Produce Safety Alliance Educators Call & Northeast Center to Advance Food Safety Monthly Meeting

May 4, 2017
1:30 PM EDT
Instructions

• All participants are muted.

• There will be time for questions and answers throughout the meeting. Only those connected online will be able to ask questions.
  – 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 NECAFS & Educator’s listserves after the call.
Agenda

• NECAFS Update

• Soil Summit Hosted March 28-29, 2017 in Geneva, NY
  – Recap of purpose, goals, and objectives
  – Initial highlights and observations

• FDA Key Learnings from the Summit
  – FDA Risk Assessment Activities and Research
  – Informing Guidance

• Next steps
  – Circulating notes and developing white paper
  – Engaging work groups and working with others interested in hosting Soil Summits
NECAFS Overview

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Upcoming events:
PSA TTT in NE: May 16-17, 2017 in Geneva, NY
Webinar: Friday, May 19th at 1:00pm – Regional Roundtable
Soil Summit Summary

Gretchen Wall, Betsy Bihn, and Dave Ingram
Background

• **FSMA Produce Safety Rule Subpart F - Biological Soil Amendments of Animal Origin and Human Waste (BSAAO)**

• **Proposed rule**: 9 month application interval for raw BSAAO’s

• **Final rule**: Section “Reserved” for establishing application interval; additional research and risk assessments being conducted

• Both educators and FDA recognize the need to support produce growers who use raw manure and compost in addressing:
  – Food safety risks
  – Environmental impacts
  – Crop nutrient needs
  – Farm resources and labor needs
  – Gaps in education and understanding
Soil Summit Goals

• Provide clarification of FSMA PSR Subpart F requirements
• Inform participants of current FDA risk assessment activities
• Provide opportunity for small break-out discussions and brainstorming
  – Current uses of raw manure on fruit and vegetable farms
  – Barriers and benefits to adopting composting practices
  – Development of key educational resources
  – Identify research gaps/needs to better understand practices and risks as well as improve compost quality and safety
Expected Outcomes

• Gain a better understanding of FSMA PSR Subpart F requirements
• Increase knowledge about diversity of soil amendments used on fruit and vegetable farms
• Develop a framework including a list of critical components necessary to develop a soil amendment strategy to assess and minimize food safety risks
• Create an action item list to encourage or support proper use of compost or the safe handling and use of raw manure
• Develop a list of research needs to address identified gaps in knowledge
• Publish a white paper with priority action items
Participant Affiliations

Total attendees: 70
### Participant Affiliations

#### Soil Summit 2017

<table>
<thead>
<tr>
<th>Category</th>
<th>Affiliations</th>
</tr>
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<tbody>
<tr>
<td><strong>Academia</strong></td>
<td>Cornell Univ, Cornell Cooperative Extension, Univ of Maryland, West Virginia State Univ, Univ of California – Davis, Univ of Massachusetts Extension, Rutgers Cooperative Extension, Ohio State Univ, Penn State Extension, Clemson Univ, Michigan State Extension, Univ of Vermont Extension, Purdue Extension</td>
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<tr>
<td><strong>State agencies</strong></td>
<td>MA Dept of Agricultural Resources, VT Agency of Agriculture, Food, &amp; Markets, NY State Dept of Agriculture &amp; Markets, NC Dept of Agriculture &amp; Drug Protection, WV Dept of Agriculture</td>
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<td><strong>Federal agencies</strong></td>
<td>USDA-AMS, USDA-NRCS, FDA</td>
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<tr>
<td><strong>Grower Organizations/Associations</strong></td>
<td>Carolina Farm Stewardship Association, Florida Fruit &amp; Vegetable Association, NOFA-NY, National Young Farmers Coalition, New England Farmers Union, Georgia Fruit and Vegetable Growers Association, National Sustainable Agriculture Coalition</td>
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<td><strong>Produce Industry/Retailers</strong></td>
<td>Produce Marketing Association, Wegmans</td>
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<td><strong>Compost Industry/Waste Management</strong></td>
<td>Terra Viva, WeCare Denali, Organix Green – Vermiculture, Onondaga County Resource Recovery Agency</td>
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<td><strong>Growers</strong></td>
<td>New York, Pennsylvania, Ohio, Kentucky, Connecticut</td>
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General Agenda – Day 1

• Clarifications and Background to Subpart F - FDA (Dave Ingram)
• Current Efforts on Risk Assessment & Research - FDA (Amir Mokhtari)
• Summary of Technical Forum on Produce Safety - FDA (Dave Ingram)
• Key Challenges Regarding Compliance with the FSMA Produce Safety Rule Subpart F Requirements - PSA (Betsy Bihn)
General Agenda – Day 1, Cont.

