


**FSMA Produce Safety Rule  
Farm Coverage Appendix**

**DETERMINING FARM COVERAGE STATUS  
&  
REQUIREMENTS FOR EACH**

**Leah Cook**  
Fed/State Inspection Service  
Maine Dept. of Agriculture




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**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 3<sup>rd</sup> Party Auditors/Certification Bodies
6. Sanitary Transport of Human & Animal Food
7. Prevention of Intentional Contamination/Adulteration




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## What Is Covered By The PSR?

- COVERED PRODUCE =
  - **All produce generally consumed raw.**
- COVERED ACTIVITIES =
  - **All growing, harvesting, packing, and holding activities.**
  - Certain narrowly defined processing activities on-farm.
- COVERED FARMS =
  - **Farms doing covered activities, with covered produce.**



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## What Is NOT Covered By The PSR?

- PRODUCE THAT IS RARELY CONSUMED RAW =
  - Produce **not generally consumed raw**, as substantiated by consumer data.
  - All 'rarely consumed raw' produce is listed in the 'exhaustive' list in the PSR.
- CROPS GROWN FOR ON-FARM OR PERSONAL USE.
- SEEDS AND FOOD GRAINS =
  - **Small, hard fruits or seeds of arable crops** that are primarily grown and processed for use as meal, flour, baked goods, cereals or oils.
- CROPS GROWN FOR ANIMAL FEED =
  - Covered under the Preventive Controls for Animal Food.



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## What's Special About the Produce Safety Rule?

In many parts of the US, there **has never been jurisdiction for food safety on produce farms.**

As a result, these are brand new regulations for farms in many states.

The FDA has structured the implementation of the Produce Safety Rule to build in time to learn by:

- **Funding states** to provide education & outreach.
- **Partnering with states** to do the boots-on-the-ground inspections.
- **Staggering compliance dates** by farm size to give time to get ready.
- Making **initial inspections** educational in nature, with only egregious conditions triggering official compliance action.
- **Developing collaborative partnerships** to provide resources and technical advice to farmers.



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## Who's Responsible for the PSR in Maine?




In Maine, Produce Safety Rule outreach, education, and inspections are done by the **Federal/State Inspection Service**, based in Presque Isle, operating **under FDA authority**.

We're a small team within the **Department of Agriculture, Conservation & Forestry** that does:

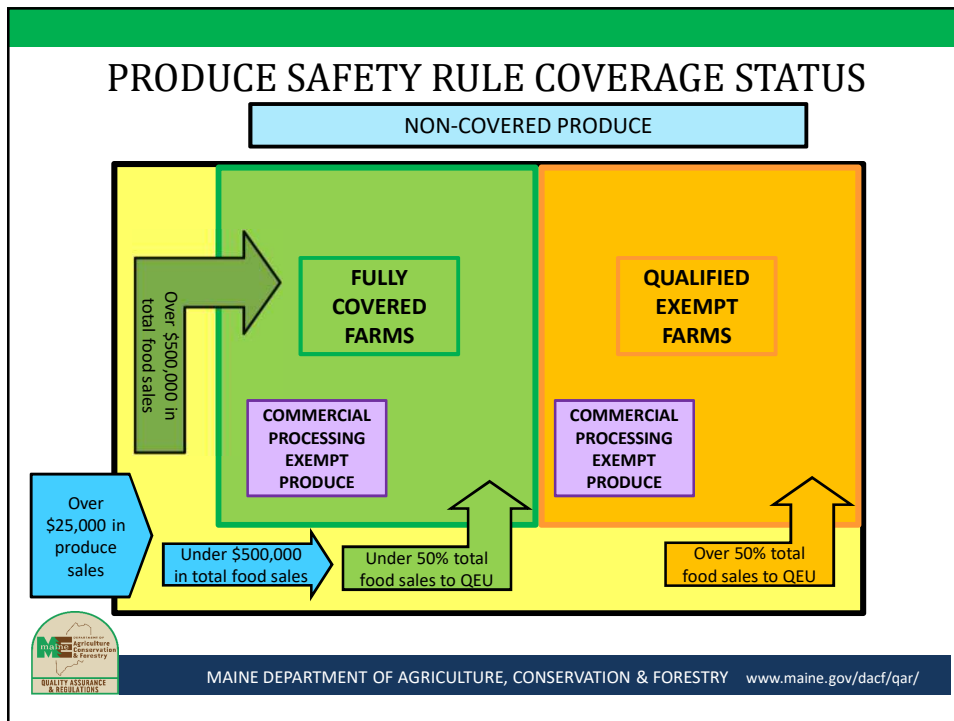
- GAP audits.
- Commodity crop inspections for potatoes, broccoli, apples, etc.
- FSMA Produce Safety Rule education & outreach.
- FSMA Produce Safety Rule inspections.

