



**COLORADO**  
Department of Agriculture

# *Produce Safety Rule*

# What Will Be Covered

- Background, Basics & Goals of the Program
- Terminology
- Key Subparts
- Registration
- Inspections
- Exemptions & Enforcement Discretion
- On-Farm Readiness and Technical Assistance
- Questions



# PSR Basics

- Covers activities such as **growing, harvesting, packing and holding covered produce**
  - Subpart A 112.2 (a)(1) is an all inclusive list of produce not covered by the rule
    - This list includes items identified as not commonly consumed raw
    - Wine Grapes and Hops are not included on the list and are covered by the rule
- Code of Federal Regulations Subpart A 112.1 (a), (b)(1) and (2).
  - Subpart A 112.1(b)(1) is a non-exhaustive list of covered produce.

# Background

- 2011 Food Safety Modernization Act (FSMA) was passed federally
  - Included the Produce Safety Rule (PSR)
  - It established for the first time, science based preventative strategies to reduce food borne pathogens risks
  - The rule focuses on risk identification and mitigation of those risks
- Supported by industry, in 2019 the Legislature passed HB19-114 authorizing a state program consistent with the federal law
  - Program oversight and inspections now conducted by staff who understand CO agriculture





# Goal of the Produce Safety Program

- Be an extra set of eyes for our produce farming community to protect them from the consequences of an unintended outbreak
- Look for potential sources and pathways of pathogens of human health concern (i.e. E.coli, Listeria, Salmonella, Cyclosporidium) that may cause a foodborne illness
- Improve Food Safety Culture



# Produce Safety Rule (PSR) Language

- Food Sales vs Produce Sales
- Covered Produce/Farm/Activity
- Holding( If you use a cooler you are Holding)
- Non Covered Produce
- BSAAO (Biological Soil Amendments of Animal Origin)
- Qualified Exempt
- Micro Exempt
- Commercial Exempt
- Enforcement Discretion
- Produce Safety Alliance (PSA) Grower training
- Food Safety Audits & Third Party Audit
- OFRR



# Key Subparts of the PSR

- Subpart C: Personnel Requirements and Training
- Subpart D: Health and Hygiene (Sick employees and restrooms)
- Subpart E: Ag Water - Is the water safe for its intended use
  - New annual written risk assessment for harvest and postharvest water
- Subpart F: Biological Soil Amendments of Animal Origin (BSAAO) (Proper treatment and use of compost)
- Subpart I - Domestic and Wild Animals
- Subpart K: Growing, Harvesting, Packing and Holding Activities (Production practices)
- Subpart L: Equipment, Tools, Buildings, and Sanitation (Cleaning, sanitizing and facility requirements)
- Subpart O: Records documenting what you are doing
  - Records do not prevent an outbreak, demonstrate your efforts in the event of an outbreak and help protect your business in the event of an outbreak



# What is Agricultural Water?

- Water that will be in direct contact with the harvestable portion of the crop
  - That would begin at the flowering stage in the production cycle
- It must be safe and of adequate sanitary quality for its intended use
  - This includes water that employees use to wash their hands
- Even if you do not have Ag Water do you have a contingency plan if water touches your produce when it is not supposed to?





# Implementation of Subpart E

- On **January 26, 2023** enforcement of the Ag Water rule for harvest and post harvest for Large Farms took effect. Enforcement Discretion for Small Farms ends on **January 26, 2024** and on **January 26, 2025** for Very Small farms.
- After Enforcement Discretion ends an inspector will assess your farm for Agricultural Water compliance.
  - An educate while we regulate approach will be taken and only observations where imminent threats exist will be enforced at this time.



# Registration

- Required on an annual basis for all farms, including Covered Farms, Qualified Exempt, Commercial Exempt and Discretionary Exempt
  - This includes Wine Grapes and Hop growers
- This is a self reporting process that takes less than 10 minutes and does not require uploading any documents
- Why Registration is important to you
  - Access to our monthly newsletter with regulatory updates, industry news and grant opportunities for produce growers
  - Allows us to quickly reach impacted parties in the event of an outbreak
  - Allows us to accurately report aggregate data on Colorado's produce community
    - Secures FDA funding to insure this remains a state program

# Micro Exempt

- Micro Exempt
  - A farm's 3 year sales average is below \$30,509 (adjusted for inflation) **\$25K**
  - Any farm that is Micro Exempt does not fall under the rule
  - We encourage farms to be aware of the rule, the principles of food safety the Rule supports and what compliance would look like
  - While not required, we encourage participation in PSA Grower Training to better understand those principles and compliance
  - Micro Exempt growers who register with the program receive our PSR monthly newsletter which includes regulatory updates, industry information, conferences, and grant opportunities that may apply to the produce industry.



# Qualified Exempt

- Qualified Exempt
  - Record verification and attestation to QE status is required annually.
  - Annual **food sales** below **\$500K** adjusted for inflation (\$610,182)
  - More than 50% of the food is sold to qualified end users
    - Consumer, restaurant, or retail stores in same state or within 275 miles of their farm
    - Does not include wholesale distribution centers
  - This exemption does not modify the records requirements under Subpart O but does modify your field inspection and PSA Grower training requirements.
  - An inspector can perform QE verification inspections. If a farm can not verify QE status a full inspection may occur.

