



First Season of Produce Inspections

Washington State Department of
Agriculture

Beth Lorence MPH



Agenda

- Basic FSMA Requirements
- Will your farm be inspected?
- First Season of Inspections
- Regulatory Updates
- What can farms do now?





FDA FOOD SAFETY MODERNIZATION ACT



Produce Safety
Rule

Preventive
Controls for
Human Food

Sanitary
Transportation
of Food

Preventive
Controls for
Animal Food

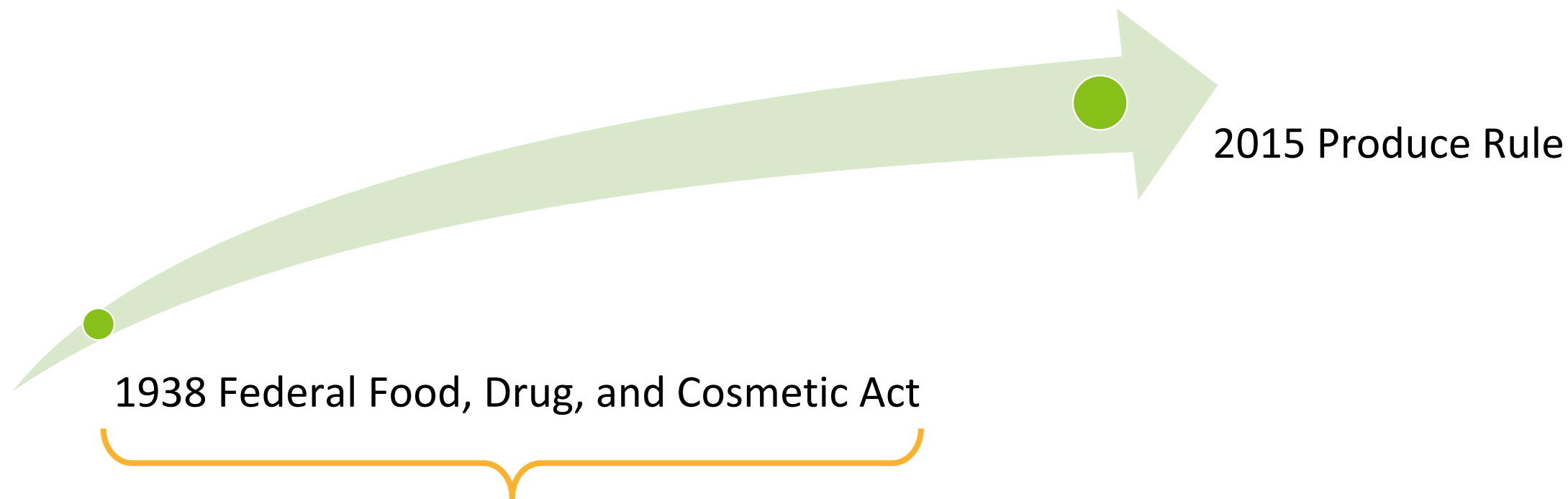
Foreign Supplier
Verification
Programs

Intentional
Adulteration of
Food

Accredited
Third Party
Certification
Rule

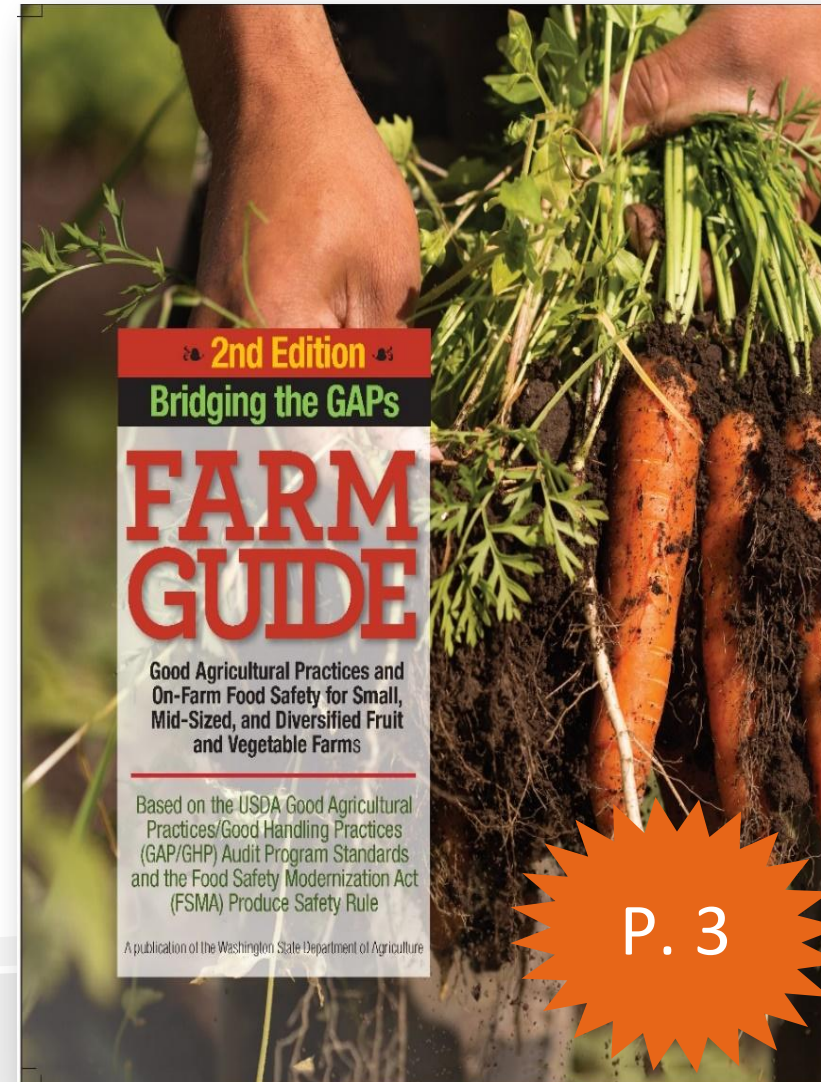
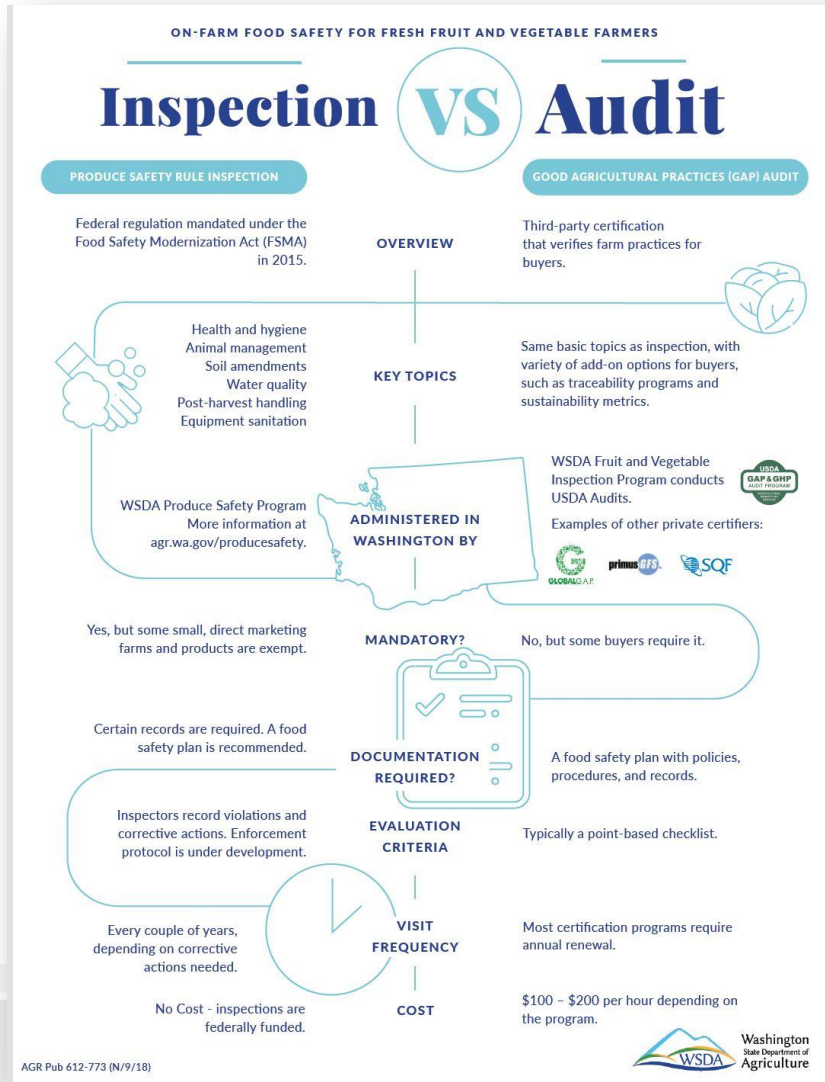


