

## On Farm Food Safety with GAPS and FSMA

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## Why is Food Safety Important?



Each year in America...

- 48 million people get sick
- 128,000 are hospitalized
- 3,000 die

...from foodborne illnesses



## Real Cost of Foodborne Illness

- FDA's estimated range of a consumer's willingness to pay to avoid foodborne illness is \$1,507 to \$6,189
- According to the annual consumer surveys performed by the Bureau of Labor Statistics, the average U.S. household purchases about \$715 of produce per year



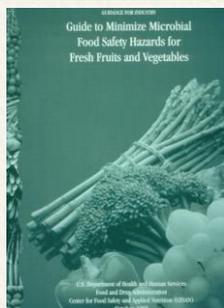
## GAPs Overview

GAPs is an acronym for **Good Agricultural Practices**

GAPs are intended to help prevent contamination from:

Pathogenic Microbes	Chemicals	Physical Objects
Viruses	Pesticides	Personal effects
Bacteria	Fertilizers	Animal & Plant Debris
Parasites	Sanitizers	Dirt

## Great Resource



<http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM169112.pdf>



## Eight Principles Of GAPs

1. Prevention of microbial contamination is better than correction
2. Grower, packers, and shippers should use GAPs and GMPs in areas where they have control
3. Prevent contamination with human or animal feces
4. Minimize microbial contamination from water
5. Manage animal manure to minimize risk of contamination
6. Worker hygiene/sanitation are critical for keeping produce safe
7. Follow all applicable laws
8. Traceback/recordkeeping/documentation = accountability



### Principle #1

**Prevention** of microbial contamination of fresh produce is preferred over **corrective action** once contamination has occurred.

*Don't use a Band-Aid: prevent problems instead*



### Principle #2

To minimize microbial food safety hazards in fresh produce, growers, packers, and shippers should use GAPs and GMPs **in those areas that they have control over.**



### Principle #3

Fresh produce can become microbiologically contaminated at any point along the farm-to-table food chain.

The major source of microbial contamination with fresh produce is associated with **human or animal feces.**



### Principle #4

Whenever **water** comes in contact with produce, its source and quality dictate the potential for contamination.

Minimize the potential for microbial contamination from water used with fresh produce.



### Principle #5

Practices using animal **manure or municipal biosolid wastes** should be managed closely to minimize the potential for microbial contamination of fresh produce.



### Principle #6

**Worker hygiene and sanitation** practices during production, harvesting, sorting, packing, and transport play a critical role in minimizing the potential for microbial contamination of fresh produce.



## Principle #7

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Follow **all applicable local, state, and federal laws and regulations.**

Follow corresponding laws, regulations, or standards for operators outside the U.S. for agricultural practices.



## Principle #8

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Traceback, recordkeeping, documentation

Accountability at all levels (farm, packing facility, distribution center and transport operation) is the key to a successful food safety program.

**Qualified personnel and effective monitoring** ensure that all elements of the program function correctly and help track produce back through the distribution channels to the producer.



## Food Safety Modernization Act

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- Signed into law by President Obama January 4, 2011
- Enables Food and Drug Administration (FDA) to better protect public health by strengthening the food safety system
- Provides FDA with new enforcement authority



## Key Components of FSMA

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1. Preventive Controls
  - Food facilities are required to evaluate the hazards in their operations, implement and monitor effective measures to prevent contamination, and have a plan in place to take any corrective actions when necessary
2. Inspection and Compliance
  - The industry will be held accountable for their responsibility to produce safe products through FDA inspection



## Key Components of FSMA, cont.

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3. Imported Food Safety
  - The FDA will work with food importers to ensure that foods coming into the US are safe and requires certification, based on risk criteria, that the imports are in compliance with food safety regulations
  - The FDA has the authority to refuse admission of imported food if the foreign facility or country refuses to allow an FDA inspection



## Key Components of FSMA, cont.

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4. Response
  - For the first time, FDA has mandatory recall authority for all food products
  - Other new FDA authorities: expanded administrative detention of products that are potentially in violation of the law and suspension of a food facility's registration
5. Enhanced Partnerships
  - Recognizes the importance of strengthening existing collaboration among all food safety agencies (U.S. federal, state, local, territorial, tribal and foreign) to achieve our public health goals



## Produce Safety Rule (PSR)

- 1 of 7 rules under FSMA
- Final Produce Rule published November 2015
- Became law January 2016

*FDA estimates that the yearly benefits over the first 10 years after publication of the rule to be approximately 365,351 illnesses averted per year, valued at \$977 million annually*



## Who Is Covered by the PSR?

<http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472499.pdf>

## Who is Covered by the PSR?

- Farms that grow, harvest, pack or hold most produce in a raw or natural state (raw ag commodity)
- With an average of > \$25K in annual produce sales

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.

