



Good Agricultural Practices and Regulatory Concerns for Fruit and Vegetable Growers

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Trips to Afghanistan to Teach Food Safety

- Topics Covered:
 - Food Safety
 - Pesticide Residue/Postharvest
 - Hygiene
 - Food safety in the home

PURDUE
UNIVERSITY



Produce Food Safety



What have you heard???

Produce Food Safety

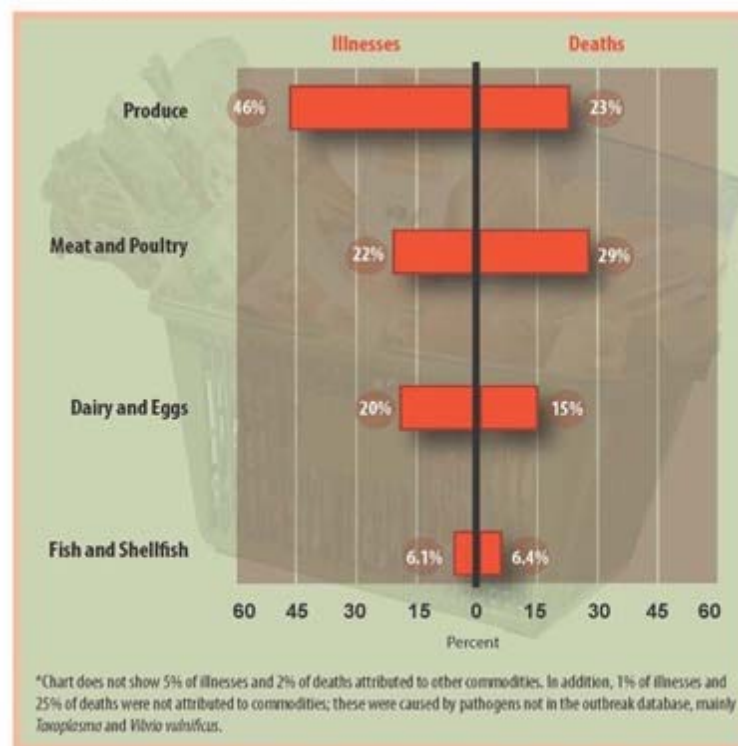
CDC estimates that each year:

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

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

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

Figure 1. Contribution of different food categories to estimated domestically-acquired illnesses and deaths, 1998-2008*



<http://www.cdc.gov/foodborneburden/attribution-image.html#foodborne-illnesses>

Source: Painter JA, Hoekstra RM, Ayers T, Tauxe RV, Braden CR, Angulo FJ, Griffin PM. Attribution of foodborne illnesses, hospitalizations, and deaths to food commodities by using outbreak data, United States, 1998-2008. *Emerg Infect Dis* [Internet]. 2011 Mar [date cited]. <http://dx.doi.org/10.13201/eid1903.111866>

