UPDATE ON FOOD SAFETY MODERNIZATION ACT: WHAT IT MEANS FOR WISCONSIN'S FARMERS

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WHAT IS FSMA?

- First major overhaul to food safety laws since the 1930's
- **Introduced in the House of Representatives as** H.R.2751 **by** June 8, 2009
- Passed the House in 2009; Passed the Senate in 2010; signed into law by President in 2011
- Aims to ensure a safe US food supply by shifting focus from response to prevention
- Gives authority to FDA (NOT USDA) to regulate the way foods are grown, harvested, and processed, including mandatory recall authority
- Have been writing the regulation since 2011
- Rules released this past November
- In effect: January 26, 2016

COMPLIANCE TIMELINE

- All farms have at least two years to come into compliance, and smaller operations have as many as three or four years

- Timelines are all based on gross annual produce sales, based on a rolling three-year average:

1. No more than $250,000 (“very small business”): four years – January 2020

2. No more than $500,000 (“small business”): three years – January 2019

3. More than $500,000: two years – January 2018

OVERVIEW OF FSMA

- Main pieces of the bill:
  - Title I: Preventing food safety problems
    - Standards for Produce Safety
    - Preventative Controls for Facilities
  - Title II: Detecting and responding to food safety problems
  - Title III: Improving safety of imported food
  - Title IV: Miscellaneous provisions

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SEVEN FINAL RULES

- Preventive Controls for Human Food
- Preventive Controls for Animal Food
- Produce Safety.
- Foreign Supplier Verification Program
- Third Party Certification
- Sanitary Transportation
- Intentional Adulteration

PRODUCE RULE

- Farms that grow, harvest, pack and hold produce for human consumption

- New Standards:
  - Personnel qualifications and training
  - Health and hygiene
  - Agricultural water
  - Biological soil amendments and manure
  - Domesticated and wild animals
  - Growing, harvesting, packing
  - Equipment, tools, buildings
  - Sprouts

WHICH FARMS ARE EXEMPT?

- Exemptions (not covered by rule at all)
  - Produce rarely consumed raw (ie, winter squash, pumpkins)
  - Produce for personal or on-farm consumption
  - Farms with annual gross PRODUCE sales $25,000 or less (averaged over 3 year period)

LIST OF EXEMPT PRODUCE

- Asparagus
- Dry beans (black, Northern, kidney, lima, navy, pinto, lentils)
- Beet roots and tops
- Sugar beets
- Cashews
- Sour cherries
- Chickpeas
- Coffee beans
- Collards
- Sweet corn
- Cranberries
- Dates
- Dill
- Eggplants
- Figs
- Ginger
- Hazelnuts
- Horseradish
- Okra
- Peanuts
- Pecans
- Peppermint
- Potatoes
- Pumpkins
- Winter squash
- Sweet potatoes
- Water chestnuts

EXEMPTION FOR PROCESSED PRODUCE

- Produce that is not a raw agricultural commodity. (A raw agricultural commodity is any food in its raw or natural state)
- The rule provides an exemption for produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, under certain conditions.

PRODUCE RULE § 112.2(B)(3)

- Under the next of the new provisions, (§ 112.2(b)(3)), you must annually obtain certain written assurances from your customer with respect to the produce for which you rely on this exemption. This may be an assurance from the customer that the customer has established and is following procedures that adequately reduce the presence of microorganisms of public health significance (§ 112.2(b)(3)(i)), or it may be an assurance from the customer that an entity after the customer in the distribution chain will perform such processing (§ 112.2(b)(3)(ii))
- Need letter annually
- Frozen and canned vegetables may apply depending on procedures

PRODUCE RULE § 112.2(B)(

- For the commercial processing exemption to be satisfied, the farm that produces the produce must, among other things, disclose in documents accompanying the produce, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance.” In this guidance, we refer to this requireddisclosure as the “produce safety regulation disclosure statement.

