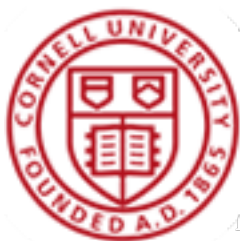


# FSMA and Produce Safety Rule Final



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Cornell Cooperative Extension  
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# Are you covered by the rule?

- If you produce and sell fresh produce and gross more than \$25,000 in produce sales, you're covered by the rule

# ***Updated: Qualified Exemptions***

- Average gross sales of food sold in previous 3 years is <\$500,000 avg.  
**AND**

- Sell to qualified end users either\*:

B. Restaurant, retail food establishment in same state or within 275 miles of where produce was grown



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# Food Safety Preventive Controls Rule

- **Do growers fall under two regulations?**
  - **PC Rule:** Focus on the manufacturing, processing, packing or holding of human food
  - Initial concern that some growers would fall into this regulation in addition to the produce rule
  - New definitions of farm, sales, holding, and packing activities have changed this



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# Farm Definitions

- A primary production farm is an operation under one management, in one general area devoted to growing crops, harvesting crops, and/or raising animals. It can pack or hold raw agricultural commodities grown by the farm, or by other farms, and perform limited manufacturing and processing activities such as drying and curing onions or cutting leaves off a head of cauliflower for packing.
- A secondary activities farm is an operation not located on the primary production farm, but it is still devoted to harvesting, packing and/or holding raw agricultural commodities. It must be majority owned by the primary production farm that supplies the majority of the raw agricultural commodities harvested, packed, or held by the secondary activities farm.

# Produce Safety Rule

In Scope

Out of Scope



In Scope,  
but Exempt

# Fruit coverage

- All fruit for fresh eating is covered
- Apples or pears for fresh cider will go through pasteurization – not covered
- Apples for hard cider – don't know, trying to find out

# Produce Rule: Areas of Focus

- Agricultural water
- Biological soil amendments
- Domesticated and wild animals
- Personnel qualifications, training, and health and hygiene
- Equipment, tools, buildings, and sanitation



