FSMA, Food Safety, and What it really means to the producer
Exports

- Giumarra export division
- Berries, stone fruit, grapes, citrus, kiwifruit, and avocados exported to Singapore, Japan, South Korea, and Brazil, among others
All of this is affected by FSMA
FSMA is different for produce farmers than other food groups

- Farms were unregulated before FSMA
- Fresh produce does not have a “kill step”
- There are many types of produce commodities
- There are many different types of produce operations
- Most produce is grown outdoors
Produce Safety Rule

• FDA understood that cGMP’s were not practical for the fresh produce industry
• FDA created the Produce Rule to address the unique needs of the industry
• FDA worked with industry experts when they created the Produce Rule
• The Final Rule is a result of this interaction
• The Produce Rule is not perfect but FDA got a lot right
A few facts...

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• FDA going from DNA fingerprints to Whole Genome Sequencing
FSMA

Produce Safety Rule

• Mostly risk based
• One-size-fits-all
• Designed with prevention in mind
• Most producers with GAP programs are in good shape
Produce Safety Rule

• This Rule will have the most impact on farmers

• It is very specific about what farms must do

• Unfortunately, just like GAP programs, it is written to cover all fresh produce

• It covers chemical, physical and biological hazards but it is predominantly concerned with microbiological hazards.
Agricultural Water

• The biggest change that most farms will see will have to do with water

• The Produce Rule is very specific about water quality

• Water quality requirements are dependent on how the water us used

• A single indicator organism will be used – generic *E. coli*
Water Testing

• Water testing requirements depend on the type of water source

• Testing is required for all Agricultural Water
No detectable E. coli is allowed in water used for:

• Handwashing
• Water used on food contact surfaces
• Water that contacts food during or after harvest
• Making ice
Irrigation Water (except sprouts)

• 126 CFU generic \textit{E. coli} / 100 ml (Geometric Mean)
  • \textit{Think of this as an average amount}

• 410 CFU generic \textit{E. coli} / 100 ml (Statistical Threshold Value)
  • \textit{STV reflects the amount of variability in water quality.}
  • \textit{Think of this as when adverse effects like rainfall or high river levels wash waste and debris into rivers and canals}

• FDA is developing an online tool for farms to use to input their water test data to calculate these values.
What if my water does not meet these criteria?

• Corrective actions are required no later than the following year.

• For water that does not initially meet microbial standards, there are some options:
  
  • Allowing time for microbial die off (No more than 4 consecutive days)
  • Allowing time for microbial die off between harvest and end of storage (Not for berries)
  • Treating the water
Surface Water

- Surface water is considered the most vulnerable
- Initial testing must have a minimum of 20 samples collected as close to harvest as practicable over the course of 2-4 years to calculate GM and STV
- Annual testing required thereafter with a minimum of 5 samples to calculate GM and STV
- The newest 5 samples plus the previous 15 samples create a rolling dataset of 20 samples to calculate the GM and STV
Untreated Ground Water

- Initial survey is required with a minimum of 4 samples taken as close to harvest as practicable over the course of 1 year to calculate GM and STV.
- After the initial survey, a minimum of 1 sample per year is required to calculate GM and STV.
- The newest sample plus the 3 previous samples create a rolling dataset of 4 samples to recalculate the GM and STV.
Untreated Ground Water Used Where No Detectable *E. coli* is allowed

- 4 tests are required over the period of 1 year
- Farm must determine if water quality is suitable based on test results.
- If first 4 samples meet the zero detectable *E. coli* criterion, only 1 sample is needed annually after that
- Farm must resume testing 4 times per growing season or year if any annual test fails to meet the microbial quality criterion
Public Water Systems

• Agricultural water that is received from public water systems are not required to be tested

• The farm must have the public water system quality reports or certificates of compliance on file

• This is more likely to apply to municipal water used in facilities
Biological Soil Amendments
Raw Manure

• FDA does not prohibit farmers from complying with USDA Organic (NOP) standards for raw manure

• 120 day interval is required between application and harvest of crops in contact with the soil

• 90 day interval is required between application and harvest of crops not in contact with the soil
Raw Manure

Continued...

