

# The FDA's Produce Safety Rule: What Iowa's Market Managers, Lead Personnel and Vendors Should Know

IFMA Workshop 2-3-18

# FDA's Produce Safety Rule



- Complicated? Dense? How about nuanced??
- Background
- Produce, Vendors and Markets:
  - What produce is covered by the Rule?
  - How might the rule affect me or my market?
  - Levels of compliance for vendor farms
- Where to go to learn more
- Opportunities



# Food Safety Modernization Act or FSMA – some background

- ▶ The “Produce Safety Rule” is a part of FSMA
- ▶ The law (FSMA) had broad bi-partisan support in Congress and was enacted on January 4, 2011
- ▶ FSMA is administered by the U.S. Food & Drug Administration (FDA)
- ▶ Since 2011, the FDA has been collecting input and formulating rules to enact this law
- ▶ The Act will be fully implemented over time

# FSMA: Background, continued

- ▶ Primary goal is prevention of food borne illnesses
  - Reduce and eliminate outbreaks of *Salmonella*, *E. Coli*, *Listeria*, etc. related illnesses and deaths
  - About 48 million people (1 in 6 Americans) get sick, 128,000 are hospitalized, and 3,000 die each year from foodborne diseases, according to recent data from the Centers for Disease Control and Prevention.
- ▶ Last major update to the nation's food safety laws was 1938
- ▶ Most sweeping reform of FDA's food safety authority in more than 70 years

# FSMA has 7 “Foundational Rules”

- 1) Accredited Third-Party Certification
- 2) Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food
- 3) Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals
- 4) Foreign Supplier Verification Programs (FSVP)
- 5) Mitigation Strategies to Protect Food Against Intentional Adulteration
- 6) Sanitary Transportation of Human and Animal Food
- 7) Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption or the “Produce Safety Rule”

# FDA quote:

- ▶ “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.”  
Final rule issued: Nov. 13, 2015.

# Common Questions Asked by Growers and Managers

- ▶ “Does my farm fall under the Rule?”
- ▶ “What do I grow that falls under the rule?”
- ▶ “Does this Rule affect the local farmers market?”
- ▶ “What do I need to do to be in compliance?”

# FSMA Produce Safety Rule:

“What do I grow or sell that is NOT covered by the rule?”

- Certain produce is “not covered by this rule...commodities the FDA has identified as rarely consumed raw”



# Certain produce is “not covered by this rule... commodities the FDA has identified as rarely consumed raw”

Is your produce (or some of it) one of the commodities that the FDA has identified as rarely consumed raw?

- ▶ Rarely consumed raw produce commodities include **asparagus**; black **beans**, great Northern beans, kidney beans, lima beans, navy 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. Also **food grains**, including barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (e.g. cotton seed, flax seed, rapeseed, soybean, and sunflower seed).
- ▶ Also...

# FSMA – Produce Safety Rule

## Other “Not Covered” Produce:

- ▶ Not Covered: Produce that is used for personal or on-farm consumption
- ▶ Not Covered: under certain conditions for produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance...examples include a “kill step” like canning (tomatoes) or commercial fermentation (wine grapes)

# FSMA Produce Safety Rule:

So that's produce not covered by the Rule...

“What do I grow that is covered by the rule?”

- ▶ Produce not mentioned in the “rarely consumed raw list”. Think produce typically or frequently consumed raw.



# FSMA Produce Safety Rule:

So we have produce covered and not covered by this rule. How do farms fall under the rule?

Farms that grow, harvest, pack or hold produce fall under three categories:

- 1) exempt
- 2) qualified exempt
- 3) full compliance



# Produce Safety Rule – Farm Types

## 1) Exempt Farms

- a) Farms that ONLY grow, harvest, pack or hold ag commodities not typically consumed raw...
- b) Farms with produce used ONLY for personal or on-farm consumption
- c) Sell produce (grown or acquired for re-selling) with an 3-year running average annual value of \$25,000 or less
- d) Sell ONLY produce that undergoes or will undergo a commercial “kill step”  
(really a subset of “a” above)



# Produce Safety Rule – Farm Types

## 2) Qualified Exempt Farms

If your farm does not land in the previous “Exempt” category, it may be eligible for a “qualified exemption” if it meets two requirements:

1. The farm must have **food sales** averaging less than \$500,000 per year during the previous three years; AND
2. The farm’s **produce sales** to qualified end-users must exceed sales to all others combined during the previous three years.
  - A qualified end-user is either (a) the consumer of the food or (b) a restaurant or retail food establishment that is located in the same state as the farm or not more than 275 miles away.