• Introduction of topic areas for discussions

• Break-out Discussion #1
  – Identifying and Clarifying Current Raw Manure Use and Practices

• Break-out Discussion #2
  – Challenges to Using Raw Manure & Transitioning to Compost

• Recap of Day 1 and Ideas to Carry Into Day 2
General Agenda – Day 2

• Recap of Day 1 and Ideas to Carry Into Day 2
• Compost Quality & Use
  - Cornell Waste Management Institute (Jean Bonhotal)
• Break-out Discussion #3
  – Addressing Challenges: Education, Resources, and Funding to Reduce Risks Associated with Raw Manure and Compost Use
• Soil Summit Reflections & Next Steps
Break-Out Session Structure

• Eight groups, predetermined before the Summit to ensure there was a diverse mix of participants in each
• 30 minutes allocated to discussion of each topic area
• Facilitator provided to guide discussion, but not lead discussion
• Each group prioritized outcomes and key discussion points for sharing with all Summit participants
Initial Thoughts on the Soil Summit

- Lots of diverse view points and opinions
- Discussions from break-outs include lots of textured details
  - Currently summarizing this data for review by the Summit attendees
- Plan to share a few highlights and things we did not expect, but these our own perspective
- ‘Next steps’ to be discussed at end of presentation
Major Themes & Highlights

• Raw Manure Use
  – Extremely difficult to discuss growers moving to compost without also discussing current uses of raw manure on farms and barriers that might exist
  – Definitions of different types of soil amendments (aged manure, composted, biological soil amendments of animal origin, etc.) need to be clarified
  – Manure is widely available and generally cheap, but growers must balance sometimes conflicting priorities (e.g., food safety vs. nutrient management)
  – Raw manure use is critical on some farms, especially if operations are organic or include animal production
Major Themes & Highlights

• Compost Use
  – Primary barriers to composting are cost, labor, and access to equipment
  – Transportation costs can be a major factor in the decision purchase and use compost
  – Composting practices can reduce food safety risks, but also introduce new ones – for example, movement of raw manure around farm or cleaning/sanitation of tools and equipment
  – Feed stocks for making compost can be an issue
  – Not all compost suppliers ready to provide required info
  – Benefits to compost use need to be conveyed to growers, but not just from educators or regulators (e.g., peer-to-peer learning or from grower organizations)
Major Themes & Highlights

• Education & Outreach
  – Fundamental gaps in knowledge exist in understanding and implementing proper composting practices
  – Educational materials will need to be tailored to different audiences to address differences in scale (e.g., large digesters vs. small composters), farm type (e.g., organic, diversified), and region (e.g., climate, manure types available)
  – Education and outreach should take a ‘systems approach’ since no component of soil quality and health can be managed without considering other impacts or unintended consequences
Planned Guidance

Produce Safety Rule

• Produce Rule Compliance Guidance
• Updated GAPs Guidance
• Sprout Guidance
• Produce Small Entity Compliance Guide
**Part 112 – Standards for the growing, harvesting, packing and holding of produce for human consumption**

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
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<tbody>
<tr>
<td>§ 112.51</td>
<td>What requirements apply for determining <strong>status</strong> of a biological soil amendment of animal origin (BSAAO) ?</td>
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<tr>
<td>§ 112.52</td>
<td>How must I <strong>handle, convey, and store</strong> BSAAO ?</td>
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<tr>
<td>§ 112.53</td>
<td>What prohibitions apply regarding use of <strong>human waste</strong>?</td>
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<tr>
<td>§ 112.54</td>
<td>What <strong>treatment processes</strong> are acceptable for a BSAAO that I apply in the growing of covered produce?</td>
</tr>
<tr>
<td>§ 112.55</td>
<td>What <strong>microbial standards</strong> apply to the treatment processes in §112.54 ?</td>
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<tr>
<td>§ 112.56</td>
<td>What <strong>application requirements</strong> and minimum <strong>application intervals</strong> apply to BSAAO ?</td>
</tr>
<tr>
<td>§ 112.60</td>
<td>Under this subpart, what requirements apply regarding <strong>records</strong>?</td>
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Steps you will need to take:

1. Determine whether your soil amendment is a BSAAO or human waste
2. Determine whether your BSAAO is “treated” or “untreated”
3. Acceptable treatment processes for generating “treated” BSAAO and the applicable microbiological standards associated with the treatment processes
4. Determine requirements for properly handling, transporting, and storing your BSAAO
5. Determine how you may introduce the BSAAO into your produce growing area and with what application intervals.
6. Determine what records you will need for treated BSAAO
§112.56 – Application Requirements

• **Untreated BSAAO** – MUST Apply in a manner that does **not contact** covered produce during application

  **(a)(1)(i)** – *and* minimizes potential for contact with covered produce after application – [Reserved] harvest interval

  **(a)(1)(ii)** – *and* No contact after application – **0 day** harvest interval

• **Treated BSAAO** - Zero days-to-harvest provided:

  **(a)(2)** – §112.54(b)/ §112.55(b) – **minimizes potential** for contact with covered produce during and after application

