FSMA FACTS:
What You Need to Know About the Produce Safety Rule

Leah Cook
Food Inspection Supervisor
Fed/State Inspection Service
Maine Dept. of Agriculture
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.
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
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
What’s In the Produce Safety Rule?

The Produce Safety Rule is divided into Subparts:

A. General Provisions
B. General Requirements
C. Personnel Qualifications & Training
D. Health & Hygiene
E. Agricultural Water
F. Biological Soil Amendments of Animal Origins
I. Domesticated & Wild Animals
K. Growing, Harvesting, Packing, & Holding Activities
L. Equipment, Tools, Buildings, & Sanitation
M. Sprouts
N. Analytical Methods
O. Records
P. Variances
Q. Compliance & Enforcement
R. Withdrawal of Qualified Exemptions
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.

• Some exemptions available to growers.
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.
C. PERSONNEL QUALIFICATIONS & TRAINING

• ALL WORKERS must 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.
C. PERSONNEL QUALIFICATIONS & TRAINING

- HARVEST WORKERS must 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.
C. PERSONNEL QUALIFICATIONS & TRAINING

- SUPERVISORS OR AT LEAST ONE RESPONSIBLE PARTY:
  - Must be **qualified by training or experience** to recognize food safety hazards and address them.
  - Must be **assigned or identified** as responsible for ensuring compliance with the Produce Safety Rule.
  - Must **attend a PSA Grower Training** (only once), **if farm is fully covered** under the Produce Safety Rule.
C. PERSONNEL QUALIFICATIONS & TRAINING

• Trainings for any required topic must be:
  – Provided upon hiring.
  – Done at least annually.
  – Done as frequently as necessary, based on observations of worker behavior.
  – Delivered in a manner that’s appropriate and understandable to workers.
  – Recorded, including dates, topics covered, and names of trainees.
D. HEALTH & HYGIENE - WORKERS

- Ill/contagious workers are **not** allowed to handle covered produce or food contact surfaces.
- Workers are required to follow hygienic practices including:
  - Handwashing
  - Maintaining personal cleanliness
  - *Not* eating, chewing gum, using tobacco in food handling areas.
  - Maintaining gloves (if used) in clean, intact, sanitary condition.
- Must remove or cover **hand jewelry** if it can’t be cleaned.
- Must avoid contact with animals when working.
- Must take steps to **minimize risk of contamination** when working with work animals.
- Must take steps to **prevent contamination** by ill/contagious people.
D. HEALTH & HYGIENE - VISITORS

• Visitors must be made aware of all food safety and hygiene practices.

• You must take reasonable measures to ensure that visitors follow these policies and rules.

• **Toilets** and **handwashing facilities** must be available to all visitors.
E. AGRICULTURAL WATER

• AGRICULTURAL WATER =
  – All water used in covered activities on covered produce where water is intended or likely to contact:
    • Covered produce.
    • Food contact surfaces (including food packaging).

• CAN INCLUDE:
  – Irrigation water.
  – Water used for dust abatement.
  – Water used for frost protection.
  – Water used for chemical or fertilizer applications.
  – Water used for washing, cooling, or misting.
  – Water used in to clean equipment and food contact surfaces.
E. AGRICULTURAL WATER

• WATER SYSTEMS must be inspected at least annually and maintained to prevent water sources and systems from causing contamination.**

• WATER QUALITY must be known—i.e. tested—before use.**

• WATER QUALITY CRITERIA**:  
  – Are currently UNDER REVIEW and ON HOLD.
  – Two different quality criteria requirements depending on the use of the water.

**Remember: water requirements are delayed for FSMA.**
E. AGRICULTURAL WATER

• ANNUAL AG WATER TESTS:
  – **Municipal water**: 1 annual report or test result certificate.
  – **Ground water**: minimum 1 sample per year **per source**.
  – **Surface water**: minimum 5 samples per year **per source**.

• INITIAL AG WATER SURVEY:
  – **Ground water**: minimum 4 samples over 1 yr or growing season **per source**.
  – **Surface water**: minimum 20 samples over minimum 2 yrs or maximum 4 yrs **per source**.