First Federal Rule for Produce Farms



Adulterated Food - Impure, unsafe, unwholesome or otherwise unfit for human consumption

FSMA vs. Good Agricultural Practices (GAP) Audit





Will your farm be inspected?



Covered Produce

- Certain types of fruits or vegetables, including mushrooms, sprouts, peanuts, tree nuts, and herbs
- Microgreens “covered” but not subject to sprout rules. Microgreens have larger growth and leaf development and are typically grown in soil.
- Not including food grains (ex: barley, corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, oilseeds)



Excluded Produce

- Personal or on-farm consumption
- Commercial processing

[provided method and documentation as per §112.(b)(2) – (b)(6)]

- Foods rarely consumed raw (exhaustive list):

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

- Transplants



Small Farm Exemptions

Exempt	Qualified Exempt
≤ \$25,000 average annual produce sales (in previous 3 years)	< \$500,000 average annual food sales (in previous 3 years) and A majority (by value) sold directly to “qualified end-users” [112.3(c)]: <ul style="list-style-type: none"><input type="checkbox"/> Consumer (not a business)<input type="checkbox"/> Restaurant or retail food establishment:<ul style="list-style-type: none">• in the same state or reservation, or• within 275 miles of farm



Knowledge Check

Hayden's Heavenly Berries in Skagit County sells berries through her farm stand (\$10,000), farmers markets (\$10,000) and to a local smoothie shop (\$10,000).

She sells her largest crop, blueberries, to a packinghouse for wider distribution at \$200,000 annually.

- (a) Exempt
- (b) Qualified exempt
- (c) Covered



Knowledge Check

Raco's Ranch in Chelan County raises high-quality beef for regional restaurants (\$100,000) and ships to consumers nationwide through online sales (\$160,000).

In addition, Raco grows several acres of potatoes (\$20,000) and carrots (\$20,000) for restaurants.

- (a) Exempt
- (b) Qualified exempt
- (c) Covered



Knowledge Check

A small, diversified grower named Winston in Yakima County specializes in a hot and sweet peppers of all varieties.

He has a WSDA Food Processing License and makes hot sauce in a rented commercial kitchen. He grows some of the produce (\$20,000) that goes into his sauces that he sells for \$125,000 annually at farmers markets in Washington State.

- (a) Exempt
- (b) Qualified exempt
- (c) Covered



Qualified Exemption Requirements

- 1) Records claiming status (**EFFECTIVE NOW**)
 - Sales records including farm info, product, date and buyer
 - Annual review with signature and date from farm manager
- 2) Food packaging label (by 2020)
 - Farm name
 - Complete business address where food grown
 - Displayed “prominently and conspicuously” on label, poster, sign, placard, documents or electronic invoice

Why should exempt farms know about FSMA?

