Good Agricultural Practices and Regulatory Concerns for Fruit and Vegetable Growers

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Food Safety Educator

Beginning Farmer Veterans Workshop
July 30th, 2016
Trips to Afghanistan to Teach Food Safety

- Topics Covered:
  - Food Safety
  - Pesticide Residue/Postharvest
  - Hygiene
  - Food safety in the home
What have you heard???
Produce Food Safety

CDC estimates that each year:

- 48 million Americans sick from foodborne illness
- 1 in 6 people
- 128,000 hospitalizations
- 3,000 deaths

A significant proportion of foodborne illnesses have been attributed to fresh produce

Source: [http://www.cdc.gov/foodborneburden/](http://www.cdc.gov/foodborneburden/)
Produce Related Illnesses

- Americans buying more fresh produce
- Range of consumer health (immunocompromised)
- Better detection and reporting systems
Causes of Illness

**Bacteria** – Single-celled organisms that live independently.

**Parasites** – Intestinal worms or microscopic protozoa that live in a host animal or human

**Viruses** – Small particles that live and can only replicate in a host
Causes of Illness

Three most common bacteria:

Salmonella
E. coli O157:H7
Listeria monocytogenes

24 Hours

1 Cell  17 Million Cells

Under ideal growing conditions

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On-Farm Microbial Sources

Soil
People
Water
Manure
Livestock
Pets
Wildlife
Washing Alone Does Not Mean Safe

*E. coli* on lettuce

Salmonella on muskmelon

Photo credits: E. Maynard, Peter Cooke, Stephen Ausmus, Scimat Science Photo Library, Institute of Food Technologists
## Cooked vs. Raw Consumption

### Cooked Does Mean Safe!

<table>
<thead>
<tr>
<th>Cooked</th>
<th>?Both?</th>
<th>Raw</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microbial ‘kill step’</td>
<td>Wash step</td>
<td></td>
</tr>
<tr>
<td>Potatoes</td>
<td>Spinach</td>
<td>Lettuce</td>
</tr>
<tr>
<td>Winter Squash</td>
<td>Sweet Corn</td>
<td>Cucumbers</td>
</tr>
<tr>
<td>Zucchini</td>
<td>Beets</td>
<td>Radish</td>
</tr>
<tr>
<td>Eggplant</td>
<td>Kale</td>
<td>Microgreens</td>
</tr>
<tr>
<td>Tomatoes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Apples</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Berries</td>
<td></td>
<td></td>
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<tr>
<td>Garlic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Herbs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Onions</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Consider Farm to Fork Risks

<table>
<thead>
<tr>
<th>Field</th>
<th>Wash/Pack</th>
<th>Cooling/Storage</th>
<th>Transportation</th>
<th>Market</th>
<th>Consumer</th>
</tr>
</thead>
</table>

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Reduce on-farm Risks

*Using Good Agricultural Practices*

GAPs are the conditions, growing practices, and harvesting practices recommended for minimizing risk of microbial contamination to produce safe and wholesome fruits and vegetables.

National GAPs Program
www.gaps.cornell.edu
ALL growers who introduce produce into the public food supply should be concerned about food safety!
Regulation of on-farm food safety

Federal Government (FDA)
  (FSMA)
Indiana State Department of Health (ISDH)
Industry
County Health Departments
Farmers’ Market Rules
Food Safety Modernization Act

FSMA = Food Safety Modernization Act

January 2011 - Signed into Law
November 2015 - Final Produce Rule Published
January 2016 – New Produce Rule Became Law

https://en.wikipedia.org/wiki/FDA_Food_Safety_Modernization_Act
Seven Rules of FSMA

Preventive Controls for Human Foods (final)

Preventive Controls for Food for Animals (final)

Produce Safety (final)

Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals (final)

Accreditation of Third-party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications (final)

Sanitary Transportation of Human and Animal Food (final)

Focused Mitigation Strategies to Protect Food Against Intentional Adulteration (final)
FSMA Terminology

**Covered** – One is held to and obligated to comply with the produce rule.

**Exempt** – One is not obligated to comply with the produce rule.

**Qualified Exemption** – One is exempt from the produce rule provided that certain conditions (qualifiers) are met.
FSMA Produce Rule – Am I Covered???
STANDARDS FOR PRODUCE SAFETY
Coverage and Exemptions/Exclusions for 21 PART 112

The Preventive Controls for Human Food rule clarified the definition of a farm to cover two types of farm operations, primary production farms and secondary activities farms. The same definition is used in the Produce Safety rule (section 112.3(c)). Below are basic criteria that determine whether an operation that meets the definition of “farm” is subject to the produce 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  X  Your farm is NOT covered by this rule.

