Biological Soil Amendments of Animal Origin (BSAAO) : FDA Risk Assessment Activities

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Outline

- Potential sources of contamination in the growing field
- Regulatory context
- Need for conducting a risk assessment
- Risk assessment process, conceptual model, and data sources
- Meta-analysis to compile data from literature
- Commissioned studies to fill the data gaps
- Next steps
Potential sources of contamination in the growing field

- Soil amendments
- Domesticated animals
- Irrigation water
- Wild animals
- Workers
- Equipment
- Environment, e.g., flood
- Birds

Pathogens in produce
Pathogen pathway from Biological Soil Amendments of Animal Origin (BSAAO) to Produce

1. Pathogens may be present in BSAAO prior to application.

2. Pathogens may persist in amended soil for a long time period considering environmental factors (e.g., soil moisture, temperature).

3. Pathogens may be transferred from amended soil to produce through different pathways (e.g., water splash, wind, animal encroachment).

4. Pathogen levels on crops may be impacted by harvesting practices, processing practices, storage conditions, etc.

Graph:
- Level (Log_{10} CFU/g) vs. Time (Days)
- Non-contaminated water
- Contaminated water

Legend:
- Soil
- Contaminated amended soil
- Rain irrigation
- Water splash
- Wind
- Animal encroachment

Image:
- Cows
- Soil
- Contaminated water
- Non-contaminated water

Regulatory Context
§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*
FDA Risk Assessment

• FDA is conducting 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.

• This process involves assessing the impact of certain interventions, such as use of a time interval or intervals between application and harvest, on the predicted risk.
Risk assessment process

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
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
Meta-analysis to compile data required for the risk assessment model:
Survival and growth in amended soil

- **Key objectives:**
  - Understand pathogen survival in amended soil
  - Identify influential factors and characterize variability
  - Identify data gaps to focus new research
Meta-analysis: key findings

• Statistical differences were observed for pathogen survival in manure in different seasons
• Data gaps resulting in model with limited statistical power for prediction
• Additional data needed to parameterize the survival model to quantitatively describe the impact of climatic and agro-ecological conditions.
• Other factors to consider in the model: temperature variation, soil moisture, solar irradiation, application method, indigenous microflora
• Survival model will be improved and used as a part of the risk assessment model to predict risk to consumers
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

1. Pathogen prevalence and levels in manure
2. Pathogen survival in manure and in manure amended soil
3. Pathogen strain survival variability in manure and manure amended soil and pathogen presence and variability in water
4. Pathogen Transfer from soil/manure to crops during growth
5. Pathogen survival on crops
6. Pathogen transfer during processing
### Selected data elements and impacting factors characterized in FDA commissioned studies

<table>
<thead>
<tr>
<th>Data Elements</th>
<th>Potential Impacting Factors</th>
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<tbody>
<tr>
<td>Likelihood and level of pathogens in manure, amended soil, water, and on crops</td>
<td>Soil type (sandy, loam, clay, conventional vs/ organic)</td>
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<tr>
<td>Likelihood and rate of transfer of pathogens from amended soil to crops</td>
<td>Geographic region (East, West, South, North)</td>
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<tr>
<td>Fate (survival) of pathogens in manure, amended soil, and on crops</td>
<td>Agricultural practices (BSAAO application method (surface vs/ tillage), irrigation technique, etc.)</td>
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<td>Climatic factors (temperature, rainfall, wind, soil moisture, UV, etc.)</td>
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<td>Crop type (root, low growing, stem)</td>
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<td></td>
<td>Manure type (cattle, chicken, horse)</td>
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<td>Pathogen strains and inoculation level (high vs. low)</td>
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</table>
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
Useful Web Links

Link to FR Notice:

Link to Q&A with Michael Mahovic:
http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm425766.htm

Link to Q&A with Samir Assar:
http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm482426.htm

Link to Produce Rule page:
http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm
Acknowledgments

BSAAO Risk Assessment Team

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• Division of Produce Safety (DPS)
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Any Questions?