Welcome

• This session is being recorded
• Recording will be available from the PSA website after the presentation
• All participants will be muted through the presentation
Questions

• **Online participants:**
  - Enter your questions into the chat box, lower right hand corner of your screen
  - Questions will be addressed as time permits

• **Audio only participants:**
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  – Leave your name, phone number, and question
Overview of the FDA Food Safety Modernization Act
Proposed Produce Safety & Preventive Controls Rules

January 24, 2013

Produce Safety Alliance

Cornell University
Department of Food Science
FDA Proposed Rule on Produce Safety
Five Proposed Rules Establish Food Safety Framework

- Produce Safety Standards - Published Jan. 16, 2013
- Preventive Controls for Human Food - Published Jan. 16, 2013
- Foreign Supplier Verification Program
- Preventive Controls for Animal Food
- Accredited Third Party Certification
Key Aspects of Proposals

- Confirm industry’s primary role on food safety
- Risk-based and flexible
  - Burden commensurate with risk
- Address small business issues
  - Additional time for small farms, businesses, to comply
- Extensive government, stakeholder Input
Key Principles

• Considers risk posed by practices, commodities

• Science- and Risk-based
  – Focus on identified routes of microbial contamination
  – Excludes certain produce rarely consumed raw
  – Excludes produce to be commercially processed (documentation required)

• Flexible
  – Additional time for small farms to comply
  – Variances
  – Alternatives for some provisions
Regulatory Framework

• Framework considers many factors associated with produce farming community
  – Examples include diversity of operations and broad range of crops and practices
• Proposing integrated approach that draws on past experiences
  – Examples include CGMPs, HACCP, shell egg regulation
Who Would be Covered?

- Farms that grow, harvest, pack or hold most produce in raw or natural state (raw agricultural commodities)
- Farms and “farm” portions of mixed-type facilities
- Domestic and imported produce
- Farms with annual sales > $25,000 per year
- Limitations on coverage are proposed
Covered Produce

- “Produce” defined as fruits and vegetables
- Produce includes mushrooms, sprouts, herbs and tree nuts
- Produce does not include grains
- Some limitations on covered produce
Limitations on Coverage

• Produce for personal or on-farm consumption
• Produce not a Raw Agricultural Commodity
• Certain produce rarely consumed raw
• Produce that will receive commercial processing
• Farms with sales of \( \leq $25,000 \) per year
• Qualified exemption and modified requirements
Standards for Produce Safety

Focus on 5 identified routes of microbial contamination

1. Agricultural water
2. Biological soil amendments of animal origin
3. Worker health and hygiene
4. Equipment, tools, buildings and sanitation
5. Domesticated and wild animals

Other requirements

- Sprouts
- Growing, harvesting, packing and holding activities
Agricultural Water

- Agricultural water must be safe and of adequate sanitary quality for intended use
- Inspection of water system components
- Treat water used if not safe and of adequate sanitary quality for intended use
- Specific criteria for quality of water for certain purposes and analytical testing
- Alternatives permitted that provide same level of public health protection
Agricultural Water-more detail

- Specific requirements for the quality of water used for specified purposes and follow-up action when water does not meet the quality standards.
  - 0 detectable generic *E. coli* standard (highest risk uses)
  - 235 CFU generic *E. coli* standard (direct contact with covered produce other than sprouts during growing)
Biological Soil Amendments of Animal Origin

- Biological soil amendments of animal origin may contaminate produce with pathogens

Requirements include:
- Definitions for determining their status as treated or untreated
- Standards for handling, conveying and storing
- Treatment methods, application methods, and application intervals

- Alternatives permitted that provide same level of public health protection
Biological Soil Amendments of Animal Origin-more detail

- Microbial standards for treatment processes
  - More stringent and less stringent standards
- Application requirements
  - Relate to whether there is contact with produce during and after application
- Minimum application intervals
  - Time from application to harvest
Worker Health and Hygiene

• Pathogens may transmitted from person to food

• Requirements include:
  – Preventing contamination by ill persons
  – Toilet facilities
  – Avoiding contact with non-working animals and minimizing contact with produce when using working animals
  – Hand washing
  – Maintaining gloves appropriately (if used)
Equipment, Tools and Buildings

- Requirements include:
  - Equipment and tools must be designed and constructed to allow adequate cleaning and maintenance
  - Food contact surfaces of equipment and tools must be inspected, maintained, and cleaned and sanitized as necessary
  - Buildings must be designed and constructed to allow adequate cleaning and reduce potential for contamination
  - Buildings must have adequate, reasonably accessible toilet and hand washing facilities
Domesticated/Wild Animals

