



Education • Collaboration • Regulation

# PRODUCE SAFETY UPDATES

Anna Wicks



# Agenda

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Overview of the Produce Safety Rule

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Regulatory Authority and Changes

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Registration and Exemption Application Process

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Exemption Analysis Tool

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Water Rule Updates

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Training and Outreach Opportunities

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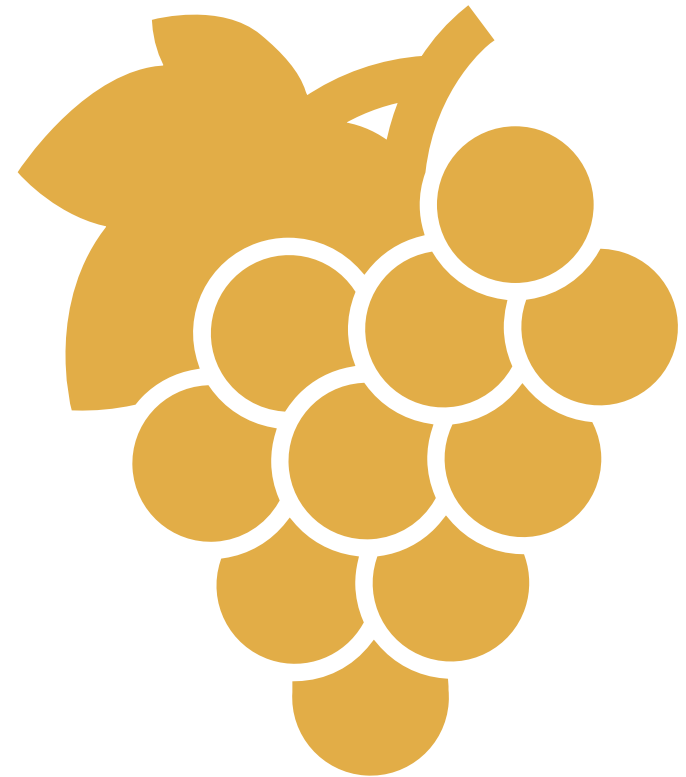
Third-Party Cost Share Updates

# Produce Safety Rule 101

## The Basics

- Went into effect January 26, 2016
- 1 of 7 rules under the Food Safety Modernization Act
- The Produce Safety 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.
- First time there have been regulatory inspections on farms
- Covered Farms Include: Growers who produce more than \$25,000 annually of generally consumed raw produce

*Inspections have started for all farms covered under this regulation.*



# Produce Safety Authority in DE

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## Primary authority: FDA

- Use FDA forms and procedures

## Secondary Authority: DE Admin Code 302: Produce Safety Regulations

- Regulations went into effect in June 2019 and amended in August 2021
- Establish:
  - Authority to operate in DE under both FDA and State Authority
  - Inspections, Record Requests and Review
  - Mandatory Registration
  - Violation/Hearing Procedures and Penalties

# Then and Now: Regulation Amendments

**2019**

DDA will require that all farms within Delaware that **grow** produce register with the Department of Agriculture



**2021**

DDA will require that all farms within Delaware that grow, *harvest, pack, or hold produce intended for human consumption and for sale*, register with the Department of Agriculture.

Registration Deadline: April 30<sup>th</sup> (Annually)

Registration is mandatory regardless of exemption status

Online Registration Portal COMING SOON

# Online Registration Portal

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New way to submit new registration, update existing information and apply for exemptions



## Benefits:

- Automatic email communications (reminders, updates, etc)
- Provides option to fill out forms by paper
- Allows for the attachment of supplemental materials needed for exemptions



If this is your first time here, please sign in by clicking on **My Account** button above and **Register as a New User**. You can then manage your business(s) and applications.

## Welcome to the Delaware Department of Agriculture's (DDA) Produce Safety Rule Online Portal!

This portal will serve as a way for farms/businesses operating in Delaware to submit their annual registration, update information, and apply for exemptions (if eligible). More information on registration and exemptions can be found below.

