

# The Food Safety Modernization Act Produce Safety Rule in Colorado

Cristy Dice

Colorado Department of Agriculture

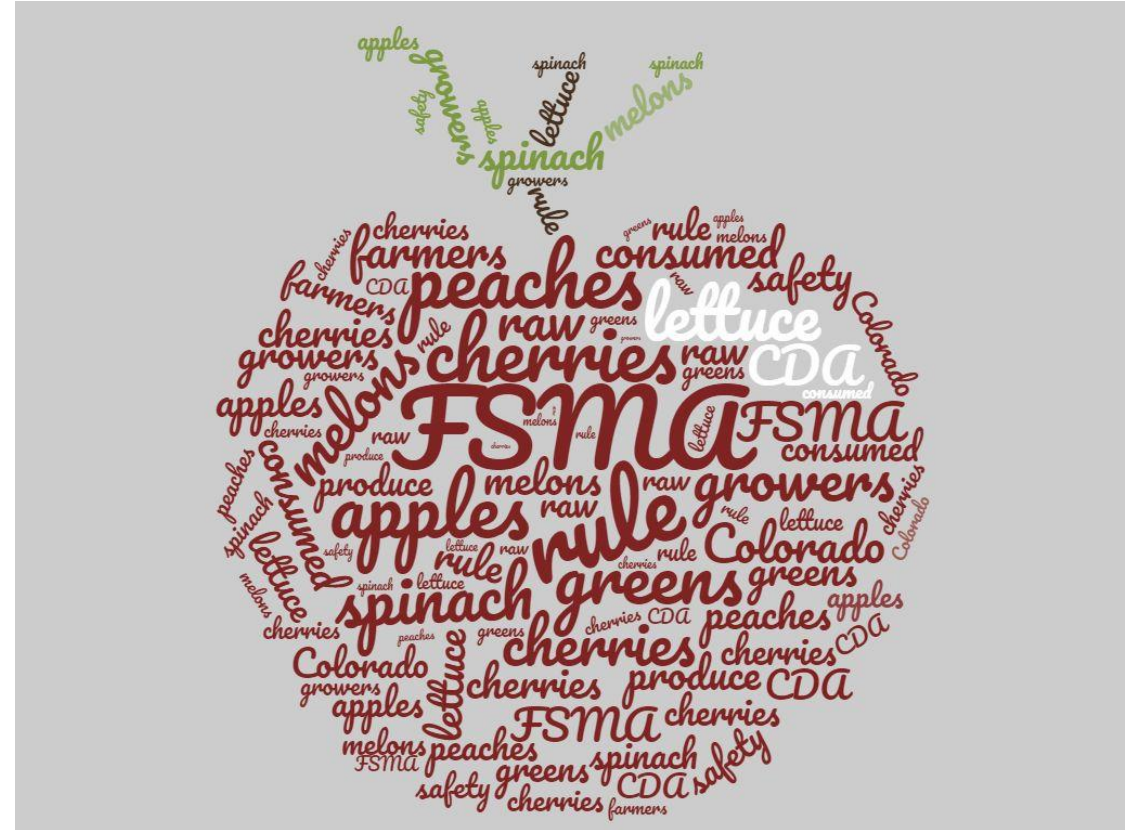
Produce Safety Rule Program Manager



**COLORADO**  
Department of Agriculture

# What are we going to cover today?

- Overview of FSMA
- Produce Safety Rule – coverage and exemptions
- Key Requirements of PSR
- Grower resources & educational opportunities
- Implementation in Colorado and Compliance Dates



