Produce Food Safety and the Food Safety Modernization Act

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Delaware County

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Produce Food Safety

What have you heard???

Produce Food Safety

Why is this an issue???

"Diets rich in fruits and vegetables may reduce the risk of some types of cancer and other chronic diseases."

Fruits and Vegetables are Good For You!

Why the Increase in Produce-Related Illness?

- We’re eating more fresh produce
- New packaging methods with less room for error
- New microbes associated with produce
- Distribution is very wide in many cases
- More people with suppressed immune systems
- Better detection, reporting

CDC estimates that each year:
- 48 million Americans sick from foodborne illness
- 1 in 6 people
- 128,000 hospitalizations
- 3,000 deaths

Source: http://www.cdc.gov/foodborneburden/

A significant proportion of foodborne illnesses have been attributed to fresh produce
The Biggest Challenge With Fresh Produce -

NO KILL STEP!!!

Cooked vs. Raw Consumption

<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>
</tbody>
</table>

- Potatoes
- Spinach
- Lettuce
- Winter Squash
- Sweet Corn
- Cucumbers
- Zucchini
- Beets
- Radish
- Eggplant
- Kale
- Microgreens
- Tomatoes
- Apples
- Berries
- Garlic
- Herbs
- Onions

All growers who introduce produce into the public food supply should be concerned about food safety!

On-farm Microbial Sources

- Soil
- People
- Water
- Manure
- Livestock
- Pets
- Wildlife

Microorganisms That Cause Foodborne 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.

Microbial Causes of Illness

*Three most common microbes*

- *Salmonella*
- *E. coli O157:H7*
- *Listeria monocytogenes*

24 Hours

1 Cell → 17 Million Cells

Under ideal growing conditions
Pathogenic Viruses

- Norovirus: most common cause of foodborne illness
- Hepatitis A
- Others

Hepatitis A and Norovirus Transmission

- Person-to-person through oral-fecal route
- Contaminated food and water
- Contaminated surfaces

Washing hands is an effective way to reduce spread.

Parasites Associated with Foodborne Illness and Produce

- Cryptosporidium
- Cyclospora
- Giardia
- Entamoeba
- Toxoplasma
- Sarcocystis
- Isospora
- Helminthes
  - Nematodes (e.g., Ascaris lumbricoides) and Plathelminthes (Fasciola hepatica)

Produce associated with illness caused by Cryptosporidium. USDA.

It will Take a Farm to Fork Approach

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
Good Agricultural Practices

GAPs focus on four main areas of production:
- Water
- Waste
- Wildlife
- Workers

Good Agricultural Practices Certification Process

1. GAPs Awareness and Training
2. Farm Self Assessment
3. Written Farm Food Safety Plan
4. Plan Implementation
5. Third Party Audit
6. Certification

Your GAPs or Mine?

Various GAPs guidelines are in use – similar but not identical:
- USDA GAPs/GHPs
- Harmonized GAPs
- Global Food Safety Initiative
- GlobalGAP
- PrimusGFS

Benefits of On-Farm Food Safety Planning

- Public health
- Longer shelf-life
- Higher quality produce
- Due diligence
- Reduce liability risk

Regulation of on-farm food safety

Industry Standards
- FSMA
- Federal Government (FDA)
- Indiana State Health Department (ISDH)
- 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
Seven rules in process by FDA

- 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 (proposed)
- Focused Mitigation Strategies to Protect Food Against Intentional Adulteration (proposed)

FSMA Produce Rule – Am I Covered???

FSMA Produce Rule definition of “farm”

- Farms are not required to register as a food facility merely because it packs or holds 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!

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.
### Commodities Rarely Consumed Raw

<table>
<thead>
<tr>
<th>Food</th>
<th>Exemption Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asparagus</td>
<td></td>
</tr>
<tr>
<td>Beans</td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td></td>
</tr>
<tr>
<td>Great Northern</td>
<td></td>
</tr>
<tr>
<td>Kidney</td>
<td></td>
</tr>
<tr>
<td>Lima</td>
<td></td>
</tr>
<tr>
<td>Navy</td>
<td></td>
</tr>
<tr>
<td>Pinto</td>
<td></td>
</tr>
<tr>
<td>Beets</td>
<td></td>
</tr>
<tr>
<td>Garden (roots and tops)</td>
<td></td>
</tr>
<tr>
<td>Sugar</td>
<td></td>
</tr>
<tr>
<td>Cashews</td>
<td></td>
</tr>
<tr>
<td>Sour Cherries</td>
<td></td>
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<tr>
<td>Chickpeas</td>
<td></td>
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<tr>
<td>Cocoa Beans</td>
<td></td>
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<tr>
<td>Coffee Beans</td>
<td></td>
</tr>
<tr>
<td>Collards</td>
<td></td>
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<tr>
<td>Sweet Corn</td>
<td></td>
</tr>
<tr>
<td>Cranberries</td>
<td></td>
</tr>
<tr>
<td>Dates</td>
<td></td>
</tr>
<tr>
<td>Dill</td>
<td></td>
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<tr>
<td>Seeds</td>
<td></td>
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<tr>
<td>Weed</td>
<td></td>
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<tr>
<td>Peanuts</td>
<td></td>
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<tr>
<td>Pecans</td>
<td></td>
</tr>
<tr>
<td>Peanuts</td>
<td></td>
</tr>
<tr>
<td>Pumpkins</td>
<td></td>
</tr>
<tr>
<td>Winter Squash</td>
<td></td>
</tr>
<tr>
<td>Sweet Potatoes</td>
<td></td>
</tr>
<tr>
<td>Water Chestnuts</td>
<td></td>
</tr>
</tbody>
</table>

