters required to inspect packaging materials for potential contamination or concerns
- ❖ *Inspectors do consider awareness and degree of intentionality*







# Agricultural Water

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Identifying Hazards and Assessing Risks



# What is “Agricultural Water”?



Water used on covered produce that is intended to, or likely to, contact covered produce or food contact surfaces







# Pre-Harvest Agricultural Water Requirements Have Changed

- FDA published a revision to Subpart E – Agricultural Water on May 06, 2024 (QR code and URL below)
  - <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-pre-harvest-agricultural-water>
- The revised Subpart E moves from reliance on testing pre-harvest water for decision making to an agricultural water assessment of the whole water system
- The expectation is that each grower understand their water quality and how their water management practices minimize risks to the crops they grow.
  - Should be prepared to explain during inspectional visits





# FDA Revised Subpart E Compliance Dates

- For pre-harvest agricultural water requirements for covered produce other than sprouts (Module 5: Part I)

Business Size	<u>Pre-harvest</u> Agricultural Water Related Compliance Dates
All other businesses (>\$500K)	April 7, 2025
Small businesses (>\$250K-500K)	April 6, 2026
Very small businesses (>\$25K-250K)	April 5, 2027



# Agricultural Water Assessment: Outcomes follow a risk-based tiered approach

*If...*

*Then...*

Ag water not safe or not of adequate sanitary quality	Immediately discontinue use <b>AND</b> Take corrective measure(s) before use at pre-harvest
Condition(s) on adjacent or nearby land uses pose risk related to animal activity, BSAAO, or human waste	Implement mitigation measures promptly, and no later than the same growing season
Other conditions that may introduce known or reasonably foreseeable hazards, not related to animal activity, BSAAO, or human waste on adjacent or nearby lands	Implement mitigation measures as soon as practicable, and no later than the following year <b>OR</b> Test water as part of the agricultural water assessment and implement measures as needed
No known or reasonably foreseeable hazards for which mitigation is necessary	Inspect and maintain water system regularly and at least once a year





# Agricultural Water Assessment: Corrective and Mitigation Measures

## Corrective measures

- Re-inspecting the entire affected agricultural water system under the farm's control and, among other steps, making necessary changes
- OR**
- Treating the water in accordance with the standards in FSMA PSR

## Mitigation measures

- Making necessary changes such as repairs
- Increasing time interval between last direct application and harvest (microbial die-off)
- Increasing time interval between harvest and end of storage (microbial die-off)
- Other activities that result in die-off or removal
- Changing water application method
- Treating water (PSR standards)
- Taking alternative mitigation measures supported by scientific information



# Probability of Contamination



**Public Water Supply**



Treated

**Ground Water**



**Surface Water**



Open to  
Environment





What hazards might impact your ag water?







Surrounding land  
use – What are your  
neighbors up to?





# Methods of Irrigation & Time Interval Before Harvest

- Overhead (sprinkler)
  - Higher risk: A direct water application method resulting in contact with produce
- Flood (surface, furrow)
  - May avoid direct contact with produce
  - Consider risk of contact with contaminated soil during harvest or from splash
- Drip (trickle, subsurface, micro, under canopy)
  - Lower risk: Produce generally not in direct contact (except root crops), reduces foliar diseases, improves water use efficiency
- **Time interval between last direct water application and harvest**







## Crop Characteristics

- Cup or bowl shape that can harbor pathogens
- Smooth vs. Rough crop surface
- Likelihood of ag water touching the harvestable portion of the crop





# Environmental Conditions

- Air Temperature
- Relative Humidity
- Solar Radiation
- Rainfall Duration
- Rainfall Quantity
- Rainfall Intensity



# <https://agwaterassessment.fda.gov/>



Site Navigation



## Welcome to the Agricultural Water Assessment Builder!

Thank you for choosing to use the Agricultural Water Assessment Builder. The Agricultural Water Assessment Builder v. 2.0 is a user-friendly tool designed to help farms understand the requirements for an agricultural water assessment in the "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water" final rule (agricultural water final rule). Relevant definitions and resources can be viewed by clicking the icon next to the title of this page.