SO, ESSENTIALLY

1) the processor gives a farmer documentation that the produce will go through a kill step, putting the produce in the exempt category

and

2) the farmer gives the processor documentation that the produce is not processed adequately to reduce the presence of microorganisms

CATEGORIES OF FULLY COVERED FARMS

- Very Small Businesses
  - Less than $250,000 in average annual sales of PRODUCE
- Small business
  - Less that $500,000 in average annual sales of PRODUCE
- All other farms

COMPLIANCE DATES (FROM JANUARY 16, 2016)

- Very small businesses, those with more than $25,000 but no more than $250,000 in average annual produce sales during the previous three year period : four years
- Small businesses, those with more than $250,000 but no more than $500,000 in average annual produce sales during the previous three year period: three years
- All other farms: two years
- The compliance dates for certain aspects of the water quality standards, and related testing and recordkeeping provisions, allow an additional two years beyond each of these compliance dates for the rest of the final rule

WHAT WILL HAVE THE BIGGEST IMPACT ON FARMERS?

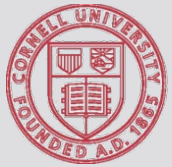
- Many growers are probably already satisfying many of the Produce Rule requirements
- New training requirements – specific classes
- Water testing and the recordkeeping requirements – biggest impacts
- Sales records needed to justify your status
- Record requirements for many of the rule's standards
- Now is a good time to start thinking about—or to start seeking information—on good systems for keeping track of your records in the least burdensome way

TRAINING REQUIREMENTS

- Specific training requirements for farm employees and supervisors
  - At least one “supervisor or responsible party” for your farm take a food safety training course at least equivalent to an FDA-recognized standardized curriculum
- FDA is currently working with the Produce Safety Alliance (PSA) to develop a standardized curriculum
- Not required to take the PSA training course as long as the training you take covers the FSMA requirements

PRODUCE SAFETY ALLIANCE

- Cooperative agreement between Cornell University, FDA, and USDA
- Established in 2010
- Focused on outreach and education
- Assist with meeting regulatory requirements



Cornell University

- Headquartered in Geneva, New York
- Regional Extension Associates in four other locations
  - Don Stoeckel, Columbus Ohio

WATER TESTING REQUIREMENTS

- **Three categories:**

1. Water used in harvest and post-harvest activities
2. Sprout irrigation water (special rules)
3. Water used during growing covered produce (other than sprouts) that is *intended to or likely to contact covered produce*.
   - The standard doesn't apply for irrigation methods where the water isn't intended to or likely to contact produce (i.e., drip irrigation of an above-ground crop such as tomatoes)
   - The standard does apply to sprays that contact produce

MICROBIAL STANDARDS FOR HARVEST AND POST-HARVEST WATER

Numeric criteria

- No detectable generic *E. coli* per 100mL water
- This is similar to the requirement for drinking water
- Untreated surface water cannot be used for harvest and post-harvest purposes

Qualitative standard

- Safe and of adequate sanitary quality for its intended use

MICROBIAL STANDARDS FOR IRRIGATION WATER

The requirements for pre-harvest water are a little more complicated

Numeric criteria

- Geometric mean (typical value) 126 or fewer generic *E. coli* per 100mL water AND
- Statistical threshold value (high-end value) 410 or fewer generic *E. coli* per 100mL water

Qualitative standard

- Safe and of adequate sanitary quality for its intended use

Big take-away

- There are corrective measures that let you manage water and use it, even if it exceeds the numeric criteria

DON'T PANIC!!!

- Calculators are available to do the math for you

123 CFU/100 mL	Geometric mean (GM) value of the date set
290 CFU/100 mL	Statistical threshold value (STV) for the data set

Data collected for generic *E. coli* concentration to develop your rolling 4-year Water Quality Profile (CFU per 100 mL) (Initial and/or Update samples)

Sample	Year 1	Year 2	Year 3	Year 4
1	209	128	42	356
2	621	82	97	152
3	186	241	185	78
4	175	67	122	64
5	52	102	71	98

- An Excel spreadsheet was created by the Western Center for Food Safety at UC Davis and can be accessed at wcfs.ucdavis.edu/
- An Ag Water App and an Online Calculator, created by University of Arizona, can be accessed at agwater.arizona.edu/ and agwater.arizona.edu/onlinecalc/

WATER QUALITY PROFILES: SURFACE WATER

START:
Establish initial water quality profile
At least 20 samples over 2-4 years

ANNUALLY AFTER START:
Collect at least 5 samples for analysis
Add to 3 prior years of profile data to create a rolling 4-year data set

IF YOUR WATER CHANGES:
If the water quality profile no longer represents the quality of the water source, or you change water sources, establish a new profile

IF YOUR PROFILE DOES NOT MEET GM OR STV CRITERIA:
As soon as practicable and no later than the following year, discontinue use of the water unless an allowed corrective measure is applied

