Fresh Produce: Impact of FSMA

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Key Goals for Today

- Identify <u>some</u> questions and challenges FSMA will bring for produce growers
- Outline what the Produce Safety Alliance (PSA) is doing to support growers
- Answer questions

How is it likely to impact growers?

It Depends!

Which is why it is good to be talking about it now!

And why I am hoping we get some discussion at the end!

FDA Food Safety Modernization Act & Proposed Produce Safety Rule

- Draft released 1-4-13
- Supplemental released 9-29-14
- **Final Rule expected October 2015**

- **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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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

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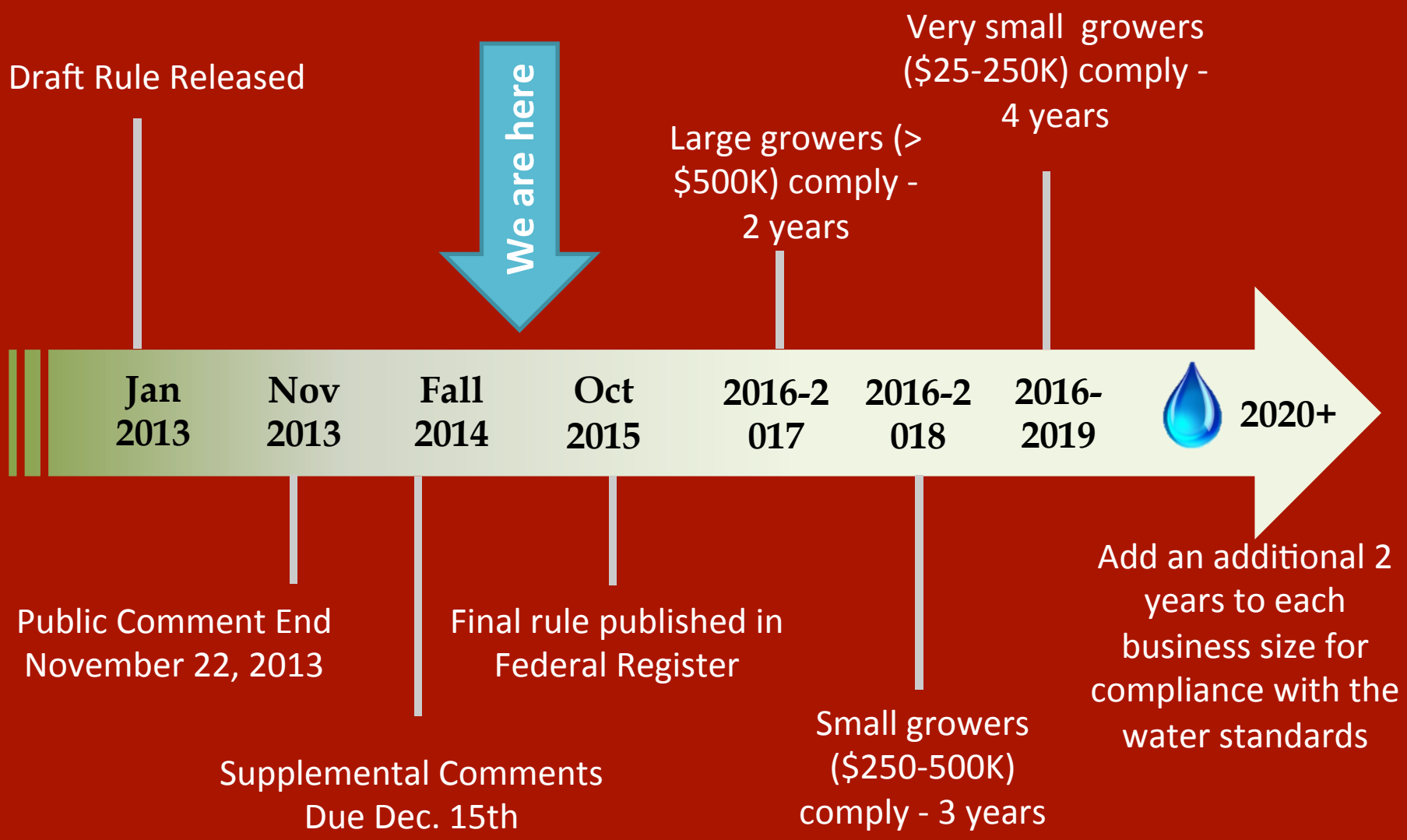
FSMA Time Frame…in Theory!