# FSMA – Produce Safety Rule

## Qualified Exempt Farms, cont'd

- ▶ Farms with qualified exemption status must disclose the name and the complete business address of their farm (“where the produce was grown”) either on the label of the produce or at the point of purchase (i.e. a sign).
- ▶ These farms must also do record-keeping to show qualified exempt status...

# FSMA – Produce Safety Rule

## Proof of Exempt or Qualified Exempt Status

- All farms that claim exemption or qualified exemption must be able to provide documentation (tax returns, etc.) to the FDA or its representatives that would verify the exemption claim. The FDA may develop forms to expedite this documentation.
  - Records that show the farm is below the sales threshold (for exempt or qualified exempt farms)
  - Records that show more sales to qualified end users than not (for qualified exempt farms)

# FSMA – Produce Safety Rule

## Proof of Exemption or Qualified Exemption Status

- ▶ All business entities underneath or part of a larger or umbrella or encompassing business entity must be taken into account when calculating the average annual value of produce sold during the previous three-year period.

Example:  
CSA Field + Farmstand +  
Restaurant Sales

> \$25,000  $\neq$  exempt



# Produce Safety Rule – Farm Types

## 3) Full Compliance

Farms that fall under full compliance of this rule:

- 1) Farms that have more than \$500K in annual **food** sales (rolling 3 year average)

OR

- 2) Farms (rolling 3 year average) that have less than \$500K in annual **food** sales but more than \$25K in **produce** sales AND the majority of **food** sales are not to qualified end-users (that is, to end users located out of state or more than 275 miles from the farm)

# FSMA – Produce Safety Rule

## Key Requirements

- Farms under full compliance of this rule must meet some key requirements in these areas:
    - 1) Agricultural Water – testing for E. coli
    - 2) Biological Soil Amendments
    - 3) Sprouts, if applicable
    - 4) Domesticated and Wild Animals
    - 5) Worker Training and Health and Hygiene
    - 6) Equipment, Tools and Buildings
- Enhanced recordkeeping for all of these areas

# FSMA Produce Safety Rule:

So we have produce covered and not covered by this rule.

And Farms fall within the rule as exempt, qualified exempt, and full compliance

How do markets fall under the rule?

- ▶ Markets do not fall under the Produce Safety Rule per se, but vendors may need to abide by certain requirements **at the market** to be in compliance...
- ▶ **Farmers Markets**: to comply, vendors with farms that fall under qualified exempt and full compliance must display on a sign, placard, etc., the complete business address of their farm (or put address labels on everything)
- ▶ How can markets help?...

# Market Managers and Lead Personnel can...

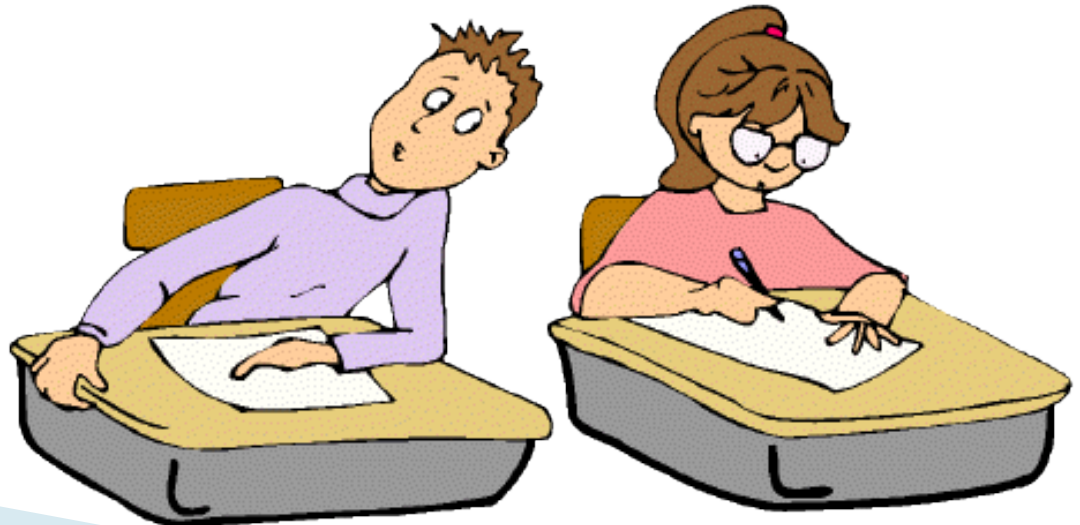
- ▶ Help get the word out to produce vendors about the Produce Safety Rule
- ▶ Help vendors understand where they fall within the Rule
- ▶ Guide vendors to online resources and state and university personnel that can assist
- ▶ Help ensure compliance when it comes to signage at the market