### Mandatory Registration Information

As of 2019, the Delaware Department of Agriculture has made it mandatory through State regulations ([Produce Safety Regulations 302 Del. Code. § 3.0](#)) that all farms within Delaware that grow, harvest, pack, or hold produce intended for human consumption and for sale, register with the Delaware Department of Agriculture by April 30th, annually.

This mandatory registration processes is intended to verify who is and who is not covered under the [Food Safety Modernization Act \(FSMA\): Produce Safety Rule \(21 CFR 112\)](#). This process allows us to provide valuable education, technical assistance, and compliance information to regulated farms and businesses, exclude farms that are not required to comply with the rule, and prioritize inspections.

### Exemption Information

The Delaware Department of Agriculture is also awarding exemption certifications by exemption type as outlined in the [Produce Safety Rule](#). Since farm information changes from year to

# Registration Portal Sneak Peak

# Dashboard

Back

My Account **A**

Select your business

DDA Garden, Anna Wicks ▾

**DDA Garden, Anna Wicks** - zz000017  
2320 S. DuPont Highway, Dover DE 19709

Registrations

Exemptions

Status: **Expired!**

## Applications for Registration

Options

Renew Registration

Date of Submission	Application	Status	Status Date	Actions
10/15/2021	Produce Safety Grower Registration	Application Expired	10/15/2021	

**Administrative Comments:**

- (10/15/2021) Application Expired
- (10/15/2021) Renewed
- (10/15/2021) Submitted for review
- (10/15/2021) Application started

## Previous applications

Date of Submission	Application	Status	Status Date	Actions
08/16/2021	Produce Safety Grower Registration	Application Expired	08/16/2021	

**Administrative Comments:**

- (08/16/2021) Application Expired





# Dashboard

My A

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Anna Wicks ▾

**DDA Garden, Anna Wicks** - zz000017  
2320 S. DuPont Highway, Dover DE 19709

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## Application for Produce Safety Rule Exemption

Apply for Exemption

Date Submitted	Status Date	Status	Valid Until	Certificate
10/04/2021	10/04/2021	Expired	10/04/2021	
08/16/2021	08/16/2021	Expired	08/16/2021	
08/16/2021	08/16/2021	Rejected	N/A	
Comments:	sr			



