



Community Alliance with Family Farmers

Food Safety – Who and What is covered by the FSMA Produce Rule

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Presentation Road Map

1. Sources of contamination of food on the farm
2. Produce Rule of the Food Safety Modernization Act (FSMA)
 - What types of produce are covered
 - Which farms are:
 - Covered farms and subject to all requirements
 - Partially exempt, “Qualified exempt,” with limited requirements
 - Fully exempt
3. Timeline for compliance and enforcement
4. Principal obligations of covered farms
5. California food safety requirements

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On-Farm Food Safety – why?

- As good stewards of the land, we are also good stewards of the produce we grow.
- What we *can* see is as important as what we *can not* see, namely microbes and foodborne illnesses
- Farms of all sizes have been involved in foodborne outbreaks, so **all growers** need to implement “right sized” food safety practices on their farms, practices that minimize risks on their farms

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3 Main Types of Food Contamination

1. Physical

- equipment parts, screws, nails, hair, staples, insects, etc.

2. Chemical

- Fertilizers, sanitizers, herbicides, pesticides, fungicides, equipment lubricant

3. Biological (Microbial)

- Viruses, bacteria, parasites, fungi
 - E. coli 0157:H7 in spinach, strawberries
 - Salmonella in tomatoes
 - Listeria in cantaloupes

FSMA mainly deals with biological contaminants

E. coli O157:H7

Sept 2006 - Spinach

Dole brand Baby Spinach
205 confirmed illnesses and three deaths



E. coli O157:H7 in spinach can be killed by cooking at 160° Fahrenheit for 15 seconds. If spinach is cooked in a frying pan, and all parts do not reach 160° Fahrenheit, all bacteria may not be killed



Outbreaks linked to Water Contamination

- Salmonella outbreak in tomatoes in Virginia
 - Associated with a pond used for irrigation
- Cyclospora outbreak in Guatemalan raspberries
 - Associated with water for chemical application
- Shigella outbreak in BC, Canada spinach
 - Associated with septic leakage contaminating wash water (surface water source)





Employee Health & Hygiene Related Outbreaks



- 1994 California Green Onions – *Shigella* – 72 cases reported
 - The spread of *Shigella* can be stopped by frequent and careful handwashing with soap and taking other hygiene measures.
- 1997 California Strawberries - Hep A Virus – 250 cases reported
- 1998 US Green Onions – Hep A Virus – 43 cases reported
 - **Hepatitis A** is a liver infection caused by the Hepatitis A virus (HAV). Hepatitis A is highly contagious. It is usually transmitted by the fecal-oral route, either through person-to-person contact or consumption of contaminated food or water.



Animal Access Contamination Linked to Produce

- 2011 Fresh Strawberries *E.coli* 0157:H7 at Oregon's Jaquith Strawberry Farm: (15 total ill, 7 hospitalized and 1 death of elderly)
 - Wildlife--specifically deer feces--was isolated as the source.
- -- Sold at farmers markets and farm stand





Equipment Contamination Linked to Produce



- 2011 Multi-state Cantaloupe Listeria outbreak
- 147 illnesses reported in 28 states, with 33 deaths and 1 miscarriage
- Isolated to a potato washer that was modified to clean melons
- First time that farmers faced criminal charges
- The Jensens (2 brothers) were sentenced in January 2014 to five years probation, six months home detention, and \$150,000 each in restitution fees to victims



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5. Manure & Chemicals Contamination linked to Produce



- E. coli 0157:H7 outbreak in shredded lettuce in California
 - Associated with irrigation water from well that was contaminated with dairy lagoon water
- 1985 – Banned insecticide (Aldicarb) used on watermelons by growers in San Joaquin Valley
 - 2000 + reported sick, 17 hospitalized, 6 deaths & 2 stillbirths (<http://www.environmentalhealthnews.org/ehs/news/aldicarb-phaseout>)



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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 (NOT crops physically covered by row cover, a greenhouse, etc)

Subject to the law/covered farm = 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

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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 Rule of greatest concern for farmers

2017-
2018

- Regulation Implementation

2018
to
2020

- Regulation Enforcement

*Farms have at least an extra 2 years to meet water regulations

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FSMA is not prescriptive

- FSMA provides regulatory language on topics, but provides very little prescriptive instructions on how you can fulfill the law.