ALLOWED CORRECTIVE MEASURES:

1. Apply a time interval to allow die-off or removal
2. Re-inspect the water system, identify problems, and make necessary changes
3. Treat the water

WATER QUALITY PROFILES:
GROUND WATER

START:
Establish initial water quality profile
At least 4 samples over 1 year

ANNUALLY AFTER START:
Collect at least 1 sample for analysis
Add to 3 prior years of profile data to create a rolling 4-year data set

IF YOUR WATER CHANGES:
If the water quality profile no longer represents the quality of the water source, or you change water sources, establish a new profile

IF YOUR PROFILE DOES NOT MEET GM OR STV CRITERIA:
As soon as practicable and no later than the following year, discontinue use of the water unless an allowed corrective measure is applied

ALLOWED CORRECTIVE MEASURES:
1. Apply a time interval to allow die-off or removal
2. Re-inspect the water system, identify problems, and make necessary changes
3. Treat the water

CORRECTIVE MEASURES

- Time interval for die-off
  - Rule allows die-off reduction of 0.5 log per day
  - This is roughly 68 percent reduction in generic *E. coli* on the crop each day after application due to sunlight, moisture, temperature, et cetera
- Re-inspect, identify problems, and fix them
  - For many, re-inspection is the preferred choice
- Treat the water
  - No product currently labeled to treat irrigation water

YES, THIS SEEMS COMPLICATED

- For the water standard requirements related to taking samples and calculating your water profile, you have **two additional years** to comply
- That means: **all farms have at least four years** to come into compliance with these requirements, allowing time for additional information, training, and technical assistance to become available
- The time allows for research that may support alternative standards and testing frequencies based on regional variations or other factors

RECORDS

- The farm must also keep a written record that reflects an annual review and verification of the farm's continued eligibility for the qualified exemption

- *Compliance timeline*: Farms do not have to begin keeping this record until a year from the farm's general compliance date (four years from the effective date of the rule for very small businesses, and three years for small businesses)

- These records that document status and annual verification do not have to be submitted to FDA, but they must be retained and made available upon request

RECORDS

- These records are subject to the same general requirements for all records kept under the Produce Rule
  - detailed
  - accurate
  - legible
  - dated and signed or initialed by the person performing the documented activity

RECORDS

- Can be stored offsite as long as they can be retrieved within 24 hours of request for official review
- Can be written or electronic
- Must be original or true copies
- Can be based on existing records.

- Sales receipts retained to document the $500,000 threshold for qualified exempt farms do not need to be initialed, but they should be retained long enough to document the qualified exempt status for the applicable year, based on the rolling three-year average

COMPLIANCE

- **When will compliance be required? When will the first inspections happen?**
- The first compliance date is January 16, 2018 for the larger farms fully covered by the rule.
- Covered farms that are smaller and aren't eligible for a qualified exemption must comply one or two years later.
- The first inspections probably will not happen until later in 2018.

INSPECTIONS: WHAT TO EXPECT

- Many growers and packers will have to put a greater emphasis on documentation (written planning and recordkeeping) than they have before.
- DATCP will be working with grower groups, UW-Extension, and other entities to provide education, outreach and technical assistance starting in 2017.
- "On-Farm Advisory Reviews" will be held at cooperating farms for interested growers and packers. DATCP personnel will evaluate the farm operations as if they were doing an inspection, providing explanations of what they are looking at, and why. Any deficiencies noted will be explained, but no regulatory action will be taken.

KEY CONTACTS

- Produce Rule:
  - Erin Silva, UW-Extension emsilva@wisc.edu
- Preventative Controls:
  - Kathy Glass, UW Food Research Institute kglass@wisc.edu
  - Barb Ingham, UW Extension bhingham@wisc.edu
- More complicated questions:
  - Regional Training Center: Angela Shaw, Iowa State Extension angelaml@iastate.edu

TAKE-HOME

- Still understanding what FSMA means "on the ground"
- Keep your eyes out for further information, especially with trainings
  - State Departments of Agriculture
  - Extension
  - Non-profit organizations (Family Farmed)
  - PSA

  - UW Extension: Erin Silva, emsilva@wisc.edu
  - Produce Safety Alliance: Don Stoeckel, dstoeckel@cornell.edu

  - National Sustainable Agriculture Coalition (NSAC):

    sustainable agriculture.net