# The Food Safety Modernization Act

Photo by Laura Harwood

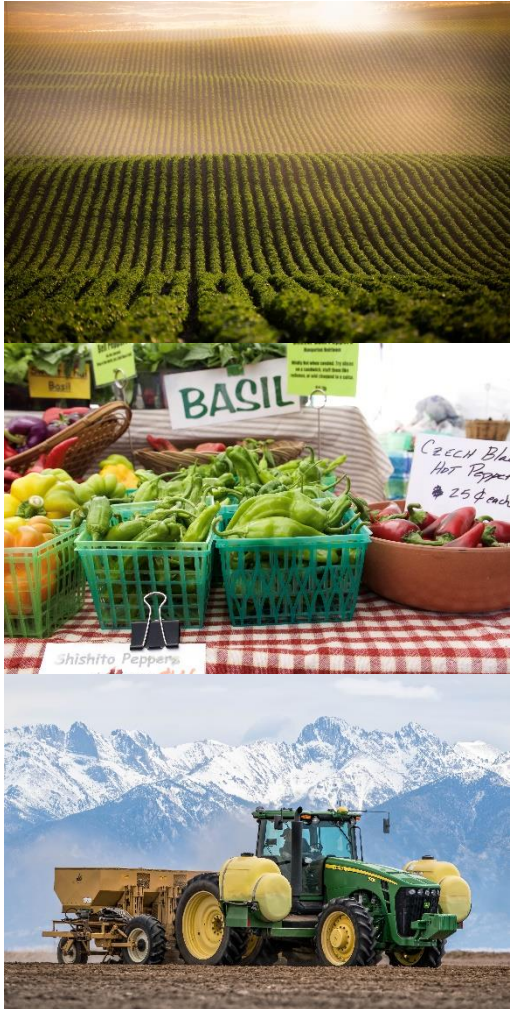


Photo by Bill Chiles

- Federal regulation to ensure an integrated food safety system
- Food safety paradigm shift from detection to prevention
- Signed into law on January 4<sup>th</sup>, 2011 with bipartisan support
- 7 primary rules finalized under FSMA, along with guidance for industry
- A whole system approach to addressing issues of food safety

# Final Rules under FSMA

FDA FOOD SAFETY  
MODERNIZATION ACT



Produce Safety Rule (November 2015)



Preventive Controls for Human Food (September 2015)



Preventive Controls for Animal Food (September 2015)



Foreign Supplier Verification Programs (November 2015)



Accredited Third-Party Certification (November 2015)



Sanitary Transportation of Human and Animal Food (April 2016)



Prevention of Intentional Contamination/Adulteration (May 2016)

**ALL SUPPLIERS MUST COMPLY WITH THE FSMA RULES**

# CDA has 5 year cooperative agreement with FDA to implement PSR

## Education before Regulation

### ✓ Implementation Plan

- Producer outreach and education
- Farm Inventory
- On-Farm Readiness Review Tool
- Inspections

### ✓ Partnership with CSU Extension

- Producer education and outreach
- On-Farm Readiness Reviews
- Produce Safety Fellowship Program

Part of a nationwide network of state departments of agriculture (National Consortium for Produce Safety Program Development) working together to uniformly implement rule.

