



Community Alliance with Family Farmers



Food Safety Modernization Act - FSMA

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Raise your hand if...

- You are a farmer.
- You work at a non-profit that supports farmers.
- You work at a school, business, or other location that interacts with farmers.
- You are totally new to farm food safety.
- You (or the farm you work at) has implemented some type of food safety protocols.
- You are familiar with the Food Safety Modernization Act (FSMA) Produce Rule.

A preface

- Don't get overwhelmed with all these details – I'm not covering everything in the next 30 minutes.
 - Reference these slides later.
 - There's a glossary of food safety & FSMA terms at the end of this slideshow.
 - Go to caff.org/programs/foodsafety for more resources.
- Remember, the government may require your farm to follow certain food safety regulations BUT industry/buyers may require you to follow additional requirements.
 - Know your farm's rights
 - Balance regulatory requirements and industry demands



Presentation Road Map

1. Produce Rule of the Food Safety Modernization Act (FSMA)
2. What type farms are:
 - Fully subject
 - Partially exempt
 - Fully exempt
3. Some examples of what you'll have to do if you're farm is fully subject or partially exempt



Overview of Food Safety Modernization Act (FSMA)

2011

- President Obama signed it into law

Nov.
2015

Food and Drug (FDA) implements the law

- 7 main rules covering different parts of the supply chain
Produce Rule, Preventive Controls

2017-
2018


- Regulation Implementation

Jan.
2018
to
2020*

- Regulation Enforcement

*Farms have an extra 2 years to meet water regulations

FSMA Exemptions

- 
- Produce that is NOT covered by the Produce Rule includes:
 - Produce grown for personal or on-farm consumption
 - Produce that is “rarely consumed raw” (by FDA)
 - Produce that goes through a “kill step”

OR

- 
- If your total gross sales of all commodities on your farm is less than \$25,000 annually you’re fully exempt from the law.

FDA's List of Produce Rarely Consumed Raw



Full list is in notes section of slide

Recap of full exemptions from FSMA

1. Produce grown for personal or on-farm consumption
2. Produce that is “rarely consumed raw” (by FDA)
3. Produce that goes through a “kill step”

OR

If your total gross sales of all commodities on your farm is less than \$25,000 annually you’re fully exempt from the law.

Tester-Hagan Qualified Exemption

- A farm must meet 2 conditions for a partial exemption from FSMA requirements:

1. Have less than \$500,000 in annual gross sales.

Remember: rolling average from previous 3 years & converted into 2011 \$

AND

2. Sells the majority of the food directly to customers (qualified end users).

Direct customer examples: consumers at farmers' markets, restaurant, or a retail food establishment (e.g., individual grocery store, not a distribution center)

Must be within the same state or 275 miles from farm





Important note on annual sales

Total Rolling 3 Year Average =

Step 1: Determine the total gross sales from farm in 2016

Step 2: Convert 2016 total gross sales to 2011 dollars

Step 3: Determine the total gross sales from farm in 2015

Step 4: Convert 2015 total gross sales to 2011 dollars

Step 5: Determine the total gross sales from farm in 2014

Step 6: Convert 2014 total gross sales to 2011 dollars

Step 7: Sum up totals in 2011 dollars from steps 2, 4, and 6. Divide by 3.

.

The FDA should be releasing an online tool that converts dollars from any year to 2011 dollars.



Tester-Hagan Qualified Exemption

Remember: the threshold is \$500,000 in **2011 dollars**

- Inflation causes money to be worth less each year
- A price index adjusts for this & FDA will use the implicit GDP deflator

2011	2015
<i>\$500,000</i>	<i>\$530,672</i>

Very important to convert in 2011 dollars if your farm is right around \$500,000 in annual sales. It may mean the difference between being partially exempt and having to follow ALL of FSMA's requirements.



My farm's qualified exempt. What do I do now?

1. Keep records to prove you're exempt.

- Sales receipts, invoices, load lists
- Total sales to qualified end users
- These records have to be signed/initialed by record keeper
- Records can be written or electronic
- If CDFA/FDA inspector asks to see your records you have to provide them in 24 hours

Important note: need to start keeping these records in March, 2016!

2. Provide name and address of where food was grown.

- If the food has a label, make sure the address and name of farm is on it.

Ex: outside of CSA box

- Or post a sign at point of purchase w/name and address.