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# ***Updated Exemptions***

1. Produce rarely consumed raw



2. Produce destined for 'kill-step' processing



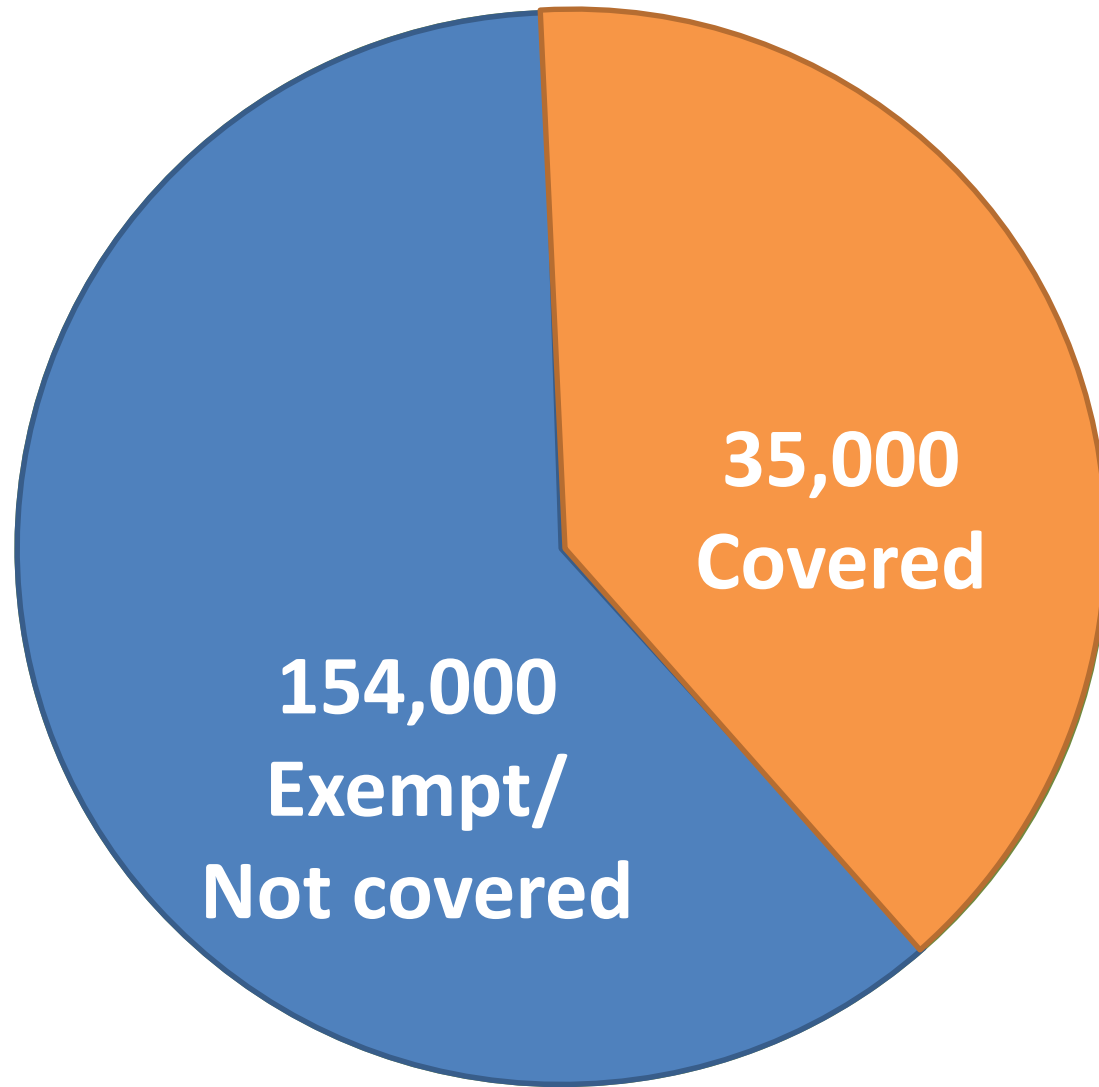
3. Produce for personal/on-farm consumption



