



FSMA and Produce Rule Update

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FDA Food Safety Modernization Act & Proposed Produce Safety Rule

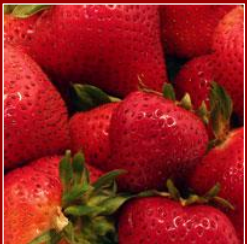
- Draft released 1-4-13
- First comment period closed 11-22-13
- Supplemental released 9-29-14
- **Proposed Produce Rule:** Focus on the growing, harvesting, and post-harvest handling of produce
- Focus is on the prevention, not detection of issues

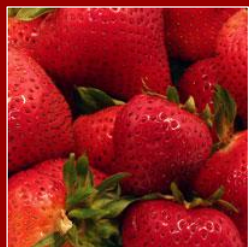


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Why are they regulating produce anyway?

- 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



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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



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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)



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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



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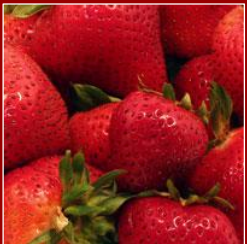
Remember:

- Growers may be exempt from the Produce Rule, but not from the market place
- Food safety is here to stay

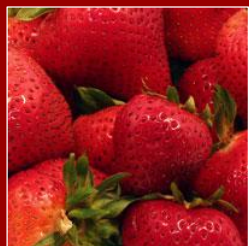


Updated: Agricultural Water Standards & Testing Requirements

- 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



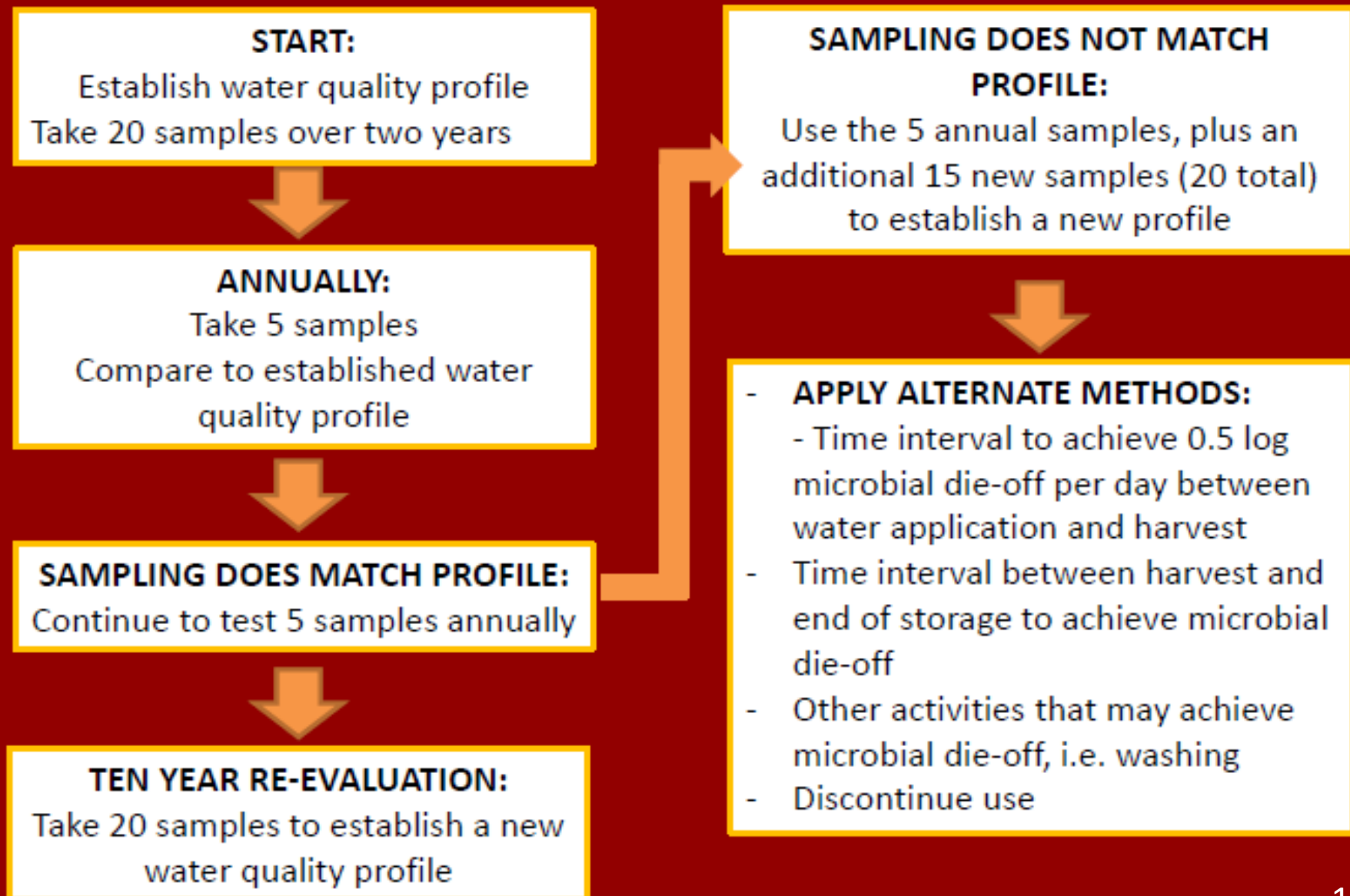
How Often Should You Test Surface Water?



