

**SESSION 2**

- Write a FS Plan, FSMA, and FS Audits
- General Information
- Traceability
- Recordkeeping

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**Long Term Goals**

**#1. Your farm has a food safety system that protects you and your customers, AND is scale-appropriate and cost-effective**

- + HGAP audit-able
- + FSMA compliant

**FSMA Compliance**

- Exempt
- Qualified Exempt
- Compliance Required

**Written Plan: Audit-able to HGAP standards and compliant with the FSMA Produce Rule.**

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**Food Safety Regulations**

**1938 Federal Food, Drug, and Cosmetic Act (FDCA)**

- Became illegal to sell adulterated food: contains any poisonous or deleterious substance which may render it injurious to health

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**History: Good Agricultural Practices (GAPs) and Audits**

**Voluntary – Buyer Driven – Not Regulatory**

- 1998 - FDA's Guide To Minimize Microbial Risks in Fruits and Vegetables (GAPs)
- 2000s – Over 12 different FS standards developed
- 2009 - Harmonized GAP Standards *“one audit by any credible third party, acceptable to all buyers”*

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**2011 Congress Passed FSMA**

- **PRODUCE RULE AND YOUR FARM**
- Establishes **science-based** food safety requirements for growing, harvesting, packing, and holding produce on domestic and foreign farms.

**1/27/16 Rule into effect**

Some areas in guidance or reserved

- Risk based, not as prescriptive as GAPs and 3<sup>rd</sup> party audits
- Most fresh produce is “covered”





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Is your operation

- Exempt
- Qualified Exempt
- Required to be in full compliance

**Am I Affected by the FSMA Produce Rule?**

The Produce Rule sets standards for farms that grow, harvest, pack, or hold produce for human consumption.

Do you grow, harvest, pack or hold produce (e.g. fruits, vegetables)?

NO


YES

Is any of the produce you

You are likely NOT covered by the Produce Rule

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**Exemptions include produce that:** 

- Is processed with a “kill step.”
- Produce for personal consumption or for consumption on the farm or another farm under the same management is not covered.

*Putting adulterated food into interstate commerce is a “prohibited act” for ALL farms!*


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**Exemptions include produce that:** 

- Farms that have an average annual value of **PRODUCE** sold during the previous three-year period of \$25,000\* (2011) or less.
- **Average 3-year 2018-2020** - \$28,561
  - **Must document sales to make this claim.**
  - **Donations are not sales**

*\* For adjusted for inflation number  
<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm554484.htm>*

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**Exemptions include produce that:** 

Audits do not exempt

- Is on the exhaustive “rarely consumed raw” 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; water chestnuts


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**Qualified Exemption and Modified Requirements**  
**Food = All food or drink consumed by animals or humans**

- Food** sales average less than \$500,000\* per year during the previous three years; (2018 -2020 = \$571,214)
- AND**, More than half of sales are sold to “**qualified end-users**”.

A qualified end-user is:

- the consumer of the food (location doesn’t matter)
- or a restaurant or retail food establishment that sells the majority of its food to the end user and that is located:
  - in the same state
  - or the same Indian reservation as the farm
  - or not more than 275 miles away




\*Adjusted for inflation, the baseline year for is 2011.

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**MORE ON QUALIFIED END USERS**  
 restaurant or retail food establishment that sells the majority of its food to the end user

**1 middle man not 2**

- **Wholesalers, food hubs, local distributors** are not QEU unless they make a majority of sales direct to consumers.



\*Adjusted for inflation, the baseline year for is 2011.

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**Annual Summary of Farm Sales of Food for Year:**

**Step 1: Enter Your Farm’s Data**

Farm Name:  Address:   
 State:  Indian Reservation (if applicable):   
 Signature:  Date:


**Step 2: Enter Sales Data**  
 Please review instructions before completing this table.

Customer	Type	State	Distance	Sales of Food to Qualified End-Users	Sales of Food to All Other Customers
Wedge Grocery	QES	MN	40 m	\$120,000	
Our Roadside Stand	QES	MN		\$80,000	
CPW Warehouse	Not QES	MN			\$100,000
Total Sales \$300,000				\$200,000	\$100,000

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Do you grow, harvest, pack or hold produce (e.g. fruits, vegetables)?