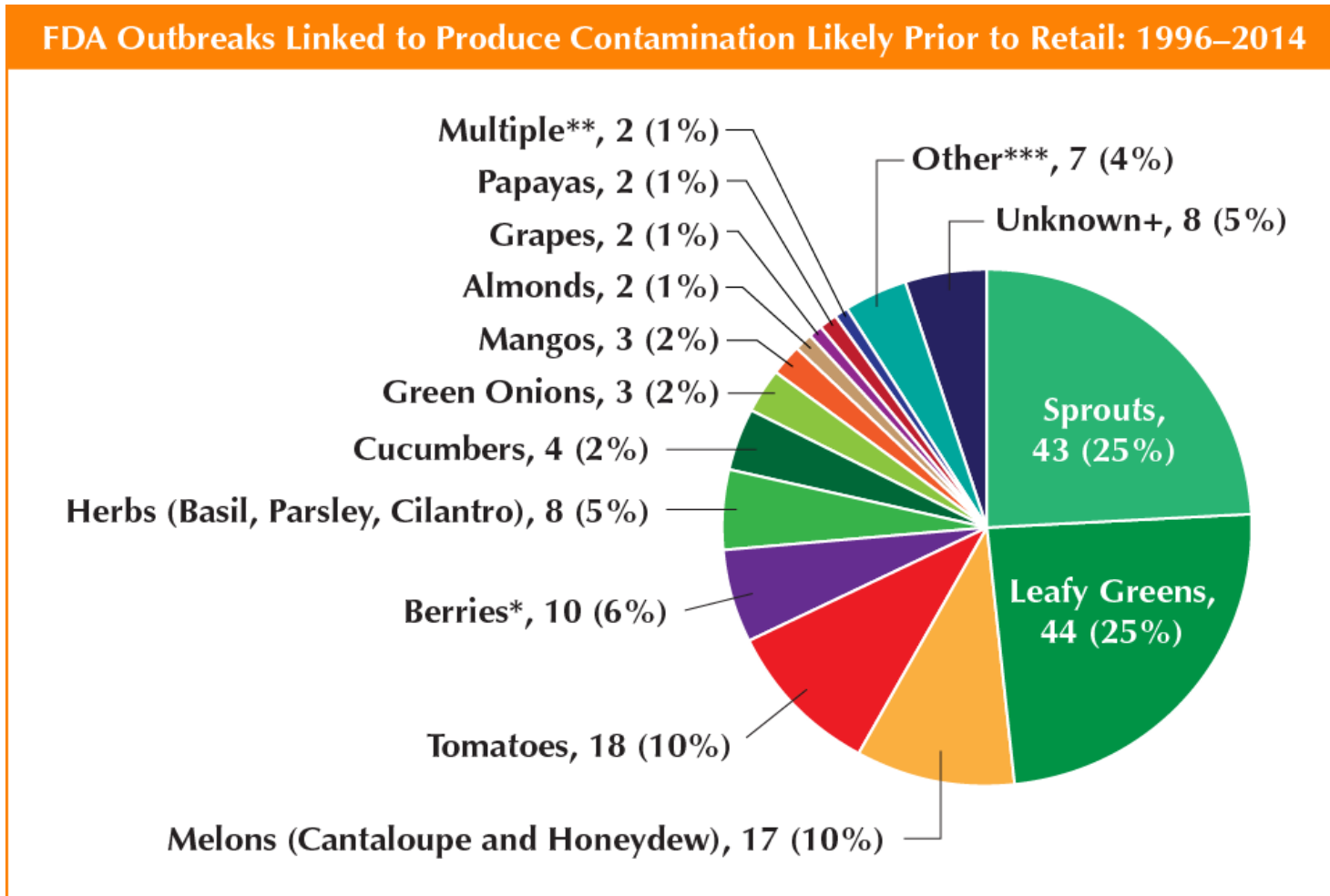


# The Produce Safety Rule



- First ever mandatory federal standard for growing, harvesting, packing, and holding of fresh produce
- Science-based minimum standards for the growing, harvesting, packing and holding of fruits and vegetables grown for human consumption
- Goal is to prevent foodborne illness outbreaks by addressing production challenges of growing, harvesting and packing of raw produce.
- Some growers may be eligible for an exemption or excluded

# Outbreaks Associated with Produce



# Produce Safety Rule:

## *Prevention of Microbial Produce Contamination*



*E. coli*



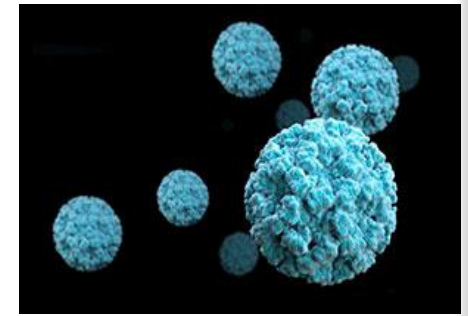
*Clostridium perfringens*



*Salmonella*



*Listeria*



*Norovirus*

*and many more...*

*Reference: pictures are from Centers for Disease Control and Prevention*



# What produce is covered under the Produce Safety Rule?

- Produce that is consumed raw (Raw Agricultural Commodity - RAC)



# What is produce NOT covered under the Produce Safety Rule?

- Produce that goes through a “kill” step (winemaking, beermaking, refining, etc.)
- Produce that is grown for on-farm consumption
- Food grains, including dent- or flint-corn, sorghum, oats, rice, rye wheat, amaranth, quinoa, buckwheat, and oilseeds



# What is Covered Produce?

- All Produce is covered except:
  - FDA has identified an exhaustive list of rarely consumed raw commodities:  
Asparagus; black beans, great Northern beans, kidney 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
- Refers to the harvestable or harvested part of the crop
- Wine grapes are considered covered produce





# What farms are covered under the Produce Safety Rule?

- ✓ Grow or harvest *covered produce*
- ✓ Sales for produce over \$25,000



If the farms meet both these requirements, then the farm is covered under the produce safety rule, but they may qualify for an exemption.