Source: Surface Water	Testing Frequency
Baseline	20 samples over 2 years
Annually	Minimum 5 samples per year
If annual test does not support water quality profile	Current annual survey, combined with new data for a total of 20 samples



Establishing a Water Quality Profile



How Often Should You Test Ground & Public Water Sources?



Source	Testing Frequency
Ground	4 times during the growing season or over the period of a year
Public Water Source	Copy of test results or certificates of compliance





Post-Harvest Water Quality Criteria



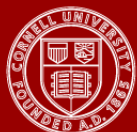
- No change from original proposed rule
- Directly contacts produce after harvest: No detectable generic *E.coli*, *i.e.* - Potable water



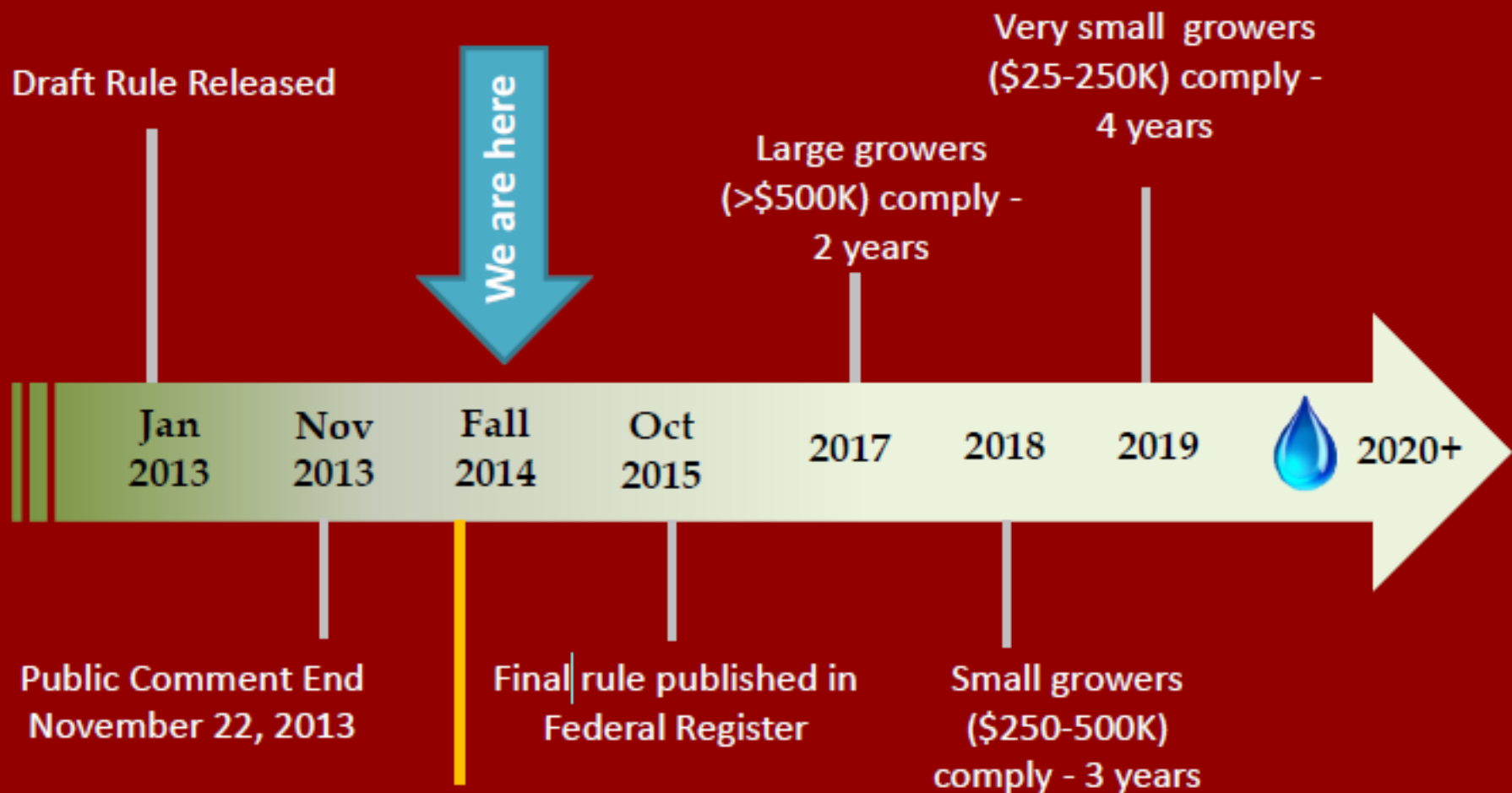
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Updated: Soil Amendments

- 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!



***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

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- 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
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GAPS training dates

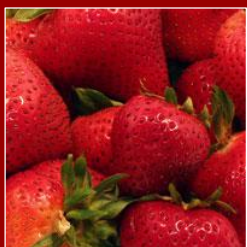
- Kingston 2/26-2/27
- Dutchess County 3/9-3/10
- Canton 3/10-3/11
- Plattsburgh 3/24-3/25
- More TBA
 - Look out for newsletters



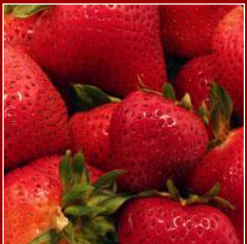
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GAPS consulting

- On-farm risk assessments for field and packinghouse
- Food safety plan drafting
- Can arrange mock audits
 - Contact me:
 - jk2642@cornell.edu
 - 845-344-1234



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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)