Example:

§112.128 What requirements apply regarding pest control in buildings?

(a) You must take those measures reasonably necessary to protect covered produce, food contact surfaces, and food-packing materials from contamination by pests in buildings, including routine monitoring for pests as necessary and appropriate.

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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,” for example processing tomatoes

OR



- If your total annual produce sales from your farm is less than \$25,000, you are fully exempt from the law.

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FDA's List of Produce Rarely Consumed Raw

Asparagus

Beans: black, Great Northern, kidney, lima, navy, pinto

Beets, garden (roots and tops)

Beets, sugar

Cashews

Cherries, sour

Chickpeas

Cocoa beans

Coffee beans

Collards

Corn, sweet

Cranberries

Dates

Dill, seeds and weed

Eggplants

Figs

Ginger

Hazelnuts

Horseradish

Lentils

Okra

Peanuts

Pecans

Peppermint

Potatoes

Pumpkins

Squash, winter

Sweet potatoes

Water chestnuts

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Full FSMA Exemption

Remember: the threshold is \$25,000 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	2012	2013	2014	2015	2016	Average 3 year value for 2014-16
25,000	25,460	25,871	26,332	26,608	26,956	26,632

Add and average your annual sales for 2014, 2015, and 2016 and see if that number is less than the \$26,632. If it is then you're fully exempt.

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm554484.htm>

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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 of ALL products--fresh, processed, feed, etc.

Rolling average from previous 3 years & converted into 2011 \$

AND



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

Direct customer examples: consumers at farmers' markets, CSA, farm stand, 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

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2011	2012	2013	2014	2015	2016	Average 3 year value for 2014-16
500,000	509,199	517,417	526,645	532,170	539,121	532,645

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

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm554484.htm>

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My farm is qualified exempt. What do I do now? → 4 Main things

1. Keep records to prove you are exempt. It is your responsibility to prove you qualify.
 - Sales receipts, invoices, load lists, tax records
 - Total sales to qualified end users vs. others
 - 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: you needed to start keeping these records in March 2016!

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My farm is qualified exempt. What do I do now? → 4 Main things

2. Provide name and address of farm where food was grown
 - If the food has a label, make sure the address and name of farm is on it.
 - Example: outside of CSA box, any packaged food
 - Or post a sign at point of purchase with name and address.
 - Example: Farmers' Market, Farm Stand
3. Record that you annually reviewed your FSMA status and the farm is still in the correct FSMA category.
 - Make sure this record is signed & dated.



My farm is qualified exempt. What do I do now? → 4 Main things

4. Comply with the compliance and enforcement requirements of the Produce Rule,

- You are not exempt from FDA oversight and the prohibition on putting adulterated food into commerce; and you are subject to the provisions regarding the withdrawal of your status as a partially covered (“qualified exempt”) operation, which could occur, for example, if you are shown to have made people sick by putting adulterated food into commerce



Timeline for Compliance – Qualified Exemption

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

***2011 dollars**

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Farm scenarios – FSMA fully exempt, qualified exempt, or fully subject?

Fully Exempt Farms	Qualified Exempt Farms
All produce crops grown on the farm are/will:	All farm gross food sales annually under 500K.
Only consumed on-farm	
All on FDA's rarely consumed as raw list	AND
Go through a "kill step"	At least half of sales are to a qualified end user (direct to customer, restaurant, grocery store)
OR	
Gross annual sales of <u>produce</u> are under 25K.	

Scenario 1: Adam's Farm grows a diverse number of vegetables (tomatoes, potatoes, melon, etc) and sells them all at his farm stand. His total gross annual sales of produce are less than 25K.