In addition to growing and harvesting, holding and packing are also *covered activities* under the PSR.

# What farms qualify for an Exemption?

- ✓ Have less than \$500,000 in total food sales (not just produce)
- AND**
- ✓ Over 50% of sales are to “qualified end users”
    - Qualified end users are consumers of the food, retail food establishments, restaurants, that are located in the same state and are not more than 275 miles from the farm.



These farms are eligible for a qualified exemption and modified requirements



# What are the Modified Requirements for an Exemption?



- Record Keeping – records must be kept that demonstrate the farm satisfies the criteria for the exemption and that it is reviewed annually
- Labeling – if labeling is required, must include the name and complete business address of the farm where the produce was grown
- If label is not required, complete business address of farm where produce was grown needs to be provided
- No Inspection of the farm will be required

Ultimately, all growers should understand and take action to reduce food safety risks on the farm

# Are there other Exemptions?

## Commercial Processing Exemption

- ✓ Grapes (or other produce) sold for winemaking qualify for the exemption
- ✓ Any grapes that are not further processed are covered under the Produce Safety Rule
- ✓ Any produce that is not further processed does not qualify for the exemption.





# What are the Requirements for the Commercial Processing Exemption?

- At the point of sale, growers must provide a disclosure in documents accompanying the produce that states the produce is “not processed to adequately reduce the presence of microorganisms of public health significance”

AND

- Maintain documentation from the processor that includes information on how the produce will be processed and details of how pathogens are killed (i.e. fermenting, cooking, etc.)\*\*

\*\*FDA is exercising enforcement discretion for the documentation from processors requirements for wine grapes that are used for wine making.

# Requirements Continued



- Disclosures can be included in labels, labeling, bills of lading, freight bills, shipment-specific certificates of analysis, and other documents or papers associated with the shipment that food
- Keep records documenting grapes that are sold for commercial processing
- Keep documentation of disclosures that you provide to customers

# Produce Safety Alliance Grower Training

- One person from each farm will need to attend a Produce Safety Alliance Grower training
- Full one day training to learn about each of the 6 standards and the importance of food safety planning
- Opportunity to ask questions about PSR
- Network with other growers





# Produce Safety Rule Standards



**Worker Health and Hygiene**



**Agricultural Water**



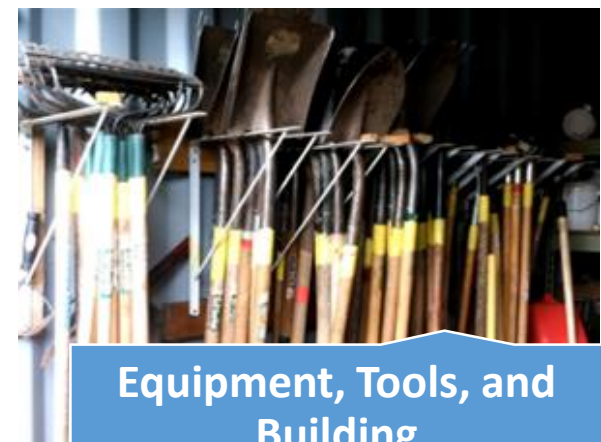
**Soil Amendments**



**Wildlife, Domestic Animals & Land Use**



**Postharvest Handling and Sanitation**



**Equipment, Tools, and Building**



# Colorado State University Extension

- Education and outreach
  - Upcoming trainings Fall/Winter 2018 – Spring 2019
    - Produce Safety Alliance Trainings in collaboration with RMFU, CFVGA & others
    - PCQI and Food Safety Plan workshops to support FSMA compliance
  - New educational modules in progress
- [www.coproducesafety.org](http://www.coproducesafety.org)
  - FSMA updates
  - Produce Safety Rule resources
- Food Safety Fellowships
  - 3 Food Safety Fellows 2017/18
  - 2 Food Safety Fellows 2018/19



# Farm Size Categories

FDA Business Categorization	Gross Annual Produce Sales*
All Other Businesses	Over \$500,000
Small Businesses	\$250,000 - \$500,000
Very Small Businesses	\$25,000 - \$250,000
Under \$25,000 – exempt from Rule	