  **(a)(3)** – §112.54(a)/ §112.55(a) – applied in any manner (no restrictions)
Sources of data for risk assessment

- Published literature (meta-analysis)
- In-house research & surveys (ORA)
- Gov’t surveys (e.g., NHANES)
- **Commissioned studies**
- Expert elicitation
- Data calls via Federal Register Notice
- Industry
- Informal; educational site visits
Federal Register Notice Request for Data, Information, and Comments (FDA-2016-N-0321-0038)

- FDA requested scientific data, information, and comments that would assist the Agency in its plan to develop a risk assessment for produce grown in fields or other growing areas amended with untreated BSAAO
- There were 59 respondents
- Several respondents (40) sent general comments and expressed their feelings about Biological soil amendment
- Some organizations submitted data or information in response to specific questions in the notice, e.g., on-farm practices, prevalence of pathogens in manure, survival data

Thank you to all who submitted!
Commissioned studies to fill data gaps

- Over the past decade, FDA-CFSAN has funded a number of studies including field trials and laboratory research experiments to gather data to fill knowledge gaps

- In February 2017, FDA met with collaborators to:
  - Review findings from different commissioned studies on fresh produce and BSAAO
  - Discuss key factors in study designs when comparing data from studies conducted in different regions under similar or different conditions
  - Discuss underlying variability and uncertainty in the results
Examples of data generated through FDA commissioned studies

- Prevalence and levels of *Salmonella* in poultry litter and *E. coli* O157:H7 and STEC in cattle manure on the West Coast (CA and AZ), East Coast (DE) and Florida
- Diversity and survival dynamics of *Salmonella* in manure, soil, water, and the farm environment
- Determining the strain survival variability of *Salmonella* spp., *E. coli* O157, STEC Non-O157 and generic E. coli, in manure amended agricultural soils
- Irrigation mediated transfer of *E. coli* O157:H7 from feces to lettuce
- Survival of *E. coli* on lettuce under field conditions encountered in the Northeastern United States
Selected data elements and impacting factors characterized in FDA commissioned studies

**Data Elements**

- Likelihood and level of pathogens in manure, amended soil, water, and on crops
- Fate (survival) of pathogens in manure, amended soil, and on crops
- Likelihood and rate of transfer of pathogens from amended soil to crops

**Impacting factors**

- Soil type (sandy, loam, clay)
- Geographic region (East, West Coast)
- Agricultural practices (BSAAO application method, irrigation technique, etc.)
- Climatic factors (temperature, rainfall, wind, moisture, etc.)
- Crop type (tomato, lettuce, melon)
- Manure type (cattle, chicken, horse)
- Pathogen strains
Next steps

- Research collaborators submit manuscripts describing studies, data, and results to peer-reviewed scientific journals.

- FDA analyze full data set to enhance and expand meta-analysis and build quantitative models.

- The risk assessment (RA) model, currently under development, will combine different data sets to provide new insights into food safety issues related to use of BSAAO.

- The risk assessment will evaluate the impact of interventions, such as use of time interval(s) between application of soil amendment and crop harvest, on the risk to consumers, to inform policy decisions within Subpart F (Biological Soil Amendments of Animal Origin and Human Waste) of the Final Produce Rule.
Acknowledgments

BSAAO Risk Assessment Team

Yuhuan Chen, David Oryang, Steven Duret (former ORISE Fellow),
David Ingram,
Jane Van Doren

Other contributors:

• Division of Risk and Decision Analysis (DRDA)
• Division of Produce Safety (DPS)
• This work was supported by the U.S. Food and Drug Administration and, in part, by an appointment of Steven Duret, Ph.D. to the Research Participation Program at the Center for Food Safety and Applied Nutrition administered by the Oak Ridge Institute for Science and Education through an interagency agreement between the US Department of Energy and the US Food and Drug Administration.
Discussion
Next Steps

• Share summarized notes and outcomes with Soil Summit attendees and working committee to elicit feedback and flesh out perspectives
• Circulate a white paper
• Begin organizing work groups interested in continuing work on outcomes
  – Framework for risk assessment and decision making
  – Action item list
  – Identification of additional research needs
• Collaborate with others interested in organizing Soil Summits
  – November 30, 2017 – Atlanta, GA
Special Thanks for Contributing to the Success of the Soil Summit

• Soil Summit Attendees
  – Open minded and willing to participate
  – Key to outcomes
• FDA
  – Dave Ingram, Amir Mokhtari, team
• Jean Bonathal
• PSA and IFS@CU teams for facilitating break-out sessions
Questions, comments, thoughts?

- Sharing experiences and key take-aways
- Suggestions for moving forward?
Next Meeting

• Tentatively: Tuesday, June 6, 2017, 2 PM EST

• Tentative Agenda:
  – Update on PSA Training Numbers and Outreach
  – Review of new resources

• Submit other topics for discussion to Gretchen (glw53@cornell.edu)

• Note: We will be moving to Zoom next month – so be prepared to use a new system. Instructions to come!
PSA Team & Regional Extension Associates

Northwest: Now Hiring

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Gretchen Wall, M.S.
Michele Humiston
Rob Way

Southwest: Donna Pahl, M.S.

Southeast: Kristin Woods, Ph.D.
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