Produce Safety Rule or Preventive Controls Rule

- PSR Supplement clarified many issues
  - Allowance for handling others produce
  - Same actions do not increase risks
- Likely still some concerns
  - Defining distance that is still same farm "one general physical location"
  - Food hubs
  - Others

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Updated: Proposed Exemptions

1. Produce rarely consumed raw

2. Produce destined for 'kill-step' processing

3. Produce for personal/on-farm consumption

4. Make <$25,000 in all **<u>produce</u>** sales (3 year average)

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Updated: Qualified Exemptions

- **Farms may be exempt if they:**
  - Average gross sales of 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

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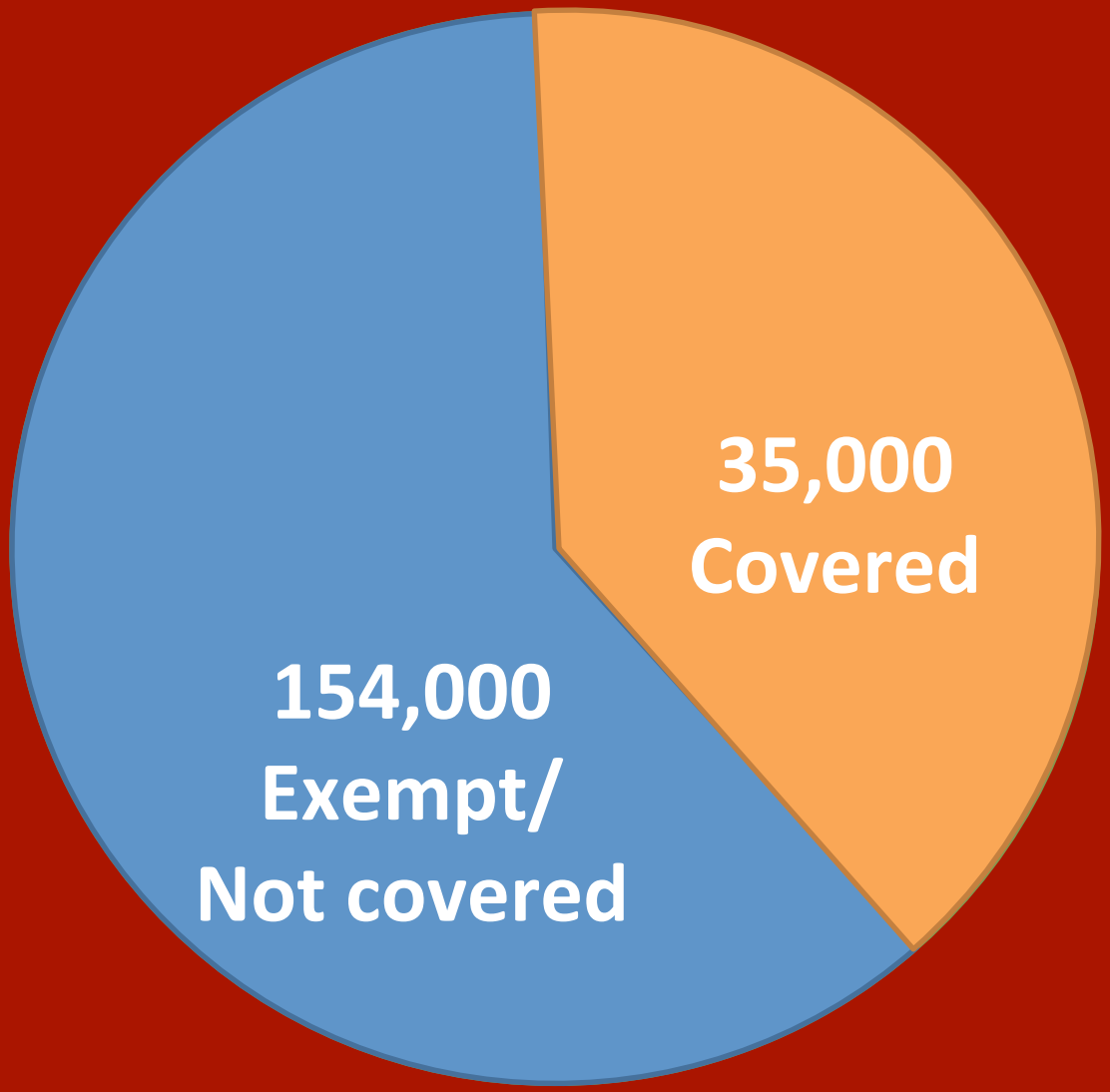
Proposed Exemptions