Does your farm on average (in the previous three years) have \$25k or less in annual produce sales?  
Section 112.4(a)

NO

Your farm is NOT covered by this rule.



## Exemptions to the PSR

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.

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

NO

This product is NOT covered by this rule.



## Exemptions to the PSR

- Produce commodities rarely consumed raw: 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
- Food grains, including barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds
- Produce that is used for personal or on-farm consumption



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In addition, five other commodities that we proposed to exempt as rarely consumed raw based on lack of uncooked code reported in the previous NHANES/WWEIA dataset are now not on our final list in § 112.2(a)(1). Black-eyed peas (or cowpea bean) does not meet the revised criteria for rarely consumed raw in that less than 1 percent weighted number of survey respondents reported consumption of these commodities in any form (Ref. 73). Therefore, we are removing black-eyed peas, crabapple, chabarb, rutabaga, and yam from the list of rarely consumed raw produce in § 112.2(a)(1). Instead, these commodities are covered produce subject to the requirements of part 112 as applicable. We intend to review the status of these commodities upon availability of updated dietary consumption information, including data obtained from NHANES/WWEIA, 2015–2016 surveys. We encourage stakeholders who may have data or information relevant to this analysis to consult with us. (See also Comment 88 for other commodities for which there is quantitative information on uncooked consumption that we proposed to exempt as rarely consumed raw but that

(i.e., at least 1 percent of weighted number of survey respondents must have reported consuming the commodity in any form for the data to provide a reasonable representation of how that commodity is consumed by U.S. consumers). We are therefore adding them to the list of rarely consumed raw produce in § 112.2(a)(1) (see column 2 of Table 5). On the other hand, while the consumption of hops is reported in the NHANES/WWEIA only in beverage form as beer, we cannot conclude that this indicates that hops were cooked as part of the process of being made into beer. We are aware that hops are regularly added to beer after all cook steps are completed in a process known as "dry hopping." (Ref. 90). Therefore it would not be reasonable to infer on this basis that hops were not consumed uncooked in any reasonable quantity by most consumers across the United States, and we are not adding hops to the list of rarely consumed raw produce. Instead, hops are covered produce subject to the requirements of part 112 as applicable. However, we note that hops used in the making of beer will be eligible for exemption from the requirements of part 112 under the provisions of § 112.2(b)(1), provided the covered farm establishes and maintains documentation in accordance with § 112.2(b)(2). Brewing beer adequately reduces the presence of microorganisms of public health significance through means other than a cook step (e.g., pH, alcohol content, fermentation). To be useful, such data would need to be sufficiently robust and representative of consumption of relevant commodities by consumers across the United States

subject to the requirements of part 112 as applicable. While lotus root and swamp cabbage are reported in NHANES, they are reported only in cooked forms, and there are no data from which their raw consumption may be analyzed. However, neither commodity satisfies the third criterion in that less than 1 percent weighted number of survey respondents reported consumption of these commodities in any form (Ref. 73). Two other commodities that we proposed in the 2013 proposed rule, to exempt as rarely consumed raw based on non-NHANES data and other references are arrowroot and arrowroot. Neither of these commodities is reported in the current NHANES/WWEIA datasets, and we have no data to which the revised criteria for rarely consumed raw may be applied for these commodities. Therefore, we are removing arrowroot and arrowroot from the list of rarely consumed raw produce in § 112.2(a)(1). Instead, arrowroot and arrowroot are covered produce subject to the requirements of part 112 as applicable. We intend to consider updating the list of rarely consumed raw commodities in the future as appropriate, such as if new data become available. We encourage stakeholders who have information relevant to consumption of these produce commodities to identify relevant data for FDA's review and evaluation. To be useful, such data would need to be sufficiently robust and representative of consumption of relevant commodities by consumers across the United States