4. Make <\$25,000 in all **produce** sales  
(3 year average)



# Produce Farms Exempt or Not Covered by the Produce Rule



# ***Updated: Proposed Exemptions***

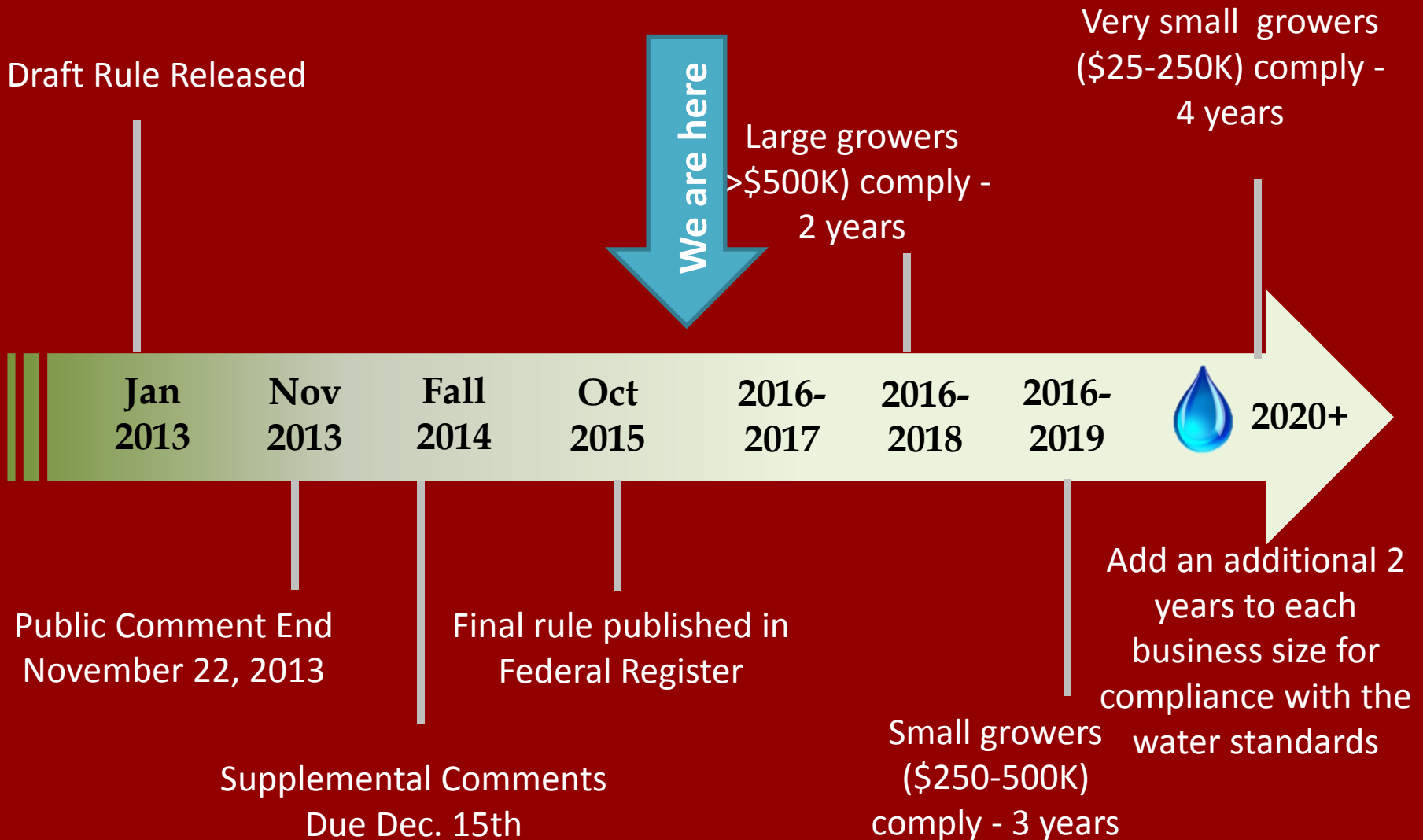
## **Application of Exemptions Based on Produce Sales**

<b>Large Business</b>	<b>&gt;\$500,000</b>
<b>Small Business</b>	<b>\$250,000-\$500,000</b>
<b>Very Small Business</b>	<b>\$25,000-\$250,000</b>
<b>Not covered</b>	<b>&lt;\$25,000</b>



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# FSMA Time Frame



# Growers may be exempt from the regulation, but not from the market place.



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# But I already have GAP certification!

- USDA or other third party certifications are not transferable
- There is a lot of overlap, but some differences
- **No matter what certifications you have, you still need to get a FSMA one day food safety training certificate**
  - More on this later
- FSMA will likely not suffice for most buyers

# ***Updated: Agricultural Water Standards & Testing Requirements***

## **Surface water requirements:**

- <126 CFU/MPN generic *E. coli* per 100 ml, geometric mean (n=5) AND a statistical threshold value of <410 CFU/MPN generic *E. coli* per 100 ml
- Testing dependent on water quality profile
- There will be an online FDA calculator...you put in your water test results and it gives you the geometric mean and STV



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# How Often Should You Test Surface Water?

Source: Surface Water	Testing Frequency
Baseline	20 samples over 2-4 years
Annually	Minimum 5 samples per year
If annual test does not support water quality profile	Current annual survey, combined with new data for a total of 20 samples





# Establishing a Water Quality Profile

## **START:**

Establish water quality profile  
Take 20 samples over two years



## **ANNUALLY:**

Take 5 samples  
Compare to established water  
quality profile



## **SAMPLING DOES MATCH PROFILE:**

Continue to test 5 samples annually



## **TEN YEAR RE-EVALUATION:**

Take 20 samples to establish a new  
water quality profile

## **SAMPLING DOES NOT MATCH PROFILE:**

Use the 5 annual samples, plus an  
additional 15 new samples (20 total)  
to establish a new profile