1. Keep customers safe
2. Meet buyer demands (including GAP/GHP requirements)
3. Manage business risk





Year 1 Produce Inspections

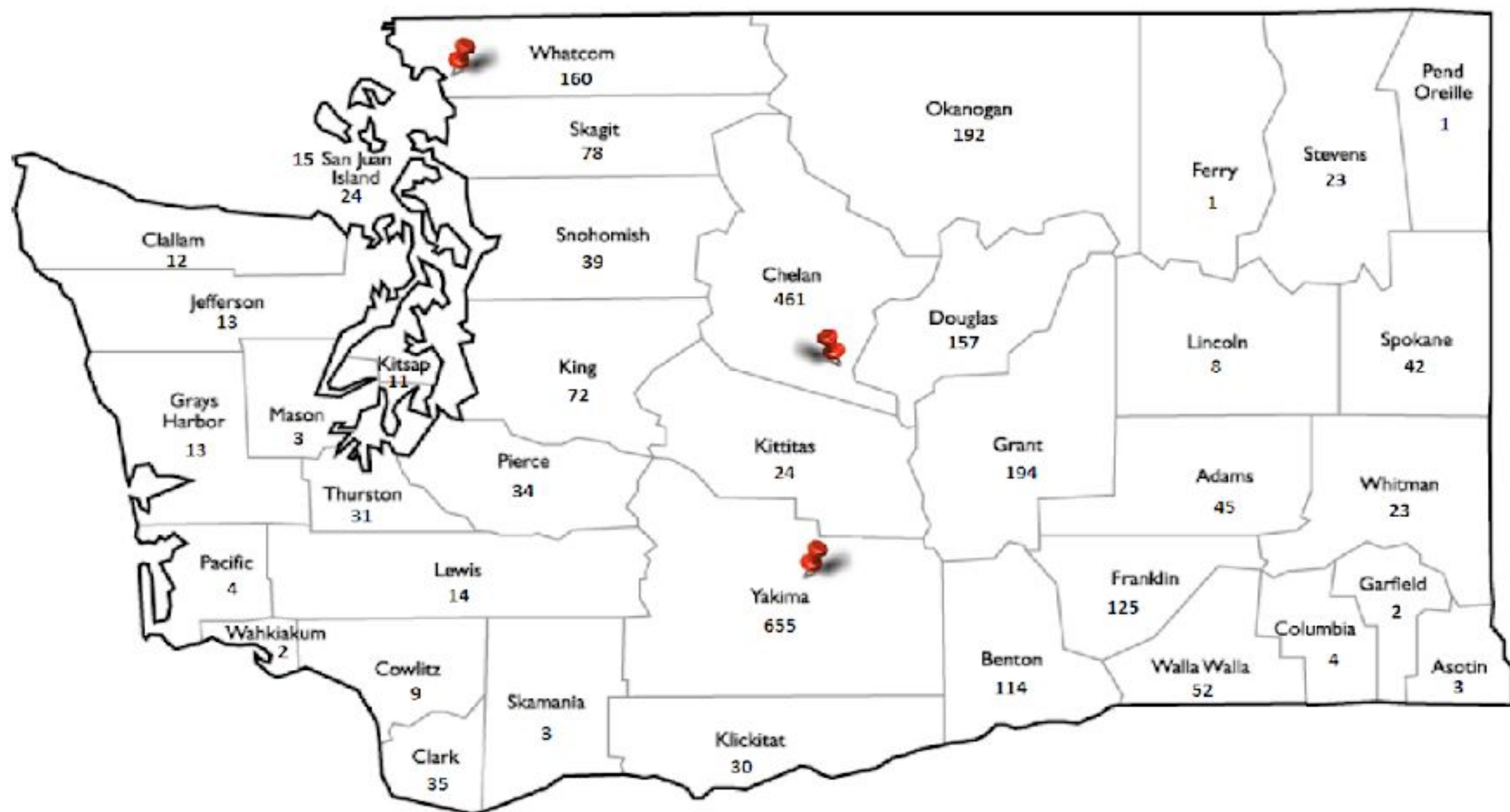
WSDA Produce Safety Program



WSDA Produce Safety Program



- Bellingham
- Olympia
- Seattle
- Yakima
- Wenatchee





Routine Inspections

- Pre-scheduled
- Designate food safety person to be available
- Review Criteria:
 - Interview
 - Observation
 - Records

Inspection Timeline

Business Size	General Compliance Dates	Proposed Water Compliance Dates
All other businesses (>\$500K)	1/26/18	1/26/22
Small businesses (>\$250-500K)	1/28/19	1/26/23
Very small businesses (>\$25-250K)	1/27/20	1/26/24

2019 Inspections Statistics

- Completed inspections: 62
 - Diversified
 - Berries
 - Tree Fruit
- Covered Farms: 2,639
- Average time: 2-4 hours



Washington
State Department of
Agriculture

Produce Safety Program
PO Box 42560
Olympia WA 98504
(360) 902-1848
producesafety@agr.wa.gov

Produce Farm Inspection Observations

Date of Inspection:

