Produce Safety Educators
Monthly Meeting #19

May 23, 2016
2PM 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 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
• Notes will be shared via the listserv after the call.
Agenda

• Welcome!

• Produce Safety Alliance Updates

• Biological Soil Amendments of Animal Origin – FDA Risk Assessment
  - David Oryang, Steven Duret, and Yuhuan Chen
  FDA Biological Soil Amendments of Animal Origin (BSAAO) Risk Assessment Team

• Group Discussion
PSA Updates

• Moving towards September 2016 launch
  – Working with FDA Division of Produce Safety to align course materials with final regulations

• Survey to determine training needs

• Introducing Barb Fick: Northwest Extension Associate
FDA FSMA – Produce Safety Rule
& FDA BSA Risk Assessment

Background and Research Needs on BSAAO: Biological Soil Amendments of Animal Origin

David Oryang, M.S.
Steven Duret, Ph.D
Jane Van Doren, Ph.D
Yuhuan Chen, Ph.D
David Ingram, Ph.D

PSA Educator’s Call - May 23, 2016
• FSMA Final Produce Rule
• Background
• Risk Assessment Approach
• Data/Research Needs:
  – Overview
  – Specific example – Modeling survival of pathogens in manure amended soil: A Meta-Analysis
  – Specific Data Needs
• Questions and Discussion
FDA issued proposed rule on Jan. 16, 2013.

FDA issued supplemental notice of proposed rulemaking on Sept. 29, 2014

FDA issued Final Produce Rule on Nov. 11, 2015
  - Four public meetings; various outreach efforts
  - About 36,000 submissions, including over 15,000 unique comments, in response to both 2013 and 2014 documents
  - Input from various sectors of stakeholder community
Focus on conditions and practices identified as potential contributing factors for microbial contamination

• Agricultural water
• Biological soil amendments of animal origin
• Worker health and hygiene
• Equipment, tools, buildings and sanitation
• Domesticated and wild animals
• Growing, harvesting, packing and holding activities
• Sprouts requirements
Risk Assessment

Regulatory context

- FDA Food Safety Modernization Act (FSMA), Produce Safety Rule published
- FDA has reserved its decision on the minimum time interval or intervals between the application of untreated Biological Soil Amendments of Animal Origin (BSAAO) and crop harvesting
FDA is conducting a risk assessment to evaluate and, if feasible, quantify the risk of human illness associated with the consumption of produce grown in fields or other growing areas amended with untreated BSAAO

- Assess Impact of certain interventions, such as use of a time interval or intervals between application and harvest, on the predicted risk.
The Center for Food Safety and Applied Nutrition,
Food and Drug Administration

Initiation and Conduct of All 'Major' Risk Assessments within a Risk Analysis Framework

A Report by the CFSAN Risk Analysis Working Group
March 2002

Conduct & Manage Process

Step 1: Commission
Step 2: Data collection, evaluation & analysis
Step 3: Develop model & report
Step 4: Review
Step 5: Issue
Growing area

Initial Level in manure at the time of application

Pathogen survival in amended soil (e.g., Weibull model)

Transfer from soil to leafy greens (e.g., irrigation event)

Produce prevalence and contamination at the time of harvest

Public Health Risk

Consumer
- Serving size
- Number of servings
- Dose - response

Food supply chain
- Time temperature
- Washing
- Growth / die-off
**Risk Assessment**

**Key points to consider in assessing exposure**

1. Pathogens may be present in BSAAO
2. Pathogens present may persist in amended soil
3. Pathogens may be transferred from amended soil to produce
4. Pathogens present may be impacted by handling practices, storage conditions

**Graph:**
- **X-axis:** Time (Days)
- **Y-axis:** Level (Log$_{10}$ CFU/g)

**Legend:**
- Non-contaminated water
- Contaminated water

**Diagram:**
- Soil
- Contaminated amended soil
- Rain irrigation
- Non-contaminated water
- Contaminated water
Introduction

Objectives of Meta-Analysis

- Understand pathogen survival in amended soil
- Identify influential factors and characterize variability
- Identify data gaps to focus new research