Scenario 2: Suzie's Farm grows potatoes, eggplant, and dried beans. She grosses 45K annually.

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Gross annual sales of produce are under 25K.	

Scenario 3: Garrett's Farm grosses 80K annually from growing only tomatoes that are all sold to a processor and turned into tomato sauce.

Scenario 4: Alexa's farm grows a diverse amount of fruit and vegetables that are all eaten by her family on the farm.

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OR	
Gross annual sales of produce are under 25K.	

Scenario 5: Joe's farm has 200K of total gross sales annually and sells 150K of the sales thru a CSA and farmers' markets.

Scenario 6: Tara's farm has 100K gross annual sales and 80K is made by selling strawberries and tomatoes to a distributor. The other 20K is from farm stand sales of strawberries & other vegetables.

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OR	
Gross annual sales of produce are under 25K.	

Scenario 7: Jenna's farm is a large CSA farm with 600K in annual gross sales with 580K from CSA sales. The other 20K is made from sales to restaurants.

Scenario 8: Debbie's farm has the following breakdown for all farm gross food sales of 555K:

- 250K from dairy
- 250K from grain
- 50K from value added products
- 5K from farm stand selling strawberries

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Small Farms with a Qualified Exemption



- Examples of California small farms with a Qualified Exemption from FSMA (if under \$500,000 in 2011 dollars)
 - Produce growers who mainly sell at farmers markets or through a CSA or at their farms
 - SE Asian strawberry growers around Sacramento who mostly sell at their farm stands
 - Growers in Sonoma or Yolo Counties who focus on producing specialty items for restaurants in the SF Bay Area
 - Farms that supply a particular store or restaurant, such as restaurant gardens in Napa or the Bi-Rite Market farm



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Small Farms subject to full FSMA



- Examples of California small farms and ethnic groups that will be subject to full FSMA requirements
 - Coastal strawberry growers, including many Latino growers, who are contracted by shippers such as Driscolls
 - H'mong vegetable growers around Fresno who sell to packing houses
 - Raisin grape growers near Fresno
 - Avocado, citrus, and other tree fruit growers who sell to packing houses, such as Punjabi growers in Sacramento Valley
 - Chinese growers south of San Jose



Covered Farms - Requirements

- At least one supervisor or responsible person from the covered farm must complete an FDA-approved training
- The only such training currently is the Produce Safety Alliance training which consists of 8 hours of power point, and then you get a binder to refer to
- CAFF will offer these trainings starting in late 2017
- We are planning to charge about \$100
- Other groups are offering these trainings, but they may be charging more

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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 testing and standards
- Harvest & Post-harvest

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

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Timeline for Compliance

Total All Farm Annual Sales	FSMA Compliance	FSMA Water Compliance ¹
\$500,000*+	2018	2020
\$250,000-499,999*	2019	2021
\$25,000-249,999*	2020	2022
Produce <i>only</i> sales less than \$25,000*	exempt	exempt

***2011 dollars**

¹Depending on FDA decision(s)

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Covered Farms - Recommendations

FSMA recommendations for fully covered 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 obligation under FSMA Preventive Controls Rule to verify that all of their suppliers meet food safety standards.

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FSMA & Organic Certification

- Overall there is overlap between FSMA and NOP
- If you are certified organic, you're already started on FSMA because you're used to keeping records of various farm practices.
- FSMA does not require you to do anything that would contradict 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
- In the next webinar, we will dive more deeply into these requirements as well as some others

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California Direct Marketing Laws with Food Safety Requirements

Even if you have an exemption or qualified exemption from FSMA, California direct marketing laws require you to implement food safety practices

- 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**

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

What are GAPs?

