

MARKET EXPECTATIONS

What are your buyer’s food safety requirements?

- Do your buyers require a 3rd party audit?
- Can you negotiate with your buyers to accept a risk-based Food Safety Plan in place of a 3rd party audit?

Minimum: Audit-able to HGAP food safety standards and compliant with the FSMA Produce Rule.

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1st 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								
G-1	Management Responsibility							
G-1.1	A food safety policy shall be in place.	WP	*					

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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

History: Good Agricultural Practices (GAPs) and Audits

- 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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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 3rd party audits
- Most fresh produce is “covered”



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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 addressee.

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>

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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](#)

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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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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)?

YES


NO

You are likely NOT covered by the Produce Rule

Is any of the produce you

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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 2015-2017 - \$28,075**
- **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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Covered produce means produce that is subject to the requirements . . .
 The term “covered produce” refers to the harvestable or harvested part of the crop.

Covered activity means growing, harvesting, packing, or holding covered produce on a farm. Covered activity includes manufacturing/processing . . . within the meaning of “farm” . . .


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Qualified Exemption and Modified Requirements

Food = All food or drink consumed by animals or humans

1. **Food** sales average less than \$500,000* per year during the previous three years; (2020 = \$561,494)
2. **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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Food Hubs – QEU? 

Through OR To? a produce auction or food hub

As long as

- the auction or hub is simply a location for buyers and sellers to meet and transfer produce, and;
- as long as the food is not stored, the farmer is selling through the auction or food hub.

the customer who purchased the food will need to be identified as either a Consumer, Restaurant, RFE, or Other.

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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
A	B	C	D	E	F
Wedge Grocery	QES	MN	40 m	\$120,000	
Our Roadside Stand	QES	MN		\$80,000	
CPW Warehouse	Not QES	MN			\$100,000
Total Sales				\$200,000	\$100,000

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NO → You are likely NOT covered by the Produce Rule

YES → Is any of the produce you

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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 **1/27/16**

Record reflecting an annual review and verification of continued eligibility for the qualified exemption. **1 year from your general compliance date**

- 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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Customer	Type	State	Distance	Sales of Food to Qualified End-Users	Sales of Food to All Other Customers
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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 Compliance & Dates


2. CONSUMER NOTICE: Packaging, label, placard indicating farm name and “complete business address” **1/1/18-20**

3. LABELING: Required product labels must include your farm's name, complete business address, common or usual product name, count or net weight. **QE - Jan. 2020.**

1938 Federal Food, Drug, and Cosmetic Act putting adulterated food into interstate commerce is a “prohibited act”, regardless of whether a farm is covered by the Produce Rule or not



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Produce Rule Compliance dates 

Exempt, or not, what is your compliance date? ▲

Produce Sales of Covered Farm	Time period starting from effective date 1.27.2016	
	For Certain Water Requirements	For All Other Requirements
Very small: Less than \$250,000	6 years – 2024	4 years - 2020
Small: \$250,000 to \$500,000	5 years – 2023	3 years - 2019
Large: More than \$500,000	4 years – 2022	2 years - 2018

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