



Community Alliance with Family Farmers



Food Safety – FSMA and NOP I
Who and What is covered by the FSMA Produce Rule
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Acknowledgement & Disclaimer

Acknowledgement:

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Presentation Road Map

Webinar #1--Today

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:
 - Fully exempt
 - Partially exempt, “Qualified exempt,” with limited requirements
 - Covered farms and subject to all requirements
3. Timeline for compliance and enforcement

Presentation Road Map

Webinar #2—November 14, 2017

- Principal obligations of fully covered farms and how FSMA rules intersect with NOP

Webinar #3—January 11, 2018

- Deep dive into key concerns of organics, including manure, compost, animals, and water

Factsheets & Updated “Farmers Guide” resource will be released this fall

Goals of this Webinar Series

1. Understand food safety metrics and FSMA regulations and how they line up with National Organic Program regulations.
2. Learn where you can direct growers who want information on food safety, FSMA, & GAPs.
3. Have a forum to ask questions about scenarios you've encountered and/or describe future food safety needs you foresee in your work with organic farmers.

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

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

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 an Oregon small 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



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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 two owners were sentenced in January 2014 to five years probation, six months home detention, and \$150,000 each in restitution fees to victims





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>)





Questions?

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

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

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.


FSMA – 3 farm categories

Fully Exempt
Farms

Qualified
Exempt Farms

Fully Subject
Farms

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.



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

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.

Be prepared to prove the farm is fully exempt from FSMA by keeping the applicable records:

- Planting schedule and/or seed receipts that shows only crops on the FDA “rarely consumed raw” list
- Affidavit from processing company that documents their “kill process”
- Financial records to prove less than \$25K in sales

FSMA has no set deadline that you need to have these records in place, but start keeping them ASAP so you’re prepared in case an inspector asks you to prove that you’re fully exempt.

FSMA – 3 farm categories

Fully Exempt
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Exempt Farms

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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



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	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.

My farm is qualified exempt. What do I do now?

→ 4 Main Requirements

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!

My farm is qualified exempt. What do I do now?

→ 4 Main Requirements

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 Requirements

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

- Your Qualified Exempt status can be revoked by FDA if your farm is involved in a foodborne outbreak.
- All farms, no matter your FSMA status, are prohibited from putting contaminated food into commerce. The FDA refers to contaminated food as adulterated food.

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**

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**

“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”****

FSMA – 3 farm categories

Fully Exempt
Farms

Qualified
Exempt Farms

Fully Subject
Farms

Farms fall into this category if:

1. Their 3 year adjusted average gross sales is greater than \$500K
2. They sell less than \$500K adjusted average gross sales, but do not sell at least 50.1% of sales to a qualified end user

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

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!

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.

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

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)

**What FSMA
farm category
do you think
most of the
farms you
interact with
fall into?**

Questions?



FSMA – 3 farm categories

Let's go through some examples!

Fully Exempt
Farms

Qualified
Exempt Farms

Fully Subject
Farms

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 produce are under 25K.	

Scenario 1 Joe's farm has 200K of total gross sales annually and sells 150K of the sales thru a CSA and farmers' markets.

Scenario 2: 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.

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

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All produce crops grown on the farm are/will:	All farm gross food sales annually under 500K.
Only consumed on-farm	
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OR	
Gross annual sales of produce are under 25K.	