**Remember: water requirements are delayed for FSMA.**
E. AGRICULTURAL WATER

AGRICULTURAL WATER QUALITY CRITERIA:

• WATER USED DURING GROWING ACTIVITIES in a direct application method on covered produce must meet a:
  1. Geometric Mean (GM) of ≤126 CFUs of generic E. coli/100 mL, AND;
  2. Statistical Threshold Value (STV) of ≤410 CFUs of generic E. coli/100 mL.

**Remember: water requirements are delayed for FSMA.**
E. AGRICULTURAL WATER

AGRICULTURAL WATER QUALITY CRITERIA:

• WATER USED FOR NON-GROWING ACTIVITIES including:
  – Irrigating sprouts.
  – Direct applications that contact covered produce during or after harvest activities.
  – Use that contacts food contact surfaces or in ice that will touch food contact surfaces.
  – Use for handwashing during and after harvest activities.

1. Must have **NO** detectable **generic E. coli**, AND;
2. May **NOT** be UNTREATED surface water.

**Remember: water requirements are delayed for FSMA.**
E. AGRICULTURAL WATER

IF WATER USED DURING GROWING ACTIVITIES DOES NOT MEET QUALITY STANDARDS:

• You must suspend use of water source and/or distribution system as soon as practicable and no later than the following year, UNLESS you:
  – Apply a time interval between water application and harvest, or between harvest and end of storage that provides an adequate reduction of microbial levels to meet microbial quality criteria, OR;
  – Re-inspect the entire water systems, take measures to address any problems, and determine whether measures were effective to ensure water meets microbial quality criteria, OR;
  – Treat (and monitor) water to meet microbial criteria.

**Remember: water requirements are delayed for FSMA.**
E. AGRICULTURAL WATER

IF WATER USED FOR NON-GROWING ACTIVITIES DOES NOT MEET QUALITY STANDARDS:

• You must immediately discontinue use of that water source and/or distribution system, and BEFORE you can use it again you must EITHER:
  – Re-inspect the entire water systems, take measures to address any problems, and determine whether measures were effective to ensure water meets microbial quality criteria, OR;
  – Treat (and monitor) water to meet microbial criteria.

**Remember: water requirements are delayed for FSMA.**
E. AGRICULTURAL WATER

• Water temperature in dump tanks/flumes must be controlled to prevent pathogen infiltration into susceptible produce.

• Reclaimed/recirculated water quality must be monitored and maintained.

• Any water treatments must be appropriate for uses and monitored properly.

• Process water must properly and freely drain.

• Condensate and overhead drip must NOT contact produce.

• Ice should be treated as a sanitary product and process.
F. BIOLOGICAL SOIL AMENDMENTS OF ANIMAL ORIGIN

- BIOLOGICAL SOIL AMENDMENTS OF ANIMAL ORIGIN:
  - Can include:
    - Manures.
    - Composts.
    - Fish emulsions.
    - Blood or bone meal.
    - Pulverized feathers.
    - Carcasses.
    - Table waste, and more...
  - Must be handled, conveyed and stored so they don’t become sources of contamination.
F. BIOLOGICAL SOIL AMENDMENTS OF ANIMAL ORIGIN

• TREATED BIOLOGICAL SOIL AMENDMENTS OF ANIMAL ORIGIN (BSAAO):
  – Must be properly treated by documented, scientifically validated controlled methods to lower microbial hazards.
  – Must be handled, conveyed, and stored in a way that prevents re-contamination.
  – Must be considered untreated if mixed with UNTREATED BSAAOs.

• TREATED BSAAO may have NO detectable:
  – Listeria
  – Salmonella
  – *E. coli* O157:H7
F. BIOLOGICAL SOIL AMENDMENTS OF ANIMAL ORIGIN

• TREATED COMPOST must maintain aerobic conditions for:
  – 3 days @ 131°F plus curing for static piles.
  – 15 days @ 131°F, with a minimum of 5 turns for turned piles.

