

# FOOD SAFETY MODERNIZATION ACT PREVENTIVE CONTROLS RULE

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# Disclaimers

- Final rules are hundreds of pages long and complex
- Our understanding is evolving (and the only interpretation that really counts is the interpretation of the FDA inspectors)
- Information we'll talk about today came from the text of the rules, and was gathered by the NH FSMA Task Force, and counterparts from other states.



# Food Safety Modernization Act

- Seven sections of the rule
  - Preventive Controls for Human Food
  - Preventive Controls for Food for Animals
  - Produce Safety
  - Foreign Supplier Verification Program
  - Third Party Certification
  - Sanitary Transportation
  - Intentional Adulteration

# 1. Hazard Analysis and Risk-Based Preventive Control for Human Food

- Two major sections:
  - Hazard analysis and written food safety plan
  - Updating Current Good Manufacturing Practices
- A closer look at
  - Farm definition
  - Modified requirements and exemptions
  - The written plan

# Who is Covered?

- In general, applies to facilities required to register with FDA
  - Who is required to register with FDA?
- Facilities that manufacture, process, pack or hold human food
- Applies to domestic and imported food
- There are exemptions and modified requirements for qualified facilities

# Farm Definition – Primary Production Farm

- An operation *under one management* in one general (but *not necessarily contiguous*) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals, or any combination of these activities
- Can pack and hold RACs regardless of whether they were grown on that farm or another farm

# Farm Definition – Primary Production Farm

- Manufacture/process, pack or hold processed foods so long as:
  - All of this food is consumed on that farm or another farm under the same management
  - The manufacturing/processing is limited to
    - Drying/dehydrating RACs to create distinct commodity without any additional manufacturing/processing
    - Treatment to manipulate ripening of RACs
    - Packaging and labeling RACs without further processing

# Farm Definition – Secondary Activities Farm

- An operation not located on a primary production farm – devoted to harvesting, packing, and/or holding RACs
  - A majority of the secondary activities farm must be owned by the primary production farm(s)
- Can do same packing and holding, and limited additional manufacturing/processing as a primary production farm



# Size qualifications

- **Small business** – fewer than 500 full-time employees
- **Very small business** – less than \$1M in average sales per year based on average sales of 3 preceding years
  - Includes sales of human food plus market value of human food manufactured, processed, packed, or held without sale

# Facilities that qualify for Modified Requirements

- Qualified facilities
  - Very small businesses; OR
  - Facility averaging less than \$500,000 for last 3 years
    - Sales to qualified end users exceed sales to others
- On-farm, low-risk activities
  - small and very small businesses

# Examples of On-farm Low-risk Activities

## Manufacturing/processing

- Many activities with fruits and vegetables with pH < 4.2
- Making certain candies
- Pasteurizing honey
- Making sugars and syrups
- Making certain products from milled grains

## Packing and holding

- Candy
- Roasted coffee beans
- Pasteurized honey
- Jams and jellies
- Milled grain products
- Syrups
- Any other processed food that does not require time/temperature control

# Requirements for On-Farm Low-Risk Activities

Requirements for on-farm LOW-RISK activities	Must complete Food Safety Plan and Supply-Chain Program?	Must complete Modified Requirements?	Must follow Current Good Manufacturing Practices (cGMPs)?
Small business	No	Yes	Yes
Very small business	No	No	Yes

# Modified Requirements

- Submit attestation to FDA stating the facility is a qualified facility
- Submit attestation to FDA of either:
  - Addressing hazards through preventive controls and monitoring; OR
  - Comply with applicable local regulations and notify consumers of the name and complete business address of facility where food was processed

# Hazard Analysis and Risk-Based Preventive Controls

- Owner, operator or agent in charge will be required to comply
- Preventive controls are flexible
  - Developed for YOUR products and operation

# Written Food Safety Plan

- Hazard analysis
- Preventive controls – hazards are significantly minimized or prevented. Sections include:
  - Supply-chain program
  - Recall plan
  - Procedures for monitoring
  - Corrective action procedures
  - Verification procedures
- Preventive controls are science- & risk-based

# Written Food Safety Plan

- Reassess the plan at least every 3 years or as appropriate
- Preventive Controls Qualified Individual would be required to prepare plan, validate controls, review records, and reanalyze plan:
  - Successfully complete standardized curriculum
  - Be qualified through job experience



