Food Safety Considerations and Good Agricultural Practices for Hops

Scott Monroe
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The good news:

Interest in hops production (and actual production) is increasing statewide.

Hops represents an opportunity for Indiana Agriculture

The not-so-good news:

Hops is a raw agricultural product and may be subject to provisions of the FSMA and/or buyers’ food safety requirements.

Photo: J. Obermeyer
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/](http://www.cdc.gov/foodborneburden/)

A significant proportion of foodborne illnesses have been attributed to fresh produce
**Microbial 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.
On-Farm Microbial Sources

Soil
People
Water
Manure
Livestock
Pets
Wildlife
### 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>Perec mark</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>
</tr>
<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>
<tr>
<td><strong>HOPS??</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Photo: J. Obermeyer*
It will Take a Farm to Fork Approach
Regulation of on-farm food safety

Industry Standards
FSMA
Federal Government (FDA)
Indiana State Health Department (ISDH)
County Health Departments
Farmers’ Market Rules
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 Awareness and Training
↓
Farm Self Assessment
↓
Written Farm Food Safety Plan
↓
Plan Implementation
↓
Third Party Audit
↓
Certification
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???
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 112.9(c).

NO X Your farm is NOT covered by this rule.

YES
Am I a FARM or a FACILITY???

Photo: J. Obermeyer

https://slowhappyliving.files.wordpress.com/2014/11/img_1784.jpg
Farms

FSMA Produce Rule
Good Agricultural Practices (GAPs)
Can pack for other farms

Facilities

FSMA Preventive Controls Rule
Applies if required to register with FDA
Chopping, grinding, and pelletizing may constitute “manufacturing”
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 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!
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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.
STANDARDS FOR PRODUCE SAFETY
Coverage and Exemptions/Exclusions for 21 PART 112

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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

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

Is your produce for personal/on-farm consumption?  
Section 112.2(a)(2)

YES  X  This produce is NOT covered by this rule.

NO
STANDARDS FOR PRODUCE SAFETY
Coverage and Exemptions/Exclusions for 21 PART 112

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

YES

This produce is eligible for exemption from the rule.

NO

providing you make certain statements in documents accompanying the produce, obtain certain written assurances, and keep certain documentation, as per Sections 112.20(i)(2) through (i)(5).
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.
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.
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.

YOU ARE COVERED
BY THIS 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

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)
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
Extension Food Safety Personnel

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Questions?
Acknowledgments

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