# Let's do some examples

Do the following farms fall under

1. Exempt?
2. Qualified Exempt?
3. Full Compliance?



# Example 1

- ▶ A farm sells \$19,000 in produce averaged over a 3 year period (so, approximately \$19K each year) at a local market and through a CSA.
  - This farm is under the \$25,000 threshold and is thus exempt from the Produce Safety Rule.



# Example 2



- ▶ A farm sells \$35,000 in food averaged over a 3 year period at a local farmers market and through a CSA. The farm grows \$23,000 worth of produce and purchases \$7,000 in produce and \$5,000 other value-added food for re-sale along with produce grown.
  - This farm would be qualified exempt: it sells on average over \$25,000 in produce (note this is regardless of whether the produce is grown on the farm or is a mix of purchased and farm-grown produce) and all of the **food** (produce plus value added) is sold to qualified end users (sold locally to end consumers).



# Example 3

- ▶ A farm sells \$35,600 in produce, and also sells \$650,000 in other food products, including sauerkraut and jam (3-year rolling average).
  - Because this produce farm sells more than \$500,000 in food, it falls under full compliance: Any produce not on the rarely consumed raw list must meet the full compliance requirements.



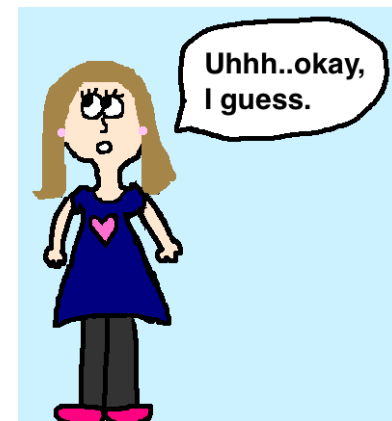
# Example 4

- ▶ A farm sells \$475,000 in produce (3-year rolling average) with these details:  
\$200,000 sold to a wholesaler out-of-state/more than 275 miles, \$200,000 to a local restaurant, and \$75,000 to a local grocery store. The farm does not grow, harvest, pack or hold any other food.
  - Because the farm sells the majority of the food to “qualified end users” and sales are under the \$500,000 threshold, the farm would be qualified exempt.



# Example 5

- ▶ A farm sells all of their \$35,000 in produce annually to a distributor located more than 275 miles away and not in the same state where the produce was grown. The farm grows potatoes, pumpkins, sweet corn, winter squash, and has 1 acre of raspberries and strawberries.
  - This farm sells more than \$25,000 in produce so the farm would **not** fall under exempt status; the covered produce – the raspberries and strawberries – **fall under full compliance** since they are **not** sold to qualified end users.
  - The potatoes, pumpkins, sweet corn, and winter squash are not covered crops and thus outside of the Rule.



# Values have to be adjusted for inflation...

Baseline Value for Cut-offs (2011)	Value in 2012	Value in 2013	Value in 2014	Value in 2015	Value in 2016	Average 3 Year Value for 2014 - 2016
\$500,000	\$509,199	\$517,417	\$526,645	\$532,170	\$539,121	\$532,645

*Not covered farm:* A farm or farm mixed-type facility with an average annual monetary value of produce sold during the previous 3-year period of less than \$25,000 (on a rolling basis).