YES
Am I a FARM or a FACILITY???
Farm

FSMA Produce Rule
Good Agricultural Practices (GAPs)

Facility

FSMA Preventive Controls Rule
Applies if required to register with FDA
Chopping, grinding, and pelletizing may constitute “manufacturing”

Mixed-type Facility
An entity that engages in both farming and processing
Farm

Minimal processing
  Drying
  Baling
  Vacuum packing
***No significant alterations

Facility

Beyond minimal processing
  Pelletizing
***Significant alterations
FSMA Produce Rule

definition of “farm”

- Farms are not required to register as a food facility merely because they pack or hold raw agricultural commodities grown on another farm under a different ownership.
  - Such activities are subject to the produce safety rule rather than the preventive controls rule for human food.
  - One can still pack for a neighbor!
Does your farm on average (in the previous three years) have $25k or less in annual produce sales?
Section 112.4(a)

Your farm is NOT covered by this rule.
FSMA Produce Rule – Am I Covered???

Farms or farm mixed-type facilities with an average annual monetary value of produce sales of $25,000 or less are not covered.
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.

This product is NOT covered by this rule.
Commodities Rarely Consumed Raw

Asparagus
Beans
  Black
  Great Northern
  Kidney
  Lima
  Navy
  Pinto
Beets
  Garden (roots and tops)
  Sugar
Cashews
Sour Cherries
Chickpeas
Cocoa Beans
Coffee Beans
Collards
Sweet Corn
Cranberries
Dates
Dill
  Seeds
  Weed
Eggplants
Figs
Horseradish
Hazelnuts
Lentils
Okra
Peanuts
Pecans
Peppermint
Potatoes
Pumpkins
Winter Squash
Sweet Potatoes
Water Chestnuts
Food Grains

Barley
Corn
   Dent
   Flint
Sorghum
Oats
Rice
Rye
Wheat

Amaranth
Quinoa
Buckwheat
Oilseeds
Cotton
Flax
Rape
Soy
Sunflower
Is your produce for personal/on-farm consumption?
Section 112.2(a)(2)

This produce is NOT covered by this rule.
Is your produce intended for commercial processing that adequately reduces pathogens (for example, commercial processing with a “kill step”)?

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).
Processing crops receive a qualified exemption if:

A. They receive commercial processing that adequately reduces the presence of microorganisms of public health significance.

B. Accompanying documents disclose that the food is “not processed adequately to reduce the presence of microorganisms of public health significance”.

C. Written assurances from the buyer are obtained annually.
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.)

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.

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STANDARDS FOR PRODUCE SAFETY
Coverage and Exemptions/Exclusions for 21 PART 112

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NO

YOU ARE COVERED
BY THIS RULE.
FSMA Produce Rule

If I’m exempt, does this really matter???
Remember!!!

While individuals may be exempt from regulations,

One is NEVER exempt from liability!
### Compliance Timeline

<table>
<thead>
<tr>
<th>Who</th>
<th>Sales</th>
<th>Time to Comply</th>
</tr>
</thead>
<tbody>
<tr>
<td>Farms</td>
<td>&gt;$500,000 food sales/year</td>
<td>2 years</td>
</tr>
<tr>
<td>Small Farms</td>
<td>$500,000 - $250,000 food sales/year</td>
<td>3 years</td>
</tr>
<tr>
<td>Very Small Farms</td>
<td>$250,000 - $25,000 food sales/year</td>
<td>4 years</td>
</tr>
</tbody>
</table>

In addition to compliance times, all will receive an additional two years to comply with water testing requirements.
Agricultural Water

“Water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce).”

FSMA Produce Rule – Section 112.3(c)
Direct Water Application Method

“Using agricultural water in a manner whereby the water is intended to, or is likely to, contact covered produce or food contact surfaces during use of the water.”

Produce

Defined, in part, as the harvestable part of a crop.

FSMA Produce Rule – Section 112.3(c)
Water Questions to Ask

1. Is my farm covered by the produce rule?

2. Is this particular crop covered by the produce rule?

3. Will I be applying water, as irrigation or crop sprays, to the harvestable part of the crop?
Produce Rule
Agricultural Water Standards

Surface water applied directly to **harvestable part** during growing
  20 samples within two years to establish a baseline
  5 samples per year thereafter

Underground water applied directly to **harvestable part** during growing
  4 samples in the first year
  1 sample thereafter

Sources: [http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm415226.htm#water](http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm415226.htm#water) and PSA Curriculum Resources
Produce Rule
Agricultural Water Standards (con’t)

For all water sources:
  Geometric Mean <126 CFU generic *E. coli* /100 ml
  Statistical Threshold Value <410 CFU generic *E. coli* / 100 ml

Sources: [http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm415226.htm#water](http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm415226.htm#water) and PSA Curriculum Resources
Produce Rule Training Requirement

One person from each covered farm must complete training in the APPROVED GAPs curriculum.