# Revisions to Current Good Manufacturing Practices

- Focused on preventing allergen cross-contact
- Basic sanitation, worker health and hygiene, facility and equipment maintenance
- No longer include suggestions, only “binding” provisions

# Operations Exempt from cGMPS

- “Farms”
- Those solely engaged in holding and/or transportation of one or more RACs
- Activities of farm mixed-type facilities that fall within “farm” definition

# Compliance Dates

Effective date: November 16<sup>th</sup>, 2015

Type of business	Time to comply
Very small business (<\$1M)	3 years
Businesses subject to PMO	3 years
Small businesses (<500 employees)	2 years
Other businesses	1 year

\*PMO – Pasteurized Milk Ordinance

- Compliance dates for supply chain program vary based on size and activity of both supplier and receiving facility

# Resources

- National Sustainable Agriculture Coalition– blog “Who is Subject to FDA’s New FSMA Food Facilities Rule?”

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# FOOD SAFETY MODERNIZATION ACT PRODUCE SAFETY RULE

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# Notes

- Produce rule became effective Jan 26, 2016.
- Farms will have 1-6 yrs to come into full compliance depending on size and activities conducted.

# Produce Safety Exemptions

- Not Covered = Sales of **produce** below \$25K/yr averaged over 3 yrs

## Produce defined as

*“any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts and herbs... produce does not include food grains... that are primarily grown and processed for use as meal, flour, baked goods, cereals and oils...”*



# Produce Safety Exemptions

- Qualified Exemption = Sales of **food** below \$500K/yr averaged over 3 yrs **AND** more than half your sales to qualified end users
  - Keep records to prove exemption
  - Covered produce must be labeled with your business name and address or with a sign featuring this information at point of sale

*BUT... if implicated in an outbreak of foodborne illness, exemption can be revoked and those you sell to may require more of you*

# Produce Safety Exemptions

- Qualified End Users
  - Consumers (who cannot be businesses)
  - Restaurants
  - Retail Food Establishments (primary function is to sell food to consumers, ex grocery stores, and convenience stores)
  - Must be in-state **or** within 275 mi of the farm

# Produce Safety Rule Covers...

- Covered produce, ie RACs normally eaten raw such as tomatoes, cucumbers, apples, mushrooms, etc
- It does **not** apply to
  - produce that is not normally eaten raw such as pumpkins and sweet corn
  - produce that receives commercial processing with a kill step

# Produce Safety Rule Specifics

- Worker health and hygiene
- Agricultural water
- Biological soil amendments
- Domestic and wild animals
- Equipment, tool and buildings

# Worker Health and Hygiene

- Workers must be trained when hired and at least annually thereafter in hygienic practices
- Trainer can be a supervisor or responsible party for your farm, but they have to take an accredited course or have food safety training at least equivalent to it
- Training records must be kept

# Agricultural Water

- Ag water is defined as water used in covered activities on covered produce that is **intended to or is likely to contact covered produce**, this includes
  - Irrigation water
  - Water used to grow sprouts
  - Water used to make crop sprays
  - Water used to wash, cool or prevent dehydration in produce
  - Water used to wash hands and food contact surfaces
- Ag water must be tested. The frequency depends on the source and use.

# Agricultural Water

## Testing Process

- Municipal/Public water → no testing, provide documentation from the water facility proving the water meets the standards
- For other sources you must establish a **microbial water quality profile**
  - Untreated ground water → Take 4 samples during the growing season for the first year and then update it annually with 1 sample taken as close to as practical but prior to harvest
  - Untreated surface water → Take 20 samples over a minimum of 2 years but no more than 4 years, then updated it annually with 5 samples per year.