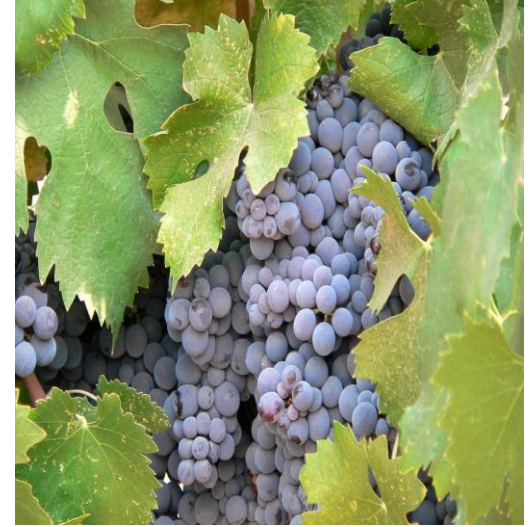


# Commercial Exempt

- All produce is intended for commercial processing that adequately reduces pathogens ( ie a “kill step” )
- Winemaking is considered a kill step
- Records on an annual basis need to show:
  - You have established and are following procedures (in the written assurance) that adequately reduce the presence of microorganisms of public health significance
  - If you are providing the written assurance then make sure to document the actions taken to satisfy the written assurance.
  - Show that it is all of your produce
  - We have template records that we can provide you
- If you are commercial exempt, still have to register with the program on an annual basis.
  - If we see that you only grow wine grapes and select yes on the commercial exempt question we will update our database accordingly.

# Enforcement Discretion

- Wine Grapes and Hops are under Enforcement Discretion
  - FDA recognizes that these specific commodities have unique post production practices that reduce the risk of foodborne illness (Wine making and brewing)
  - Currently Enforcement Discretion for these crops specifically has modified requirements.
    - You must register with the program annually
    - You must have documentation showing ALL grapes or hops have been used for Winemaking or brewing
    - Your production location would not be subject to inspection



# Wine Grapes & Other Crops

- If you grow wine grapes and other covered crops (i.e Peaches, Cherries, Apples, Pears) you are covered by the Rule.
  - You must register annually with the program, take a PSA Grower Training and your covered crops may be eligible for inspection (Qualified Exemption discussed earlier may apply)
  - We would not inspect the vineyard
- If you grow Wine Grapes and no other covered crops you are covered by the rule with modified requirements
  - You must register with the program annually
  - You must be able to provide a certificate stating that ALL grapes have been sold or processed for wine production
  
- We have a flow chart available to help determine your farm's specific requirements for compliance.



# Before an Inspection

- A minimum of 20% of our covered farms are inspected each year.
  - This is about 20-25 farms a year.
- You will receive an email in April/May with your notice of inspection during the next year.
  - An inspector will reach out by phone or email to set up an inspection. If there is no response an unannounced inspection will occur.
  - The focus will be on your harvest period, but the inspector will want to see packing and holding if applicable.





# Initial Inspections

- Educational in Nature (Educate while you Regulate)
  - All significant observations are documented including imminent threats to human health.
    - This does not change the educational nature of an initial inspection
    - Issues found will be discussed at the close of the inspection and documented on the Summary Report that will sent to the farm.
      - This includes issues that are resolved during the inspection and any follow up that is needed.
  - The information collected during the inspection, along with OFRR data which is not shared with inspectors, is used by the program to identify areas where added education and outreach may help the industry improve their food safety practices.



# Routine Inspections

- More regulatory approach (Regulate and Educate)
  - Focus is more on improving compliance and how you are assessing your risk on your operation in relation to the rule.
    - Anything of note from previous inspections will be checked to make sure that they were addressed.
  - Observations found will be noted and marked if needing further regulatory action or follow up from the farm.
  - There is more focus on the follow up and timelines for anything that is found as non-compliant.



# Other Inspections

- Follow Up Inspections may be conducted to verify observations found during an Initial or Routine inspection has been corrected
- For Cause inspection may be conducted when an outbreak occurs or a complaint is received
- Qualified Exempt Verification inspections may be conducted to confirm records are sufficient for a farm to meet the exemption requirements



# After an Inspection

- An inspection summary report will be sent to you with everything that was discussed during the inspection.
- Follow ups after the inspection may include an additional inspection, supplemental documentation that the issue has been addressed, or a request for a written Corrective Action Plan from the farm.
- All significant finds will be documented
  - This is a change from the past where only imminent threats were documented





# On Farm Readiness Reviews (OFRR) & Technical Assistance

- This is a free service offered by CDA to farms to prepare for their initial inspection.
  - Educational in nature
  - No records or notes are kept
  - Conducted near harvest to review practices the inspector will review
- On Farm Technical Assistance
  - Similar to an OFRR more focused on a single or select part of the Rule
  - Available any time including after an initial inspection
- Resource materials would be sent in a follow up email
- For more information or to schedule an OFRR or Technical Assistance support contact Sarah Musick



## Contact Information

- If you have any questions about the program, please reach out!
  - Sarah Musick, Produce Safety Coordinator  
303-869-9282 [sarah.musick@state.co.us](mailto:sarah.musick@state.co.us)
  - Duane Sinning, Program Manager 303-869-9284 [duane.sinning@state.co.us](mailto:duane.sinning@state.co.us)



Questions?



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