Produce Safety Rule

Biological Soil Amendments of Animal Origin

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Fresh Produce Branch

FDA’s Center for Food Safety and Applied Nutrition

Produce Safety Alliance: Soil Summit, Geneva, NY
March 28-29, 2017

www.fda.gov
Produce Safety Rule

• 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
* Only applies to certain water requirements
Small Businesses – average produce sales over 3 years > $250,000 and ≤ $500,000
Very Small Businesses – average produce sales over 3 years > $25,000 and ≤ $250,000
≤ $25,000 in average produce sales over 3 years is not a covered farm
FSMA Implementation
“A Continuum”

• **Phase 1: Set Standards**
  – Develop regulations, guidance, policy

• **Phase 2: Design Strategies to Promote and Oversee Industry Compliance**
  – Identify performance metrics to measure success

• **Phase 3: Implement, Monitor, Evaluate, Refresh**
  – Transition strategies and performance metrics from design to operational, evaluate success
FDA’s Produce Safety Network

Roles and Responsibilities

• Technical assistance
• Outreach and training
• Work planning
• Outbreak investigations
• Inspections (*particularly* foreign)
• Enforcement
FSMA Technical Assistance Networks

Preventive Controls Scientific & Technical Questions from Industry – submit a web form at: www.iit.edu/ifsh/alliance

FSMA Regulation & Policy Interpretation Questions – submit a web form at: www.fda.gov/fsma

FDA FSMA Technical Assistance Network

CVM
CFSAN
ORA
OIP

Extension Specialists
Land Grant Universities
International Partners

FDA FSMA Technical Assistance Network

Land Grant / Extension Specialists
International Partners
PSA
SSA
States/NASDA
FDA-NIFA/National & Regional Centers

Produce Scientific & Technical Questions from Industry

Produce Technical Assistance Network
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
Guide to the use of Biological Soil Amendments of Animal Origin

Draft Guidance

This guidance is being distributed for comment purposes only.

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance within ___ days of publication in the Federal Register of the notice announcing the availability of the draft guidance. Submit electronic comments to:

http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number [insert docket number] listed in the notice of availability that publishes in the Federal Register.
Part 112 – Standards for the growing, harvesting, packing and holding of produce for human consumption

§ 112.51 – What requirements apply for determining status of a biological soil amendment of animal origin (BSAAO)?

§ 112.52 – How must I handle, convey, and store BSAAO?

§ 112.53 – What prohibitions apply regarding use of human waste?

§ 112.54 – What treatment processes are acceptable for a BSAAO that I apply in the growing of covered produce?

§ 112.55 – What microbial standards apply to the treatment processes in §112.54?

§ 112.56 – What application requirements and minimum application intervals apply to BSAAO?

§ 112.60 – Under this subpart, what requirements apply regarding records?
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
What is a BSAAO?

Soil Amendments
- Chemical (i.e. elemental fertilizers)
- Biological (BSA) (i.e. organic matter)
- Physical (i.e. perlite, rock dust, sand)

BSAAO
What is a BSAAO?

BSA

BSAAO
- Manure
- Non-fecal animal byproducts
- Table waste

Yard Trimmings

Stabilized Compost

Pre-Consumer Vegetative Waste
§112.53 – Human Waste

• You may not use human waste for growing covered produce **EXCEPT FOR BIOSOLIDS**, in accordance with the requirements of 40 CFR part 503, subpart D, or equivalent regulatory requirements.
2. Determine whether your BSAAO is “treated” or “untreated” (§ 112.51)

- BSAAO processed in accordance with requirements (§ 112.54)

- BSAAO must be “processed to completion” (§ 112.51(b)(1))

- You must classify a treated BSAAO as “untreated” in cases where your treatment process is:
  1. Ineffective (not scientifically validated)
  2. Incomplete (not processed to completion)
  3. Or has been contaminated after treatment
  4. Or you know contains a hazard
2. Determine whether your BSAAO is “treated” or “untreated” (§ 112.51)

- **Agricultural Tea** may be considered “treated” if:
  - “treated” BSAAO feedstock is used
  - No untreated surface water is used
  - Water has NO detectable *E. coli* per 100ml
  - No agricultural tea additives are used
3. **Acceptable treatment processes and applicable microbiological standards (§ 112.54 and § 112.55)**

- Flexibility – any chemical, physical and/or biological treatment process that is scientifically validated to meet microbiological standard.