# Exemption Type Review/Recap

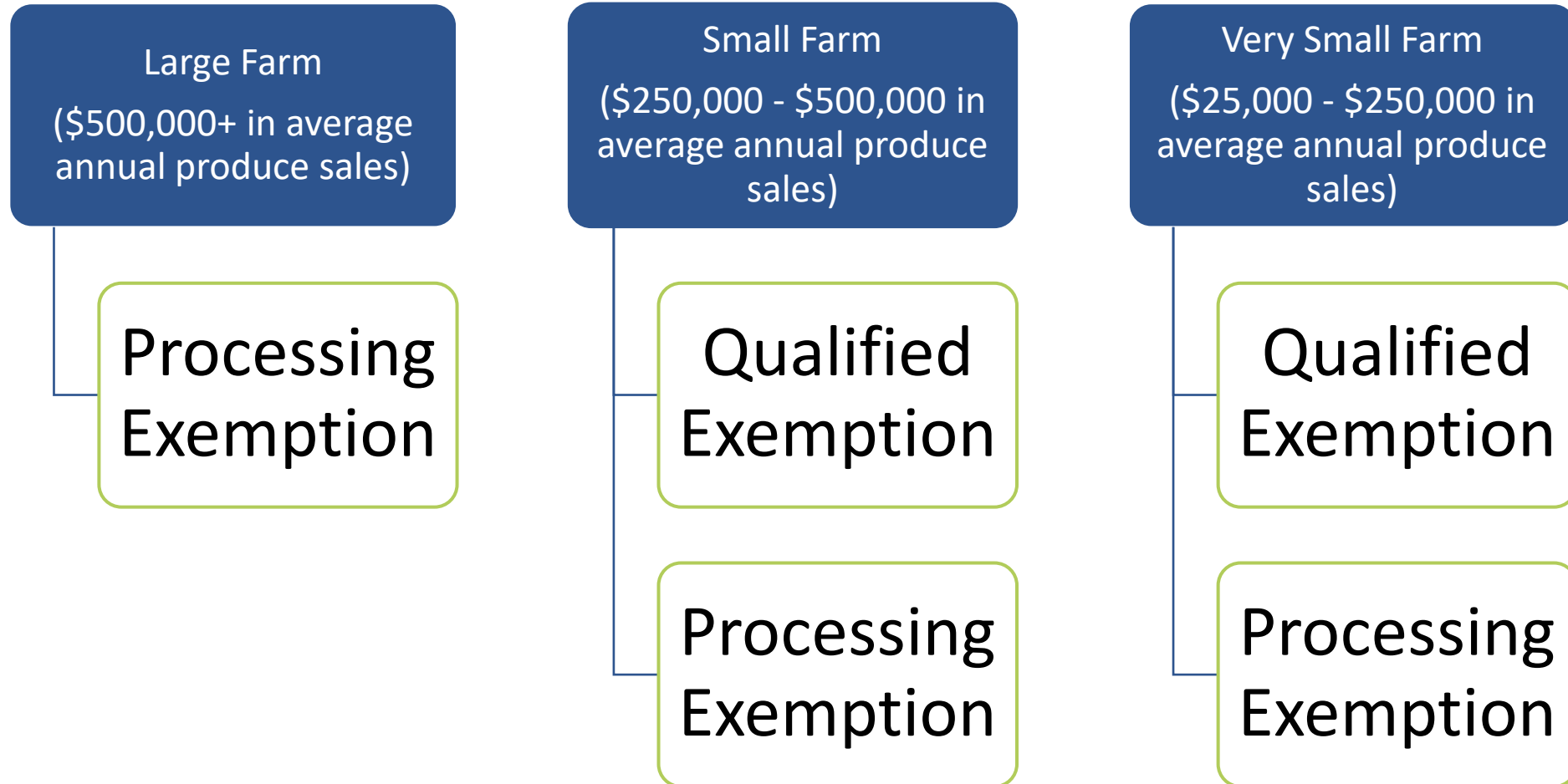
## Exempt

- Only grow produce considered Rarely Consumed Raw
- Produce is grown only for personal consumption
- Under \$25,000 in average annual produce sales

## Covered

- Large Farms (\$500,000+ in average annual produce sales)
- Small Farms (\$250,000 - \$500,000 in average annual produce sales)
- Very Small Farms (\$25,000 - \$250,000 in average annual produce sales)

# Exemptions Recap: “Covered Farms”



# Qualified Exemption

Eligible Farms: Those between \$25,000 - \$500,000 in average annual produce sales

**Both requirements  
must be met**

**A. During the previous 3-year period, annual food\* sales are less than \$500,000 (adjusted for inflation)**

**B. 51% or more of your annual food sales are to qualified end-users**

**a. Qualified End- User:**

**i. The consumer of the food**

**ii. Restaurant or Retail food establishment located in Delaware**

**iii. Restaurant or Retail Food Establishment that is located no more than 275 miles from the farm that produced the food**

\*The term "food" is defined as (1) items that could be used for food or drink for man or other animals (i.e. meat, eggs, grains), (2) chewing gum, and (3) articles used for components of any such article.