• To be considered TREATED, AGRICULTURAL TEAS must be made with water with no detectable generic *E. coli* and no additives.

• **NO** HUMAN WASTE is allowed on covered produce.

• SEWAGE SLUDGE BIOSOLIDS can be used if they meet requirements of 40 CFR part 503 subpart D.
F. BIOLOGICAL SOIL AMENDMENTS OF ANIMAL ORIGIN

• APPLICATION INTERVALS FOR UNTREATED BSAAOs:
  – Are currently UNDER STUDY and PENDING MORE DATA.
  – Currently no interval if application does not contact produce.
  – Can use NOP Standard of:
    • 90 days before harvest for crops that do not contact the soil.
    • 120 days before harvest for crops that do contact the soil.

• APPLICATION INTERVALS FOR TREATED BSAAOs:
  – 0 days for any treated manures, applied in any manner.
I. DOMESTICATED & WILD ANIMALS

DOMESTICATED & WILD ANIMALS IN OUTDOOR OR PARTIALLY ENCLOSED BUILDINGS:

- Areas used for covered activities (includes outdoor areas and partially-enclosed buildings) must be assessed for signs of animal intrusion and potential contamination.

- In areas with significant evidence of potential contamination, crops must be evaluated to determine if they can be harvested in compliance with Subpart K.

- In areas with significant evidence of potential contamination, measures must be taken during growing season to help identify contaminated produce later to prevent harvesting.
I. DOMESTICATED & WILD ANIMALS

• The Produce Safety Rule does **NOT**:
  – Authorize or require the ‘taking’ of threatened or endangered wildlife or the destruction of wildlife habitat.
  – Require covered farms to exclude animals from outdoor growing areas.

**Working animals are allowed.**
**Domesticated animals are allowed.**
**Pets are allowed.**
**IF** you are managing the potential for contamination.**
K. GROWING, HARVESTING, PACKING, & HOLDING ACTIVITIES

HANDLING DURING COVERED ACTIVITIES:

• **Covered** and **non-covered produce** must be stored separately **IF** both are not handled according to the PSR.

• **Food contact surfaces** must be cleaned and sanitized, as necessary, between **non-covered produce** and **covered IF** both are not handled according to the PSR.

• Harvested covered produce must be handled in a manner that protects against contamination.
K. GROWING, HARVESTING, PACKING, & HOLDING ACTIVITIES

HARVESTING:

• Must preform a **visual assessment** of production areas and all covered produce to be harvested for signs of contamination or potential risks **prior to harvest**.

• Product **contaminated by animal feces** must **NOT** be harvested.

• **Harvest containers** and **equipment** must be clean, maintained, and in good repair.

• **Damaged harvest containers** must **NOT** be used.
K. GROWING, HARVESTING, PACKING, & HOLDING ACTIVITIES

- DROPPED PRODUCE =
  - Produce dropped before harvest.
  - Must **NOT** be *harvested* or *distributed*.
  - Does not include produce normally grown on or under the ground, or intentionally dropped as part of harvest.
K. GROWING, HARVESTING, PACKING, & HOLDING ACTIVITIES

• PACKAGING must:
  – Prevent the formation of *C. botulinum* toxin is that is a known or reasonably foreseeable hazard.

• PACKAGING MATERIALS must be:
  – Adequate for its intended use.
  – Cleanable or designed for single use.
  – Unlikely to support growth or transfer of bacteria.
  – Clean prior to re-use (can use liners).
L. EQUIPMENT, TOOLS, BUILDINGS, & SANITATION

• BUILDINGS =
  – Fully OR partially enclosed buildings.
  – Includes equipment and packaging storage areas.

• Building, equipment, tools, and sanitation rules look to protect:
  – COVERED PRODUCE.
  – Food contact surfaces (including packaging).
  – Areas used for covered activities.
  – Water sources.
  – Water distribution system.
L. EQUIPMENT, TOOLS, BUILDINGS, & SANITATION

• BUILDINGS:
  – Must take measures to prevent contamination.
  – Must have suitable size, construction, & design to facilitate maintenance and cleaning.
  – Must have enough space for storage of materials.
  – Must be kept orderly and clean.
  – Must have adequate drainage to keep free from standing water.