# Agricultural Water

## Testing Standards (potable)

- Water that contacts covered produce during or after harvest, is used for sprout irrigation, handwashing or cleaning food contact surfaces it must have no E. coli (less than detectable levels) per 100 mL sample (**potable water**)
- If your water doesn't meet the standard you must discontinue using it, until you can resolve the problem or treat the water



# Agricultural Water

## Testing Standards (during growing activities)...

- Water used during growing activities for covered produce other than sprouts → samples must have
  - a geometric mean (GM) no more than 126 CFU generic E. coli per 100 mL sample, **and**
  - a statistical threshold value (STV) no more than 410 CFU generic E. coli per 100 mL sample

**FDA is exploring creating a computer program to help farms do these calculations**

# Agricultural Water

- If the water doesn't meet the standard, you have options
  - Apply a time interval between last irrigation and harvest **no greater than 4 days** that you calculate using a microbial die-off rate of 0.5 log per day
  - OR apply a time interval between harvest and end of storage
  - OR apply a calculated log reduction using microbial removal rates during activities such as commercial washing
- **Appears you have to determine the microbial die off rate for bullets 2 and 3 and document the evidence that is effective.**
- **If you can't use any of the above tactics you must discontinue the use of the water as soon as practiceable but no later than the beginning of the next season.**

# Biological Soil Amendments

- **Treated →**
  - processed to completion to adequately reduce microorganisms of public health significance or
  - in the case of agricultural teas made from treated biological soil amendments of animal origin and potable water
- **Untreated →**
  - Anything that doesn't meet the standard above, or
  - Has become contaminated after treatment, or
  - Has been recombined with untreated amendments after treatment, or
  - Is an agricultural tea containing an agricultural tea additive

# Treated Amendments

- Three standards have been established based on testing for listeria, salmonella, and E. coli 0157:H7
- Commercial products like blood meal will need documentation such as a **certificate of conformance** from the seller to show that the above standards have been met
- On farm treatments that meet the standards are
  - Static composting → aerobic conditions 131° F for three consecutive days followed by adequate curing
  - Turned composting → 131° F for 15 days which don't need to be consecutive with a minimum of 5 turnings followed by adequate curing
  - Records

# Biological Soil Amendments

Type of Amendment	Days to Harvest
Treated	0
Untreated but applied in a way that does not contact covered produce before or after harvest	0
Untreated but applied in a way that may contact covered produce	Reserved

In the meantime the FDA has no objection to farms following the NOP standards.

# Domestic and Wild Animals

- Must assess potential or evidence of contamination
  - seeing animals in the field
  - finding animal excreta
  - crop destruction
- Must take steps to ensure you can find affected areas later
- Must not harvest covered produce reasonably likely to be contaminated

# Equipment, Tools, Buildings and Sanitation

- Covers equipment or tools likely to contact covered produce, such as knives, harvest buckets, thermometers, mechanical harvesters, dump tanks, tractors and vehicles and equipment used for transport.
- The above items must be of proper design so that they can be kept clean, and they must be inspected, maintained, cleaned, and sanitized as needed and stored properly in order to **minimize** the risk of contamination of covered produce and harboring pests.

# Equipment, Tools, Buildings and Sanitation

- Instruments or controls used to measure, regulate or record temperature, pH, or other conditions must be accurate, precise, maintained, and adequate in number for their designated uses.



# Equipment, Tools, Buildings and Sanitation

- “Buildings” includes fully or partially enclosed buildings used for covered activities including storage of food contact surfaces.
- Greenhouses, high tunnels, and storage facilities are classified as buildings
  - Must implement measures to prevent contamination of covered produce and food contact surfaces through floors, walls, ceilings, fixtures, ducts or pipes and drip or condensate.
- Operations where contamination is likely to occur must be separated by location, time, partition, enclosed systems or other effective means

# Compliance Timeline

## From Jan 26, 2016

- Very Small businesses (ave \$25<\$250K/yr)
  - 4 yrs, 6 for some water reqs
- Small businesses (ave \$250K<\$500K/yr)
  - 3 yrs, 5 for some water reqs
- Everyone else – 2 yrs, 4 for some water reqs
- Sprout growers get 1 year less in ea category above
- Qualified Exempt Farms have until Jan 1, 2020 to comply with labeling requirements and **must begin keeping records to show they qualify now.**

# Recommendation

- Look at your records
- Go back 3 yrs if possible
  - Can you show...
    - Total sales figures
    - Food vs non-food sales
    - Produce vs non-produce sales
    - Sales to qualified end users vs all others
- If you CANNOT do this -- make changes starting this season

# Technical Assistance Network

- Address questions related to FSMA rules, program, and implementation
- FDA Technical Assistance Network
- Feel free to contact Extension if you want assistance drafting up a question for TAN



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