- Total Produce Sales applies to $25,000 exemption
- Total Food Sales applies to "Qualified Exemptions"
- Is likely to be confusion because of Food including animal food
- Confusion about qualified exemptions vs. full exemptions
- Others

Produce Farms Exempt or Not Covered by the Produce Rule



Growers may be exempt from the regulation, but not from the market place.

Food Safety Begins on the Farm

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EVERY produce grower should have some produce safety knowledge AND access to education and training

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

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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

TEN YEAR RE-EVALUATION:
Take 20 samples to establish a new water quality profile

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

Production Water Challenges

- Calculation Issues
  - Rolling geometric mean
  - Statistical threshold value
  - 0.5 log reduction
    - Think it is half of a 1.0 log reduction!
    - Reasonable to depend on labs or apps?

Production Water Challenges

- 20 samples over two years for the baseline is perceived as being too much
  - Some farms only use water for a month
  - Some farms might be stuck in a unending loop depending on water quality
- Availability of labs
- Costs ($30-50 per test)
- Others

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

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Soil Amendments: Raw Manure Use

- PSR Supplement is perceived as saying zero days to harvest is ok for raw manure
  - I do not believe this is the intent
- NOP limits used by many
- How does FDA intend to make a decision about application to harvest interval?

PSA will be hosting webinars and a Soil Summit on December 1-2, 2015 in Geneva, NY

Post-Harvest Water Quality Criteria

- Produce Safety Rule says zero *E. coli* for postharvest water
- If using water for drinking water it needs to be zero total coliforms
  - EPA drinking water standards
- Confusion in balancing/delivering message
- Others

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Cleaning and Sanitation

- Many questions about wood
  - Can we use it?
  - Are they going to outlaw it?
- All the many things that cannot be taken apart for cleaning and sanitizing
- Little knowledge of detergents or sanitizers
  - Not sure where to begin
  - Not sure how they differ
- Guidance documents
- Others

Other Concerns

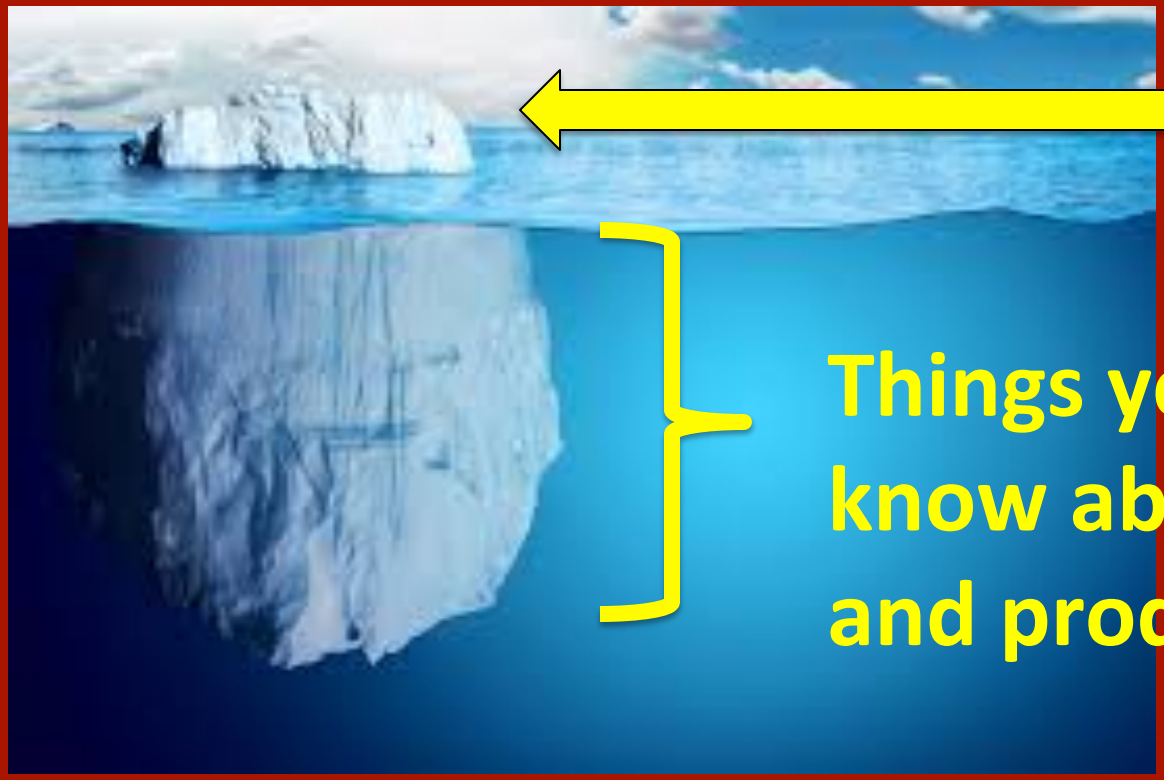
- Domesticated and wild animals
  - There is no perfect exclusion AND growers are already doing what they can to avoid crop loss
- Personnel qualifications, training, and health and hygiene
  - Development of multi-lingual SOPs
- Recordkeeping
  - Many recordkeeping requirements