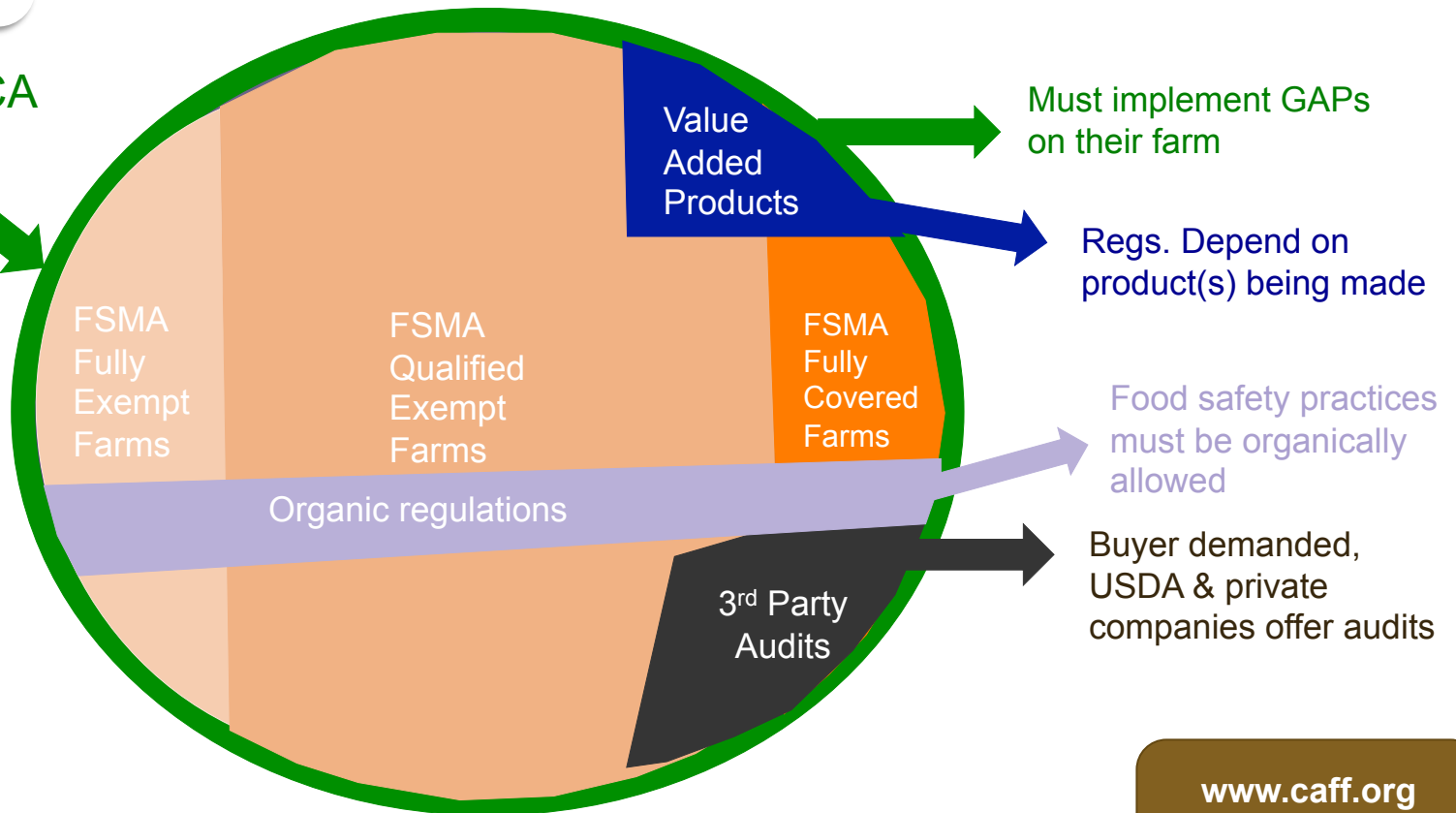


- GAPs = Good Agricultural Practices
 - 5 key areas of Focus:
 1. **Water**
 2. **Employee Training (Health & Hygiene)**
 3. **Land Use & Animal Access**
 4. **Equipment, Tools & Buildings**
 5. **Manure, Compost & Chemicals**
 - Start by understanding your practices and the potential risks associated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



How does this all fit together?

All Farms in CA





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