Produce Related Illnesses

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

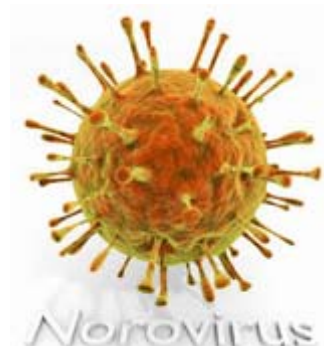


Causes of Illness

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



On-Farm Microbial Sources

Soil

People

Water

Manure

Livestock

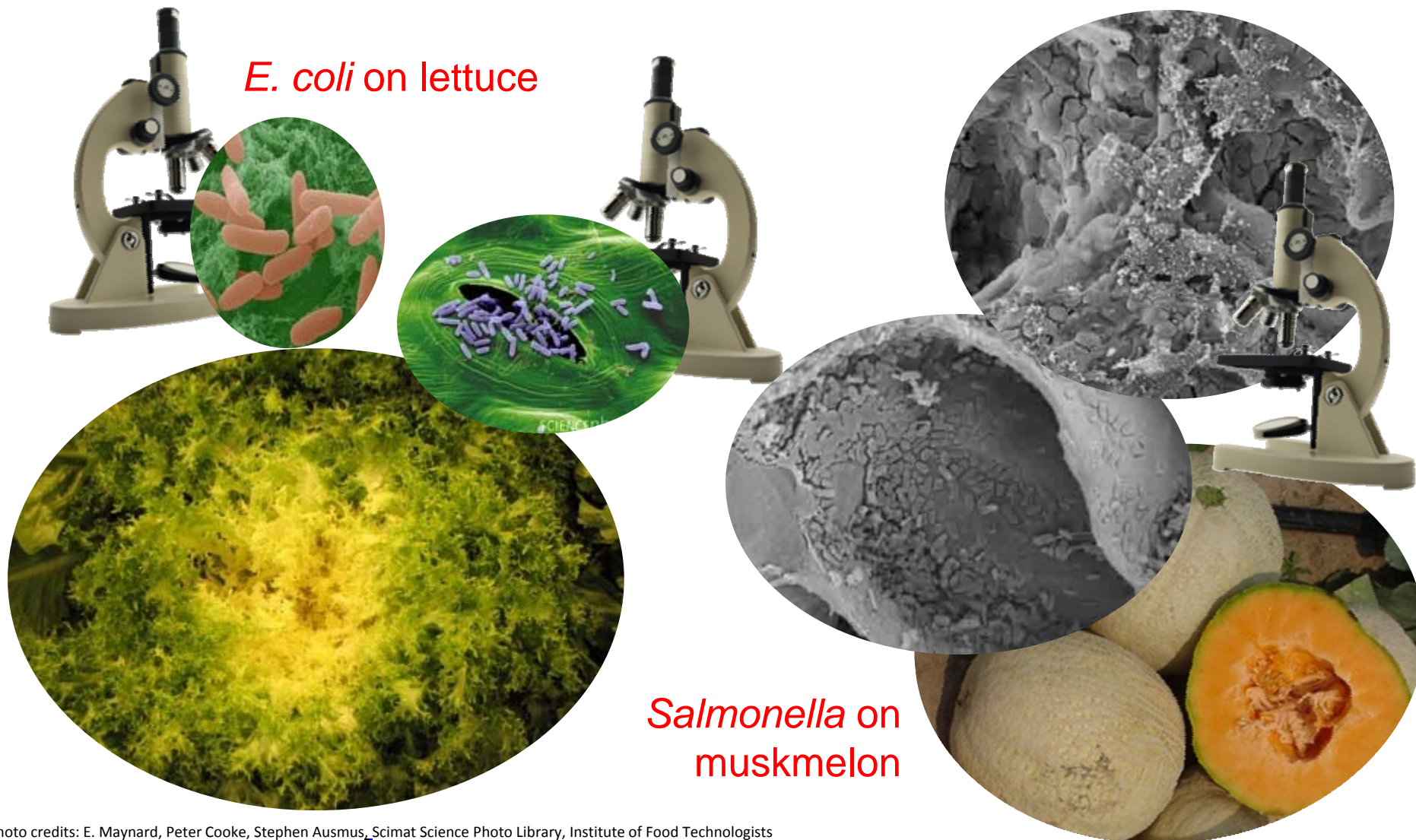
Pets

Wildlife



Washing Alone Does Not Mean Safe

E. coli on lettuce



Salmonella on
muskmelon

Cooked vs. Raw Consumption

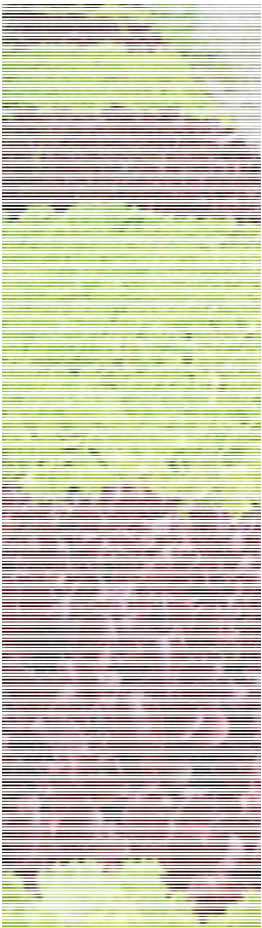
Cooked Does Mean Safe!

Cooked	?Both?	Raw
Microbial 'kill step'		Wash step
Potatoes	Spinach	Lettuce
Winter Squash	Sweet Corn	Cucumbers
Zucchini	Beets	Radish
Eggplant	Kale	Microgreens
	Tomatoes	
	Apples	
	Berries	
	Garlic	
	Herbs	
	Onions	