### Food Grains

<table>
<thead>
<tr>
<th>Grain</th>
<th>Exemption Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barley</td>
<td></td>
</tr>
<tr>
<td>Corn</td>
<td></td>
</tr>
<tr>
<td>Dent</td>
<td></td>
</tr>
<tr>
<td>Flint</td>
<td></td>
</tr>
<tr>
<td>Sorghum</td>
<td></td>
</tr>
<tr>
<td>Oats</td>
<td></td>
</tr>
<tr>
<td>Rice</td>
<td></td>
</tr>
<tr>
<td>Rye</td>
<td></td>
</tr>
<tr>
<td>Wheat</td>
<td></td>
</tr>
<tr>
<td>Amaranth</td>
<td></td>
</tr>
<tr>
<td>Quinoa</td>
<td></td>
</tr>
<tr>
<td>Buckwheat</td>
<td></td>
</tr>
<tr>
<td>Oilseeds</td>
<td></td>
</tr>
<tr>
<td>Cotton</td>
<td></td>
</tr>
<tr>
<td>Flax</td>
<td></td>
</tr>
<tr>
<td>Rape</td>
<td></td>
</tr>
<tr>
<td>Soy</td>
<td></td>
</tr>
<tr>
<td>Sunflower</td>
<td></td>
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</tbody>
</table>

### 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 must 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.
What about Food Hubs, Produce Auctions, and CSA's???

FSMA Produce Rule

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

Exemptions

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.
Produce Rule Water Standards

Surface water applied directly to produce during growing
- 20 samples within two years to establish a baseline
- 5 samples per year thereafter

Underground water applied directly to produce during growing
- 4 samples in the first year
- 1 sample thereafter

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

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)

ISDH Produce Initiative

- As announced last year, all wholesalers of fresh ready-to-eat produce must register with ISDH
- New form created specifically for farms
- Authorized under Indiana Code 16-42-1-6 of the Food, Drug & Cosmetic Act
- No fee for registration
- New fact sheet about initiative

Whole Sale Food Establishments

- 410 IAC 7-21, Section 34
  - (a) “Wholesale food establishment” means any establishment within the state of Indiana that manufactures, packages, stores, repackages or transports human food products for distribution to another entity for resale or redistribution.
  - The term does not include the following:
    - (3) An establishment engaged solely in the harvesting, storage, or distribution of one (1) or more raw agricultural commodities, that is not ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public.

Food Establishments

- If not classified as a “wholesale food establishment”, then the farm will be classified as a “food establishment” under IC 16-18-2-137
- This definition states any building, room, basement, vehicle of transportation, cellar, or open or enclosed area occupied or used for handling food is a food establishment

ISDH Produce Initiative

- Created two (2) new positions within Food Protection Program
- Food Safety Farm Consultants
- Work exclusively with farmers, trade associations and other stakeholders
- Improve human food farms via education, technical assistance, lab testing and environmental assessments
- Focus on ready-to-eat vegetables/fruit
Food Safety Activities and Programming

- Establish and verify what we have in Indiana
- Combine the current patchwork of databases and membership lists
- Amount of acreage of these crops by farm is not known
- Identify best practices from other states
- Evaluate 3rd party certifiers
- Work with Purdue Extension and Indiana State Department of Agriculture

Food Safety Joint Effort

- Expectations are that affected farms will have the opportunity to cooperate and help ISDH develop a strong model
- Stakeholder participation is crucial to success
- ISDH will do significant outreach and education

Extension Food Safety Personnel

Amanda Deering
Clinical Assistant Professor
Fresh Produce Food Safety

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Thank You

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“The real Arsenal of Democracy is a fertile soil, the fresh produce of which is the birthright of the nations.”
— Sir Albert Howard