Baseline Value for Cut-offs (2011)	Value in 2012	Value in 2013	Value in 2014	Value in 2015	Value in 2016	Average 3 Year Value for 2014 - 2016
\$25,000	\$25,460	\$25,871	\$26,332	\$26,608	\$26,956	\$26,632

# Compliance Dates – labeling & “general compliance”

- ▶ If packaging label is required, a proper label must be used no later than January 1, 2020.
- ▶ Business address required on signs & placards at farmers markets...on a three-year rolling average for:
  - Farms grossing no more than \$250,000 in produce sales have until **January 26, 2020**
  - Farms grossing no more than \$500,000 but more than \$250,000 in produce sales annually have until **January 26, 2019 (essentially next year's market season)**

# Compliance Dates – recordkeeping

- Farms claiming qualified exemption (QE) status or full exempt (E) status
  - The FDA expects farms to begin keeping these records NOW (as of January 26, 2016)
  - For QE and E: Proof that produce sales are what you say they are...
  - For QE: Proof that food sales are what you say they are...
  - For QE: Proof you sell most of your produce to “qualified end users” – consumers of the food and/or restaurants and/or retail food establishments located in Iowa or within 275 miles from the farm.
  - FDA is working on list of acceptable records to keep
  - Keep your tax forms, receipts...anything to help prove your exempt or qualified exempt status