Ex: Farmers' Market, Farm Stand

Timeline for Compliance

Total Farm Annual Sales	FSMA Compliance
<i>\$500,000*+</i>	<i>2018</i>
<i>\$250,000-499,999*</i>	<i>2019</i>
<i>\$25,000-249,999*</i>	<i>2020</i>
<i>Less than \$25,000*</i>	<i>exempt</i>

***2011 dollars**

Covered Farms - Requirements

FSMA requirements overview of categories:

- Recordkeeping
- Worker health and hygiene
- Natural resources; domesticated and wild animals
- Crop nutrient and plant protection management
- Water
- Harvest & Post-harvest

Bottom line: On farm food safety is a process, you can't make all these changes overnight. Start now!

Covered Farms - Water



SURFACE WATER SOURCES

Baseline: 20 samples over 2-4 years for each surface water source

-5 samples annually thereafter

VS.



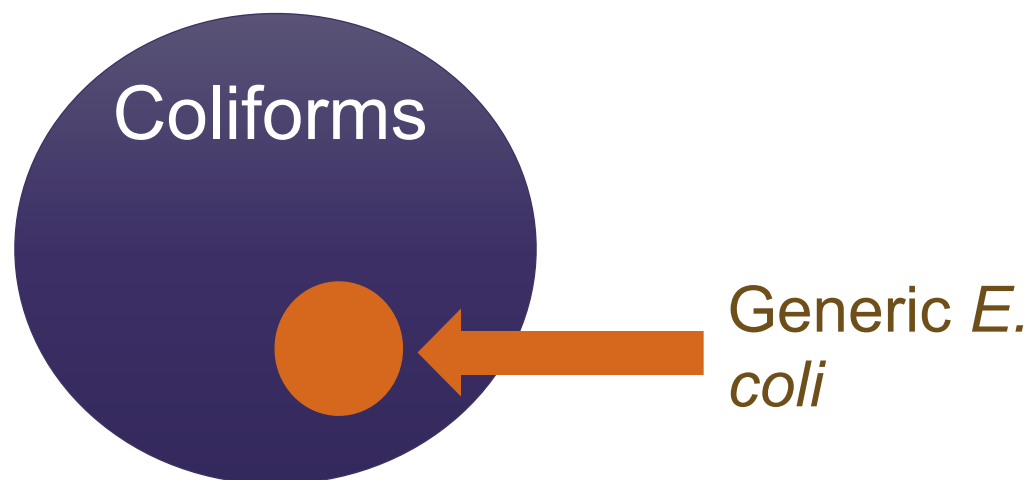
GROUND WATER SOURCES

Baseline: 4 samples over 2-4 years for each groundwater source.

-1 sample annually after

Water testing – generic *E. coli*

- Water tests must test for generic *E. coli* because:
 - Generic *E. coli* is an indicator of pathogens that could cause harm to humans



Covered farms – water testing methodology

- FDA currently allows one methodology to be used on water tests: Method 1603 with colony forming units analysis

	Method 1603	Most Probable Number (MPN)
<i>Tests for generic E. coli using:</i>	colony forming units (CFUs)	<i>Multiple Probable Number (MPN)</i>
<i>CA labs using this method:</i>	<i>None/very few</i>	<i>Most labs</i>

Timeline for Compliance

Total Farm Annual Sales	FSMA Compliance	FSMA Water Compliance
<i>\$500,000*+</i>	<i>2018</i>	<i>2020</i>
<i>\$250,000-499,999*</i>	<i>2019</i>	<i>2021</i>
<i>\$25,000-249,999*</i>	<i>2020</i>	<i>2022</i>
<i>Less than \$25,000*</i>	<i>exempt</i>	<i>exempt</i>

***2011 dollars**

Covered Farms - Recommendations

FSMA recommendations for not exempt farms:

- Have a farm Food Safety Plan
- Conduct an operational/risk assessment
 - CAFF has templates (English & Spanish) for these on our website:
<http://www.caff.org/programs/foodsafety/templates/>

FSMA does NOT require a 3rd party food safety audit!

However, distributors can require 3rd party audits to meet their requirement as a distributor to verify that all their suppliers meet food safety standards.





FSMA & Organic Certification

- Overall there is overlap.
- You're already started because you're used to keeping records of various farm practices.
- FSMA does not require you to do anything that would be against National Organic Program standards.
- FSMA has major additions beyond what you're doing for NOP in these areas:
 - Worker Health and Hygiene
 - Production and Post-Harvest Water
- Make sure to take a copy of the Farm Food Safety and Organic Federal Co-Compliance Chart provided by our friends at ALBA and NCAT.