\* Based on total produce sales, for the previous 3 year average

# FSMA PSR Compliance Dates

FDA Business Categorization	FDA Compliance Date for Covered Produce	On-Farm Inspections	Water Compliance Dates*
<b>All Other Businesses</b> Over \$500,000	January 26, 2018	Growing Season 2019	January 26, 2022
<b>Small Businesses</b> \$250,000 - \$500,000	January 28, 2019	Growing Season 2020	January 28, 2023
<b>Very Small Businesses</b> \$25,000 - \$250,000	January 27, 2020	Growing Season 2021	January 27, 2024

Under \$25,000— Exempt from Produce Safety Rule

\*proposed dates





# Colorado Implementation

## Education before regulation

1. Farm Inventory Development
2. On-Farm Readiness Reviews
3. On-Farm Inspections



# Role of Farm Inventory in Colorado

- Inventory will consist of a database of general information regarding:

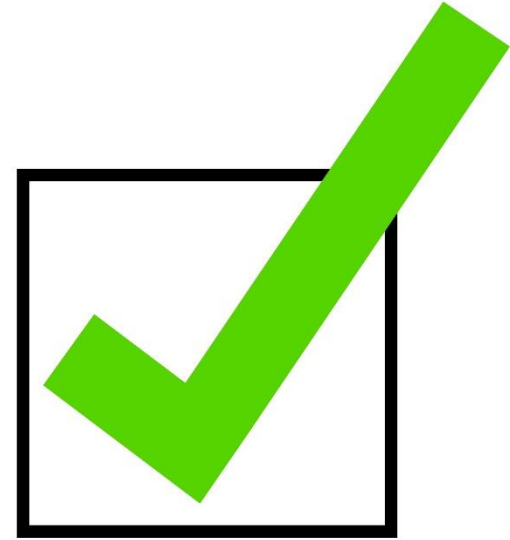
- Contact Information
- Location of farm
- Business Size
- Crops
- On Farm Activities



- Help determining if/how growers are covered under the PSR
- Provides access to resources
  - CDA created an easy online form or by phone
  - Visit [www.coproducesafety.org](http://www.coproducesafety.org)

# Farm Inventory Update

- CDA has begun contacting farms to verify their information
  - Growers contacted via email and phone calls
- Verified about 60% of our farms
- We are still determining what the farm inventory update will look like from year to year



Contact Danielle Duni – 303-869-9046 or [danielle.duni@state.co.us](mailto:danielle.duni@state.co.us)

# What is an On-Farm Readiness Review?



- A voluntary pre-inspectional review to assess readiness
- Non-regulatory
- Build relationships between farmers and regulatory staff

# Why would growers want to participate in an On-Farm Readiness Review?

- ✓ It is voluntary, free and confidential
- ✓ It helps align what they are doing on the farm with what is required in the rule
- ✓ It helps them figure out what they are missing
- ✓ It provides personalized discussion on farm food safety activities



## *An Audit is:*

- Market/buyer driven
- Usually points based
- Annual
- Farmer defines the scope within the audit scheme
- Consequences of failure could be loss of sales
- Fee based

## *An Inspection is:*

- Regulatory
- NOT points based
- May or may not be annual
- Regulator defines the scope within the PSR
- Consequences of unaddressed non-compliance may be recalls or closure
- Not fee based