• Overhead fixtures must not become a source of contamination.
L. EQUIPMENT, TOOLS, BUILDINGS, & SANITATION

- TOILETS AND HANDWASHING FACILITIES must be:
  - Available, accessible, and numerous enough for workers.
  - Equipped with:
    • Toilet paper.
    • Water for handwashing that has no detectable generic E. coli.
    • Soap.
    • Single-use drying device.
  - Directly accessible for servicing.
  - Serviced, cleaned, and maintained regularly.
  - Handwashing facilities must be close to toilets.
L. EQUIPMENT, TOOLS, BUILDINGS, & SANITATION

• PLUMBING must:
  – Distribute water under pressure as needed, to all areas where used in covered activities, for sanitary operations, or for handwashing and toilet facilities.
  – Properly convey sewage and liquid disposable waste.
  – Avoid being a source of contamination to all food and food contact surfaces.
  – **NOT** allow backflow from or cross connection between piping systems for waste and piping systems for clean water.
L. EQUIPMENT, TOOLS, BUILDINGS, & SANITATION

• SEWAGE & WASTEWATER:
  – All sewage and wastewater must be disposed of properly.
  – Sewage and wastewater systems must be properly functioning.
  – Must be inspected for proper functioning after flood events.
  – Must be managed to prevent any spills or leakage from contaminating produce or food handling areas.

• TRASH & LITTER must be:
  – Removed from production areas.
  – Kept contained.
  – Managed to prevent contamination of food and food handling areas.
L. EQUIPMENT, TOOLS, BUILDINGS, & SANITATION

• EQUIPMENT AND TOOLS must be:
  – Inspected and maintained in good condition.
  – Cleaned and, when necessary and appropriate, sanitized before use.
  – Designed and constructed so they can be cleaned and maintained.
  – Installed and maintained to facilitate cleaning.
  – Stored and maintained so they don’t contaminate covered produce.
  – Stored and maintained so they don’t attract or harbor pests.

• SEAMS on food contact surfaces must be:
  – Smoothly bonded, OR;
  – Maintained to minimize accumulation of organic matter.
L. EQUIPMENT, TOOLS, BUILDINGS, & SANITATION

• MECHANICAL EQUIPMENT used for harvesting, packing, and storage must be maintained and used in a manner that **minimizes risk of contamination**.

• TRANSPORT VEHICLES:
  – Must be clean before use.
  – Must be in good condition.
  – Must **NOT** become a potential source of contamination.
  – Must be adequate for use in transporting covered produce.
  – Must be considered “equipment” when transporting covered produce.

• Instruments that **take measurements** must be accurate.
L. EQUIPMENT, TOOLS, BUILDINGS, & SANITATION

• CLEANING & SANITATION:
  – Food contact surfaces must be cleaned and, when necessary and appropriate, sanitized as frequently as reasonably necessary to prevent contamination.
  – NON-food contact surfaces must be maintained and cleaned as frequently as reasonably necessary to prevent contamination.
  – Toilet facilities must be cleaned and serviced at a frequency sufficient to ensure suitability for use.
  – Harvest containers must be clean before use.
  – Transport vehicles must be clean before use for harvested produce.
  – Cleaning and sanitation must be recorded.

**SANITIZING cannot happen without cleaning happening first.**
L. EQUIPMENT, TOOLS, BUILDINGS, & SANITATION

• PEST CONTROL IN BUILDINGS:
  – Must take reasonable, necessary measures, including routine monitoring to **protect** the following **from contamination by pests**:
    • Covered produce.
    • Food contact surfaces.
    • Food-packing materials.
  – Must take measures to **exclude pests** from **fully enclosed buildings**.
  – Must take measures to **prevent pests from becoming established** in **partially-enclosed buildings**.
L. EQUIPMENT, TOOLS, BUILDINGS, & SANITATION

• DOMESTICATED ANIMALS:
  • Must **exclude domesticated animals** from fully enclosed buildings where there is:
    – Covered produce.
    – Food contact surfaces.
    – Food packaging.
  • Must **separate domesticated animals** from food activity areas by:
    – Location.
    – Time.
    – Partition.
DOMESTICATED & WILD ANIMALS

• **Guide** or **guard dogs** are allowed **IF** they are unlikely to result in contamination.