Farm Information			
Farm Name (include business name, if different)		Farm Number	
Farm Mailing Address			
Name and Title of Individual to Whom Report is Issued		Owner / Operator	
Phone Number	Email	Website	Facebook
Operating Schedule <input type="checkbox"/> Seasonal <input type="checkbox"/> Year Round Hours of operation/further description, if known:			
Farm Physical Location (if different) <input type="checkbox"/> Field <input type="checkbox"/> Packing House <input type="checkbox"/> Other:		Farm Activities (check all that apply) <input type="checkbox"/> Growing <input type="checkbox"/> Harvesting <input type="checkbox"/> Packing <input type="checkbox"/> Holding	
Covered Produce			
Farm Classification (check all that apply) <input type="checkbox"/> Primary Production <input type="checkbox"/> Secondary Activities <input type="checkbox"/> Packing House		Farm Size <input type="text"/>	Water Source (check all that apply) <input type="checkbox"/> Surface <input type="checkbox"/> Ground <input type="checkbox"/> Municipal
Exemptions (check all that apply) <input type="checkbox"/> Qualified Exemption <input type="checkbox"/> Processing <input type="checkbox"/> Rarely Consumed Raw <input type="checkbox"/> On-Farm Consumption <input type="checkbox"/> Donated Food <input type="checkbox"/> None			
Participation in Food Safety Audit <input type="checkbox"/> Yes <input type="checkbox"/> No Name:		Food Safety Plan <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Name of PSR Trained Individual(s)
Where is Covered Produce Packed (example: field packed or name of warehouse(s))			
Inspection Observations			
Type of Inspection <input type="text"/>		Activities Observed During Inspection <input type="checkbox"/> Growing <input type="checkbox"/> Harvesting <input type="checkbox"/> Packing <input type="checkbox"/> Holding	
Produce Observed During Inspection			

This form lists factual observations made by the WSDA Produce Safety Program field inspector(s) during the inspection of the farm's operation pursuant to [chapter 15.135 RCW](#).

THIS IS NOT A FINAL WSDA DETERMINATION OF COMPLIANCE, OR NON-COMPLIANCE, WITH THE PRODUCE SAFETY RULE ([21 CFR Part 112](#)) OR ANY OTHER LEGAL REQUIREMENT.

Produce Safety Field Inspectors (Inspector) should record their observations on this form as clearly and specifically as possible and should order their observations by significance within each area (most important first). In some cases, an observation may relate to more than one topic area. The Inspector should record observations in the topic area listed below that, in the Inspector's judgment, is the most appropriate topic. Not all topic areas may be applicable in every situation. In addition, Inspector might not examine every aspect

Lessons Learned: Tree Fruit Growers

- High majority required to comply
- Packing house manages post-harvest
- Few using soil amendments
- Who is responsible for picking bag/bin cleaning and sanitizing?
- Water quality concerns with irrigation districts

Pear-loving bears picnic in orchard

By DAN WHEAT Capital Press Sep 13, 2019 Updated Sep 13, 2019



Black bears photographed by a game surveillance camera in Burnett Orchards near Leavenworth, Wash., on Aug. 24.

Courtesy of Tony Burnett

[Buy Now](#)

Lessons Learned: Small Fruit Growers

- Potential processing exemption
- High majority are GAP certified
- Soil amendments applied early if used
- Most covered farms use machine harvesters
- Some drip irrigation systems do not contact fruit



Lessons Learned: Diversified Row Crop Growers

- Diverse customers and product mix
- Combination field and outdoor packing
- Post-harvest handling infrastructure and material questions
- Visitor management



Recordkeeping Requirements

Qualified Exemption Review Template

Name and address of farm: _____

Date: _____

Sales receipts or records reflecting total food sales over the previous 3 years:

Year 1 (Sales year: _____) \$ _____

Year 2 (Sales year: _____) \$ _____

Year 3 (Sales year: _____) \$ _____

Average total food sales \$ _____

Total food sales to qualified end users (E.g. consumers, or grocery stores 275 miles or within the same state or Indian reservation) \$ _____

$\$ \text{Sales to qualified end users} \div \$ \text{Average sales} \times 100 = \text{Percent sales to qualified end users} \%$

*Sales receipts must also be retained to support this record.

Reviewed by: _____ Title: _____

FSMA PSR Reference § 112.7(b)

Worker Training Record Template

Name and address of farm: _____ Date: _____

Trainer: _____ Training time: _____

Topics Covered: _____
Training materials: Please attach any printed materials related to the training. Also reference any relevant SOPs or sections of the farm food safety plan that apply.