# Processing Exemption

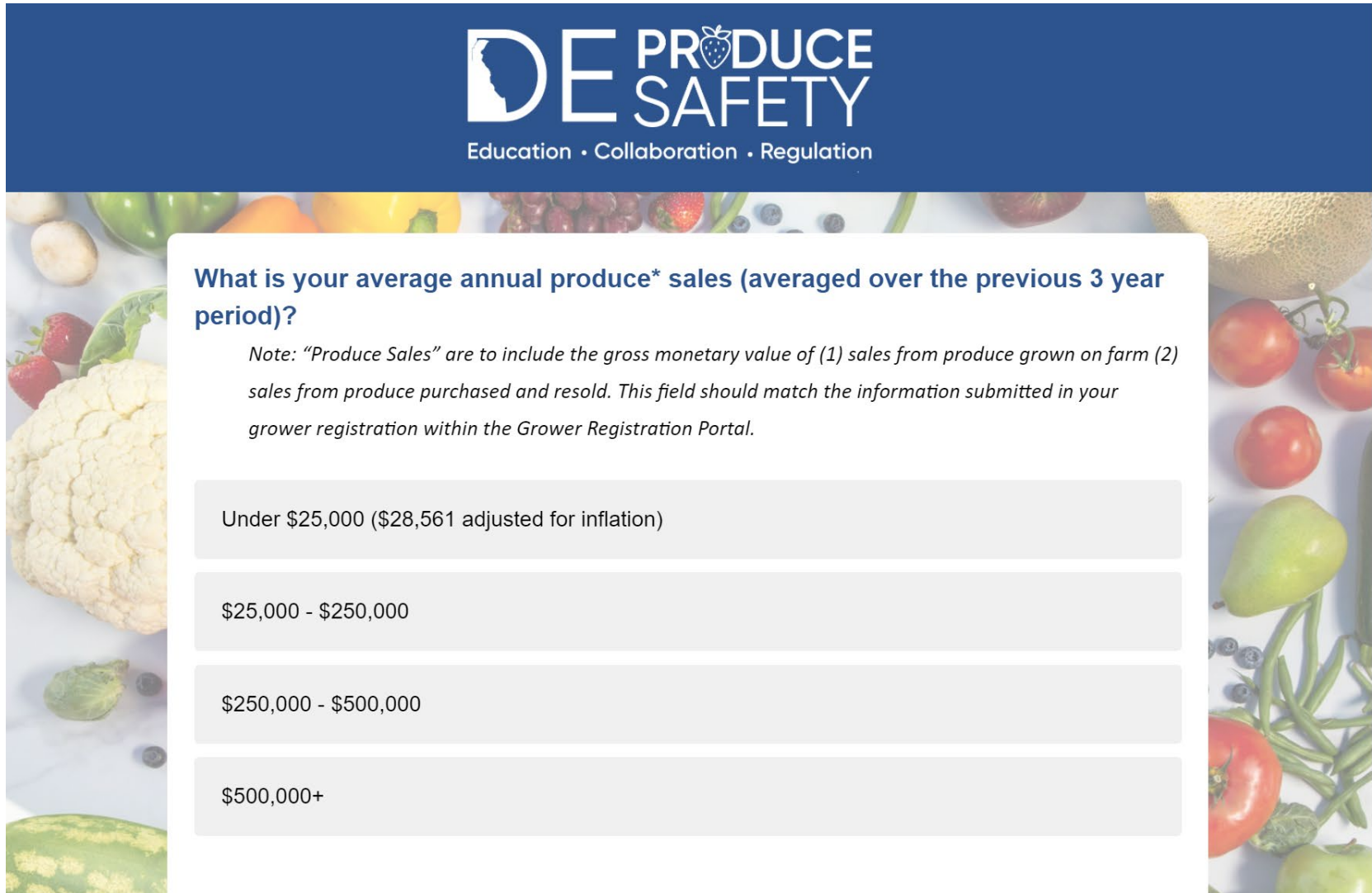
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**Covered farms are eligible when produce grown receives commercial processing that adequately reduces the presence of microorganisms of public health significance.**

- **If eligible for this exemption, you must follow the modified requirements outlined in the rule.**