## **- APPLY ALTERNATE METHODS:**

- Time interval to achieve 0.5 log microbial die-off per day between water application and harvest
- Time interval between harvest and end of storage to achieve microbial die-off
- Other activities that may achieve microbial die-off, i.e. washing
- Discontinue use

# How Often Should You Test Ground & Public Water Sources?

Source	Testing Frequency
Ground	4 times during the growing season or over the period of a year
Public Water Source	Copy of test results or certificates of compliance



# Post-Harvest Water Quality Criteria

Directly contacts produce after harvest:

- No detectable generic E. coli (drinking water quality)



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# ***Updated: Soil Amendments***

- FDA has proposed deferring action on the use of raw soil amendments and has proposed to remove the 9 month application interval
- FDA will be working with USDA ARS to facilitate research, risk assessment, and incentivizing composting practices



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# What Can You Do NOW?

- Read FDA guidelines (link at end of presentation)
- Attend a Good Agricultural Practices workshop
- Write a farm food safety plan
  - Start with basic risk assessment
  - Prioritize practices to reduce risks
- Stay up to date with the regulation and educational opportunities

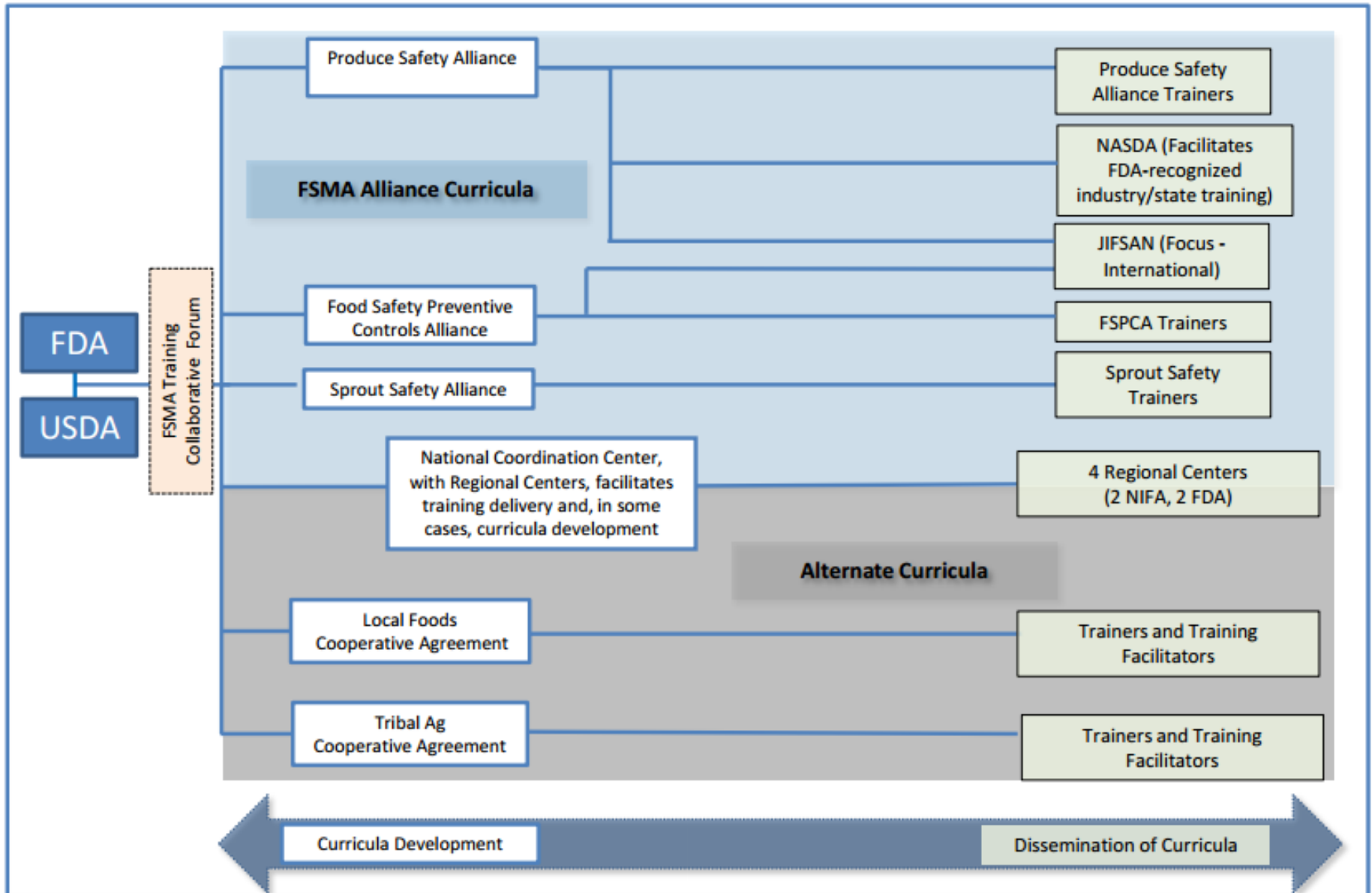


# What will be available from CCE?

- FSMA regulations include a **mandatory one day food safety training certification class**
- Cornell and the Produce Safety Alliance have created the curriculum (finished over a year ago)
- FDA has pushed back approval process of the curriculum to September 2016
- Once we get the green light, we will offer the classes ASAP in most counties

# FSMA Framework for Industry Curriculum Development and Dissemination

October 2015



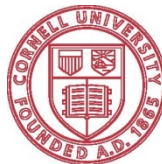
# Other resources

- ENYCHP – Myself, other vegetable educators
- FDA online resources
- Produce Safety Alliance



# Produce Safety Alliance

- Cooperative agreement between Cornell University, FDA, and USDA
- Established in 2010
- Focused on outreach and education to assist growers with meeting regulatory and market food safety requirements



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# PSA Resources You Should Know About


- General PSA listserve
  - Visit the website to sign up