Employee Name (please print)

1. _____
 2. _____
 3. _____
 4. _____
 5. _____
 6. _____
 7. _____
 8. _____
 9. _____
 10. _____
 11. _____
 12. _____
- Reviewed by: _____ Title: _____

Produce Safety ALLIANCE

Records Required by the FSMA Produce Safety Rule

K. Woods, D. Pahl, D. Stoeckel, B. Fick, G. Wall, and E.A. Bihn

*This publication has not been approved by the FDA and should not be considered legal guidance. It is provided in response to PSA training participants who asked for examples of records required by the FSMA Produce Safety Rule.

The FSMA Produce Safety Rule (PSR) requires a few specific records. This publication summarizes the provisions requiring records and includes template records to help establish records to meet FSMA PSR requirements. Growers may want or need to keep additional records to ensure that required practices are being carried out correctly, to meet buyer requirements, and/or participate in a third party audit. Other documentation, such as Standard Operating Procedures (SOPs), may be helpful to support the implementation of practices on the farm.

Cleaning and Sanitizing Record Template

Name and address of farm: _____

List the date, time, tool or equipment name, and method for each for each cleaning or sanitizing activity.

Date	Time	List tools/equipment	Cleaned and/or Sanitized?	Method used	Cleaned By (initials)
10/11/16	10:07 AM	Harvest tools	cleaned	See Cleaning SOP (Removed dirt with brush, washed with detergent, rinsed, air dried)	EAB
10/11/16	10:30 AM	Dump Tank	cleaned and sanitized	See Dump Tank Cleaning and Sanitizing SOP (drained tank, washed with detergent, rinsed, sanitized with 150 ppm NaOCl)	EAB



Water Update

- Extension of water compliance dates
- No enforcement of Subpart E (Water) during extended compliance period
- Extended list of water methods
- Presence/absence accepted for post-harvest water

EQUIVALENT TESTING METHODOLOGY FOR AGRICULTURAL WATER

FDA has determined that the following methods are scientifically valid and at least equivalent to the method of analysis in § 112.151(a), "[Method 1603](#): *Escherichia coli* (*E. coli*) in Water by Membrane Filtration Using Modified membrane-Thermotolerant *Escherichia coli* Agar (Modified mTEC)" (December 2009), in accuracy, precision, and sensitivity in quantifying generic *Escherichia coli* in agricultural water.

1. [Method 1603](#): *Escherichia coli* (*E. coli*) in Water by Membrane Filtration Using Modified membrane-Thermotolerant *Escherichia coli* Agar (Modified mTEC) (September 2014). U.S. Environmental Protection Agency. EPA-821-R-14-010.
2. [Method 1103.1](#): *Escherichia coli* (*E. coli*) in Water by Membrane Filtration Using membrane-Thermotolerant *Escherichia coli* Agar (mTEC) (March 2010). U.S. Environmental Protection Agency. EPA-821-R-10-002.
3. [Method 1604](#): Total Coliforms and *Escherichia coli* in Water by Membrane Filtration Using a Simultaneous Detection Technique (MI Medium) (September 2002). U.S. Environmental Protection Agency. EPA-821-R-02-024.
4. 9213 D – Natural Bathing Beaches (2007). In: Standard Methods for the Examination of Water and Wastewater, 22nd Edition (Rice E.W.,



Agricultural Water Standards

Production Water

- Irrigation
- Fertigation
- Crop sprays
- Cooling
- Frost protection
- Dust abatement

Post-Harvest Water

- Produce washing
- Food contact surfaces
- Cooling/Hydrating
- Hand washing
- Treated agricultural tea
- Irrigating sprouts

Standard

Geometric Mean (GM):
≤ 126 CFU generic E. coli / 100 mL H₂O

Standard Deviation (STV):
≤ 410 CFU generic E. coli / 100 mL H₂O

Zero detectable E. coli in 100 mL
of agricultural water



Water: What should you do now?

- Continue Testing and Maintaining
- Develop Water Management Strategies
- Test if system has never been tested

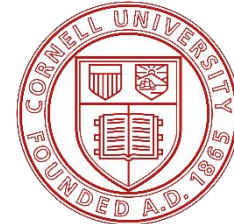


What can farms do now?