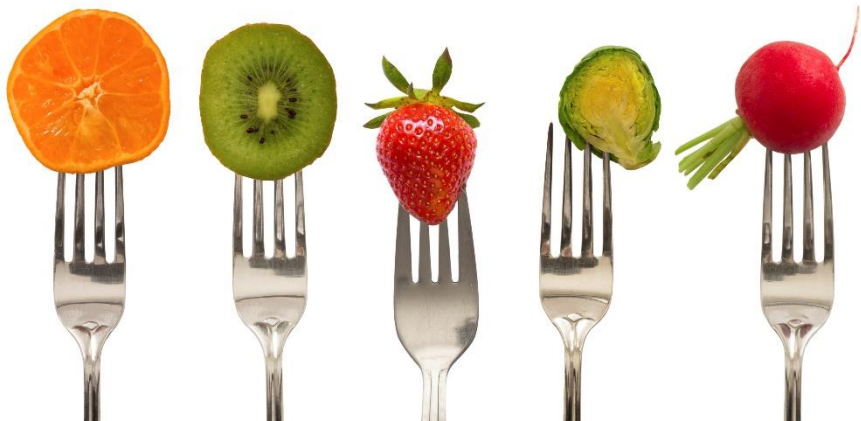


# What are On-Farm Inspections?

- Required under FSMA
- Will begin in 2019 to allow for training and education for farmers and regulators
- Inspection will be announced and emphasis will be education-based
- Priority based inspection schedule
- Discussions ongoing regarding frequency and number of inspections
- Conducted by credentialed state inspectors to assess compliance with FSMA
- Growers can use the On-Farm Readiness Review to prepare



# What can growers do now to improve food safety on their farms?



- ✓ Attend a Produce Safety Alliance Grower Training
- ✓ Request an On-Farm Readiness Review
- ✓ Understand that the Produce Safety Rule is focused on prevention and risk mitigation

# Other Takeaways

- CDA is focused on education, prior to and during regulation
- PSR is flexible = Good for growers!
- Meeting the requirements of third party audits does not necessarily mean growers are compliant with FSMA standards
- Visit [www.coproducesafety.org](http://www.coproducesafety.org) for PSR resources and updates



# Key FSMA Partnerships in Colorado



**COLORADO STATE UNIVERSITY**  
**EXTENSION**



**COLORADO**  
Department of Agriculture



**Rocky Mountain**  
**Farmers Union**



# Upcoming Produce Safety Alliance Grower Trainings

**November 8<sup>th</sup>, 2018: PSA Grower Training, Boulder**

**January 9<sup>th</sup>, 2019: PSA Grower Training, Grand Junction**

**January 31<sup>st</sup>, 2019: PSA Grower Training, Greeley**

**Feb/March 2019 – El Paso County, details TBA**

**TBD 2019 – Eagle County, possible training location**

**February 19<sup>th</sup>-21<sup>st</sup>, 2019: PCQI Training, Location TBA**

This course is organized by Western Growers Association. Registration coming soon.

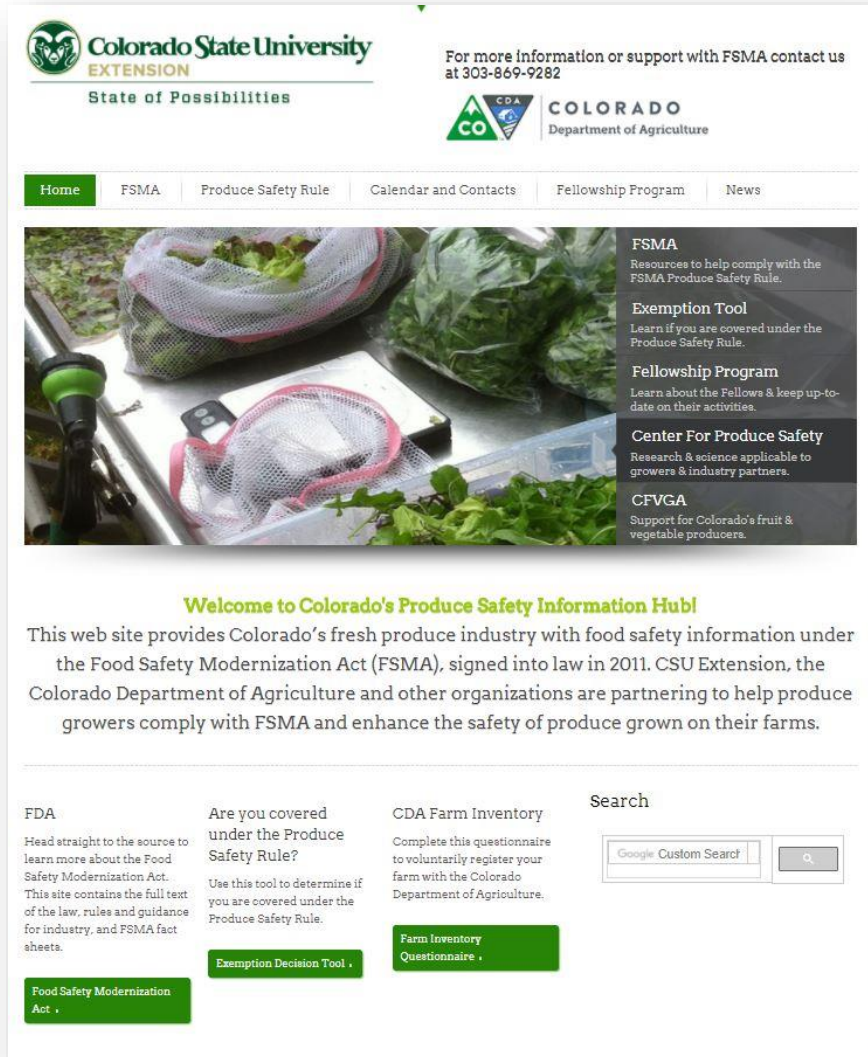
Visit [www.coproducesafety.org](http://www.coproducesafety.org) for registration information.