**Our team is credentialed by the FDA to authorize us to do these inspections.**



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## DETERMINING FARM COVERAGE STATUS


**QUESTION 1: Are your total produce sales over \$25,000 as a 3-yr average?**

*(Adjusted for inflation, this 3-yr average would be \$28,075.)*

If **NO**, your farm is **NOT COVERED** by the Produce Safety Rule.

If **YES**, you **are** covered by the Produce Safety Rule in some way.

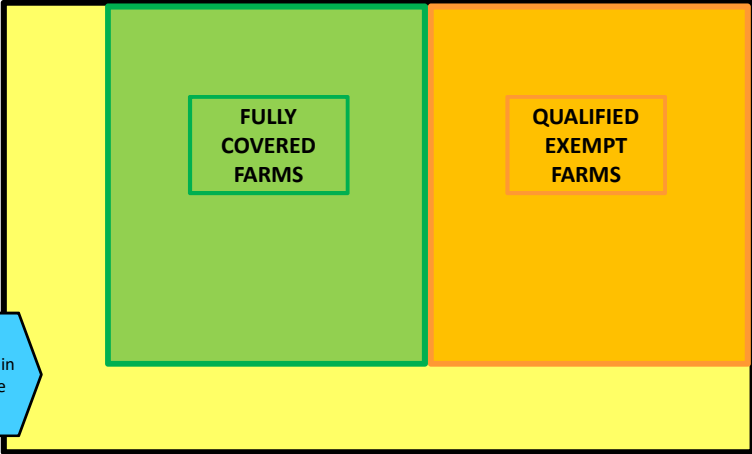
CONTINUE ON TO QUESTION 2...




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## DETERMINING FARM COVERAGE STATUS



Over \$25,000 in produce sales



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## DETERMINING FARM COVERAGE STATUS


**QUESTION 2: Are your total food sales over or under \$500,000 as a 3-yr average?**

*(Adjusted for inflation, this 3-yr average would be \$561,494.)*  
*(This is ALL foods for man or animal, including hay, grain, jam, eggs, produce, etc.)*

If your total food sales are **over** \$500,000 , you are a **FULLY COVERED FARM** under the Produce Safety Rule.

If your total food sales are **under** \$500,000,

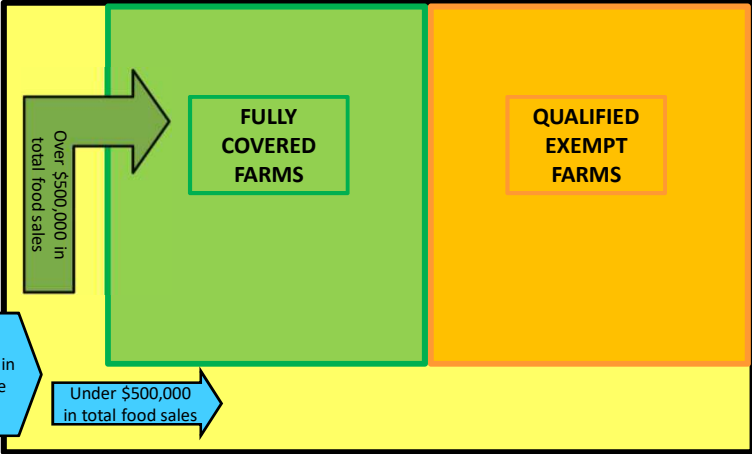
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## DETERMINING FARM COVERAGE STATUS



