

2024 Food Safety Update

Peach Growers Society Meeting

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Safety – Fresh Produce
Department of Horticultural
Sciences



Outline

FSMA Produce Safety Rule Updates

- Requirements
- Inspections
- Enforcement of guidelines for Water used at harvest and post harvest



Outline

USDA GAP Harmonized Audit

- Changes for 2024 audit season



FSMA Produce Safety Rule

- Focus on microbial contamination
- Inspections will continue
- Since March 2023 “significant observations” are documented in writing during inspections
- Areas of concern:
 - Employee training/ Health and hygiene practices
 - Cleaning and sanitation of food contact surfaces
 - Record keeping
- Need help?
 - Work with Extension



FSMA Produce Safety Rule (2023)

1

Farms **not covered** by the Produce Safety Rule

Average sales <\$30,509
Produce Sales for last 3 years

2

Farms **eligible for a qualified exemption and modified requirements**

3

Covered Farms
>\$610,182 food sales for last 3 years OR most sales are not to end consumer

Covered
Very small farms (\$30,509-\$250,000)
Small farms (\$250,000-\$610,182)

Determine where your farm falls under the Produce Safety Rule (PSR) Template for 2023

Name and address of farm: _____ Date: _____

The objective of this document is to help farms determine their status within the Produce Safety Rule. The questions outlined follow a specific order so that the reader can have the pertinent information required to determine if the farm is not covered, eligible for a qualified exemption and modified requirements or a covered farm. If you need assistance, contact information for NCSU Produce Safety Team is listed on page 6.

Definition of Produce

Produce means any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs. A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange, and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. A vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro).

1. Do you **only** grow produce for personal or on-farm consumption?

Yes _____ No _____

If your answer is **Yes**, then you are not covered by the Produce Safety Rule.

If your answer is **No**, go to question 2.



Template to determine your farm's status

- Answer the questions in the order they are listed
- Page 1: Focus on farms that are “not covered”
- Page 2: Focus on rarely consumed raw produce and processing exemptions
- Pages 3, 4 and 5: Focus on **qualified exemptions and modified requirements** (If you fall in this category you may use this paper as your written record)
- Page 5 and 6: Outline general requirements for farms.

Rates adjusted for inflation

- Every year the original figures used in 2011 for produce sales (\$25,000) and food sales (\$500,000) that help us determine where a farm falls are adjusted for inflation by FDA
- Figures adjusted for inflation published for **2023**
 - Produce sales: \$30,509
 - Food sales: \$610,182

Requirements

Not covered

No requirements, recommend having a written record of produce sales.

Responsible for selling apples that are safe for human consumption.

Qualified Exempt

Financial record and receipts.

Labeling produce

Responsible for selling produce that is safe for human consumption.

Not subject to regular inspections but exemption can be withdrawn

Covered Farms

Subject to inspections

Attend a Produce Safety Alliance Training

Responsible for implementing all practices outlined in the PSR

Qualified Exempt farms

Labeling produce

- Starts January 20, 2020
- Label must have name and business address of the farm where apples were grown on any packaging label.
- When food packaging label is not required, a poster, sign or placard or documents delivered with the produce can be used.
- Business address: Street address or PO Box, City, State and zip code

Sunshine Farms

160 Beaver Rd

Taylorsville, NC 28681

FDA Releases Fact Sheet, Reminds Produce Stakeholders of Upcoming End of Intended Enforcement Discretion Period for Harvest and Post-Harvest Agricultural Water

1 message

U.S. Food and Drug Administration <usfda@public.govdelivery.com>
Reply-To: usfda@public.govdelivery.com
To: emtoro@ncsu.edu

Fri, Jan 13, 2023 at 12:52 PM

**FDA announced
January 13, 2023
the end of the
enforcement
discretion for
requirements for
water used
during harvest
and post harvest
effective Jan. 26,
2023**



Constituent Updates

Center for Food Safety and Applied Nutrition

The following is an update of interest to our Constituent Update, Food Safety Modernization Act (FSMA), and New Era of Smarter Food Safety subscriber lists.

FDA Releases Fact Sheet, Reminds Produce Stakeholders of Upcoming End of Intended Enforcement Discretion Period for Harvest and Post-Harvest Agricultural Water

January 13, 2023

The intended enforcement discretion period for the harvest and post-harvest agricultural water provisions for covered produce (other than sprouts) in the Produce Safety Rule ends on January 26, 2023 for all businesses other than small and very small businesses. To help prepare growers, the FDA has released a fact sheet with questions and answers on the requirements.

In December 2021, the FDA issued a [proposed rule](#) that would revise subpart E of the FDA Food Safety Modernization Act (FSMA) Produce Safety Rule to change certain pre-harvest agricultural water requirements for covered produce other than sprouts. The proposal did not include changes to the harvest and post-harvest requirements for agricultural water. Subsequently, the FDA [issued](#) a supplemental notice of proposed rulemaking to extend the compliance dates for the pre-harvest requirements and announced end dates for the intended enforcement discretion provided for the harvest and post-harvest agricultural water requirements, as follows:

FSMA - Produce Safety Rule

1. Personnel qualifications and training
 2. Worker health and hygiene
-

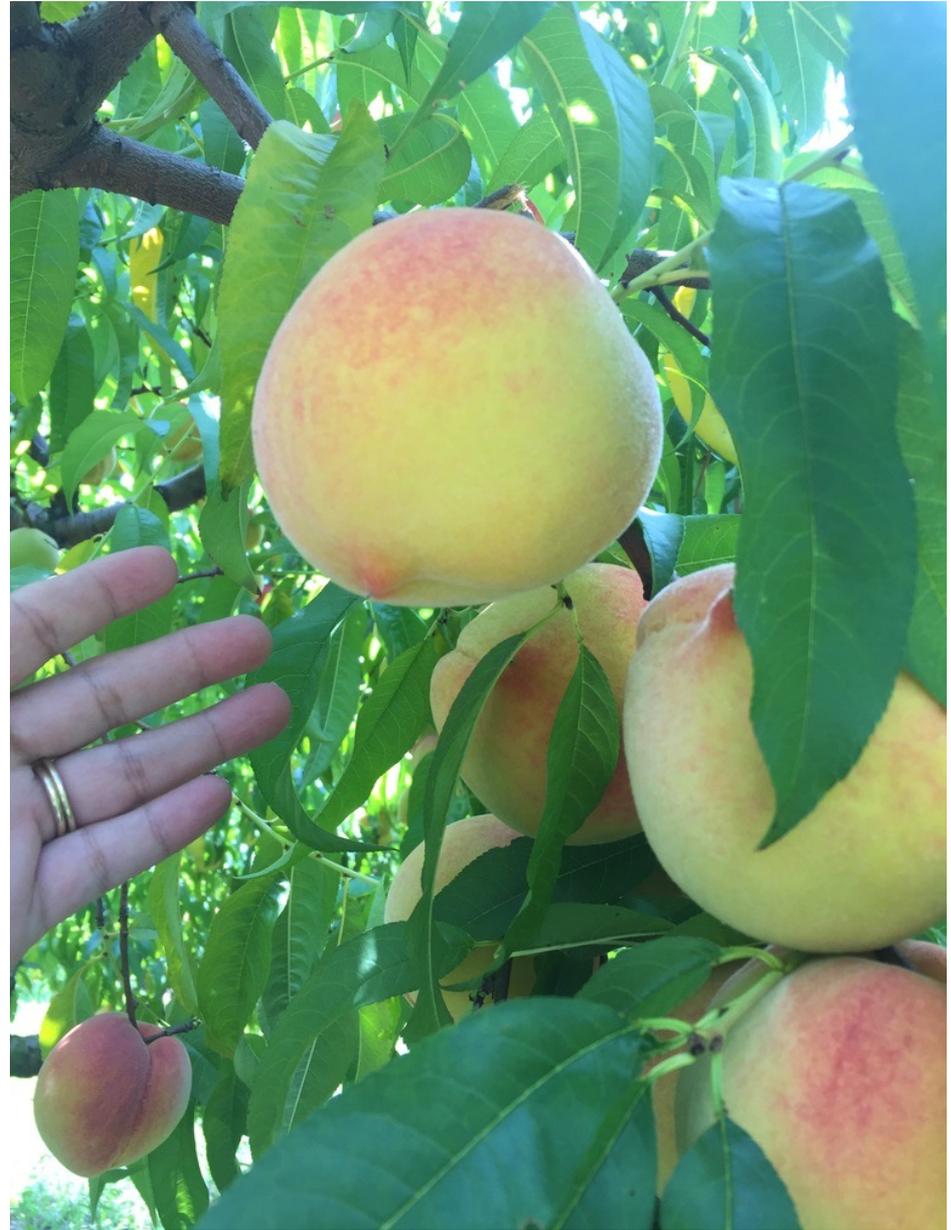
3. Agricultural water

- **Water used during growing season- NOT FINAL (Jan. 2024)**
 - **Water used at harvest and post harvest- FINAL (Jan. 2023)**
-

4. Biological soil amendments of animal origin and human waste

5. Domesticated and wild animals
6. Equipment, tools, buildings and sanitation
7. Growing, harvesting, packing and holding activities

What does the end of the enforcement discretion period mean for produce farms?



Farms and packing houses

- **This regulation affects “covered” farms ONLY.**
- Determine where the farm falls under the Produce Safety Rule.
- Only after its determine that the farm is a “covered” farm then calculate average **produce sales for the past three years** to determine the compliance date.

Compliance dates (average of last 3 years of produce sales)

- January 26, 2023 for covered farms (more than \$500,000)
- January 26, 2024 for covered small businesses (\$250,000 and \$500,000)
- January 26, 2025 for covered very small businesses (\$30,509 and \$250,000)



What water does this apply to?

- Water used for handwashing during harvest and post harvest
- Water used to clean and/or sanitize harvest containers (that are not single use) such as buckets, baskets, trays, pick sacks, bins and any other containers that come in contact with the produce.
- Water used to clean and/or sanitize loading conveyor belts, tanks, packing lines, sorters and other food contact surfaces in packing houses.
- Any water that is likely to come in contact with the edible portion of the fruit or food contact surfaces during and after harvest is also included.

Overall requirements

1. Quality: No detectable generic *E. Coli* per 100 mL of water.
2. Annual inspection of the agricultural water system.
3. Maintain agricultural water sources and distribution systems.
4. If water treatments are used, the process must be monitored.
5. Monitor water quality when washing produce.

Requirements based on water source

Public water system/ public water supply	Ground water - wells	Surface water- Creeks, springs, rivers, ponds
<p>No testing is required.</p> <p>Public Water System results or certificates of compliance that demonstrate that the water meets standard must be on file annually.</p>	<p>For untreated water: Year 1: Test 4 times during growing season OR over a 1-year period test 4 times.</p> <p>Year 2: Test annually thereafter.</p> <p>If annual test fails to meet standard, resume testing four times per growing season.</p>	<p>Never use untreated surface water.</p> <p>If this is the only source, treat it before using it in harvest and post harvest operations.</p>

Collecting samples to test wells at packing houses in 2023 if the farm's compliance date is January 2024

Option 1



Option 2



If water testing is conducted the laboratory has to use one of these methods :

1. EPA Method 1603
2. Method 1103.1
3. Method 1604
4. 9213 D
5. 9222 B
6. D 5392-93
7. Hach Method 10029 for Coliforms
8. IDEXX Colilert Test Kit, but only if using IDEXX Quanti-Tray/2000 for quantification.
9. IDEXX Colilert-18 Test Kit, but only if using IDEXX Quanti-Tray/2000 for quantification.



If water treatment is used for the water source

1. The method used (including physical treatment, an EPA-registered antimicrobial pesticide product, or other suitable method) must be effective.
2. Treatment must be delivered in a manner, and monitored at a frequency adequate, to ensure that the treated water is consistently safe and of adequate sanitary quality
3. Records must be kept
4. Don't have to test water if protocol and records are followed

Agricultural Water System

- Conduct annual inspection of the source of agricultural water, the water distribution system, any building or structure that is part of the water distribution system (such as a well house, pump station, or shed), and any equipment used for application of agricultural water during growing, harvesting, packing, or holding activities.
- Conduct inspection at the beginning of the growing season and as needed.
- Consider: degree of protection of each water source, adjacent and nearby land use and likelihood of introduction of hazards to the water by another user before the water gets to you.

Maintain agricultural water sources and distribution systems

- Adequately maintain all agricultural water sources to the extent they are under your control (such as wells).
- Maintenance includes regularly inspecting each source to identify any conditions that are likely to introduce hazards that can contaminate source or produce.
- Correct any significant deficiencies (e.g., repairs to well cap, well casing, sanitary seals, piping tanks and treatment equipment, and control of cross-connections); and keeping the source free of debris, trash, domesticated animals, and other possible sources of contamination.

Water used during harvest and post harvest operations

Records and recordkeeping

- Records pertaining to agricultural water system inspections
- Testing results including method used by the Lab
- Corrective actions
- If water treatment is conducted, records proving treatment is applied correctly.
- Annual record from municipality/water company showing water is safe.

Water used during growing season

- **Pending** on publication of final rule
- Encouraged to do an inspection of the agricultural water system at least once annually.



FDA's proposed rule

- Water use risk assessments
- Water management plan

FDA Food Traceability Rule

its) / Food Safety Modernization Act (FSMA) / FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods

FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods

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The FDA final rule on Requirements for Additional Traceability Records for Certain Foods (Food Traceability Final Rule) establishes traceability recordkeeping requirements, beyond those in existing regulations, for persons who manufacture, process, pack, or hold foods included on the Food Traceability List (FTL). The final rule is a key component of FDA's

New Era of Smarter Food Safety Blueprint and implements Section 204(d) of the FDA

- [Federal Register Notice](#)
- [Docket No. FDA-2014-N-0053](#)

- Published Nov 21, 2022
- Tomatoes, cucumbers, peppers, leafy greens, melons, herbs are in the food traceability list.
Peaches are not in the list but...
- Fresh cut fruits and vegetables are included
- Will be implemented in 2026



Key Questions for Regulators During Outbreak Investigations

DEVELOPED BY A WORKGROUP OF THE IFPA FOOD SAFETY COUNCIL

Objective: The questions below may be helpful as a company that has been contacted by a regulator seeks to better understand a situation. These questions can be considered if a regulator/ investigator approaches a firm with a request for records or other suggestion of involvement in an outbreak.

This document is not intended to be a recall or regulatory visit policy or guide, but, instead is supplemental material for a firm's internal programs.

<https://www.freshproduce.com/siteassets/forms/22-outbreakquestions-regulators-v3.pdf>

BASICS & BACKGROUND

The questions below might be appropriate for the investigator who reaches out to you and/or is your primary point of contact. "You" refers to the investigator/agency you are working with.

1. What agency do you work for? If the FDA, which division are you from?

a. What is the best way for me to reach you? Does this include evenings and weekends?

b. What is the contact information (phone & email) for you and your supervisor?

c. Under what authority is this visit being conducted?

(i. Produce Safety Rule, ii. Preventive Control Rule, iii. General Authority of Food, Drug, and Cosmetics Act, iv. Other, such as state authority)

d. Who can I contact for additional information about what led you to contact us?

(Epi, cases, traceback etc.)

Key questions for regulators during outbreak investigations

- Basics and background
- Tracebacks requests
- Investigation details



United States Department of Agriculture

Marketing and
Regulatory
Programs

Agricultural
Marketing
Service

Specialty
Crops
Program

Specialty
Crops
Inspection
Division

Produce GAPs Harmonized Food Safety Standard

February 8, 2021

Effective for audits 2024
New format will be released in early February.
Workshops will be offered to go over changes.

USDA Food Safety Cost Share

 An official website of the United States government [Here's how you know](#) 

 [Translations](#) | [Service Centers](#) | [Contact](#)

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Food Safety Certification for Specialty Crops Program

Did your specialty crop operation recently incur on-farm food safety program expenses related to obtaining or renewing a food safety certification in calendar years 2022 or 2023? You may be eligible for financial assistance through USDA's Food Safety Certification for Specialty Crops Program (FSCSC).