## Modified Requirements

- If your farm on average over the previous 3 years has less than \$500,000 in gross annual sales AND the majority of the food is sold directly to a "qualified end-user,"\* then you must:
  - Provide the name and complete address of the farm where the produce was grown on either a food packaging label or on a sign at the point of purchase;
  - Comply with the compliance and enforcement requirements of the Produce Rule; and
  - Be subject to the provisions regarding the withdrawal of your status as a partially covered ("qualified exempt") operation.



## Produce Safety Rule Compliance

	Compliance Dates	Water Compliance
In general	1/26/18	1/27/20
Small*	1/28/19	1/26/21
Very Small**	1/27/20	1/26/22

See Produce Safety Alliance for more details:

<https://producesafetyalliance.cornell.edu/food-safety-modernization-act/produce-safety-rule-compliance-dates-timeline>



## Parts of the PSR

- Agriculture Water
- Biological Soil Amendments
- Sprouts
- Domesticated and Wild Animals
- Worker Training and Health and Hygiene
- Equipment, Tools and Buildings



## Agricultural Water

- The requirements apply to "agricultural water"
  - i.e., water that is used in the growing, harvesting, packing, or holding of "covered" produce
- FDA considers water to be "agricultural water" if it is intended to or likely to contact covered produce or food-contact surfaces



## Agricultural Water, cont.



- Examples of agricultural water:
  - Irrigation water that is directly applied to the harvestable portion of a crop
  - Water used for preparing crop sprays
  - Water used for washing or cooling harvested produce



## Water Testing

### Untreated Surface Water

- Collect minimum of 20 samples, as close as is practicable to harvest, over 2-4 years
- After baseline- annual survey of 5 per year

### Untreated Ground Water

- Collect minimum of 4 samples, collected as close as is practicable to harvest, during the growing season or over a period of one year
- After baseline- annual survey of 1 per year



## Biological Soil Amendments

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- A soil amendment is a material, including manure, that is intentionally added to the soil to improve its chemical or physical condition for growing plants or to improve its capacity to hold water
- Rule applies to raw manure and stabilized compost:
  - Definitions for determining whether the soil amendment is treated or untreated;
  - Microbial standards applied to treatment processes;
  - Application requirements and minimum interval requirements;
  - Instructions for how to convey, handle, and store soil amendments;
  - Prohibitions on the use of human waste; and
  - Recordkeeping requirements



## Manure

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- Interval between manure application and harvest is pending completion of a risk assessment
- USDA's National Organic Program calls for
  - 120 days interval between application of manure and harvest for a crop in contact with soil
  - 90 days interval for crops that not in contact with the soil



## Manure, cont.

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- Untreated biological soil amendments of animal origin, such as raw manure, must be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application



## Compost

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- Composted biological soil amendments of animal origin (including composed manures):
  - Must be processed to meet PSR specifications
  - Must be applied in a manner that minimizes potential contact with produce during and after application



## Sprouts

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- Prevent the introduction of dangerous microbes into or onto seeds or beans used for sprouting, in addition to treating seeds or beans that will be used for sprouting
- Testing of spent sprout irrigation water from each production batch of sprouts, or in-process sprouts from each production batch, for certain pathogens
- Testing the growing, harvesting, packing and holding environment for the presence of *Listeria* species
- Taking corrective actions if spent sprout irrigation water, sprouts, and/or an environmental sample tests positive



## Animals

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- The main goal of the standards for domesticated and wild animals is to prevent the contamination of covered produce by "animal excreta" – solid or liquid animal waste
- The three main animal populations that FDA identifies are:
  - Domesticated animals (e.g. livestock, working animals, and pets);
  - Domesticated animals from a nearby area (e.g., livestock from a nearby farm); and
  - Wild animals (e.g., deer and wild swine)



## Animals, cont.

- Farmers are required to take all measures reasonably necessary to identify and not harvest produce that is likely to be contaminated
- At a minimum, this requires all covered farms to visually examine the growing area and all covered produce to be harvested, regardless of the harvest method used
- In addition, under certain circumstances the rule requires farms to do additional assessment during the growing season, and if significant evidence of potential contamination by animals is found, to take measures reasonably necessary to assist later during harvest
  - For example, placing flags outlining the affected area