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## DETERMINING FARM COVERAGE STATUS

**QUESTION 3: Do you sell more than or less than 50% of your total food sales to Qualified End Users?**


*(Qualified End Users are direct consumers, or retail stores and restaurants within Maine or a 275 mile radius.)*

*(This is ALL foods for man or animal, including hay, grain, jam, eggs, produce, etc.)*

If you sell **less than** 50% of your food to QEU's, you are a **FULLY COVERED FARM** under the Produce Safety Rule.

If you sell **more than** 50% of your food to QEU's, you are a **QUALIFIED EXEMPT FARM** under the Produce Safety Rule.

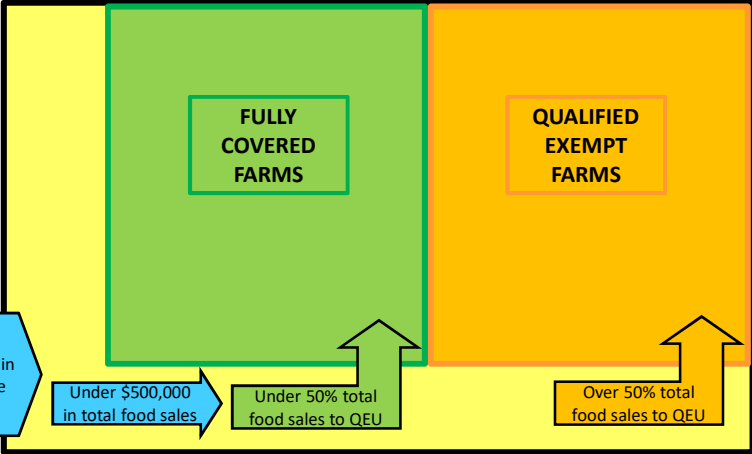
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## DETERMINING FARM COVERAGE STATUS



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## DETERMINING PRODUCE COVERAGE STATUS


**QUESTION 4: Is any of your covered produce sold to a commercial processor?**

*(Produce must receive commercial processing that will adequately reduce the presence of microorganisms of public health significance.)*

If **YES**, that specific produce sold may be **COMMERCIAL PROCESSING EXEMPT**.

If **NO**, that covered produce is **COVERED PRODUCE** under the Produce Safety Rule.

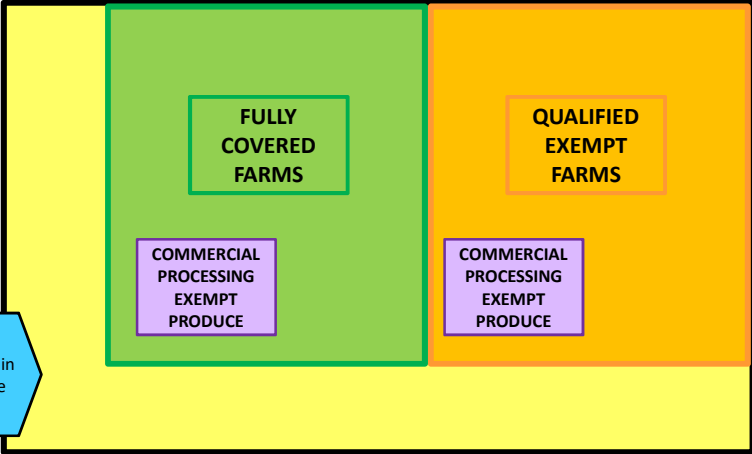
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## DETERMINING PRODUCE COVERAGE STATUS