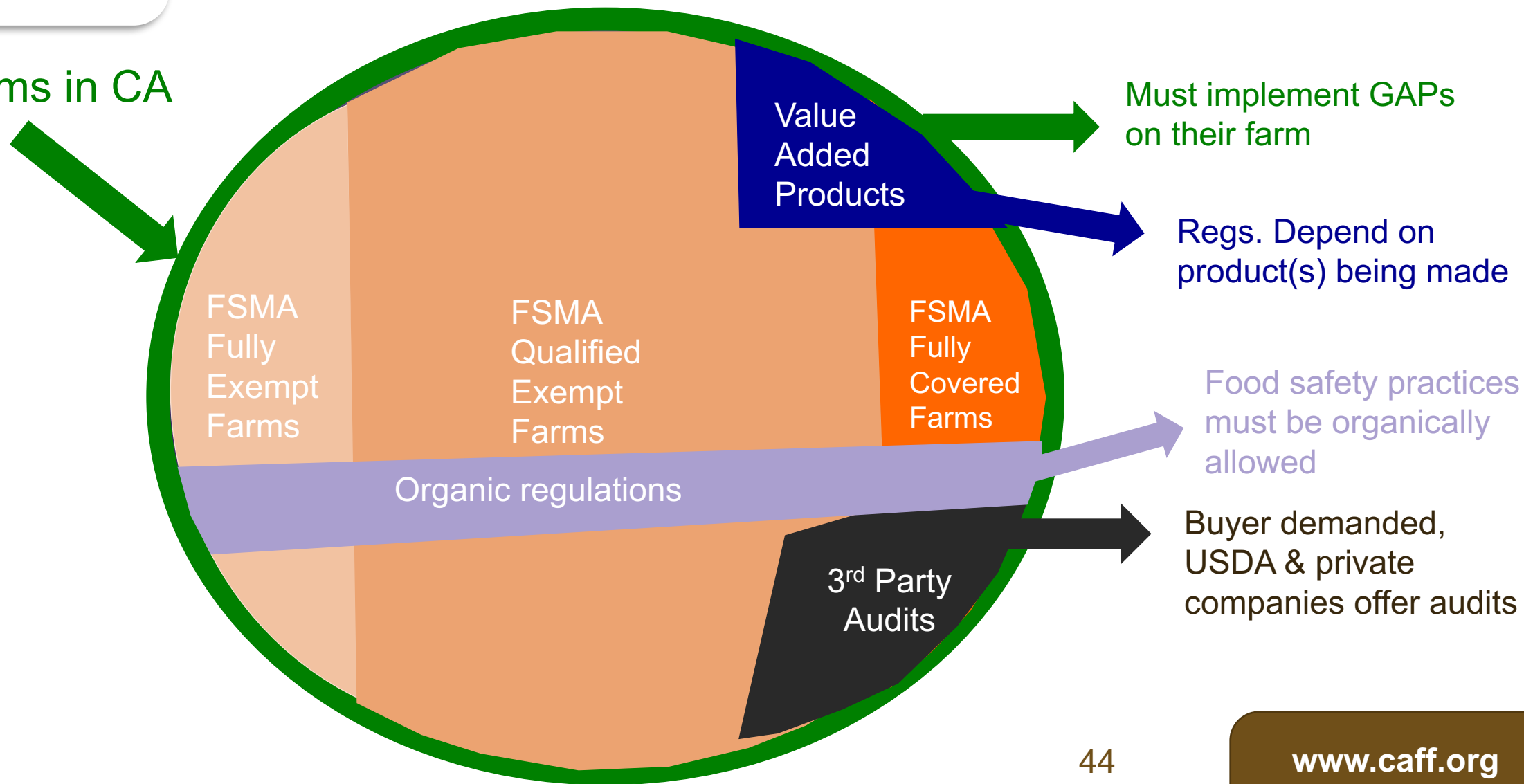
Scenario 3: Jenna's farm is a large CSA farm with 600K in annual gross sales with 580K from CSA sales. The other 20K is made from sales to restaurants.

Scenario 4: 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

How does this all fit together?

All Farms in CA



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Resources

- CAFF Food Safety webpages:
<http://www.caff.org/programs/foodsafety/>
- National Sustainable Agriculture Coalition FSMA Flow Chart:
<http://sustainableagriculture.net/wp-content/uploads/2015/02/NSAC-FSMA-flowchart-final-v2.pdf>
- Wild Farm Alliance Co-Management Resources:
http://www.wildfarmalliance.org/food_safety_and_conservation_resources
- Actual FSMA Law text:
<https://www.federalregister.gov/documents/2015/11/27/2015-28159/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption>