

Ask Me Anything: Produce Safety Rule Hot Topics & Questions



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Quality Assurance & Regulations

What is FSMA?

The Food Safety Modernization Act is:

- Mandatory food safety law passed in 2011.
- First major update to the federal food code since 1938.
- Establishes science-based minimum standards for produce handling on farms.
- Applies a preventive approach to ensuring food safety.
- Uses systems-based thinking to provide adaptability of Rules to a wide range of businesses.
- Implemented in 7 different parts.



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What is FSMA?

The Food Safety Modernization Act's 7 parts:

1. **Produce Safety Rule**
2. Preventive Controls for Human Food
3. Preventive Controls for Animal Food
4. Foreign Supplier Verification Programs
5. Accreditation of 3rd Party Auditors/Certification Bodies
6. Sanitary Transport of Human & Animal Food
7. Prevention of Intentional Contamination/Adulteration



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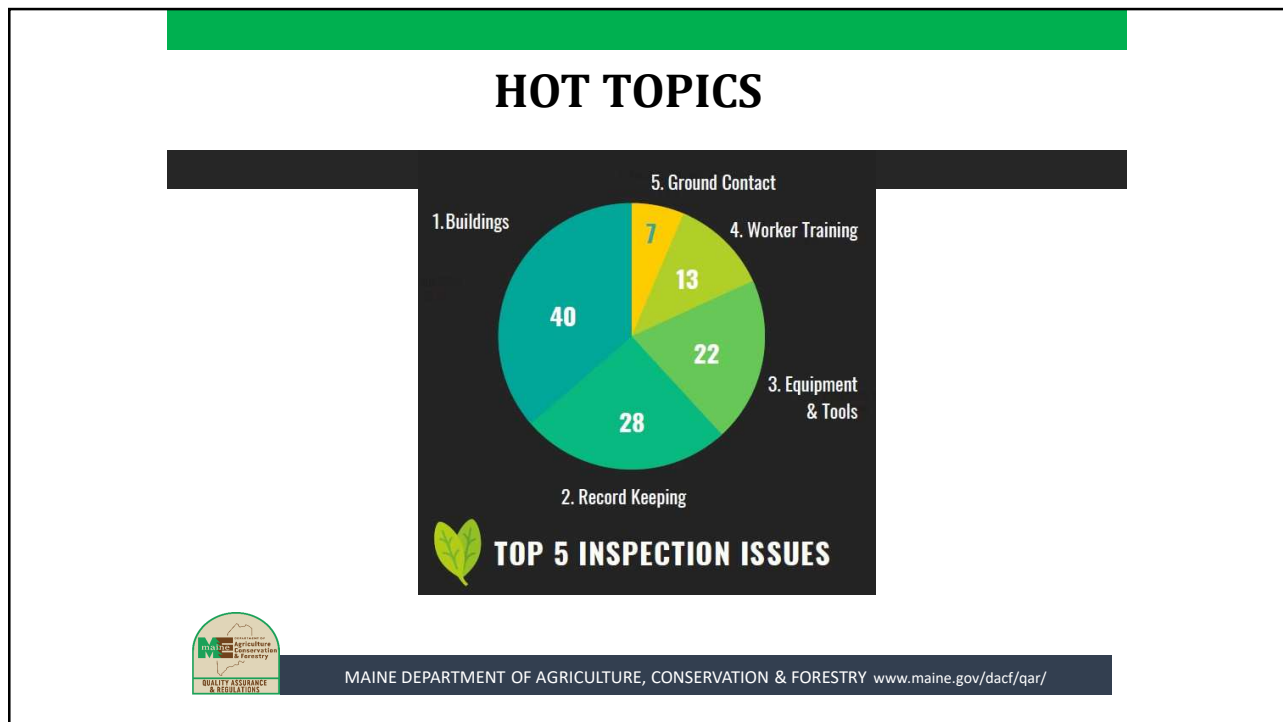
What Are the Underlying Ideas?

The **Produce Safety** Rule is based on consumer health and produce safety fundamentals:

- Microbiological pathogens can make people sick.
- Pathogens are more likely to make vulnerable people sick, including the **young**, the **elderly**, the **pregnant**, and the **immunocompromised**.
- Pathogens are commonly found in animal and human feces.
- Pathogens most commonly contaminate food via:
 - People
 - Water
 - Food contact surfaces, including equipment
 - Biological soil amendments



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01 BUILDINGS



**DRIPPING CONDENSATE
HAND-WASHING STATIONS
ABILITY TO MONITOR FOR PESTS
MAINTAINED & CLEANABLE**



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BUILDINGS DRIPPING CONDENSATE

The Produce Safety Rule requires farms to implement measures to minimize potential for contamination through:

- Floors, walls, ceilings, fixtures, ducts, or pipes; and
- Drip or condensate.

ISSUES WE RUN INTO:

- Overhead drips from pipes.
- Condensate dripping on product and containers from evaporator pans.
- Condensate dripping onto product or containers by doorways.



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BUILDINGS HAND-WASHING STATIONS

The Produce Safety Rule requires that hand-washing stations be made available to both workers and visitors. All hand-washing stations:

- **Must** be close to toilets and readily accessible during growing activities that take place in a fully-enclosed buildings and during covered harvest, packing, and holding activities.
- Must include:
 - Water for handwashing that has no detectable generic E. coli
 - Soap
 - Single-use drying devices
- Must provide for proper disposal of waste, including paper products and waste water.
- Must be close enough to toilet facilities to make it practical for all workers to wash their hands after use.



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BUILDINGS HAND-WASHING STATIONS

The Produce Safety Rule requires that hand-washing happen:

- Before starting work.
- Before putting on gloves.
- After using the toilet.
- Upon returning to work station after any break or other absence.
- As soon as practical after touching animals.
- At any other time when hands may have become contaminated.

ISSUES WE RUN INTO:

- Hand-washing stations not close enough to toilet facilities for field workers to use all the times they're supposed to.
- Waste water from hand-washing stations puddling on ground or in travel lanes where workers walk through it.
- Stations running out of supplies (soap, paper towel).



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BUILDINGS MONITORING FOR PESTS

The Produce Safety Rule requires farms to:

- Take measures to **protect** produce, food contact surfaces, and food packaging from contamination by pests, including pest monitoring.
- Take measures to **exclude** pests from fully-enclosed buildings.
- Take measures to **prevent establishment** of pests in partially-enclosed buildings.

ISSUES WE RUN INTO:

- Supplies stored too tightly to allow monitoring for pests along walls.
- Buildings not cleaned recently enough to allow determination of past vs. current pest activity.
- Birds nesting in rafters of loading docks.
- Holes and openings in buildings where pests can get in.
- Brush and debris alongside buildings, providing harborage for pests.



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BUILDINGS MAINTAINED & CLEANABLE

The Produce Safety Rule requires that buildings:

- Must take measures to **prevent contamination**.
- Must be in **suitable size, construction, & design** to facilitate maintenance and cleaning.
- Must have **enough space** for equipment placement & storage of materials.
- Must have **adequate drainage** to keep free from standing water.

ISSUES WE RUN INTO:

- Cracked floors that aren't cleanable.
- Rough pitted floors.
- Building materials that are porous, crumbling, or rotting.
- Cleaning and maintenance doesn't keep up with facility needs.



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RECORD KEEPING
MISSING INFO
TOPICS OF TRAININGS
METHODS OF CLEANING



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RECORDS MISSING INFO

The Produce Safety Rule requires records to include:

- Name and location of your farm.
- Actual values and observations collected during monitoring.
- Adequate description of covered produce that’s applicable to the record.
- Location of the growing area or other area, as applicable to the record.
- Dates and times activities were recorded.
- Initialed by the person who performed the activity being recorded.
- Review, signature, and date by a supervisor for certain records.

ISSUES WE RUN INTO:

- Records missing farm names and addresses.
- Records not being descriptive enough when there are multiple crews or locations involved.
- Records missing times that activities were performed.
- Records not filled out by the person who did the activity being recorded.
- Records not being reviewed, signed, and dated by a supervisor when required.



RECORDS TOPICS OF TRAININGS

The Produce Safety Rule requires that TRAINING RECORDS include:

- The date of training.
- Topics covered.
- The people trained.
- Review, signature, and date by a supervisor or responsible party.

ISSUES WE RUN INTO:

- Missing topics of trainings on records.
- No supervisor review, signature, & date.



RECORDS TOPICS OF TRAININGS

Worker Training Log

PSR Required FSMA PSR reference § 112.30 Frequency: At Least Annually

The Produce Safety Rule (PSR) requires that farms covered by the rule establish and keep records of training that document required training of personnel. Training records must include the date of training, topics covered, and the person(s) trained. Training should be conducted as needed but at least annually. Keep this record for at least 2 years.


Farm Name & Address: High Hill Produce 1845 S. Ridge Rd, Buxton MO 68345 Date of Training: 3/24/19

Name of Trainer: Johnny S Wright Time of Training: 10:00 am

Topics Covered in Training: Worker health and hygiene, bathroom facilities, proper and safe harvesting, use of detergent and sanitizers (cleaning and sanitizing activities), inspecting harvest containers and equipment, principles of food hygiene and food safety, applying soil amendments of animal origin

Please attach any training materials used. Attach additional sheets if needed.

<small>Employee Name (printed)</small>	<small>Employee Signature</small>
1. Pam Wright _____	<u>Pam Wright</u> _____
2. Sam Johnson _____	<u>Sam Johnson</u> _____



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RECORDS METHODS OF CLEANING

The Produce Safety Rule requires that SANITATION RECORDS related to Subpart L (Equipment, Tools, Buildings, and Sanitation) must include:

- The date sanitation activities were performed.
- Method of cleaning and sanitizing of equipment used in covered harvesting, packing or holding.
- Review, signature, and date by a supervisor or responsible party.

ISSUES WE RUN INTO:

- No cleaning records at all.
- Missing methods of cleaning.
- No supervisor review, signature, & date.



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RECORDS METHODS OF CLEANING

Cleaning and Sanitizing Record *Template*

Name and address of farm: _____

List the date, time, tool or equipment name, and method 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



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EQUIPMENT & TOOLS
CLEANABLE MATERIALS
FREQUENCY OF CLEANING



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CLEANABLE MATERIALS

The Produce Safety Rule requires:

- Equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained.
- Seams must be either smoothly bonded, or maintained to minimize accumulation of dirt, filth, food particles, and organic materials so it minimizes opportunity for microbial growth.

ISSUES WE RUN INTO:

- Foam bumpers or rollers that can't be adequately cleaned.
- Carpet cushions on equipment that can't be cleaned.
- Jury-rigged cushioning or splashguards of mixed materials, fastened with duct tape that can't be cleaned.
- Aging, cracked, feathered wood that can't be cleaned.



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FREQUENCY OF CLEANING

The Produce Safety Rule requires that you must:


- Inspect, maintain, and clean and, when necessary and appropriate, sanitize all food contact surfaces of equipment and tools used in covered activities as frequently as reasonable necessary.

ISSUES WE RUN INTO:

- Tools not cleaned as frequently as they need to be to prevent contamination.
- Equipment not cleaned frequently enough to prevent build up.
- Equipment soiled enough to pose a risk to the produce in contact with it.




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04  **WORKER TRAINING**
 MISSING TOPICS
 GLOVE USE
 HARVEST CONTAINERS
 SYMPTOMS OF HEALTH CONDITIONS

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WORKER TRAINING MISSING TOPICS

The Produce Safety Rule requires ALL WORKERS to be trained:

- To perform their duties/tasks.
- In the principles of food hygiene and food safety.
- In the importance of health and personal hygiene for all workers and visitors, including recognizing symptoms of contagious health conditions (vomiting, diarrhea, jaundice, fever, open wounds, etc...)
- In the minimum standards required by the Produce Safety Rule, as applicable to their jobs.

The Produce Safety Rule requires HARVEST WORKERS to be trained to:

- Recognize produce that should NOT be harvested.
- Inspect harvest containers & equipment to make sure they're clean, maintained, & functioning.
- Correct problems with harvest containers or equipment, or notify their supervisor of problems.

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WORKER TRAINING MISSING TOPICS

ISSUES WE RUN INTO:

- A responsible party for the farm hasn't attended a PSA Grower Training as required.
- Worker training includes required topics, but doesn't record them.
- Worker training doesn't include:
 - WHAT the symptoms of communicable health conditions are.
 - Reporting to a supervisor when they have reason to think they've been exposed to a communicable health condition.
 - ALL instances when hand-washing is required by the Rule.
 - Avoiding contact with animals where possible, and minimizing the risk of contamination from work animals.
 - Removing or covering hand jewelry that can't be cleaned and sanitized.
 - Not chewing gum in food areas.
 - Harvest worker training.



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WORKER TRAINING GLOVE USE

The Produce Safety Rule requires that personnel hygiene practices, when handling covered produce or food contact surfaces, must include:

- Washing hands before putting on gloves.
- Maintaining gloves (if used) in an intact and sanitary condition and replacing such gloves when no longer able to do so.

ISSUES WE RUN INTO:

- Not washing hands before putting on gloves.
- Giving no instructions to workers to maintain gloves in clean and intact condition.
- Giving no instructions to workers to replace their gloves when they can't maintain them that way.



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WORKER TRAINING HARVEST CONTAINERS

- **The Produce Safety Rule requires HARVEST WORKERS** to be trained to:
 - Recognize produce that should NOT be harvested.
 - Inspect harvest containers & equipment to make sure they're clean, maintained, & functioning.
 - Correct problems with harvest containers or equipment, or notify their supervisor of problems.

ISSUES WE RUN INTO:

- Not training workers to recognize contaminated produce because it seems obvious.
- Not training workers to inspect harvest containers for cleanliness and condition.
- Not training workers to correct problems with harvest containers, or to inform a supervisor of the problems.



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SYMPTOMS OF HEALTH CONDITIONS

The Produce Safety Rule requires ALL WORKERS to be trained:

- In the importance of health and personal hygiene for all workers and visitors, including recognizing symptoms of contagious health conditions (vomiting, diarrhea, jaundice, fever, open wounds, etc.)

ISSUES WE RUN INTO:

- Telling people not to work sick, but not training them to recognize the symptoms of communicable health conditions.
- Not training workers to report to supervisors when they have reason to believe they've been exposed to communicable health conditions.
- Not making visitors aware of what symptoms can indicate a communicable health condition.



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05



GROUND CONTACT
DROPPED PRODUCE
STACKING HARVEST CONTAINERS



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DROPPED PRODUCE & STACKED HARVEST CONTAINERS

The Produce Safety Rule requires that dropped covered produce must **NOT** be **distributed**.


- Dropped covered produce is covered produce that drops to ground before harvest.
- Dropped covered produce does not include root crops that grow underground, crops that grow in contact with the ground, or produce that is intentionally dropped to the ground as part of harvesting.


ISSUES WE RUN INTO:

- Farms picking dropped covered produce.
- Harvested (often cut) produce resting on the ground.
- Harvest containers set on/dragged across the ground, then stacked up with no protection for produce in lower harvest containers.



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06



HOSES & PLUMBING

HOSES ON GROUND

HOSES SUBMERGED

BACKFLOW PREVENTION DEVICES

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HOSES & PLUMBING
HOSES ON GROUND

The Produce Safety Rule requires that plumbing must:

- Avoid being a source of contamination to covered produce, food contact surfaces, areas used for a covered activity, or agriculture water sources.

ISSUES WE RUN INTO:

- Hoses lying on the ground or floor.
- Hoses on the ground or floor are often dusty or dirty.
- Hoses on the ground or floor are often in puddles.

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HOSES & PLUMBING **HOSES SUBMERGED**

The Produce Safety Rule requires that plumbing must

- Avoid being a source of contamination to covered produce, food contact surfaces, areas used for a covered activity, or agriculture water sources.

ISSUES WE RUN INTO:

- No air gaps left on hoses filling wash tubs; hoses are clipped to sinks or wash tubs and end up submerged when the water rises.
- Often the same hose is left on the ground, then used to fill wash tubs or spray down produce.



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HOSES & PLUMBING **BACKFLOW PREVENTION DEVICES**

The Produce Safety Rule requires that plumbing must:

- Avoid being a source of contamination to covered produce, food contact surfaces, areas used for a covered activity, or agriculture water sources.
- Not allow backflow from, or cross connection between, piping systems for waste water or sewage and piping systems for water used for covered activity, for sanitary operations, or for use in hand-washing facilities.

ISSUES WE RUN INTO:

- No backflow prevention devices protecting wells.
- No backflow prevention devices on hoses to protect water systems.




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07  **FOOD PACKAGING**
SANITARY STORAGE
PREVENTION OF HARBORAGE
RE-USE



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FOOD PACKAGING **SANITARY STORAGE**

The Produce Safety Rule requires that equipment, including food packaging materials, be:

- Stored and maintained to protect covered produce from being contaminated with known or foreseeable hazards and to prevent the equipment and tools from attracting and harboring pests.

ISSUES WE RUN INTO:

- Food packaging stored in semi-open sheds and barns with no protection from barn cats, birds, or pests.
- Food packaging stored directly on floors of storage areas.
- Often stored in mixed storage with other materials that could contaminate food packaging with other adulterants.



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FOOD PACKAGING PREVENTION OF HARBORAGE

The Produce Safety Rule requires that equipment, including food packaging materials, be:

- Stored and maintained to protect covered produce from being contaminated from hazards and to prevent the equipment and tools from attracting and harboring pests.

ISSUES WE RUN INTO:

- Food packaging is tightly packed against walls or in a jumble of mixed storage, providing harborage for pests.



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FOOD PACKAGING RE-USE

The Produce Safety Rule requires packaging materials to be:

- Adequate for their intended use.
- Cleanable or designed for single use.
- Unlikely to support growth or transfer of bacteria.
- Clean prior to re-use if re-used (can use liners).

ISSUES WE RUN INTO:

- Re-used packaging that can't be cleaned—most often waxed or cardboard boxes.
- Packaging being re-used that isn't adequately clean.



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08 **QUALIFIED EXEMPTION**
ELIGIBILITY CRITERIA
MODIFIED REQUIREMENTS
RECORDS



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QUALIFIED EXEMPTION **ELIGIBILITY CRITERIA**

QUALIFIED EXEMPT farms =

- Sell >\$25,000* in produce sales.**
- Sell <\$500,000* in total food sales.**
- Sell >50% of total food sales to Qualified End Users.**
*(*3-year average, adjusted for inflation, using 2011 as the baseline for adjustment.*)*

- **QUALIFIED END USERS =**
 - Individual consumer of the food.
 - Restaurants or retail stores:
 - Within the same state or Tribal reservation as the farm.
 - Within 275 miles of the farm.



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MODIFIED REQUIREMENTS

REQUIREMENTS for QUALIFIED EXEMPT farms:

1. LABELING:

- **MUST** include your **farm name** and **complete business address** on any food packaging label normally required by the FD&C Act.
- **MUST** prominently and conspicuously display your **farm name** and **complete business address** at the point of purchase for foods **NOT** requiring food packaging labels by the FD&C Act.

2. RECORDS:

- **MUST** keep sales records demonstrating your eligibility for the Qualified Exemption.
- **MUST** do a written annual review and verification of your Qualified Exempt Status.



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QUALIFIED EXEMPTION RECORDS

Qualified Exemption Review Template

Name and address of farm: _____ Date: _____

Total food sales (in addition to produce, these sales include all other food for humans, feed for animals, and sales of live food animals)

Year 1 (Sales year: _____) \$ _____
 Year 2 (Sales year: _____) \$ _____
 Year 3 (Sales year: _____) \$ _____

A must be smaller than B for eligibility

Average total food sales \$ _____ A

Inflation adjusted¹ threshold for (range) \$ _____ B

(for example, B is \$550,551 for 2016-2018)

Sales to qualified end users (QEUs) (e.g. consumers anywhere, or grocery stores and restaurants within 275 miles or within the same state or Indian reservation)

Year 1 (Sales year: _____) \$ _____
 Year 2 (Sales year: _____) \$ _____
 Year 3 (Sales year: _____) \$ _____

Average food sales to QEUs \$ _____ C



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QUALIFIED EXEMPTION RECORDS

Sales to non-QEUs (e.g. wholesale buyers)

Year 1 (Sales year: _____)	\$ _____	C must be larger than D for eligibility
Year 2 (Sales year: _____)	\$ _____	
Year 3 (Sales year: _____)	\$ _____	
Average food sales to non-QEUs	\$ _____	D


Based on this information, this farm meets the criteria for a qualified exemption.

Reviewed by: _____ Title: _____ Date: _____

 Sales receipts must also be retained to support this record.
 *FDA updates the inflation adjusted value (B) yearly:
<https://www.fda.gov/food/guidanceregulation/fsma/ucm554484.htm>

FSMA PSR Reference § 112.7(b) Confidential Record

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QUALIFIED EXEMPTION FAQ

WILL THE QUALIFIED EXEMPTION GO AWAY AT ANY TIME?

- No, the qualified exemption is written into the rule. It is a long, formal process to open up the regulation to make any changes. The only way the qualified exemption would be “taken away” is in the case of a withdrawal of the qualified exemption for an individual farm. This process is outlined in Subpart R of the PSR.

WILL I BE INSPECTED IF I’M A QUALIFIED EXEMPT FARM?

- You definitely can be. Fully covered farms are the inspectional priority, but you’re responsible for being ready for inspection by the compliance dates based on farm size.



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QUALIFIED EXEMPTION **FAQ**

SO YOU JUST CHECK MY PAPERWORK IF I'M QUALIFIED EXEMPT?

- Not quite. We will review the modified requirements for Qualified Exempt farms (labeling with farm name and address, maintaining sales records, & annual written verification of QE status).
- We **also** are responsible for looking around Qualified Exempt farms to ensure there are no practices or conditions that might result in adulteration or public health risks.



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THANK YOU!



QUESTIONS?

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