• Requirements apply if there is a reasonable probability that animals will contaminate covered produce

• Requirements include:
  – Wait an adequate amount of time between grazing and harvesting
  – If working animals are used in a planted growing area, take measures to prevent pathogens from being introduced onto the produce
  – Monitor for animal intrusion and if observed, evaluate for harvest (no harvesting of visibly contaminated covered produce)
Requirements for Sprouts

• Warm, moist, and nutrient-rich conditions are ideal conditions for pathogen growth

• Requirements include:
  - Facility requirements
  - Treating seed before sprouting
  - Testing spent sprout irrigation water (or sprouts, in some cases) for certain pathogens
  - Monitoring the growing, harvesting, packing, and holding environment for *Listeria* species or *Listeria monocytogenes*
Growing, harvesting, packing and holding activities

• Proposal includes science-based, minimum standards related to growing, harvesting, packing and holding

• Requirements include:
  – Separating covered and excluded produce and cleaning and sanitizing as necessary
  – Not distributing covered produce that drops to the ground before harvest unless it receives commercial processing
  – Food-packing material must be appropriate for use
Alternatives Permitted

• Farms may establish alternatives to certain requirements related to water and biological soil amendments of animal origin

• Alternatives must be scientifically established to provide the same amount of protection as the requirement in the proposed rule without increasing the risk of adulteration
Variances Provide Flexibility

- A state or foreign country may petition FDA for a variance from some or all provisions if deemed necessary in light of local growing conditions.

- Practices under the variance would need to provide the same level of public health protection as the proposed rule without increasing the risk of adulteration.
Recordkeeping Required But Not Burdensome

• The proposed rule would require certain records, for example, to document that certain standards are being met
  – Example: agricultural water testing results
• Records already kept for other purposes need not be duplicated
Qualitative Assessment of Risk Reflects Science Behind Rule

- Draft qualitative assessment of risk helps to inform proposed rule
- Provides a scientific evaluation of potential adverse health effects resulting from human exposure to hazards in produce
- Available for public comment as part of the proposed rule
Compliance Dates Staggered

• **Effective Date:** 60 days after final rule is published

  Compliance Dates

• **Very small farms**
  - Average annual value of food sold >$25,000 and \leq $250,000
  - Four years after the effective date to comply
  - For some water requirements, six years
Compliance Dates

• **Small farms**
  - Average annual value of food sold > $250,000 and ≤ $500,000
  - Would have three years after the effective date to comply
  - Would have five years for some water requirements

• **Other covered farms**
  - Other covered businesses would have to comply two years after the effective date
  - Would have four years for some water requirements
Preventive Controls for Human Food
Summary of Requirements

• Hazard Analysis and Risk-Based Preventive Controls
  – Each facility would be required to implement a written food safety plan that focuses on preventing hazards in foods

• Updated Good Manufacturing Practices
More Information Available

- Web site: http://www.fda.gov/fsma
- Subscription feature available
- Send questions to FSMA@fda.hhs.gov
Outreach Will Continue

- Public meetings
- Presentations
- Listening sessions

Partnerships will be essential
Technical Assistance

• Alliances
  – Produce Safety
  – Preventive Controls
  – Sprouts Safety
• Guidance documents
• National technical assistance network

Partnerships will be essential
Education and Outreach for the Produce Industry
Primary Goals

• Education and outreach to improve understanding and implementation of Good Agricultural Practices (GAPs) and co-management strategies

• Developing a standardized training and education program to assist with the implementation of FDA's requisite produce safety regulation
Produce Safety Alliance
Curriculum Goals

Our aim is to build seven hours of dedicated instruction including six preventive controls modules:

1. Worker Health, Hygiene, and Training
2. Soil Amendments
3. Wildlife and Domestic Animals
4. Water (Production and Postharvest)
5. Facilities, Equipment, and Tools
6. How to Develop a Farm Food Safety Plan
Looking Ahead...

- Train-the-trainer workshops will build a network of qualified trainers across the country
  - Spring/Fall of 2013
- Growers workshops
  - Winter/Spring of 2013-1014
The PSA Website
http://producesafetyalliance.cornell.edu/

• Join the PSA listserv
• Follow progress, updates, and outcomes of PSA activities
• Find fact sheets on how to stay engaged with proposed regulation
• Contact us!
Questions?

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