Resources and Recommendations for FSMA Alignment

Produce Rule Training Requirement

At least one supervisor or responsible party for your farm must successfully complete a food safety training recognized as adequate by the FDA





Upcoming Produce Safety Alliance Trainings

	11/8/2019	Wenatchee
	2/7/2020	Tri-Cities
	2/11/2020	Moses Lake
	2/18/2020	Lynden
	2/20/2020	Sequim
	2/25/2020	Walla Walla
	2/26/2020	Manson

<https://producesafetyalliance.cornell.edu/>

<http://foodsafety.wsu.edu/>

On-Farm Readiness Review

- Farm visit by WSDA and other subject matter experts
- Individualized assistance
- Non-regulatory
- Voluntary
- No cost

Washington
State Department of
Agriculture

**PRODUCE SAFETY
PROGRAM**

Washington State On-Farm Readiness Reviews

The Washington State Department of Agriculture (WSDA) is offering free, educational on-farm assessments to help farmers comply with the Food Safety Modernization Act's (FSMA) Produce Safety Rule.

These On-Farm Readiness Reviews (OFRR) are non-regulatory and voluntary. WSDA staff trained in the new rule will visit your produce farm to help you assess whether your produce safety practices meet the requirements of the Produce Safety Rule (PSR) and prepare you for produce safety inspections.



These voluntary farm assessments are being done in partnership with the U.S. Food and Drug Administration (FDA), Washington State University (WSU), the Washington State Tree Fruit Research Commission (WSTFRC) and other industry partners.

An OFRR is personalized.

Every farm is different which means the produce safety risks will vary. The results of an OFRR are customized for the needs of your farm. An OFRR is an opportunity for reviewers to observe practices in action and make tailored suggestions. Reviews should be conducted as close as possible to harvest time with each visit lasting approximately 2 hours.




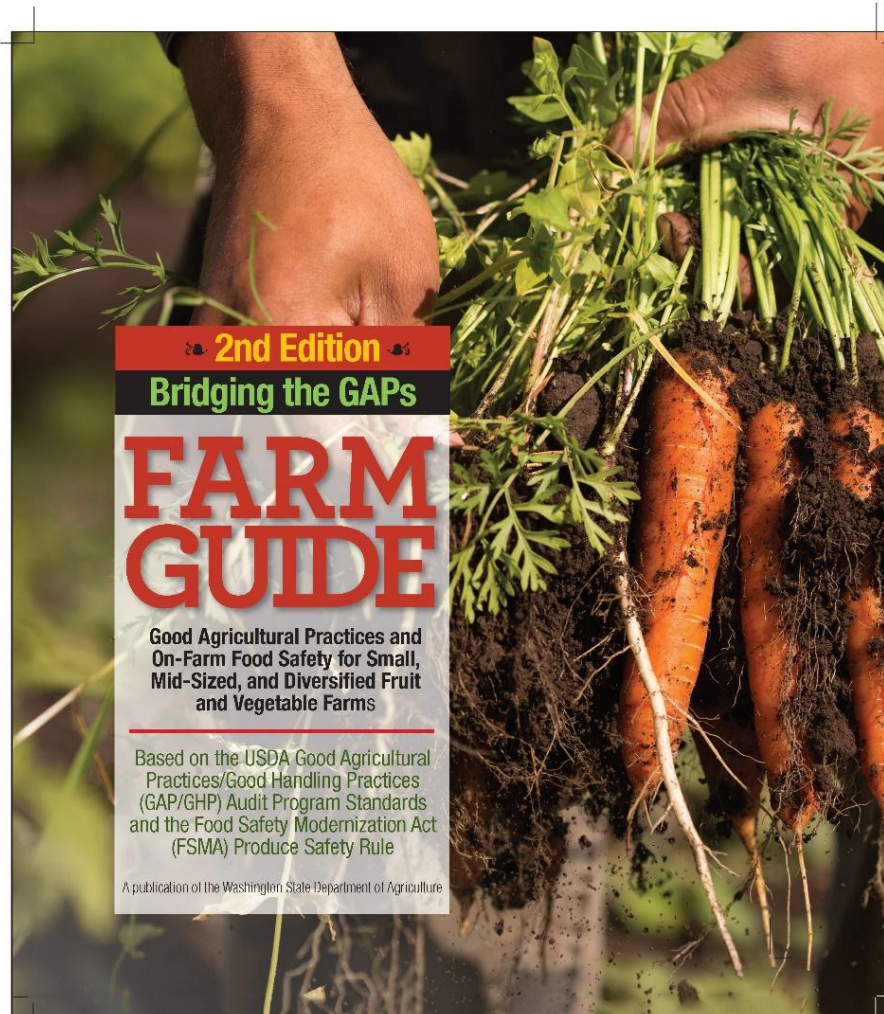
During the visit, you can ask your specific food safety questions. The reviews are discussion-based between farmers and a small review team that will include WSDA staff and additional subject matter experts at the discretion of the farm.