Climatic conditions

- Season
- Geographical location
- Solar irradiation

Pathogen survival in amended soil

Agro-ecological conditions

- Manure type
- Soil type
- Application method

Sandy

Clay
Examples of survival of *E. coli* O157:H7 in soil amended with cattle manure

- **Islam (2004)**
  - Sandy soil
  - Winter
  - Surface application

- **Hutchison (2004)**
  - Clay soil
  - Summer
  - Surface application

- **Nyberg (2010)**
  - Sandy soil
  - Summer
  - Incorporated manure
Characterizing variability in survival – conceptual model

1. Variability of the survival of pathogens in soil amended with BSAAO
2. Identify the factors influencing the survival

Pathogens survival in amended soil

Condition A:
Season 1, Soil type 1 ...

Condition B:
Season 2, Soil type 2 ...
Conclusion - Perspectives

How Survival Module would be used in the Risk Assessment?

- **Climatic conditions**
  - Season
  - Geographical location
  - Solar irradiation

- **Initial Level in manure at the time of application**

- **Pathogen survival in amended soil (Weibull model)**

- **Transfer from soil to leafy greens (e.g. irrigation event)**

- **Agro-ecological conditions**
  - Manure type
  - Soil type
  - Application method

- **Consumer**
  - Serving size
  - Number of servings
  - Dose - response

- **Food supply chain**
  - Time temperature
  - Washing
  - Growth / die-off

- **Produce prevalence and contamination at the time of harvest**

- **Public Health Risk**
1. Data on the prevalence and level of pathogens.
2. Data and information on survival of pathogens in amended soil and transfer to produce.
3. On-farm practices with regard of the use of untreated BSAAO.
4. Harvesting, handling practices and storage conditions between harvest and retail.
5. Storage conditions from retail to consumption (e.g., time – temperature profiles), and consumer handling practices.

... and other information or comments you wish to share.
Risk Assessment of Foodborne Illness Associated with Pathogens from Produce Grown in Fields Amended with Untreated Biological Soil Amendments of Animal Origin; Request for Comments, Scientific Data, and Information

FDA, in consultation with USDA, is conducting the risk assessment to evaluate and, if feasible, quantify the risk of human illness associated with the consumption of produce grown in fields or other growing areas amended with untreated BSAAO.

– Assess Impact of certain interventions, such as use of a time interval or intervals between application and harvest, on the predicted risk
Specific Data Needs

Biological Soil Amendment Risk Assessment

We need scientific data and information concerning, but not limited to, the following factors that may affect the risk of human illness associated with the consumption of produce (e.g., leafy greens and other row crops, root crops, and tree crops) grown in fields amended with untreated biological soil amendments of animal origin (BSAAO) (including raw manure):
1. **Data on the prevalence and levels of pathogens.**
   
a. The frequency of detecting the presence of pathogens in untreated BSAAO and soil amended with BSAAO, such as *Salmonella* in poultry litter, *E. coli* O157:H7 and other pathogenic Shiga-toxin producing *E. coli* (STEC) in cattle manure. Samples may be obtained at different stages of untreated BSAAO storage prior to application, or after application. If available, for each data point, we also invite information regarding the following:
   
   - how the untreated BSAAO, including raw manure, was sampled and handled prior to analysis;
   - the size of the analytical unit (i.e., detection limit) and test method;
   - the number of positives, the total number of samples, and the time period in which the testing was conducted; and
   - sampling protocol (e.g., simple random, stratified random, targeted).