Expectation that growers know how to assess risks and implement food safety practices!

…And to quote Joe Reardon

"Someone needs to have the checkbook to pay for this"

- Funding for implementation is definitely a concern and an issue
  - Equipment that is sanitarily designed
  - Water tests
  - Training support
  - Infrastructure, recordkeeping, etc.



We are here!

Things you should know about FSMA and produce safety!

Produce Safety Alliance

- Cooperative agreement between Cornell University, FDA, and USDA
- Established in 2010
- Focused on outreach and education to assist growers with meeting regulatory and market food safety requirements

Food Safety Begins on the Farm

USDA

Cornell University

FDA

Target Audience

- Fresh produce growers, packers, and grower cooperatives with special emphasis on small and very small scale farms and packinghouses
  - Not to the exclusion of any farmer!
- Regulatory personnel
- All others interested in produce food safety, GAPs, and co-management

Primary Goals

- Education and outreach to improve understanding and implementation of Good Agricultural Practices (GAPs), co-management strategies, regulatory requirements associated with Produce Rule
- Collecting information related to produce safety, GAPs, co-management and FDA's produce safety regulation
  - GAPs Education and Training Materials Conference in June 2011
  - www.producesafetyalliance.cornell.edu

More Primary Goals

- Develop a standardized educational curriculum to increase understanding of produce safety
  - As proposed, training will be required
  - 112.22 (c) *At least one supervisor from the farm must complete food safety training at least equivalent to the standardized curriculum recognized by the FDA*
- Build national networks
- Train trainers to build cadre of qualified instructors
- Conduct grower trainings
- Collaborate for international training

Curriculum Development Process

- 10 WCs, 72 calls
- 178 Unique WC Members
- 549 Total WC Members

- 8 Nationwide grower focus groups

Identify GAPs Challenges

Complete: May 2012

Set Goals

Complete: June 2012

Develop Learning Objectives

Complete: Dec 2012

Create Content

- TTT Pilot Dec 17-18, 2014
- Grower Pilot Jan 26, 2015

Produce Safety Alliance Curriculum

~ Seven hours of dedicated instruction that can be delivered in one day:

- **Worker Health, Hygiene, and Training**
- **Water**
- **Soil Amendments**
- **Wildlife and Domestic Animals**
- **Facilities, Equipment, and Tools**
- **How to Develop a Farm Food Safety Plan**

Completion of course results in certificate from Association of Food and Drug Officials (AFDO) to meet regulatory requirement for training

Common Training Questions

- Will growers be grandfathered in if they are already GAPs trained/certified?
  - No, not to my knowledge
  - FSMA PSR is new as is the PSA curriculum
  - Note: It WILL be basic for these growers!
- Are other curriculums acceptable for this training requirement?
  - FSMA PSR outlines options for equivalency
  - FDA has not yet said how to do this
  - PSA is open access and has been a national development effort

Challenges to Developing a Cadre of Qualified Trainers

- Diverse expertise required
  - Many competency areas
- Ability and desire to be involved
  - Extension people already busy or GONE
  - Private trainers need to make it pay
- Funding
  - Growers have limited funds to pay for all associated expenses
- Trainers required to be trained
  - Expense and effort involved
  - Certification through Association of Food and Drug Officials (AFDO)

Collaboration Key to Success!