- PSA-FDA Q & A Series Recordings
- Resources, University contacts, and more!
- Future site for training information



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**Produce Safety**  
ALLIANCE


# www.producesafetyalliance.cornell.edu



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SEARCH CORNELL:

Pages People more options



## Produce Safety Alliance

[Home](#) [News](#) [Resources](#) [FSMA](#) [The Alliance](#)

*Providing fundamental, science-based, on-farm food safety knowledge to fresh fruit and vegetable farmers, packers, regulatory personnel and others interested in the safety of fresh produce*

**Welcome to the Produce Safety Alliance (PSA) website!**

[Click here](#) to view the press release.

The PSA is developing a nationwide curriculum to increase understanding of the principles of Good Agricultural Practices (GAPs) and to facilitate the implementation of food safety practices on fresh fruit and vegetable farms and in packinghouses. [View the PSA's current Curriculum Modules and Learning Objectives.](#)

**PSA-FDA Question & Answer Series**


PSA-FDA Question & Answer Series on FSMA Proposed Produce Safety Rule. [Click here](#) to listen to all of the recordings from March 18–May 13, 2013.

[Click here for the PSA October newsletter.](#)

**Stay up-to-date!**

**Produce Safety ALLIANCE**

Sign up for the Produce Safety Alliance listserve...



**Join the PSA Listserve!**

The listserve is a great way to receive the most current information related to educational and training opportunities, FSMA updates, and produce safety research and events.



Find us on  
**Facebook**



# FDA Food Safety Modernization Act & Proposed Produce Safety Rule

- **Produce Rule:**  
Focus on the growing, harvesting, and post-harvest handling of fresh produce
- Focus is on the prevention, not detection of issues (**no product pathogen testing required**)



fsma produce rule fact sheet

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[\[PDF\] FSMA Proposed Rule for Produce Safety - Food and Dru...](#)

[www.fda.gov/.../GuidanceRegulation/FS...](http://www.fda.gov/.../GuidanceRegulation/FS...) ▾ Food and Drug Administration ▾  
**Summary.** On January 4, 2013, FDA released for public comment its proposed **rule** to establish science-based standards for growing, harvesting, packing and ...



# Questions?



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