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Instructions

• All participants are muted.
• There will be time for questions and answers throughout the meeting. Only those connected online will be able to participate.
  – To ask a question or make a comment, please ‘raise your hand’ using the small button on the right hand panel
  – We may not get around to all comments/questions, BUT you may leave additional comments in the comment box to be compiled after the session
• This session will be recorded and notes will be shared via the listserv after the call.
Agenda

• Welcome!

• FSMA Preventive Controls Rule:
  Discussion of the farm definition
  – Jenny Scott, FDA Senior Advisor, Office of Food Safety, Center for Food Safety and Applied Nutrition

• Produce Safety Alliance Updates
  – Training updates
  – Introduction of new PSA team members
  – FDA FSMA Training Strategy
Preventive Controls Rules: Farm Definition

 Produce Safety Educator’s Call, October 13

 http://www.fda.gov/fsma

FDA FOOD SAFETY MODERNIZATION ACT
THE FUTURE IS NOW
Farms

• A farm is exempt from FDA’s food facility registration requirement.
• Facilities that do not have to register with FDA are not subject to the preventive controls requirements.
  - Depending on certain factors, farms may be subject to PCHF or the forthcoming Produce Safety rule.
• PCHF revises the farm definition to reflect modern farming practices.
Evolution of the Farm Definition

- Original definition came from the Bioterrorism Act which was concerned about traceability.
- Based on the need to have records for farms packing and holding raw agricultural commodities (RACs) from another farm.
- As a result, different requirements would have applied when a farm packs/holds its own RACs (e.g., produce rule) than when it packs/holds others’ RACs or packs off-farm (preventive controls rule).
Evolution of the Farm Definition

- In September 2014, in response to stakeholder input, FDA proposed a revised farm definition for public comment.
  - A farm would no longer be required to register as a food facility if it packs or holds RACs grown on another farm under different ownership.
  - In general, on-farm packing or holding of produce would fall under produce safety rule.
Evolution of the Farm Definition

- The final Preventive Controls for Human Food rule clarifies the definition and expands it further to cover two kinds of farming operations:
  - Primary production farm
  - Secondary activities farm
Primary Production Farm

- An operation under one management in one general, but not necessarily contiguous, location
- Devoted to the growing of crops, the harvesting of crops, the raising of animals, or any combination of these activities
  - The definition has been expanded to include operations that just grow crops and operations that just harvest crops.
Primary Production Farm

- In addition to these activities, a primary production farm can:
  - Pack or hold RACs (regardless of who grew or raised them)
  - Manufacture/process, pack, or hold processed foods so long as:
    - all such food is consumed on that farm or another under the same management; or
    - the manufacturing/processing falls into limited categories
Manufacturing/Processing within the Farm Definition

- Drying/dehydrating RACs to create a distinct commodity (e.g., drying grapes to produce raisins)
- Treatment to manipulate the ripening of RACs (e.g., treating produce with ethylene gas)
- Packaging and labeling RACs
Secondary Activities Farm

- An operation not located on a primary production farm that is also devoted to farming activities, like harvesting, packing and/or holding RACs.
- The primary production farm(s) that grow, harvest, and/or raise the majority of those RACs must own or jointly own a majority interest in the secondary activities farm.
Secondary Activities Farm

- The definition also allows certain, limited additional manufacturing/processing, packing, and holding
  - Same as those for a primary production farm
Activities That Do Not Fall Under Farm Definition

- Activities that do not fall within the farm definition include manufacturing/processing that goes beyond what falls within the farm definition. As examples:
  - Pitting dried plums, chopping herbs
  - Making snack chips or flours from legumes
  - Roasting peanuts, tree nuts, or seeds (e.g., pumpkin, sunflower, or flax seeds)
Activities that Do Not Fall Under Farm Definition

- FDA expects to issue guidance on activities that fall within the farm definition and activities that do not in the near future.
Produce Packing Houses

- Produce packing houses that fall under the new farm definition ➔ produce safety rule
- Produce packing houses that do not fall under the new farm definition ➔ PCHF
- Specific steps necessary to ensure the safety of produce would generally be the same
Off-farm Produce Packing House

- CGMP requirements have analogues in produce safety rule (new PCHF provision allows packing house to choose)
- We expect off-farm packing houses subject to PCHF to look to the produce safety rule in developing food safety plans and establish preventive control management components
Off-farm Produce Packing House

- Food safety plan would focus on a few key preventive controls, generally with counterparts in the produce safety rule
  - Maintaining and monitoring water temperature
  - Sanitation controls
- PC management components
  - Product testing: unlikely
  - Environmental monitoring: some facilities may choose as a verification activity
For More Information

- Web site: http://www.fda.gov/fsma
- Subscription feature available
- To contact FDA about FSMA and find the new online form for submitting questions: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm
PSA Training Updates

• PSA will **not** be hosting any Train-the-Trainer or Grower Training Courses until January 2016
• Currently awaiting the final Produce Safety Rule to align curriculum materials with final regulatory language
• There will be many opportunities to attend a PSA TTT Course in 2016
• Train-the-Trainer and Grower Training Courses will be announced via the general listserv, once available
PSA New Hires

Northwest: Reviewing/Accepting Applications
- Don Stoeckel, Ph.D.

Southwest: Donna Pahl, M.S.

Midwest: Don Stoeckel, Ph.D.

Southeast: Kristin Woods, Ph.D.

PSA Extension Aide
- Michele Humiston
PSA & The FSMA Training Strategy

- FDA released their training strategy on October 6
  - [http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm461513.htm](http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm461513.htm)

- PSA is included as one of the major components for outreach and training

- PSA personnel will work with both the newly established National Coordination Center and the Regional Centers (once awarded)

- PSA REAs will help facilitate and host PSA trainings with regional and national collaborators
This is not an all-inclusive list of entities that will be developing training curricula and delivery for domestic and foreign food businesses.
Contact Us!

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Pew Charitable Trusts

- Need stakeholder involvement on the importance of giving FDA robust funding for FSMA in FY2016
- Extension educators and Land Grant Universities are stakeholders needing to be engaged since we play a vital role in providing education, outreach, and assistance with FSMA compliance
- Is there interest in developing and co-signing a letter encouraging funding to be committed to extension?
Next Meeting

- Tuesday, November 10, 2015 at 2PM EST
- Send in agenda topics to glw53@cornell.edu
- An audio recording and notes will be available after this meeting.
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