FSMA and Produce Rule Update

Erik Schellenberg
GAPS coordinator CCE Orange
February 10, Kingston NY
FDA Food Safety Modernization Act & Proposed Produce Safety Rule

- Draft released 1-4-13
- First comment period closed 11-22-13
- Supplemental released 9-29-14
- **Proposed Produce Rule:** Focus on the growing, harvesting, and post-harvest handling of produce
- Focus is on the prevention, not detection of issues

Cornell University
Department of Food Science
Why are they regulating produce anyway?

• Produce accounts for about 15% of all foodborne outbreaks (n=454), but over 37% of individual illnesses (n=23,428) (FDA 2006)

• That is more than any single other food group!

• Market has not self-regulated food safety sufficiently
• Over 15,000 comment received during the first open comment period
• Key provisions reopened for comment on September 29, 2014, including:
  • Water quality standards
  • Raw manure and compost
  • Mixed use facilities
  • Procedures for withdrawing the qualified exemption for certain farms
• Second Comment period ended Dec 15 2014.
Produce Rule: Areas of Focus

• Agricultural water
• Biological soil amendments
• Domesticated and wild animals
• Personnel qualifications, training, and health and hygiene
• Equipment, tools, buildings, and sanitation
• Postharvest handling, record keeping, traceability
Food Safety Preventive Controls Rule

- Will growers fall under two regulations? PC Rule: Focus on the manufacturing, processing, packing or holding of human food
- Initial concern that some growers would fall into this regulation in addition to the produce rule
- New definitions of farm, sales, holding, and packing activities have changed this
**Updated: Definition of a ‘Farm’**

- On-farm packing and holding of produce are not subject to PC Rule unless they meet the definition of processing or manufacturing.
- Farms that pack or hold produce from another farm are not subject to the PC Rule.
- A farm would no longer need to register as a food facility merely because it packs or holds raw agricultural commodities grown on another farm under different ownership.
Updated: Proposed Exemptions

- Produce rarely consumed raw
- Produce destined for ‘kill-step’ processing
- Produce for personal/on-farm consumption
- Produce sales vs. food sales
- Make <$25,000 in all produce sales (3 year average)
Updated: Qualified Exemptions

• Farms may be exempt if they:
  Average gross sales of all food sold in previous 3 years is <$500,000
  AND

• Sell to qualified end users* either:
  – A. Direct to consumer
  – B. Restaurant, retail food establishment in same state or within 275 miles of where produce was grown
Updated: Proposed Exemptions

• Why not change the qualified exemption to produce sales too? Statutory language of Section 419 (f) of the FD&C Act includes ‘all food’ be used to calculate sales for qualified exemptions.

• Produce sales will be applied to the definition of business sizes only
  – Exempt - <$25,000
  – Very small businesses $25,000 - $250,000
  – Small businesses - $250,000 - $500,000
Produce Farms Covered

• About 80% of all farms (154,000) will be exempt from produce rule
• About 35,000 will have to comply
Remember:

- Growers may be exempt from the Produce Rule, but not from the marketplace.
- Food safety is here to stay.
**Updated: Agricultural Water Standards & Testing Requirements**

- Originally proposed for surface water:
  - <235 CFU/100ml generic *E. coli* single sample or a rolling geometric mean <126 CFU
  - Test once every 7 days during growing season

- Supplemental for surface water:
  - <126 CFU/MPN generic *E. coli* per 100 ml, geometric mean (n=5) AND a statistical threshold value of <410 CFU/MPN generic *E. coli* per 100 ml
  - Testing dependent on water quality profile
## How Often Should You Test Surface Water?

<table>
<thead>
<tr>
<th>Source: Surface Water</th>
<th>Testing Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>20 samples over 2 years</td>
</tr>
<tr>
<td>Annually</td>
<td>Minimum 5 samples per year</td>
</tr>
<tr>
<td>If annual test does not support water quality profile</td>
<td>Current annual survey, combined with new data for a total of 20 samples</td>
</tr>
</tbody>
</table>
Establishing a Water Quality Profile

START:
Establish water quality profile
Take 20 samples over two years

ANNUALLY:
Take 5 samples
Compare to established water quality profile

SAMPLING DOES MATCH PROFILE:
Continue to test 5 samples annually

SAMPLING DOES NOT MATCH PROFILE:
Use the 5 annual samples, plus an additional 15 new samples (20 total) to establish a new profile

- APPLY ALTERNATE METHODS:
  - Time interval to achieve 0.5 log microbial die-off per day between water application and harvest
  - Time interval between harvest and end of storage to achieve microbial die-off
  - Other activities that may achieve microbial die-off, i.e. washing
  - Discontinue use

TEN YEAR RE-EVALUATION:
Take 20 samples to establish a new water quality profile
## How Often Should You Test Ground & Public Water Sources?

<table>
<thead>
<tr>
<th>Source</th>
<th>Testing Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ground</td>
<td>4 times during the growing season or over the period of a year</td>
</tr>
<tr>
<td>Public Water Source</td>
<td>Copy of test results or certificates of compliance</td>
</tr>
</tbody>
</table>
Post-Harvest Water Quality Criteria

• No change from original proposed rule

• Directly contacts produce after harvest: No detectable generic \textit{E. coli}, i.e. - Potable water
Updated: Soil Amendments

• FDA has proposed deferring action on the use of raw soil amendments and has proposed to remove the 9 month application interval

• FDA will be working with USDA ARS to facilitate research, risk assessment, and incentivizing composting practices
FSMA Time Frame...in Theory!

- Draft Rule Released: Jan 2013
- Final rule published in Federal Register: Nov 2013
- Public Comment End: November 22, 2013
- We are here: Fall 2014
- Large growers ($>500K) comply: Oct 2015
- Small growers ($250-500K) comply: 2017
- Very small growers ($25-250K) comply: 4 years
- Small growers ($250-500K) comply: 2018
- Supplemental Comments Due Dec. 15th
- Small growers ($250-500K) comply: 2019
- Small growers ($250-500K) comply: 2020+

*Supplemental Comments Due Dec. 15th*
What should you do to prepare?

• Food safety plan
  – Agricultural water, soil amendments, animals, worker hygiene, packing, storage, and transport systems, recordkeeping, traceability
  – We have templates and information to use
Third Party Audits

• USDA (GAPS)
  – GHP/GAP, Harmonized

• Other private auditors (SQF, Primus)

• Benefits
  – Market access
  – Management tool (workers, records)
  – Lower risk of outbreaks and associated liability
GAPS trainings

• We are offering a number of GAPS two day trainings
  – Give you all the food safety knowledge you need
  – Help prepare food safety plan
  – Get ready for third party audit if you choose
  – Meet and talk with USDA auditors
GAPS training dates

• Kingston 2/26-2/27
• Dutchess County 3/9-3/10
• Canton 3/10-3/11
• Plattsburgh 3/24-3/25
• More TBA
  – Look out for newsletters
GAPS consulting

• On-farm risk assessments for field and packinghouse
• Food safety plan drafting
• Can arrange mock audits

– Contact me:
  • jk2642@cornell.edu
  • 845-344-1234
Questions?

• Special thanks to:
  – Local Economies Project of New World Foundation for funding the wholesale readiness project
  – Produce Safety Alliance
  – Cornell University Dept. of Food Science (Betsy Bihn and Gretchen Wall)