# Want more info?

## Colorado Produce Safety Webpage

<http://freshproduce.colostate.edu>



**Colorado State University**  
EXTENSION  
State of Possibilities

For more information or support with FSMA contact us at 303-869-9282

**COLORADO**  
Department of Agriculture

Home | FSMA | Produce Safety Rule | Calendar and Contacts | Fellowship Program | News

**FSMA**  
Resources to help comply with the FSMA Produce Safety Rule.

**Exemption Tool**  
Learn if you are covered under the Produce Safety Rule.

**Fellowship Program**  
Learn about the Fellows & keep up-to-date on their activities.

**Center For Produce Safety**  
Research & science applicable to growers & industry partners.

**CFVGA**  
Support for Colorado's fruit & vegetable producers.

**Welcome to Colorado's Produce Safety Information Hub!**

This web site provides Colorado's fresh produce industry with food safety information under the Food Safety Modernization Act (FSMA), signed into law in 2011. CSU Extension, the Colorado Department of Agriculture and other organizations are partnering to help produce growers comply with FSMA and enhance the safety of produce grown on their farms.

**FDA**  
Head straight to the source to learn more about the Food Safety Modernization Act. This site contains the full text of the law, rules and guidance for industry, and FSMA fact sheets.

**Are you covered under the Produce Safety Rule?**  
Use this tool to determine if you are covered under the Produce Safety Rule.

**CDA Farm Inventory**  
Complete this questionnaire to voluntarily register your farm with the Colorado Department of Agriculture.

**Search**  
Google Custom Search

**Exemption Decision Tool**

**Farm Inventory Questionnaire**

**Food Safety Modernization Act**

## FSMA Produce Safety Rule

[www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm](http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm)

### FSMA Final Rule on Produce Safety

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#### Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

[Produce Safety Standards under the FSMA Main Page](#)

View the Final Rule Contents in the [Federal Register Notice](#)

Below is a fact sheet provided by FDA.

In this fact sheet:

- [Introduction](#)
- [Key Requirements](#)
- [Exemptions](#)
- [Variances](#)
- [Compliance Dates](#)
- [Environmental Impact Statement](#)
- [Assistance to Industry](#)

#### About the Final Rule

- [Federal Register Notice](#)
- Docket Folder [FDA-2011-N-0921](#)
- [Questions & Answers](#)
- [Coverage and Exemptions/Exclusions Flowchart \(Color PDF: 95KB\)](#)
- [Coverage and Exemptions/Exclusions Flowchart \(Black & White PDF: 67KB\)](#)
- [How Did FDA Establish Requirements for Water Quality and Testing of Irrigation Water?](#)
- [What the Produce Safety Rule Means for Consumers](#)
- [What to Expect Now That Larger Farms Must Comply with the FSMA Produce Safety Rule](#)
- [Print-Friendly Fact Sheet \(PDF: 405KB\)](#)
- [Proposed Extension of Agricultural Water Compliance Dates \(Federal Register\)](#)

#### Related Guidance

#### Introduction

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. The rule is part of the agency's ongoing efforts to implement the FDA Food Safety Modernization Act. The final rule went into effect January 26, 2016.



Photo by Carolyn Keller

# Questions?

Cristy Dice

303-869-9282

[cristy.dice@state.co.us](mailto:cristy.dice@state.co.us)

Danielle Duni

303-869-9046

[danielle.duni@state.co.us](mailto:danielle.duni@state.co.us)