An OFRR is non-regulatory.

An OFRR is an educational assessment, not an inspection or audit. The goal is to identify areas for

AGR PUB 612-730 (N/9/16)WASHINGTON STATE ON-FARM READINESS REVIEWS | 1

Small Business Modified Requirements – PC Rule



IF YOUR FACILITY IS A VERY SMALL BUSINESS OR A SMALL (OR VERY SMALL) FARM MIXED-TYPE FACILITY, WHAT PC HUMAN FOOD EXEMPTIONS/MODIFIED REQUIREMENTS APPLY TO YOU?

Certain facilities that are very small businesses or small (or very small) farm mixed-type facilities may be exempt from or subject to modified requirements regarding the preventive controls requirements of the Preventive Controls (PC) for Human Food Rule, one of the FDA Food Safety Modernization Act (FSMA) foundational rules.

Does that include your facility or farm mixed-type facility? This fact sheet will help answer that question.

■ **What are a "small business" and "very small business"?**

A "small business" is a business, including any affiliates and subsidiaries, employing fewer than 500 full-time equivalent employees.

A very small business is a business (including any subsidiaries or affiliates) that averages less than \$1,000,000 (adjusted for inflation) in sales of human food plus the market value of human food that is manufactured, processed, packed, or held without sale (for example, held for a fee), per year during the previous three-year period. For current values adjusted for inflation, see "FSMA Inflation Adjusted Cutoffs" at: <https://www.fda.gov/food/guidanceregulation/fsma/ucm554484.htm>

■ **Who is subject to the preventive controls requirements in the PC Human Food Rule?**

Generally, domestic and foreign human food facilities that are required to register with FDA under the Federal Food, Drug, & Cosmetic Act are required to comply with the preventive controls requirements in the PC Human Food Rule, entitled Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food. Note that applicability of the Current Good Manufacturing Practices (CGMP) requirements is determined separately and is not based on registration.

■ **Who is not subject to the preventive controls requirements in the PC Human Food Rule?**

Certain establishments are exempt from the PC Human Food Rule because they do not have to register with FDA. These include farms, restaurants (including cafeterias, fast food establishments, catering facilities, and hospital kitchens), retail food establishments (including grocery stores, convenience stores, and vending machine locations), nonprofit food establishments, and establishments that process only meat, poultry, and egg products that are inspected by the U.S. Department of Agriculture.



On-Farm Food Safety Best Practices

1. Provide accessible and well-maintained bathrooms and hand washing facilities
2. Train employees on basic health and hygiene practices
3. Be mindful of soil amendment application timing and method
4. Deter animals from the crop production area
5. Do NOT harvest produce that has been visibly contaminated



On-Farm Food Safety Best Practices

6. Sample and test your irrigation at least once annually
7. Use water with no detectable generic E.coli during harvest and post-harvest activities
8. Avoid placing harvest bins on the ground during harvest and post-harvest activities
9. Maintain or replace equipment that is in poor condition or difficult to clean
10. Set a cleaning and sanitizing schedule for tools and equipment

Questions?



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FDA Farm Definition & Covered Activities



- cool
- field core
- filter
- gather
- hull
- remove stems/husks
- shell
- sift
- thresh
- trim outer leaves
- wash (intact produce)

- sort
- cull
- grade
- label
- weigh
- coat with wax/oil/resin

- store food
- fumigate
- dry/dehydrate
- break down pallets
- distribution

What packing and packaging materials can be reused? Select the best answer.

Only packing materials such as harvest crates and bins

Only cardboard packaging materials with a clean liner

Only packing and packaging materials that are not wood

All food contact surfaces that can be cleaned and sanitized