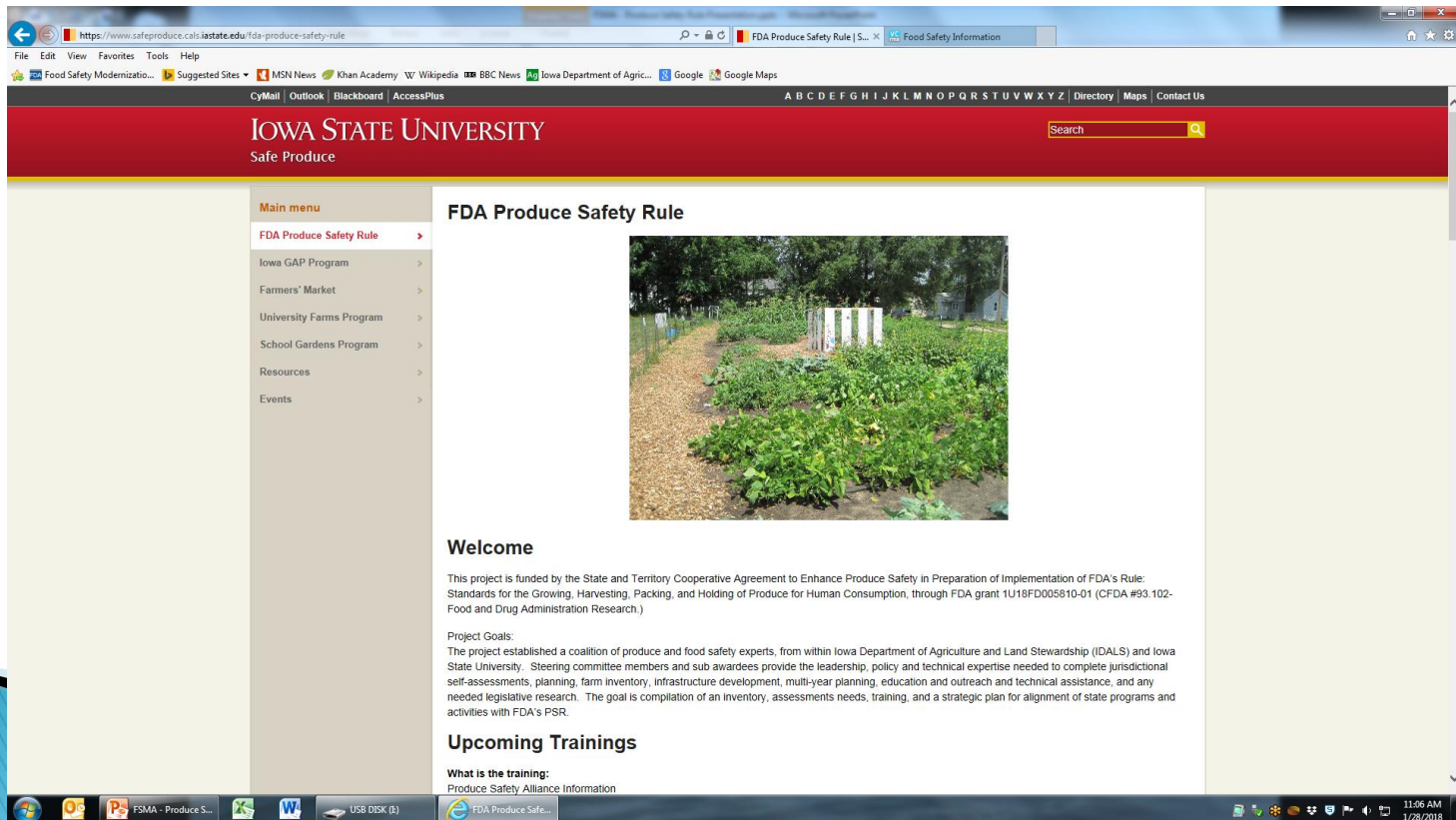
# Compliance Dates – self review

- Farms must keep a written record that reflects an annual review and verification of the farm's continued eligibility for exempt or qualified exempt status
  - Farms grossing no more than \$250,000 in **produce** sales have until **January 26, 2020**
  - Farms grossing no more than \$500,000 in **produce** sales but more than \$250,000 annually have until **January 26, 2019 (less than a year away)**
  - These reviews are not turned over to the FDA but should be on hand if the FDA asks for them

# Where to learn more?

IDALS has partnered with ISU Extension...

- ▶ [www.safeproduce.cals.iastate.edu/fda-produce-safety-rule](http://www.safeproduce.cals.iastate.edu/fda-produce-safety-rule)



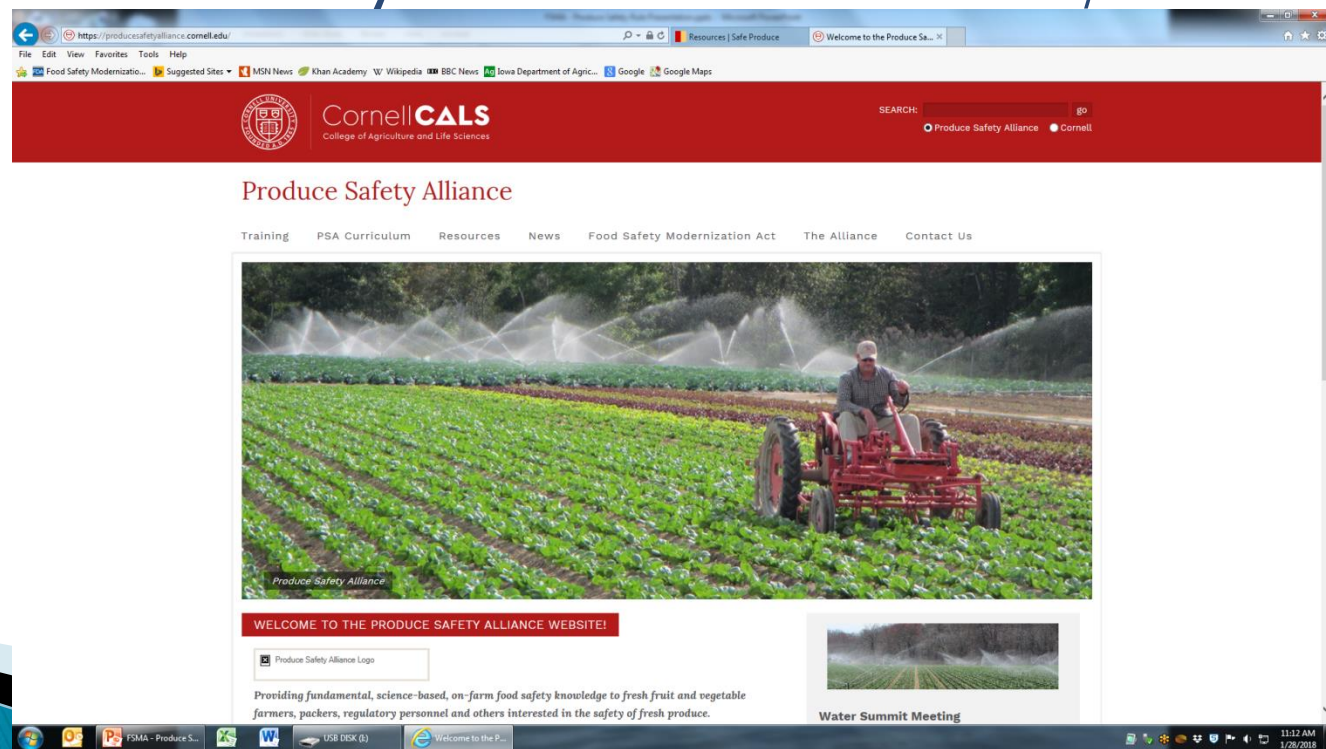
# Where to learn more?