Over \$25,000 in produce sales

FULLY COVERED FARMS

COMMERCIAL PROCESSING EXEMPT PRODUCE

QUALIFIED EXEMPT FARMS

COMMERCIAL PROCESSING EXEMPT PRODUCE



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## DETERMINING PRODUCE COVERAGE STATUS

**QUESTION 5: Is any of your produce: rarely consumed raw, for on-farm or personal consumption, or for animal feed?**

If you answered **YES** to any of these, that *specific produce* is NOT COVERED under the Produce Safety Rule.

If **NO**, that produce is COVERED PRODUCE under the Produce Safety Rule.



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## WHAT'S COVERED BY THE RULE

NON-COVERED PRODUCE

<p>COVERED ACTIVITIES, COVERED PRODUCE</p> <div style="border: 1px solid green; padding: 5px; display: inline-block;"><p><b>FULLY COVERED FARMS</b></p></div> <p>COMMERCIAL PROCESSING EXEMPT PRODUCE</p>	<p>COVERED ACTIVITIES, COVERED PRODUCE</p> <div style="border: 1px solid orange; padding: 5px; display: inline-block;"><p><b>QUALIFIED EXEMPT FARMS</b></p></div> <p>COMMERCIAL PROCESSING EXEMPT PRODUCE</p>
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INSIDE THE PRODUCE SAFETY RULE "HOUSE"




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## COVERAGE STATUS & REQUIREMENTS

- There are **3 coverage categories** for farms:
  1. NOT COVERED BASED ON PRODUCE SALES.
    - Sales < \$25,000 (adjusted for inflation, based on 3-year average)
  2. FULLY COVERED FARMS.
    - Must comply with full requirements.
  3. QUALIFIED EXEMPT FARMS.
    - > \$25,000 in **produce sales** (adjusted for inflation, based on 3-year average)
    - < \$500,000 in **total food sales** (adjusted for inflation, based on 3-year average)
    - > 50% of food sales to QUALIFIED END USER
      - Individual consumer of food or restaurants or retail stores within the same state/Tribal reservation or within 275 miles of the farm.
  
- In addition, **produce** can be:
  1. COMMERCIAL PROCESSING EXEMPT.
    - Will receive commercial processing that adequately reduces the presence of microorganisms of public health significance.




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## COVERAGE STATUS & REQUIREMENTS

1. Farms **NOT COVERED BASED ON PRODUCE SALES** =  
**Sell <\$25,000\* in produce sales.**  
*(\*3-year average, adjusted for inflation, using 2011 as the baseline for adjustment.\*)*

- REQUIREMENTS for farms NOT COVERED BASED ON PRODUCE SALES :
  - Do **NOT** have to meet any of the requirements of the PSR.
  - **ARE** required to produce safe food and prevent adulteration under the Federal Food, Drug, & Cosmetics Act (FD&C Act).



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**COVERAGE STATUS & REQUIREMENTS**


**2. FULLY COVERED farms =**

**Sell >\$25,000\* in produce sales.**  
**Sell >\$500,000\* in total food sales.**

OR:

**Sell >\$25,000\* in produce sales.**  
**Sell <\$500,000\* in total food sales.**  
**Sell <50% of total food sales to Qualified End Users**

*NOTE: \*3-year average, adjusted for inflation, using 2011 as the baseline for adjustment. Current inflation adjustments for each come to \$28,075 for produce sales, and \$561,494 for food sales.*




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**COVERAGE STATUS & REQUIREMENTS**

• **REQUIREMENTS for FULLY COVERED FARMS :**

- Must meet **ALL** requirements of the Produce Safety Rule.
- Must attend a food safety training with a curriculum at least equivalent to those recognized as adequate by the FDA (currently only the PSA Grower Training).
- **ARE** required to produce safe food and prevent adulteration under the Federal Food, Drug, & Cosmetics Act (FD&C Act).
- **WILL** be inspected for compliance by the DACF acting under FDA authority.