Is any of the produce you

YES

NO

You are likely NOT covered by the Produce Rule.

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**Separate Business Entities To Qualify For Exemption?**

Are they truly separate? If not, they are likely one entity. FDA has not defined. Will determine case-by-case.

**CONSIDER**

- Is there common control - management
- Common business purpose
- Related activities
  - Helpful if division is produce versus beef rather than different types of produce
- Shared employees, parking spaces, buildings, tools, equipment, bank accounts
- Land, how is the land separated?

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**Qualified Exempt farms are subject to parts of the Rule**

**Subpart A General Provisions, "QE" and Labeling 1/1/20**

- C. Personnel Qualifications and Training
- D. Health and Hygiene
- E. Agricultural Water
- F. Biological Soil Amendments of Animal Origin
- I. Domesticated and Wild Animals
- K. Growing, Harvesting, Packing, and Holding Activities
- L. Equipment, Tools, and Buildings

**O. General record keeping requirements. 1/27/16**

1 year later: Record reflecting an annual review and verification of continued eligibility for qualified exemption

**Q. (Compliance and Enforcement)**

*It is illegal to sell adulterated food*

**R. (Withdrawal of Exemption)**

Traceability




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**Qualified Exemption Compliance & Dates**

**1. RECORDS:** Retention of records (3-years) supporting a qualified exemption

Record reflecting an annual review and verification of continued eligibility for the qualified exemption.

- Records must be dated, legible and accurately identify the locations and times where you carried out activities relating to food safety.
- Records can be kept on paper or electronically
- Must be available within 24 hours of official request.



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**Annual Summary of Farm Sales of Food for Year:** \_\_\_\_\_


**Step 1: Enter Your Farm's Data**

Farm Name: \_\_\_\_\_ Address: \_\_\_\_\_  
 State: \_\_\_\_\_ Indian Reservation (if applicable): \_\_\_\_\_  
 Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**Step 2: Enter Sales Data**

Please review instructions before completing this table.

Customer	Type	State	Distance	Sales of Food to Qualified End-Users	Sales of Food to All Other Customers
Wedge Co-op	QES	MN	40 m	\$120,000	
Our Roadside Stand	QES	MN		\$80,000	
CPW Warehouse	Not QES	MN			\$100,000
Total				\$200,000	\$100,000




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**Qualified Exemption Labeling Requirement**

**2. DIRECT MARKET:** Packaging, label, placard indicating farm name and "complete business address"

**3. LABELING:** Required product labels must include your farm's name, complete business address, common or usual product name, count or net weight.



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Business Size	Compliance Dates for Sprouts	Compliance Dates For Most Produce	Water Related Compliance Dates <sup>1</sup>	Compliance Date for Qualified Exemption Labeling Requirement <sup>2</sup>	Compliance Date for Retention of Records Supporting a Qualified Exemption
All other businesses (>\$500K)	1/26/17	1/26/18	1/26/22		
Small businesses (>\$250K-500K) <sup>3</sup>	1/26/18	1/28/19	1/26/23	1/1/2020	1/26/16
Very small businesses (>\$25K-250K) <sup>4</sup>	1/28/19	1/27/20	1/26/24		

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## 1<sup>st</sup> Step

# Write Your Food Safety Plan

## Audit-able

1. Write your food safety plan
2. Implement
3. Perform a self audit
4. We will talk about audits again on the last zoom.

Req. #	Requirement	DOC	MAN	C	CAN	IAR	NA	Auditor Comments
General Questions								
Management Responsibility								
G-1.1	A food safety policy shall be in place.	WP	*					

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Agricultural Marketing Service