b. The pathogen concentration, i.e., the number of pathogen cells per amount (unit volume or weight), in contaminated untreated BSAAO or soil amended with untreated BSAAO, especially cattle manure and poultry litter. If available, for each data point, we ask that the data be provided in unaggregated form and that Most-Probable Number (MPN) patterns as well as raw data (e.g., number of positive and negative tubes per serial dilution) be provided.
2. Data and information on survival of pathogens (e.g., *Salmonella*, *E. coli* O157:H7), and pathogen transfer to produce.
   a. Kinetic data that describes the survivability (die-off) of pathogens in untreated BSAAO, especially cattle manure and poultry litter;
   b. Kinetic data that describes the survivability (die-off) or growth of pathogens in soil amended with untreated BSAAO, especially cattle manure and poultry litter, as influenced by soil type, untreated BSAAO type, application method, geographic locations/climatic factors (e.g., temperature, days of sunlight, intensity of solar irradiation, moisture, rainfall) and other factors;
   c. The mechanisms for pathogen transfer from soils to produce such as leafy greens and associated transfer coefficients, including irrigation and rain water splash, direct contact between produce and soil, machinery or people contaminated by soil and directly contacting produce during growth and harvest of produce;
   d. Pathogen transfer rates (i.e., transfer coefficients) from amended soils to produce such as leafy greens as influenced by soil type, untreated BSAAO type, application method, climate factors, commodity type or any other pertinent factors not listed here;
   e. The survival of pathogens such as *Salmonella* and *E. coli* O157:H7 on produce in the field before harvest;
   f. The variability in the survival of different *Salmonella* serotypes, different subtypes of *E. coli* O157:H7, or other pathogens of significance in amended soils under field (preferred), greenhouse or laboratory conditions.
3. On-farm practices with regard to the use of untreated BSAAO, including but are not limited to the following aspects.

a. The extent to which untreated BSAAO is used in different regions in the U.S., as well outside the U.S. that export produce to the U.S.;

b. The untreated BSAAO type and the soil type, and associated physico-chemical parameters (including but not exclusive to nutrient content, moisture and pH); the proportion of produce farms per soil type;

c. The amount of untreated BSAAO applied per unit surface (e.g., per acre) or the ratio of untreated BSAAO/soil, including typical ratio and variability by type commodity, including row crops such as leafy greens;

d. The time in the year, the number of applications and agronomic rates of untreated BSAAO that is applied;

e. The method of application (e.g., surface, incorporated), and whether or not the amended soil is covered (e.g., with plastic mulch);

f. Produce commodity type and cropping cycles;

g. Climate conditions and irrigation practices after soil is amended, before and after planting; and

h. The crop density (e.g., spinach crop), the number of rows per bed, the distance between adjacent rows in a bed, distance between two crop beds (furrow width), and the influence of such factors on pathogen transfer
4. Harvesting, handling and storage conditions that may affect pathogen detection and levels, survival, growth, or inactivation between harvest and retail sale along the farm-to-fork continuum.
   a. The harvesting practices and climactic conditions prior to harvesting (e.g., time and temperature, rain events) under which produce is handled in the field and in packing facilities;
   b. The survival, growth or inactivation of pathogens on produce such as leafy greens during transportation and storage, potentially as a function of relative humidity during storage, geographic region, or season;
   c. Typical storage conditions (e.g., time, temperature, relative humidity) for produce such as leafy greens, from harvest until consumer purchase at retail and whether and how those storage conditions affect pathogen levels;
   d. The types and concentration of sanitizers, if any, applied to produce in the water used for wash or transport at the packing house and/or processing environment prior to retail, and the efficacy of these treatments in reducing pathogen levels, as well as the likelihood of cross contamination during wash or transport;

5. Storage conditions such as times and temperatures that may affect pathogen growth and/or survival during transportation and storage of produce in the consumer’s home. Consumer handling practices of produce after purchase, including data and information on consumer washing practices.
Submit comments and scientific data and information:


- Written / Paper Submissions: Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

- FOR FURTHER INFORMATION CONTACT: Jane Van Doren, Center for Food Safety and Applied Nutrition (HFS–05), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2927
• Questions about the Produce Safety Rule can be addressed in a followup meeting.
Acknowledgement:
FDA BSA Risk Assessment Team

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Thank you!

Questions?
Questions, Comments, & Discussion
Next Meeting

- TENTATIVE: Monday, June 13, 2016 at 2PM EDT
- Send in agenda topics to glw53@cornell.edu
- Notes will be available after this meeting.
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