California Laws with Food Safety

- California laws do not require a food safety plan nor a third party audit. Direct marketing laws require you to implement Good Agricultural Practices (GAPs):
 - AB 224 (2013) CSA Law
 - AB 1871 (2014) Farmers Markets
 - AB 1990 (2014) Community Food Producers (Urban Gardens)
- Buyers may still require a food safety plan and/or a third party audit
- Insurance Companies may also
- We encourage farms to develop a food safety plan

“I further certify that I am knowledgeable and intend to produce in accordance with good agricultural practices as published by the department.”

Value Added Products

- Your farm may be subject to another FSMA Rule called the Preventive Controls Rule.
- If your farm and your value added products don't fit any of the exemption categories you'd have to register your farm as a facility with FDA.
- Must follow updated Current Good Manufacturing Processes (CGMPs)





Raise your hand if...

- You learned something new today about food safety.
- Your farm is fully exempt.
- Your farm is qualified exempt.
- Your farm is fully subject to FSMA.



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Covered Farms - Water test results

- Rule is very prescriptive
- Water test results:

Type of Water	Geometric Mean Limit	Statistical Threshold Limit
<i>Used during growing activities</i>	<i>126 or less colony forming units (CFUs) of generic E. coli per 100mL</i>	<i>410 or less CFU of generic E. coli per 100mL</i>
<i>Used during harvest, postharvest, food contact surfaces, hand</i>	<i>0</i>	<i>0</i>



Covered farms – production water options after test results outside the allowable range

You have 3 options:

1. Stop using the water
 - Inspect water system and see if you can rectify the problem
2. Treat the water
 - Currently FDA has not approved any treatment products for irrigation water
3. Utilize the microbial die off
 - Use UC Davis excel tool to calculate
 - 1-4 days is allowed for die off window, no longer

FSMA – Preventive Controls Rule

One of the 7 main rules of FSMA

Could apply to your farm if:

- You make value added products (on or off farm)
- You have an off farm processing/manufacturing facility

FSMA – Preventive Controls Rule (PC)

Exempt from registration if:

- If your farm fits the definition of “farm”
 - Primary Production Farm
 - Secondary Activities Farm
- Retail food establishments:
Any business making food with at least 50.1% of sales direct to consumer

FSMA - Preventive Controls Rule (PC)

Farms that do any of the following manufacturing/processing activities may be subject to PC:

- Baking
- Boiling
- Bottling
- Canning
- Cooking
- Cooling
- Cutting
- Distilling
- Dehydrating
- Evaporating
- Eviscerating
- Extracting Juice
- Formulating
- Freezing
- Grinding
- Homogenizing
- Irradiating
- Labeling
- Milling
- Mixing
- Packaging
- Pasteurizing
- Peeling
- Rendering
- Treating to manipulate ripening
- Trimming
- Washing
- Waxing

Preventive Control Rule

If your farm is not exempt you must:

1. Register your facility with the FDA

+

2. Follow updated Current Good Manufacturing Processes (CGMPs)

+

Follow new Hazard Analysis and Risk Based Preventive Controls (HARPC)

- Only have to follow HARPC if you're not exempt (very small sized operations)
 - Very small sized = less than \$1 million in annual sales

What are GAPs?



- GAPs = Good Agricultural Practices
 - 5 key areas of Focus:
 1. **Water**
 2. **Employee Training (Health & Hygiene)**
 3. **Land Use & Animal Access**
 4. **Equipment, Tools & Buildings**
 5. **Manure, Compost & Chemicals**
 - Start by understanding your practices and the potential risks associated with them
 - Identify what you could do to minimize any identified potential risks
- ****No such thing as “Zero-Risk”****



FSMA Glossary

FSMA = Food Safety Modernization Act: law signed in 2011 that updated U.S. federal food safety regulations for the first time in 70 years

Covered Produce = Crops that FSMA regulates

Subject to the law = A farm that meets certain criteria and has to abide by all parts of FSMA

Qualified Exempt Farm = A farm that meets certain criteria to be partially exempt from FSMA requirements

Qualified End User = A consumer, or a restaurant, or a retail food establishment (e.g., a grocery store, not a distribution center) that is located in the same state as the farm or not more than 275 miles from the farm