- PSA success due to collaboration
  - Educational Materials Conference
  - Working Committees and Focus Groups
  - Pilots
- PSA Educators Group

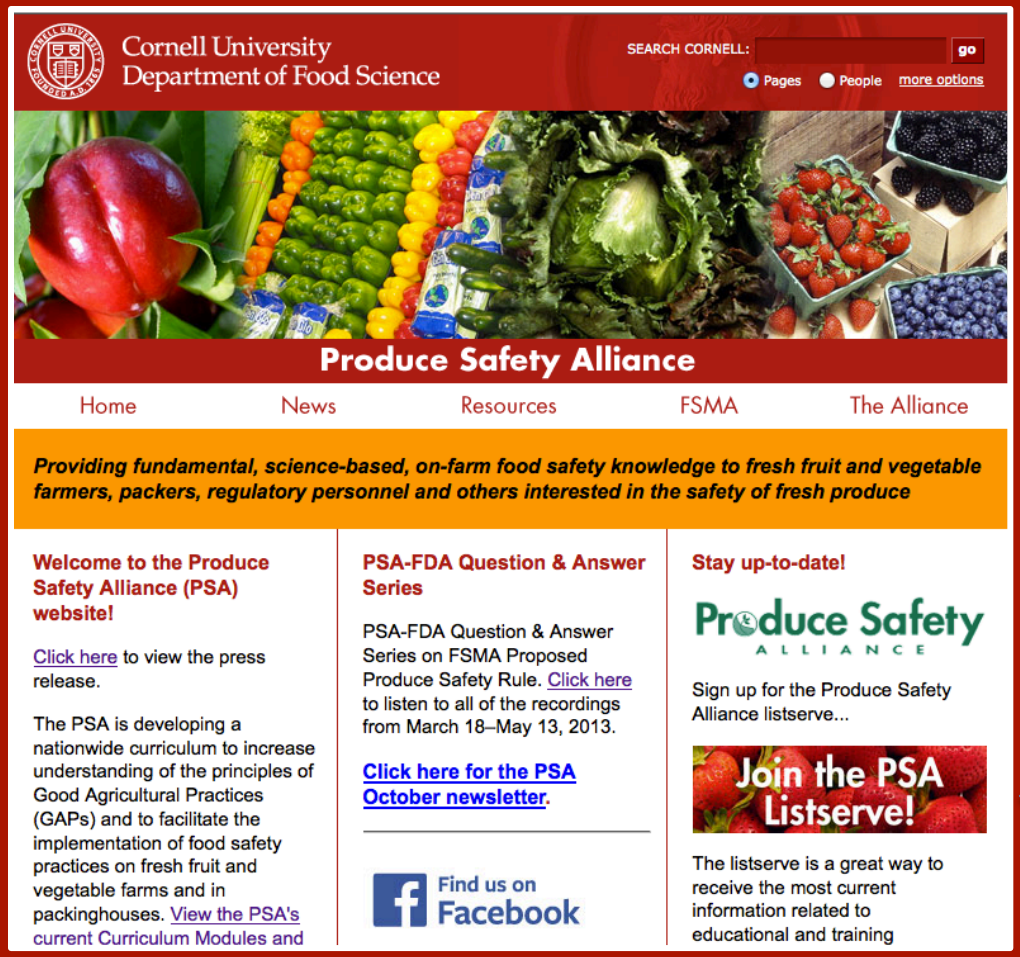
NC colleagues have been generous and key contributors!

PSA Right Now!

- Planning to launch in June 2015
  - Initially focus on train the trainers to build network of qualified trainers nationally
- Expanding the PSA
  - Hiring regional extension associates to expand training options
- Make grower trainings widely available and accessible
  - Prepare growers to meet market demand and regulatory requirements
- Continue to expand collaborative networks

The PSA Website

http://producesafetyalliance.cornell.edu/



Produce Safety ALLIANCE

- You can even friend us on Facebook!
- **Join the listserve!**
- **Contact us!**

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