## Animals, cont.

- Although the final rule does not require establishing waiting periods between grazing and harvest, the FDA encourages farmers to voluntarily consider applying such intervals as appropriate for the farm's commodities and practices
  - The agency will consider providing guidance on this practice in the future, as needed
- Farms are not required to exclude animals from outdoor growing areas, destroy animal habitat, or clear borders around growing or drainage areas



## Worker Training and Health and Hygiene

- Prevent contamination of produce and food-contact surfaces by ill or infected persons
  - For example, instructing personnel to notify their supervisors if they may have a health condition that may result in contamination of covered produce or food contact surfaces
- Use hygienic practices when handling produce or food-contact surfaces
  - For example, washing and drying hands thoroughly at certain times such as after using the toilet



## Worker Training and Health and Hygiene, cont.

- Prevent visitors from contaminating produce or food-contact surfaces
  - For example, by making toilet and hand-washing facilities accessible to visitors



## Training

At a minimum, all personnel who handle (contact) covered produce during covered activities or supervise the conduct of such activities must receive training that includes all of the following:

1. Principles of food hygiene and food safety
2. The importance of health and personal hygiene for all personnel and visitors, including recognizing symptoms of a health condition that is reasonably likely to result in contamination of covered produce or food-contact surfaces with microorganisms of public health significance



## Equipment, Tools and Buildings

- Prevent equipment, tools, and buildings and inadequate sanitation, from contaminating produce
- This section of the rule covers greenhouses, germination chambers, and other such structures, as well as toilet and hand-washing facilities
  - Required measures include, for example, appropriate storage, maintenance and cleaning of equipment and tools



## Recordkeeping

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- The general recordkeeping standards require records to include:
  - Name and location of the farm
  - Actual values and observations collected during monitoring activities
  - An adequate description of the produce applicable to the record (e.g., commodity name, specific variety, or other identifier, such as a lot number)
  - Location of the growing area or other area applicable to the record
  - Date and time that an activity was performed or observed
- The records must be taken at the time an activity is performed or observed, must be accurate and legible, and must be dated and signed by the person doing the activity



## Recordkeeping, cont.

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- The FSMA Produce Safety Rule does not require a written farm food safety plan but writing a plan helps growers get organized and focused on produce safety, as well as prepare for buyer requirements and third party audits
- Find Farm Food Safety Plan Writing Resources at <http://producesafetyalliance.cornell.edu/resources/farm-food-safety-plan-writing-resources>



## Food Safety Plan

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The food safety plan must include:

- A written hazard analysis
- Written preventive controls
- Written procedures for monitoring the implementation of preventive controls
- Written corrective action procedures
- Written verification procedures
- A written recall plan



## GAPs Guides

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Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables

- <http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM169112.pdf>

The Guide at a Glance

- <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/ucm187676.htm>

Food Safety Begins on the Farm

- <https://gaps.cornell.edu/sites/gaps.cornell.edu/files/shared/documents/FSBFEngLOW.pdf>



## FSMA Resources

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FSMA Final Rule on Produce Safety

- <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>

Easy to Read PSR information

- <http://sustainableagriculture.net/blog/produce-rule-analysis-part-1/>
- <http://sustainableagriculture.net/blog/produce-rule-analysis-part-2/>

FSMA and PSR Guidance from the Produce Safety Alliance

- <http://producesafetyalliance.cornell.edu/food-safety-modernization-act>
- <http://producesafetyalliance.cornell.edu/food-safety-modernization-act/produce-safety-rule>



## Additional Resources

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UNL GAPs Page

- <http://cropwatch.unl.edu/gaps>

Impacts of the Food Safety Modernization Act on Diversified Organic Vegetable Farms Webinar

- <http://articles.extension.org/pages/73471/impacts-of-the-food-safety-modernization-act-on-diversified-organic-vegetable-farms>

Resources for Produce Farmers (Updated 7/13/15)

- <http://www.fda.gov/downloads/food/guidanceregulation/fsma/ucm360295.pdf>

