Current FDA Risk Assessment Efforts

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Outline

- Potential sources of contamination in the growing field
- Biological soil amendment of animal origin (BSAAO)
- 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
- Birds
- Equipment
- Environment, e.g., flood

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.

- Contaminated water
- Non-contaminated water
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 BSAAO and crop harvesting
FDA Risk Assessment

• FDA, in consultation with USDA, 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
## Conduct & Manage Process

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### Risk assessment process

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

A Report by the CFSAN Risk Analysis Working Group

March 2002
Risk assessment conceptual model

- **Initial level in manure**
- **Survival in amended soil**
- **Transfer from soil to crops**
- **Survival on crops**

**Food supply chain**
- **Harvest (Prevalence & level)**
- **Transportation (time/temperature)**
- **Washing**
- **Survival/die-off**

**Public health risk**
- **Serving size**
- **Number of servings**
- **Dose-response relationship**
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

![Diagram showing factors affecting survival in amended soil](image-url)
Meta-analysis: search strategy

- Comprehensive literature review for pathogen survival in amended soil: *E. coli* O157 in cattle manure and *Salmonella* in poultry manure
Meta-analysis: experimental conditions for *E. coli* O157:H7 survival

- **Field studies**: C=18
  - Summer: C=16
  - Winter: C=2
  - Fall/Spring: C=2
- **Greenhouse studies**: C=4
  - Summer: C=2
  - Winter: C=2
  - Fall/Spring: C=2
- **Lab studies**: C=22
  - Summer: C=1
  - Winter: C=1
  - Fall/Spring: C=20

C: Number of curves
Meta-analysis: experimental conditions for *E. Salmonella* survival

C: Number of curves
Meta-analysis: comparison between *E. coli* O157 and *Salmonella* (field data)

- Survival significantly influenced by pathogens and/or type of manure
Meta-analysis: examples of survival of *E. coli* O157 in amended soil with cattle manure

![Graph showing survival of *E. coli* O157 in amended soil with cattle manure over time.]

**Survival model: Primary Weibull model**

\[
y = y_0 - \left( \frac{t}{D} \right)^p
\]

- \(t\): time (day)
- \(y\): Level in soil (log_{10} CFU g^{-1})
- \(y_0\): Initial level in soil (log_{10} CFU g^{-1})
- \(D, p\): Weibull model parameters
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
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
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
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

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