The approved curriculum is the Produce Safety Alliance Curriculum

The training and registrations will be managed by the Association of Food and Drug Officials (AFDO)

More information regarding trainings will be available in early December
Where can I sell my produce?

• **Directly to consumers at your farm** – Always acceptable! Recommended to take a GAPs course and follow GAPs.

• **At roadside stands** – Yes, but make sure produce is intact and avoid excess trimming. Recommended to take a GAPs course and follow GAPs.

• **At farmers markets** – Yes, but make sure produce is intact and avoid excess trimming. Strongly encouraged to take a GAPs course and follow GAPs.

  All of these sales are directly to the end user.
Where can I sell my produce?

- **To restaurants and other produce distributors** – Must register with the ISDH as a Wholesale Fruit and Vegetable Grower and Distributor. Registration forms can be found at: [http://www.in.gov/isdh/25773.htm](http://www.in.gov/isdh/25773.htm)

  It is strongly encouraged that growers take a GAPs course. In addition, the distributor may require a 3rd party audit.

Registering with ISDH does not mean they will come to inspect your farm. It provides a list of growers they can easily contact should food safety issues arise.
What should I sell?

• Unless your buyers demand it, avoid washing produce
  • Drying product can be difficult and the addition of water allows bacteria to grow
• Avoid excess trimming and selling bruised fruits and vegetables
  • Cuts and bruises allow for the release of plant nutrients that are food for bacteria
Indiana House Enrolled Act (HEA) 1309

• Better known as the Indiana Home Based Vendor Rule (IC 16-42-5-29)
  • Allows certain foods that are not potentially hazardous food products to be sold at 2 locations: Farmers markets and roadside stands
  • Products have to be made in the individual’s primary residence
  • Must still use sanitary procedures to make the food products (proper hand washing, etc.) and label with the following: Producer’s name and address, common name of product, ingredients, net weight, date product was processed.
Indiana Home Based Vendor Rule (IC 16-42-5-29)

• Must also label the product with the following:

“This product is home produced and processed and the production area has not been inspected by the State Department of Health.”

<table>
<thead>
<tr>
<th>Type of Food</th>
<th>Non-Potentially Hazardous (may be sold by home-based vendor [HBV])</th>
<th>Potentially Hazardous (may NOT be sold by home-based vendor [HBV])</th>
</tr>
</thead>
</table>
| Baked Goods           | Cookies, cakes, fruit pies, cupcakes, fruit breads, dessert bars, baguettes | • Products containing meat, poultry, and/or aquatic animals  
                        |                                                                  | • non-baked dairy products, including cheese, butter, and yogurt  
                        |                                                                  | • non-baked, egg-containing products and fresh shell eggs  
                        | Unprocessed, whole and uncut produce, e.g., oranges, cherries, berries, tomatoes, corn, lettuce, green beans, peppers, etc. | • Any cut produce, e.g., cut tomatoes or melons  
                        |                                                                  | • Raw seed sprouts  
                        | Fermented vegetables, i.e., vegetables placed in a brine (saltwater) solution in which bacteria produce lactic acid to acidify the product and do not require refrigeration | • Non-fermented, pickled vegetables (e.g., pickles, beets, etc.) that are acidified (i.e., vinegar added) and do not require refrigeration. Note: Vegetables that require the addition of any acid (e.g., vinegar) are NOT considered fermented.  
                        |                                                                  | • Garlic in oil mixtures  
                        |                                                                  | • Herb and oil mixtures  
                        | Traditionally prepared fruit-based jams and jellies, e.g., grape, strawberry, blueberry, raspberry, blackberry, etc. | • Fruit butters (e.g., apple, pear, pumpkin) and "low sugar" or "no sugar added" jams and jellies  
                        | Canned Foods          | Only naturally acidic products (i.e., natural pH below 4.6). These may include fruit-based products (e.g., grape, strawberry, blueberry, raspberry, blackberry, etc.) and some other non-chunky sauce products (e.g., barbecue sauce). Note: The pH of all canned food products should be verified before sale. | • Acidified and low-acid canned foods (i.e., in hermetically sealed containers including cans, glass jars, plastic containers, etc.), examples include canned vegetables, salsas, chutney, chow-chow, pickles, beets, and other pickled vegetables, etc.  
                        |                                                                  | • Foods in reduced-oxygen packaging (i.e., vacuum packaging)  
                        | Meat, Poultry, Seafood | ---                                                              | All meat, poultry, or aquatic animal products |
| Syrups                | Honey, maple syrup, sorghum, and molasses                        | ---                                                           |
| Tree Nuts and Legumes | Peanuts, almonds, cashews, walnuts, pistachios, etc.              | ---                                                           |
| Candies and Confections | Caramels, chocolates, fudge, peanut brittle, chocolate-covered fruits and/or nuts, and bonbons. | ---                                                           |
Extension Food Safety Personnel

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Questions???