## The Right USDA GAP Audit Service for You

There is one USDA GAP service that meets all of your buyers' needs

Buyer Requirement	Adherence to Industry and FDA Best Practices	FSMA Produce Safety Rule Alignment	Produce GAP Harmonization Initiative Alignment	Global Food Safety Initiative Technical Equivalence
USDA GAP Audit for You	USDA Harmonized GAP Plus+ Audit			
	USDA Harmonized GAP Audit			
	USDA GAP & GHP			

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## HGAP Audit Verification Checklist

- Ask your buyer if they require a specific audit program
- Write to the audit

Req. #	Requirement	DOC	MAN	C	CAN	IAR	NA
Field Operations and Harvesting							
F-1 Field History and Assessment							
G-10.17	Drinking water shall be available to all employees.			R			
G-10.18	Workers and visitors who show signs of illness shall be restricted from direct contact with produce or food contact surfaces.	WP	*				

**Code Key:**  
 A=Assessment of Risk  
 R = Record  
 WP = Written Policy, Procedure/Plan  
 CAN=Corrective Action Needed  
 IAR=Immediate Action Required

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<https://www.ams.usda.gov/sites/default/files/media/HarmonizedStandard.pdf>

Req. #	Requirement	DOC	MAN	Procedure	Verification	Corrective Action
G-1: Management Responsibility						
G-1.1	A food safety policy shall be in place.	WP	*	A written policy shall outline a commitment to food safety, in general terms, how it is implemented and how it is communicated to employees, and be signed by Senior Management.	The auditor observes the food safety policy, observes that it is signed by Senior Management, and observes that it has been communicated to all employees in a manner that can be understood.	The Operation creates or revises the policy, or its communication to employees, to be in compliance.

**Requirement:** Is a specification of the conditions expected to be met by the auditee.

**DOC:** The auditing standards require verification of written policies, procedures and plans (WP); records (R); and risk assessment (A). To help auditors identify where documents (DOC) are required, the Standard includes a DOC column that designates the type of documentation to verify WP, R, A, or a combination of these document types.

**Written Policies, Procedures, and/or Plans (WP):** A policy is high-level guidance that describes general goals and acceptable procedures for an organization. A procedure is a specified way to carry out an activity or process. A plan outlines actions that will be taken by an organization to mitigate risk. Policies, procedures and plans may be communicated orally or in writing. They are only required to be written if a WP is indicated in the DOC column in this standard.

**Records (R):** A record is a document stating results achieved or providing evidence of activities performed. Records may include checklists, service records, billing forms, and water tests.

**Risk Assessment (A):** A risk assessment is a process to identify potential hazards on a farm and/or packinghouse as well as the likelihood the hazards will impact the safety of fruits and vegetables.

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<https://www.ams.usda.gov/sites/default/files/media/HarmonizedGAPChecklist01252018.pdf>

Req. #	Requirement	DOC	MAN	C	CAN	IAR	NA	Auditor Comments
General Questions								
Management Responsibility								
G-1.1	A food safety policy shall be in place.	WP	*					

**Compliant (C)** - The operation meets the requirements . . .

**Corrective Action Needed (CAN)** - The operation does not meet the requirement(s), however the nonconformance is not considered to be an immediate food safety risk.

**Immediate Action Required (IAR)** - The operation does not meet the requirement(s) and the non-conformance is considered an imminent food safety risk.

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**Additional Resources for Writing a Food Safety Plan**

- [1. Fundamentals of On-Farm Food Safety || Carolina Farm Stewardship](#)
- [2. Bridging the GAPS || WA State](#)
- [3. Food Safety Plan Template || Cornell](#)
- [4. SOPs and Logs Templates || Cornell](#)

FSMA Produce Rule Resources

**FSMA Produce Rule Status**

- Interactive FSMA Produce Rule Flowchart || Carolina Farm Stewardship
- [FSMA Produce Rule Status Template](#)
- Qualified Exemption Template

**FSMA Produce Rule Information**

- Complete FSMA Produce Rule
- Glossary
- FSMA Produce Rule Record Keeping Requirements
- TAN Technical Assistance Network

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