FDA website:

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

Produce Safety Alliance:

- <https://producesafetyalliance.cornell.edu/>



# Opportunities – Producer Trainings

- ISU Extension training opportunities
  - Nine sessions being held winter of 2017–18 throughout Iowa – three remaining:
    - **February 9**  
Linn County Extension Office, 383 Collins Road NE, Suite 201  
Cedar Rapids, IA 52402  
This training is currently full.
    - **March 8**  
NCC–603 West Park Street; Building C; Room 304  
Sheldon, IA
    - **March 29**  
Cerro Gordo County Extension Office, 601 S Illinois Avenue  
Mason City, IA 50401
  - Ten sessions will be held over the winter of 2018–19 in Iowa
  - All are encouraged to attend

# Opportunities – Market Managers

The FSMA Produce Safety Rule encourages water testing for produce growers who use well and surface water as their water source. Through an FDA grant, the Produce Food Safety Team at Iowa State University and the Iowa Department of Agriculture and Land Stewardship would like to help growers assess their well and surface waters.

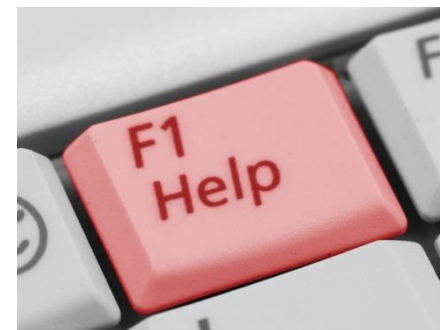
Please consider scheduling a day for our team to come to a farmer's market session to offer water testing to produce vendors at a reduced cost. Growers would bring their water samples to the market on the designated day and drop them off with our team. We will analyze the water samples and communicate the results to the grower within a week. We anticipate the cost to the grower would be approximately \$15 (private lab costs \$25–50).

Managers: your job would be to:

- **Schedule a day that works for the produce safety team and your growers**
- **Distribute water testing kits (instructions and water containers) prior to the collection date**
- **Communicate with growers to remind them to bring their samples**
- **Interested? Grab a handout from the Produce Safety Rule table**



# Questions?



- Contact Information:

- Paul Ovrom / [paul.ovrom@iowaagriculture.gov](mailto:paul.ovrom@iowaagriculture.gov) / 515-242-6239
- Dr. Angela Shaw, ISU Extension / [angelaml@iastate.edu](mailto:angelaml@iastate.edu) / 515-294-6773
- Other team members include Maury Wills, Shannon Coleman, Joe Hannan, Sandy Andrews, Manreet Bhular, Linda Naeve, Lakshman Rajagopal, Teresa Wiemerslage, Morgan Hoenig, and John Krzton-Presson

The following slides were not part of the IFMA Workshop presentation, but may be of assistance to producers...

# FSMA Farm Definition

- Operations whose only activities are within **the farm definition** are not required to register with FDA as food facilities and thus are not subject to the preventive controls regulations (1 & 2 above).
  - ...so does your operation fall within the farm definition?
- 
- ▶ FDA's FSMA farm definition:
  - ▶ The FSMA definition of a 'farm' covers two types of farm operations. Operations defined as farms are not subject to the preventive controls rule (#s 1 & 2 on slide 4).