 USDA's Farm Service Agency will accept FSCSC applications for program year 2022 from June 27, 2022, through January 31, 2023. Applications for program year 2023 will be announced at a later date.

On This Page

 [How FSCSC Works](#)

 [Eligible Expenses](#)

 [Webinars](#)

 [Apply for FSCSC](#)

 [Program Eligibility](#)

 [Additional Resources](#)

USDA Food Safety Cost Share



Eligible Expenses

Please click below to learn more about the categories of eligible expenses and payment amounts for eligible expenses.

Developing a Food Safety Plan



Maintaining or Updating a Food Safety Plan



Food Safety Certification



Certification Upload Fees



Microbiological Testing



Training Expenses



NCDA Food Safety Cost share

- N.C. Good Agricultural Practices Certification Assistance Program- \$900 for Year 1, \$300 for Year 2
- Water testing expenses – Up to \$1000/ year for farms that will be GAP certified
 - Contact Kevin Hardison, NCDA
- Cost Share Programs - Agricultural Water Resources Assistance Program (AgWRAP)

Upcoming workshops

- Feb. 13, 2024. Produce Safety Alliance Training – Monroe, NC
- March 13, 2024. Cleaning and sanitation workshop. Clinton, NC
- March 21, 2024. Produce Safety Alliance Training – Mills River, NC
- March 27, 2024. Water systems workshop. Clinton, NC
- April 17, 2024. Water systems workshop. Mills River, NC

NC Fresh Produce Safety

[Meet Our Staff](#)

[Events](#)

[Food Safety Modernization Act \(FSMA\)](#)

Produce Safety Rule, How Is Produce Classified Under the Produce Safety Rule?, Exemptions ...

[Good Agricultural Practices](#)

GAPs Information, Audits and Plans, Risk & Crisis Management ...

[Growers](#)

Farmers Market Resources, Production Considerations, Worker Health and Safety ...

[Industry](#)

Pathogens, Food Safety for Processors, Industry Guidelines ...

[Trainers](#)

Agent Resources, Training Manuals, Educational Resources

[Spanish Resources](#)

Worker Resources, Consumer Resources, Reference Materials

[Consumers](#)

Health and Wellness, Educational Resources, Foodborne Illness

[Glossary and FAQs](#)

Glossary, Frequently Asked Questions (FAQs)

[Publications & Factsheets](#)



Events

< > **ALL EVENTS**

JAN 17 WED	Produce Safety Alliance Grower Training- Mills River, NC Wed 1/17 8:30am - 5pm 1 week away	JAN 18 THU	Produce Safety Alliance Grower Training - Jacksonville, NC Thu 1/18 8:30am - 5pm 1 week away	JAN 31 WED	Produce Safety Alliance Grower Training- Rockingham, NC Wed 1/31 8:30am - 5pm 3 weeks away	FEB 7 WED	Produce Safety Alliance Grower Training- Nashville, TN Wed 2/7 8:30am - 5pm 4 weeks
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News and Updates



Registration for the Produce Safety Rule Growers Training Courses in North Carolina

This one-day training course on the Produce Safety Alliance (PSA) standardized curriculum is for produce



FSMA for Small Farms: Six



Scholarships Available From the Rural Food Center

Contact Information

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<https://ncfreshproducesafety.ces.ncsu.edu>

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Template to determine your status in the PSR (2023)

1. Do you **only** grow produce for personal or on-farm consumption?

Yes _____ No _____

If your answer is **Yes**, then you are **not covered** by the Produce Safety Rule. If your answer is **No**, go to question 2.

2. Use sales receipts or records to determine **produce** sales for the farm over the previous 3 years. Count **all** produce sold by the farm.

Year 1 (Sales year: 2020) \$ _____

Year 2 (Sales year: 2021) \$ _____

Year 3 (Sales year: 2022) \$ _____

Add produce sales for Years 1-3 \$ _____ divide

this number by 3

**Are the average farm produce sales for the last 3 years
above or below \$30,509?***
(Adjusted rate for 2023)

Template to determine your status in the PSR (2023)

3. Do you **only** grow rarely consumed raw produce?

Yes _____ No _____

If your answer is **Yes**, then you are **not covered** by the Produce Safety Rule. If your answer is **No**, go to question 4.