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## COVERAGE STATUS & REQUIREMENTS

**3. 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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## COVERAGE STATUS & 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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## COVERAGE STATUS & REQUIREMENTS

**COMMERCIAL PROCESSING EXEMPT PRODUCE=**

**Produce that will receive commercial processing that adequately reduces the presence of pathogens.**  
*(It is the **produce** NOT the farm that is exempt here.)*

- **COMMERCIAL PROCESSING =**
  - Treating with a scientifically validated process to eliminate spore-forming microorganisms.
  - Processing products such as sugar, oil, wine, beer, or similar products.
  - Refining, distilling, etc.

**\*\*FREEZING is NOT considered a pathogen kill-step by the FDA.\*\***




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## COVERAGE STATUS & REQUIREMENTS

- **REQUIREMENTS for COMMERCIAL PROCESSING EXEMPT PRODUCE:**
  1. **DISCLOSURE:**
    - **MUST** disclose in your paperwork accompanying the product that it is:  
*“not processed to adequately reduce the presence of microorganisms of public health significance”*




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## COVERAGE STATUS & REQUIREMENTS

- REQUIREMENTS for COMMERCIAL PROCESSING EXEMPT PRODUCE:
  2. YOUR COMMERCIAL PROCESSOR CUSTOMER **MUST** give you annual written assurances that:
    - **They, or their subsequent customer**, will adequately process your produce to reduce pathogens.
    - If your customer has **NOT** performed the commercial processing, they will **disclose in their paperwork** accompanying the product to subsequent customers that it is:  
*“not processed to adequately reduce the presence of microorganisms of public health significance”*
    - They will only sell to entities that agree **IN WRITING** to commercial processing of product.

**\*\*NOTE: This requirement for written assurances from commercial processing customers has been delayed by 2 years.\*\***




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## When Are Compliance & Inspection Dates?

COVERED FARM SIZE:	PRODUCE SAFETY RULE COMPLIANCE	COMPLIANCE INSPECTIONS	WATER SUBPART COMPLIANCE
<b>LARGE FARMS</b> Produce Sales = \$500,001+	January 26, 2018	Spring 2019	January 26, 2022
<b>SMALL FARMS</b> Produce Sales = \$250,001 - \$500,000	January 28, 2019	Spring 2020	January 26, 2023
<b>VERY SMALL</b> Produce Sales = \$25,000-\$250,000	January 27, 2020	Spring 2021	January 26, 2024



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## Who Gets Inspected?

**FULLY COVERED FARMS**


**1<sup>st</sup>: LARGE FARMS**  
Total produce sales = \$500,001+

**2<sup>nd</sup>: SMALL FARMS**  
Total produce sales = \$250,001 - \$500,000

**3<sup>rd</sup>: VERY SMALL FARMS**  
Total produce sales = \$25,001 - \$250,000

**QUALIFIED EXEMPT FARMS**

**INSPECTIONAL PRIORITY IS FULLY COVERED FARMS**



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## PRODUCE SAFETY RULE COVERAGE STATUS

NON-COVERED PRODUCE

**FULLY COVERED FARMS**

COMMERCIAL PROCESSING EXEMPT PRODUCE

**QUALIFIED EXEMPT FARMS**

COMMERCIAL PROCESSING EXEMPT PRODUCE


Over \$25,000 in produce sales

Over \$500,000 in total food sales

Under \$500,000 in total food sales

Under 50% total food sales to QEU

Over 50% total food sales to QEU



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If you have any questions about your farm's coverage status under **FSMA's Produce Safety Rule**, just give us a call and we can help walk you through it and give you a definitive answer.

**Thank you!**

**QUESTIONS?**  
Call us at: 207-764-2100  
Email us at: [leah.cook@maine.gov](mailto:leah.cook@maine.gov)

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