# FSMA Farm Definition, cont'd

- ▶ **1) Primary Production Farm:** This is an operation under one management in one general, but not necessarily contiguous, location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. This kind of farm can pack or hold raw agricultural commodities such as fresh produce and may conduct certain manufacturing/processing activities, such as dehydrating grapes to produce raisins and packaging and labeling raisins.
- ▶ This definition of “farm” includes packing or holding raw agricultural commodities (such as fresh produce) that are grown on a farm under a different ownership. The final rule also includes within the “farm” definition companies that solely harvest crops from farms.

# FSMA Farm Definition, cont'd

- ▶ **2) Secondary Activities Farm:** This is an operation not located on the Primary Production Farm that is 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.

# FSMA – Produce Safety Rule

## Key Requirements

- ▶ **1) Agricultural Water – essentially two types...**
- ▶ a) “*E. coli*-free water” – Water that should contain no detectable *E. coli*. This is water that if contaminated with potentially dangerous microbes would reasonably likely be transferred to produce through direct or indirect contact.

Uses: Examples include water for washing hands during and after harvest, used on food-contact surfaces, water used to directly contact produce during or after harvest (including to make ice), water used for sprout irrigation

# FSMA – Produce Safety Rule

## Key Requirements

- ▶ 1)Agricultural Water
- ▶ a) “*E. coli*–free water” **cont’d**:
  - Where “*E. coli*–free water” is required for use...
    - it cannot be obtained from untreated surface water
    - Its use must be immediately discontinued if *E. coli* is detected
    - Corrective actions must be taken before re–use of this water can resume

# FSMA – Produce Safety Rule

## Key Requirements

- ▶ 1)Agricultural Water
  - ▶ a) “*E. coli*-free water” cont’d:
  - ▶ There is no requirement to test agricultural water that is received from public water systems
  - ▶ “*E. coli*-free water” (water used where sanitation is paramount – see slide 15) obtained from untreated ground water must be initially tested at least four times during the growing season or over a period of one year to determine its safety. If the four initial sample results show no detectable *E. coli*, testing can be done once annually thereafter

# FSMA – Produce Safety Rule

## Key Requirements

- ▶ 1)Agricultural Water
- ▶ b) Water directly applied to growing (pre-harvest) produce (other than sprouts)
- ▶ This water must be tested to determine a “microbial water quality profile.” If these profiles or tests show that certain microbial levels are not exceeded, the water can be used on growing produce.
  - If this water does not meet these criteria, corrective actions are required as soon as practicable, but no later than the following year.

# FSMA – Produce Safety Rule

## Key Requirements

- ▶ 1)Agricultural Water
- ▶ b) Water directly applied to growing produce (other than sprouts), **cont'd**:
- ▶ There is “flexibility” for farmers that are using water applied to growing produce that does not pass the microbial tests.
  - Options include allowing time for potentially dangerous microbes to die off in the field by using a certain time interval between last irrigation and harvest, but no more than four consecutive days
  - Allowing time for these microbes to die off between harvest and end of storage – or to be removed during commercial activities such as washing, within appropriate limits
  - Treating the water

# FSMA – Produce Safety Rule

## Key Requirements

- ▶ **2) Biological Soil Amendments**
- ▶ Raw manure: at this time, the FDA does not object to farmers complying with the USDA's National Organic Program standards, which call for a 120-day interval between the application of raw manure for crops in contact with the soil and 90 days for crops not in contact with the soil.
- ▶ Untreated biological soil amendments of animal origin must be applied in a manner that does not contact covered produce during application and minimizes the potential for contact after application.

# FSMA – Produce Safety Rule

## Key Requirements

- ▶ **3) Sprouts**
- ▶ Sprouts have been frequently associated with foodborne illness
- ▶ There are requirements specific to sprout production including testing spent sprout irrigation water from each production batch of sprouts for certain pathogens. More information can be found on the FDA's FSMA website.

# FSMA – Produce Safety Rule

## Key Requirements

- ▶ **4) Domesticated and Wild Animals**
- ▶ Farms that rely on grazing animals or working animals and entry to production sites by wild animals: farmers are required to take all measures reasonably necessary to identify and not harvest produce that is likely to be contaminated with fecal material or other potentially hazardous animal biological materials.