Consider Farm to Fork Risks

Field



Wash/Pack



Cooling/Storage



Market



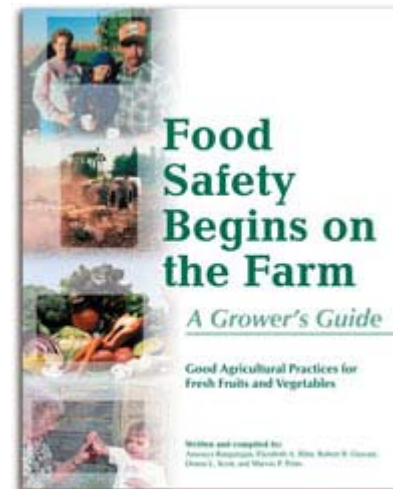
Consumer



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



https://en.wikipedia.org/wiki/FDA_Food_Safety_Modernization_Act

January 2011 - Signed into Law

November 2015 - Final Produce
Rule Published

January 2016 – New Produce
Rule Became Law

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

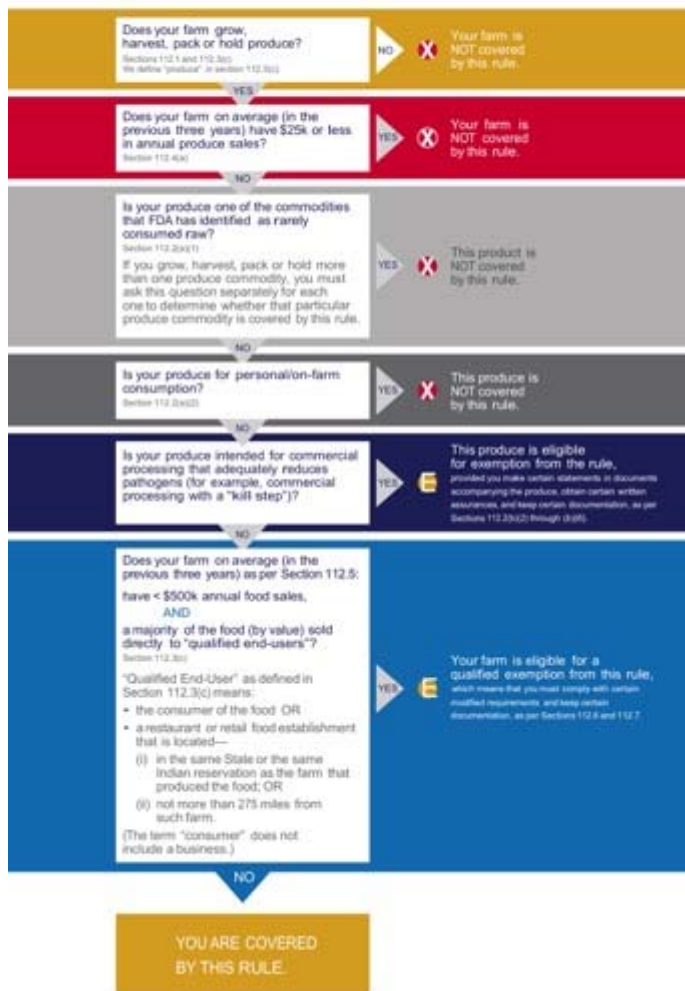
Covered – One is held to and obligated to comply with the produce rule.

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.

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.



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



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

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



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

Farm

Minimal processing

Drying

Baling

Vacuum packing

***No significant alterations

Facility

Beyond minimal processing

Pelletizing

***Significant alterations



Photo: J.
Obermeyer

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)

YES



Your farm is NOT covered by this rule.

NO

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.

YES



This product is NOT covered by this rule.

NO

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

NO

Is your produce for personal/on-farm consumption?

Section 112.2(a)(2)

YES



This produce is NOT covered by this rule.

NO

NO

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

NO

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).

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.)

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

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.

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

Who	Sales	Time to Comply
Farms	>\$500,000 food sales/year	2 years
Small Farms	\$500,000 - \$250,000 food sales/year	3 years
Very Small Farms	\$250,000 - \$25,000 food sales/year	4 years

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> 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> 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

PURDUE
EXTENSION

LOCAL FACES
COUNTLESS CONNECTIONS

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>
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 road side 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.”

More information at:

http://www.in.gov/isdh/files/HEA_1309_guidance_final_6_11_09.pdf

Type of Food	Non-Potentially Hazardous (may be sold by home-based vendor [HBV])	Potentially Hazardous (may NOT be sold by home-based vendor [HBV])
Baked Goods	Cookies, cakes, fruit pies, cupcakes, fruit breads, dessert bars, baguettes	<ul style="list-style-type: none"> • 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
Fruits and Vegetables	Unprocessed, whole and uncut produce, e.g., oranges, cherries, berries, tomatoes, corn, lettuce, green beans, peppers, etc.	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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
Fruits/Canned Fruits	Traditionally prepared fruit-based jams and jellies, e.g., grape, strawberry, blueberry, raspberry, blackberry, etc.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • 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	---	<ul style="list-style-type: none"> • 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???