• Application must be done in a manner that does not contact covered produce and minimizes potential contact after application

• FDA is conducting extensive research in this area
Stabilized Compost

• Microbial limits on detectable levels of bacteria (including Listeria monocytogenes, Salmonella spp., fecal coliforms, and E. coli O157:H7) have been established for composting.

• The rule includes 2 examples of validated composting methods that meet this standard

• Stabilized compost must be applied in a manner that minimizes potential contact with produce during and after application
Domesticated and Wild Animals

• Farms are required to take reasonable measures to identify and not harvest produce that is likely to be contaminated by livestock or wildlife

• At a minimum, this requires farms to visually examine growing areas and produce to be harvested

• The same standard applies for all animals, wild or domesticated
Domesticated and Wild Animals

• If significant evidence of potential contamination by animals is found, farms must conduct an additional assessment during the growing season to assist later during the harvest.

• Farms are not required to exclude animals for outdoor growing areas, destroy animal habitats, or clear borders around growing areas.

• Berry growers will want to keep animals away from crops.
Worker Training and Health

• Requirements include:
  • Preventing contamination of produce and food contact surfaces by ill or infected persons
  • Using unhygienic practices when handling produce or food contact surfaces
  • Preventing visitors from contaminating produce or food contact surfaces
    • Require visitors to comply with food safety policies such as handwashing and by making toilets available
Worker Training and Health

• Requirements continued:

• Farm workers and supervisors who handle produce and/or food contact surfaces must be trained in food safety basics, including health and hygiene.
• Farm workers and supervisors are also required to have a combination of training, education and experience necessary to perform their assigned tasks.
  • This could include on-the-job training or work experience related to current duties.
Equipment, Tools & Storage

• The rule establishes sanitation standards for equipment, tools and buildings to prevent them from becoming sources of contamination

• This includes toilets and handwashing facilities

• Measures are required to prevent contamination of produce and food contact surfaces
  • *E.g. proper storage, maintenance and cleaning of equipment*
Compliance Dates

- Very small businesses $25-250K annually: 4 years
- Small businesses $250-500K annually: 3 years
- All other farms: 2 years
- Certain aspects of water quality, testing and recordkeeping: Additional 2 years
## Staggered Compliance Dates

<table>
<thead>
<tr>
<th>Size of covered farm</th>
<th>Covered activities involving sprouts covered under subpart M (i.e., subject to all requirements of part 112)</th>
<th>Covered activities involving all other covered produce (i.e., subject to part 112, except subpart M)</th>
<th>Farms eligible for a qualified exemption (if applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Compliance date for certain specified agricultural water requirements</td>
<td>Compliance date for all other requirements</td>
<td>Compliance date for retention of records supporting eligibility in § 112.7(b)</td>
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<tr>
<td></td>
<td>Time periods starting from the effective date of rule (60 days after final rule is published)</td>
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<tr>
<td>Very small business</td>
<td>3 years</td>
<td>6 years</td>
<td>4 years</td>
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<td>≤$250,000</td>
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<tr>
<td>Small business</td>
<td>2 years</td>
<td>5 years</td>
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<tr>
<td>All other businesses</td>
<td>1 year</td>
<td>4 years</td>
<td>2 years</td>
</tr>
</tbody>
</table>

* Farms with <25,000 in produce sales are exempt*
Enforcement

• FDA has fewer than 15K employees
• USDA has more than 105K employees
• FDA plans on working with the states for enforcement
• FSMA gives government authority to inspect farms
• FDA plans on outreach programs to help
Listeria

• After the Jensen Farms incident, Listeria control is here to stay

• FDA vs. USDA approach

• FDA sampling assignments

• Differences between Listeria, *Salmonella* spp. & STEC’s

• Health and regulatory risks
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