# Tool: DDA Exemption Determination



**DE PRODUCE SAFETY**  
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**What is your average annual produce\* sales (averaged over the previous 3 year period)?**

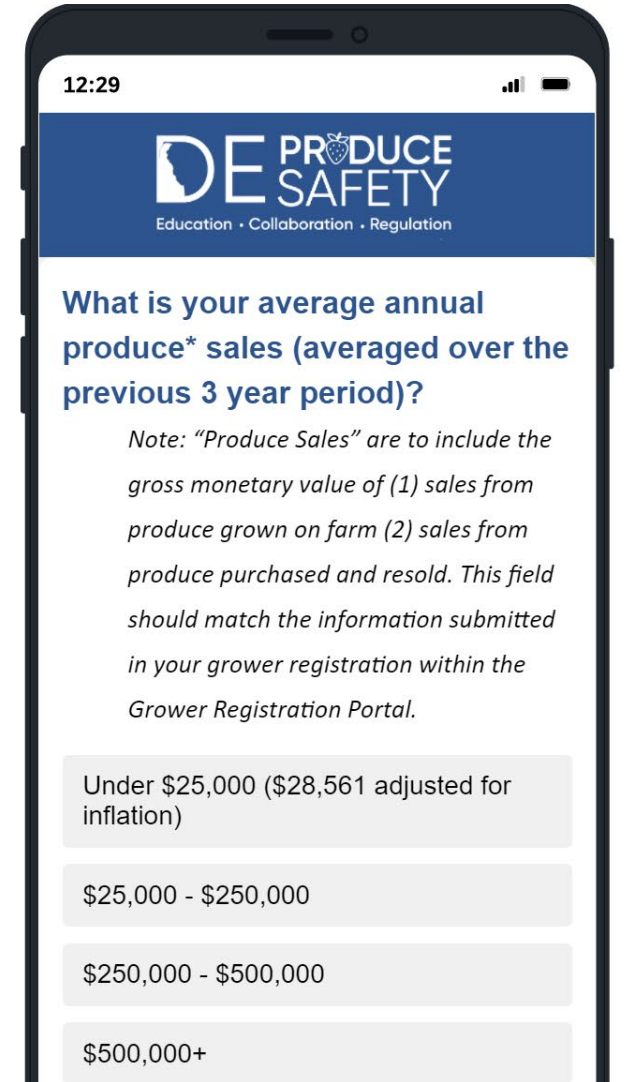
*Note: "Produce Sales" are to include the gross monetary value of (1) sales from produce grown on farm (2) sales from produce purchased and resold. This field should match the information submitted in your grower registration within the Grower Registration Portal.*

Under \$25,000 (\$28,561 adjusted for inflation)

\$25,000 - \$250,000

\$250,000 - \$500,000

\$500,000+



12:29

**DE PRODUCE SAFETY**  
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**What is your average annual produce\* sales (averaged over the previous 3 year period)?**

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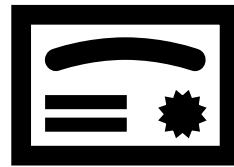
***Will be available from within the Grower Portal***

# Exemption Certificates

- Awarded for ALL eligible registered farms based on their exemption types
- Issued annually and expire April 30<sup>th</sup> of the following year
- Once approved in the registration portal, the certificate will be automatically sent.
- Deadline for exemption applications: April 30<sup>th</sup>

Need an exemption for now?

Contact us: [DE.ProduceSafety@delaware.gov](mailto:DE.ProduceSafety@delaware.gov)



No. 2021- \_\_\_\_

## Delaware Produce Safety Rule

# CERTIFICATE OF EXEMPTION

Is hereby presented to

# DDA's Farm

Expires: April 30, 2022



**Andrea Jackson**  
Food Products Inspection Administrator



DELAWARE DEPARTMENT OF  
**AGRICULTURE**



**Michael T. Scuse**  
Secretary of Agriculture

Funding for this was made possible, in part, by the Food and Drug Administration through grant PAR-16-137. The views expressed in written materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services; nor does any mention of trade names, commercial practices, or organization imply endorsement by the United States Government.