# FSMA – Produce Safety Rule

## Key Requirements

- ▶ **5) Worker training and health and hygiene**
- ▶ Take measures to prevent contamination of produce and food-contact surfaces by ill or infected persons
- ▶ Using hygienic practices when handling covered produce or food-contact surfaces
- ▶ Measures to prevent visitors from contaminating covered produce or food-contact surfaces
- ▶ Farm workers required to have combination of training, education and experience to perform assigned tasks

# FSMA – Produce Safety Rule

## Key Requirements

- ▶ **6) Equipment, Tools and Buildings**
- ▶ The rule establishes standards to prevent these sources from contaminating produce. The rule covers greenhouses, germination chambers, toilet and hand-washing stations
- ▶ Covers appropriate storage, maintenance and cleaning of equipment and tools

**Does your farm grow, harvest, pack or hold produce?**

Sections 112.1 and 112.3(c)  
We define "produce" in section 112.3(c).

NO



**Your farm is NOT covered by this rule.**

YES

**Does your farm on average (in the previous three years) have \$25k or less in annual produce sales?**

Section 112.4(a)

YES



**Your farm is NOT covered by this rule.**

NO

**Is your produce one of the commodities that FDA has identified as rarely consumed raw?**

Section 112.2(a)(1)

If you grow, harvest, pack or hold more than one produce commodity, you must ask this question separately for each one to determine whether that particular produce commodity is covered by this rule.

YES



**This product is NOT covered by this rule.**

NO

**Is your produce for personal/on-farm consumption?**

Section 112.2(a)(2)

YES



**This produce is NOT covered by this rule.**

NO

Is your produce for personal/on-farm consumption?

Section 112.2(a)(2)

YES



This produce is  
**NOT** covered  
by this rule.

NO

Is your produce intended for commercial processing that adequately reduces pathogens (for example, commercial processing with a “kill step”)?

Section 112.2(b)

YES



This produce is eligible  
for exemption from the rule,

provided you make certain statements in documents accompanying the produce, obtain certain written assurances, and keep certain documentation, as per Sections 112.2(b)(2) through (b)(6).

NO

Does your farm on average (in the previous three years) as per Section 112.5:

have < \$500k annual food sales,

**AND**

a majority of the food (by value) sold directly to “qualified end-users”?

Section 112.3(c)

“Qualified End-User” as defined in Section 112.3(c) means:

- the consumer of the food OR
- a restaurant or retail food establishment that is located—
  - (i) in the same State or the same Indian reservation as the farm that produced the food; OR
  - (ii) not more than 275 miles from such farm.

(The term “consumer” does not include a business.)

YES



Your farm is eligible for a  
qualified exemption from this rule,

which means that you must comply with certain modified requirements and keep certain documentation, as per Sections 112.6 and 112.7.

NO

You are covered by  
this rule

**Does your farm grow, harvest, pack or hold produce?**

Sections 112.1 and 112.3(c)  
We define "produce" in section 112.3(c).

NO



**Your farm is NOT covered by this rule.**

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Section 112.2(a)(2)

YES



**This produce is NOT covered by this rule.**

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**Is your produce intended for commercial processing that adequately reduces pathogens (for example, commercial processing with a "kill step")?**

Section 112.2(b)

YES



**This produce is eligible for exemption from the rule,** provided you make certain statements in documents accompanying the produce, obtain certain written assurances, and keep certain documentation, as per Sections 112.2(b)(2) through (b)(6).

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**Does your farm on average (in the previous three years) as per Section 112.5:**

**have < \$500k annual food sales,**

**AND**

**a majority of the food (by value) sold directly to "qualified end-users"?**

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  - (i) in the same State or the same Indian reservation as the farm that produced the food; OR
  - (ii) not more than 275 miles from such farm.

(The term "consumer" does not include a business.)

YES



**Your farm is eligible for a qualified exemption from this rule,** which means that you must comply with certain modified requirements and keep certain documentation, as per Sections 112.6 and 112.7.

NO

**You are covered by this rule**