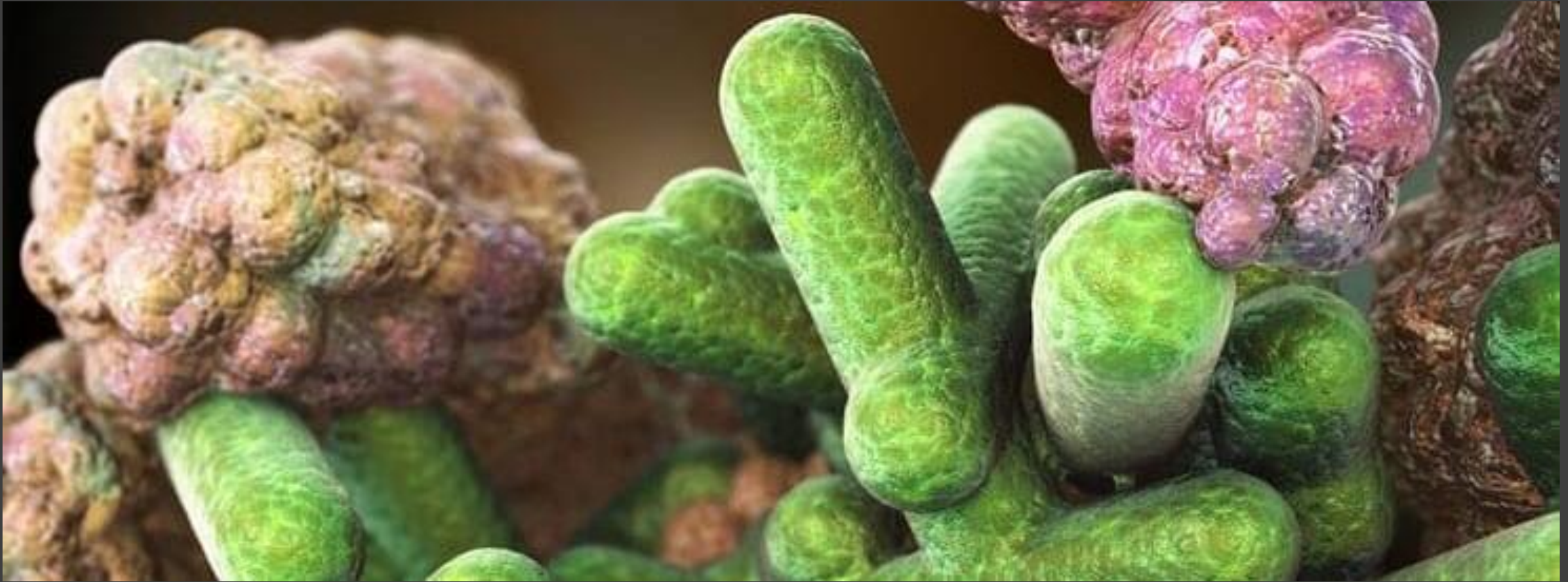
We welcome feedback on v. 2.0 of this optional tool, such as suggestions related to the tool's functionality and useability. Feedback on the tool can be given by selecting the contact us link in the action menu in the upper right corner of the site.

Use of this tool is not required by law (see legal disclaimer). FDA expects this tool to supplement and not replace other education, training, and experience that is needed to understand and implement the requirements of the rule. Although the content of the Agricultural Water Assessment Builder is consistent with the FDA's existing regulations, use of this tool does not mean that farms' agricultural water assessments, corrective or mitigation measures, or other food safety procedures are approved by FDA or comply with FDA requirements.

**The information entered into this page will not be shared with FDA and will not be saved. If you need to pause while entering information, we recommend that you export a copy of your data and save it to your local machine.** Once the document is saved, you may resume at a later time, and upload the file to begin from where you paused. Once you have reached the end of this tool, you will be given the opportunity to print out a summary of the information entered. Remember, the data that is entered here is not saved unless your export a file to save on your computer.

**Legal disclaimer:** Use of the Agricultural Water Assessment Builder v. 2.0 does not constitute FDA approval of an agricultural water assessment or guarantee compliance with FDA's requirements. FDA has taken all reasonable precautions in creating the Agricultural Water Assessment Builder v. 2.0. However, FDA is not responsible for errors, omissions or deficiencies regarding the tool. The Agricultural Water Assessment Builder v. 2.0 is available "as is" and without warranties of any kind, either expressed or implied, including, but not limited to, warranties of performance, merchantability, and fitness for a particular purpose. FDA is not making a commitment in any way to regularly update the tool. Responsibility for the interpretation and use of the Agricultural Water Assessment Builder v. 2.0 lies solely with the user. Third parties' use of or acknowledgment of the tool does not in any way represent that FDA endorses such third parties or expresses any opinion with respect to their statements.

CONTINUE



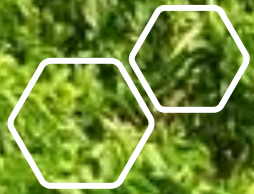
## Assessing Risk – Ag Water Activity

- High (RED)
- Medium (YELLOW)
- Low (GREEN)
- Don't know, or need more information (BLUE)





















































**cdfa**  
**PRODUCE**  
**SAFETY**  
**PROGRAM**

**Schedule a free  
On-Farm  
Readiness  
Review (OFRR)  
today!**

**1**

## **EDUCATE**

The California Department of Food and Agriculture is committed to educating California produce farmers on how to follow the Produce Safety Rule >>

**2**

## **IMPLEMENT**

All required food safety practices under the Produce Safety Rule must be followed on California produce farms >>

**3**

## **REGULATE**

The Produce Safety Rule is now mandatory. Any produce farm found to be out of compliance may be subject to regulatory action >>