# Inspections: 2021 Recap

**In 2021, inspections started for all farms subject to the Produce Safety Rule.**





“How often  
will I be  
Inspected?”

**Fully covered farms will receive  
annual Inspections**

# 2021-2022: UD Cooperative Extension

## MOU with University of Delaware Cooperative Extension:



- **Assists on On-Farm Readiness Reviews:**
  - Confidential, free, “risk-assessment” of growing facilities to prepare farmers for what to expect during a regulatory inspection and designed to help growers mitigate potential risk areas.
  - TEAM: Dr. Gordon Johnson, Dr. Kali Kniel, Jennifer Jones, Anna Wicks, Amanda Ziegler and Andrea Jackson
  - Signup: [DE.ProduceSafety@delaware.gov](mailto:DE.ProduceSafety@delaware.gov)
- **Assists in delivering Produce Safety Alliance Grower Trainings**

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# Upcoming Training Opportunities

- Produce Safety Alliance Grower Training (PSA Training)
  - **Wednesday, February 23rd (Virtual)**
    - Registration Required (Eventbrite)
  - If covered under the Produce Safety Rule, at least one person of supervisory authority **must take** a PSA Grower Training.
  - The training is open to everyone
  - One-time, all-day course
  - Certificate awarded upon completion of course



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# Upcoming Training Opportunities

- United Fresh Listeria Workshop
  - Date TBD (Tentative: March/April)
- The Workshop itself will feature general sessions on hygienic design and sanitation best practices and environmental monitoring.
- The training will include breakout sessions, panel discussions, produce-specific case studies and much more



# Water Update: Proposed Regulations

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**NEW** FDA Proposed Regulatory Changes published December 6, 2021

- Public comment period closes April 5, 2022

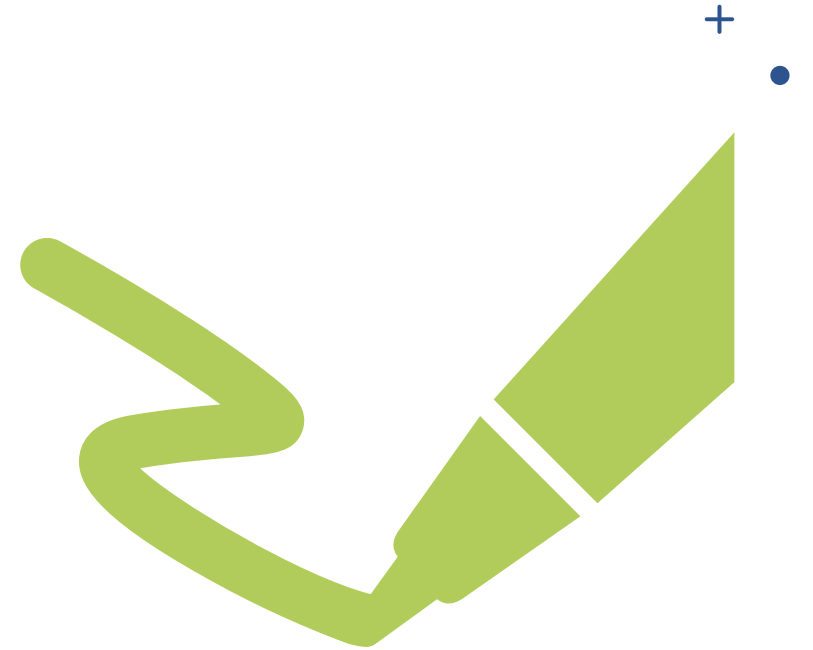
**Summary:** Removal of certain testing requirements for pre-harvest agricultural water and replacing them with requirements to conduct an annual water assessment.