• Must control **excreta and litter** from **domesticated animals** and maintain system of control.
M. SPROUTS
N. ANALYTICAL METHODS

• SPROUTS:
  – Maine has chosen not to accept jurisdiction for the Sprouts Rule, which means farmers producing sprouts will be directly inspected by the FDA for compliance with this Subpart.

• ANALYTICAL METHODS:
  – Lays out specific analytical requirements for the testing methods required by Subpart E. Agricultural Water, and Subpart M. Sprouts.
0. RECORDS

• RECORDS must be:
  – Created in real time, as the activities occur.
  – Accurate, legible, and indelible.
  – Dated and signed by the person who performed the documented activity.
  – Reviewed, dated, and signed by a supervisor or responsible party, for many records.
  – Kept for at least 2 years past the date they were recorded.
  – Readily accessible and available to inspectors during inspections, or provided to inspectors within 24 hrs of inspection.

**See handout for complete list of documentation requirements.**
O. RECORDS

• RECORDS must 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.
  – Dates and times activities were recorded.

• They can be original records, true copies, or electronic copies.

• Existing records that fulfill the PSR’s requirements are acceptable.
P. VARIANCES
Q. COMPLIANCE & ENFORCEMENT

• VARIANCES:
  – This subpart lays out the processes and options by which government entities (State, Tribal, or foreign country) may request variances from the requirements listed in the Rule.

• COMPLIANCE & ENFORCEMENT:
  – Establishes that failure to comply with the requirements of this regulation is a prohibited act under the Federal Food, Drug, & Cosmetic Act (FD&C Act).
  – Establishes the provisions that the FDA coordinate education and enforcement activities by helping develop education, training, and enforcement approaches.
R. WITHDRAWAL OF QUALIFIED EXEMPTION

• QUALIFIED EXEMPTION can be withdrawn if:
  – There is an active investigation of a foodborne illness outbreak that is directly linked to your farm.
  – Conduct or conditions on your farm make it necessary in order to prevent or mitigate foodborne illness outbreaks via the food produce, handled, or held on your farm.

• If your qualified exemption is withdrawn, you:
  – MUST satisfy the full requirements of the Produce Safety Rule.
  – Will have 120 days to resolve your compliance issues.
  – May have to take certain actions sooner than 120 days to resume normal operations.
  – Can appeal the withdrawal and/or apply to get it reinstated.
R. WITHDRAWAL OF QUALIFIED EXEMPTION

• Before the FDA issues an order to withdraw your qualified exempt status, they:
  – **Will** consider preliminary options such as:
    • warning letters.
    • Recalls.
    • Seizures.
    • Administrative detention (of product).
    • Injunctions.
  – **MUST** notify your person in charge of the circumstances that are prompting that potential withdrawal, and
  – **MUST** provide you with an opportunity to respond in writing within 15 days, and,
  – **MUST** consider the actions you’ve taken to address the original circumstances.
EXEMPTIONS, NON-COVERAGE, & COMPLIANCE DATES

- EXEMPTIONS and NON-COVERAGE available in the language of the PSR are based on risk assessments.

- There are 3 specific types of EXEMPTIONS or NON-COVERAGE:
  1. FARMS NON-COVERED BASED ON PRODUCE SALES.
  2. QUALIFIED EXEMPT FARMS.
  3. COMMERCIAL PROCESSING EXEMPT PRODUCE.

- Each has different eligibility criteria and compliance requirements.