4. Do you grow produce that will be further processed and in which there will be a kill step?

Yes _____ No _____

If your answer is **Yes**, then that produce may be exempt from inspection if you are a covered farm. If your answer is **No**, go to question 5.

If you answered yes to these questions, you may be exempt from the Produce Safety Rule but you are still fully liable for growing safe produce under the Federal Food, Drug & Cosmetic Act.

5. Determine if a farm is eligible for a Qualified Exemption and Modified Requirements for 2023.

To be eligible for this category, a farm must meet both requirements:

Requirement 1: Average food sales must be under \$610,182* for years 2020-2022.

Requirement 2: The majority of food sales must be made to Qualified End Users (QEU) during that time frame.

Requirement 1: Average food sales must be under \$610,182* for years 2020-2022.

1. Calculate food sales

Year 1 (Sales year: 2020) \$ _____

Year 2 (Sales year: 2021) \$ _____

Year 3 (Sales year: 2022) \$ _____

Add food sales for Years 1-3 \$ _____ divide this number by 3

Average total food sales for years 1-3 \$ _____

Are the average food sales over **\$610,182** for the last three years?

Yes _____ No _____

If you answer Yes, you are not eligible for the exemption.

If you answer No, go to requirement 2.

Requirement 2: The majority of food sales must be made to Qualified End Users (QEU) for 2020-2022.

Qualified End Users are:

The consumer of the food (regardless of location) your farm, farmers market, CSA and/or via internet sales

Restaurants and grocery stores (that you deliver to directly) within 275 miles of your farm



Requirement 2: The majority of food sales must be made to Qualified End Users (QEU) for 2020-2022.

Who do you sell the majority of your produce to?

A

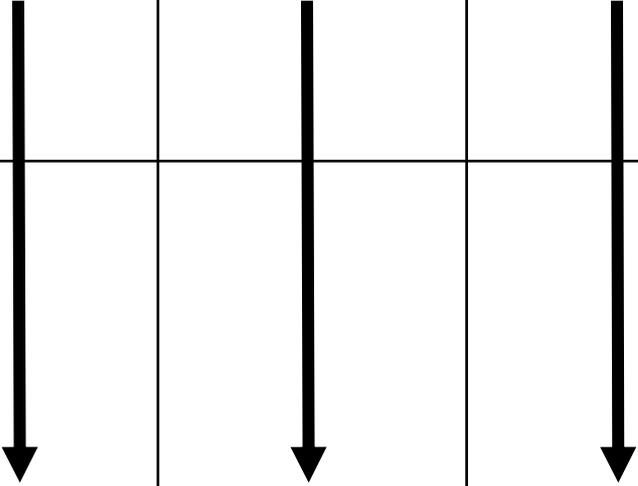
The consumer of the food (regardless of location) your farm, farmers market, CSA and/or via internet sales

Restaurants and Grocery stores within 275 of your farm (Qualified end users)

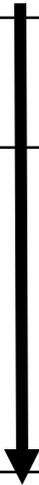
B

Businesses
Brokers
Processors
Distribution centers

Restaurants and grocery stores more than 275 miles of your farm

Sales to Qualified End Users (QEU)	2020	2021	2022	Average food sales (2020-2022)
1. Directly to consumers (regardless of location)				
2. Retail food establishments within 275 miles of the farm (grocery stores) or restaurants				
3. Others				
A- Total Food Sales to QEU by year	A1	A2	A3	$A4 = (A1 + A2 + A3) / 3$

Sales to businesses (not Qualified End Users)	2020	2021	2022	
Brokers				
Distribution centers				
Retail food establishments or restaurants farther than 275 miles from the farm				
Processors				
Packers				
Others				
B- Total Food Sales to businesses (not QEU)	B1	B2	B3	$B4 = \frac{B1+B2+B3}{3}$



Requirement 2: The majority of food sales must be made to Qualified End Users (QEU) during that time frame.

Are the majority (51%) or more of your sales to qualified end consumers?

Yes _____ No _____

If you answer Yes, you are eligible for the qualified exemption.

If you answer No, you are a covered farm.