- Water assessments would include an individual farm's evaluation of elements such as their water system(s), water use practices, crop characterizes, environmental conditions (like adjacent land use).
- *The elements mentioned above are not-exhaustive*

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# Public Comment Options

1. Attend an FDA Public Comment Meeting
  - Comments may be made verbally during these meetings
  - February 14th and February 25th (registration required)
2. Submit written comments on Regulations.gov
  - Docket #FDA-2021-N-0471
  - Public comments accepted through April 5<sup>th</sup>
  - FDA is looking for comments that are thoughtful and substantive, containing real life examples and solutions



*Any questions on these regulatory changes should be submitted to [AqWater@fda.hhs.gov](mailto:AqWater@fda.hhs.gov)*

# Virtual Water Rule Overview Session(s)

- January 21, 2022
  - 8:30 am – 10:00am
  - 10:30 am – noon
  - Register online -> <https://delawarewaterrulemeeting.eventbrite.com>
- The sessions will review the proposed changes of the water rule and best practices for the writing and submission of questions/public comments. There will be an open discussion period.
- These sessions will be led by Dr. Kali Kniel and Dr. Gordon Johnson



# Water: What hasn't changed

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Current agricultural water compliance dates are set to begin this month for large farms (over \$500,000 in average annual produce sales)

FDA intends to exercise Enforcement Discretion

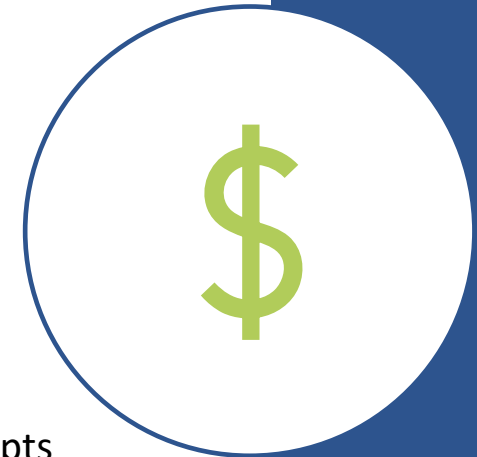
Excludes requirements for sprouts

***Recommendation: Test each water source, on your “covered” crops at least once annually.***

# Audit and Water Testing Cost-Share

Delaware Department of Agriculture Cost-Share:

- Funded through USDA Specialty Crop Block Grant funding awarded to the Delaware Department of Agriculture
  - Project End: **July 31, 2022 (Extended)**
- If you successfully pass a third-party food safety audit (USDA and/or Commercial) you are eligible for reimbursement of:
  - Up to 80% of the cost of an audit with a max reimbursement of \$1,000 per year, per farm
  - AND, 80% of the cost of associated water testing up to \$500 per year, per farm (receipts required).
  - First come-first serve



We will accept requests for reimbursement for successful audits that were completed after October 2018

# What to expect in 2022

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**Register or update  
your information by  
April 30<sup>th</sup>**

Online registration



**Apply for an  
Exemption (if  
applicable)**



**If your fully covered:  
Prepare for annual  
inspections**



**Additional Grower  
Trainings to be  
offered**

PSA Training  
United Fresh Listeria  
Workshop



**On Farm Readiness  
Reviews**



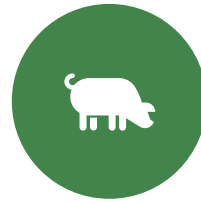
**Technical Assistance  
opportunities**

# Contact Us

DE.ProduceSafety@delaware.gov



Farm Registration



On – Farm Readiness  
Review Sign up



Produce Safety  
Alliance Grower  
Training Sign Up



Fact Sheets



Technical questions



SCBG Reimbursement  
forms

# QUESTIONS?

**Contact Information:**

Anna Wicks  
Environmental Health Specialist II  
(302) 698-4582  
[Anna.Wicks@delaware.gov](mailto:Anna.Wicks@delaware.gov)