- There are NO exemptions for produce farms with total food sales OVER $500,000.
EXEMPTIONS, NON-COVERAGE, & COMPLIANCE DATES

1. FARMS NON-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 NON-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).
EXEMPTIONS, NON-COVERAGE, & COMPLIANCE DATES

2. 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.
EXEMPTIONS, NON-COVERAGE, & COMPLIANCE DATES

• 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.
EXEMPTIONS, NON-COVERAGE, & COMPLIANCE DATES

3. 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.**
EXEMPTIONS, NON-COVERAGE, & COMPLIANCE DATES

• 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”
EXEMPTIONS, NON-COVERAGE, & COMPLIANCE DATES

• 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.**
## EXEMPTIONS, NON-COVERAGE, & COMPLIANCE DATES

### COMPLIANCE DATES:

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<th>COVERED FARM SIZE:</th>
<th>VERY SMALL Produce Sales = $25,000-$250,000</th>
<th>SMALL FARMS Produce Sales = $250,001 - $500,000</th>
<th>LARGE FARMS Produce Sales = $500,001 and above</th>
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</tbody>
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WAYS WE CAN HELP

• PSA GROWER TRAININGS:
  – Presented by UMaine’s Cooperative Extension.
  – Full day training in Food Safety and the Produce Safety Rule.
  – Required for all fully covered farms.
  – Open to everyone.
  – Costs only $25 (includes good food and detailed training).

• UPCOMING TRAINING DATES:
  – FEB. 8, at MOFGA in UNITY.
  – Planning for 3 more dates this Winter/Spring in:
    • HOULTON – FEB. 22
    • DOVER-FOXCROFT – MAR. 29
    • FARMINGTON – APR. 5
WAYS WE CAN HELP

• ON-FARM READINESS REVIEWS:
  – FREE non-regulatory visits by Department of Agriculture inspectors, and either Linda Titus or Cooperative Extension partners.
  – Helpful advice to assess your readiness for PSR compliance.
  – Specific, technical answers to any questions your may have.
  – Brainstorming solutions with you on-farm with trained staff.

• CONTACT LEAH TO REQUEST AN OFRR:
  – PHONE: 207-764-2100
  – EMAIL: leah.cook@maine.gov
WAYS WE CAN HELP

• ONE-ON-ONE PSR CONSULTING:
  – FREE grant-funded technical advising by Linda Titus of AgMatters, LLC.
  – Can give you customized advice and coaching to help you navigate the PSR and prepare for inspection.
  – Can help you set up logs and records requirements.
  – Can help you get staff training programs in place.

• CONTACT LINDA TITUS TO GET STARTED:
  – PHONE: 207-631-3303
  – EMAIL: lindatitus@hotmail.com
WAYS WE CAN HELP

• PRODUCE SAFETY ALLIANCE:
  – Collaboration between Cornell University, FDA, & USDA to help growers prepare for FSMA compliance.
  – Has produce safety guidance and fact sheets.
  – Has records and food safety plan templates.
  – Offer trainings, including the PSA Grower Trainings.

• TO LOOK UP THEIR RESOURCES:
  – WEBSITE: https://produc saf etyalliance.cornell.edu/
WAYS WE CAN HELP

• **FDA TECHNICAL ASSISTANCE NETWORK (TAN):**
  – Subject matter experts available to answer technical questions.
  – Can give guidance on specific questions not fully explained in the Rule.
  – Comes straight from the FDA, so answers are fact checked and verified for compliance with the Rule before they answer you.

• **TO LOOK UP THEIR RESOURCES:**
  – **WEBSITE:**
    https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm
WAYS WE CAN HELP

• MAINE’S BUREAU OF AGRICULTURE:
  – Responsible for implementation of the Produce Safety Rule in Maine.
  – Trained in the Rule and on-farm requirements.
  – Funded and tasked with helping farmers get ready for this.
  – Funded and tasked with trying to reach every farm in the state of Maine.
  – Knowledgeable and motivated to empower Maine’s farmers be confident, not just compliant.

• GIVE US A CALL OR EMAIL ANY TIME:
  – PHONE: 207-764-2100
  – EMAIL: leah.cook@maine.gov
QUESTIONS?
Call us at: 207-764-2100
Email Leah at: leah.cook@maine.gov