<table>
<thead>
<tr>
<th>21 CFR § 112.55(a)</th>
<th>The microbial standard is -</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>L. monocytogenes</strong></td>
<td>Not detected using a method that can detect one colony forming unit (CFU) per 5 gram (or milliliter, if liquid is being sampled) analytical portion.</td>
</tr>
<tr>
<td><strong>Salmonella species</strong></td>
<td>Not detected using a method that can detect three most probable numbers (MPN) per 4 grams (or milliliter, if liquid is being sampled) of total solids.</td>
</tr>
<tr>
<td><strong>E. coli O157:H7</strong></td>
<td>Not detected using a method that can detect 0.3 MPN per 1 gram (or milliliter, if liquid is being sampled) analytical portion.</td>
</tr>
</tbody>
</table>
3. Acceptable treatment processes and applicable microbiological standards (§ 112.54 and § 112.55)

<table>
<thead>
<tr>
<th>21 CFR § 112.55 (b)</th>
<th>The microbial standard is -</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Salmonella species</strong></td>
<td>Not detected using a method that can detect three most probable numbers (MPN) per 4 grams (or milliliter, if liquid is being sampled) of total solids.</td>
</tr>
<tr>
<td><strong>Fecal coliforms</strong></td>
<td>Less than 1,000 most probable numbers (MPN) per gram (if liquid is being sampled) of total solids</td>
</tr>
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- **Static Composting** - § 112.54(b)(1)
  131°F / 55°C for 3 consecutive days + adequate curing

- **Turned Composting** - §112.54(b)(2)
  131°F / 55°C for 15 days + adequate curing
4. Determine requirements for properly handling, transporting, and storing your BSAAO (§ 112.52)

• You must ensure that your BSAAO do not become sources of contamination for (§ 112.52(a)):
  - covered produce
  - food contact surfaces
  - Areas used for covered activity
  - Water sources
  - Water distribution systems

• Protect your treated BSAAO from becoming contaminated with (§ 112.52(b)):
  - Untreated BSAAO or in-process 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)
Requirements for Records (§ 112.60)

• Documentation only necessary for treated BSAAO:

• 3rd party purchased BSAAO
  §112.60(b)(1) – Documentation required (annual)
    (i) – Process used to treat BSAAO is scientifically validated with appropriate process monitoring
    (ii) – BSAAO has been handled, conveyed and stored in a manner and location to minimize the risk of contamination by an untreated or in-process BSAAO

• On-farm prepared BSAAO
  §112.60(b)(2) – Documentation that process controls were achieved
Questions and Answers

For More Information


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
Discussion
JIFSAN Technical Forum
Produce Safety for FDA Funded Researchers

BSAAO Risk Assessment Team
February 8-9, 2017

FDA’s Center for Food Safety and Applied Nutrition
Produce Safety Alliance: Soil Summit, Geneva, NY
March 28-29, 2017
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
Attendance

• Scientists who have been funded to conduct produce safety research, and who have submitted their research data to FDA

• Relevant FDA risk analysts, scientists, and technical experts
Goal

1. Enable FDA funded researchers to present their research methods and results;
2. Provide an environment for discussion of research data and findings (Research Scientists/FDA/USDA)
3. Enhance understanding of differences between various studies, and the impact of experimental design/parameter differences on the results.
4. Gain understanding of the scope and limits of application of the research results to risk assessment.
5. Get to know one another better.
Technical Forum Topics

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
Objective of Panel discussions

Discuss how soil type (sandy, loam, clay), geographic region (Pacific Coast, North East), agricultural practices (mulch/no mulch, staked/non staked, drip/strip irrigation, etc.), climatic factors (temperature, rainfall, moisture, wind, etc.), crop (tomato/lettuce), manure type (cattle, chicken, horse), or pathogen strain, impact:

a. likelihood and levels of pathogens (such as *Salmonella* and *E. coli* O15:H7) in manure, in manure amended soil, and on crops;

b. fate (survival) of pathogens (such as *Salmonella* and *E. coli* O15:H7), virulence-attenuated strains, and generic *E. coli*. in manure, in manure amended soil, and on crops;

c. likelihood, amount and rate of transfer of pathogens (such as *Salmonella* and *E. coli* O15:H7), virulent-attenuated strains, or generic *E. coli* from manure amended soil to crops before harvest; and

d. nature, likelihood, amount, and rate of cross contamination occurring between units of produce during post-harvest processing.
1. Pathogen prevalence and levels in manure

- **Prevalence and levels of Salmonella in poultry litter and E. coli O157:H7 and STEC in cattle manure on the West (AZ, CA) and East (DE) and Florida**
  - UC-Davis WCFS (Michele Jay-Russell, Peiman Aminabadi, Pramod Pandey, Sagor Biswas)
  - U. Delaware (Kali Kniel, Thais De Melo Ramos)
  - U. Arizona (Paula Rivadeinera)
  - U. Florida (Michelle Danyluk, Keith Schneider)

- **Sample Design:** n=546 cattle and poultry manure samples collected over 26 weeks divided evenly between fall and spring seasons on each coast
1. Pathogen prevalence and levels in manure

- *Salmonella prevalence and levels in poultry litter in the Eastern Shores of Virginia*
  - Virginia Tech (Ganyu Gu, Steven L. Rideout)

- **Results:**
  - There were spatial (broiler farm/house) and temporal (detection year/month) differences (population and serovar diversity) for *Salmonella* in poultry litter.
  - Most houses of the tested chicken farms were *Salmonella* positive at certain sampling points. However, *Salmonella* was only detected once from the composting shed of one broiler farm during the study.
2. Pathogen Survival in Manure and in Manure Amended Soil

- Survival and persistence of generic E. coli and attenuated E. coli O157:H7 in soils amended with treated and untreated animal manure in greenhouse and high tunnel environments
  - USDA-ARS-BARC: Pat Millner, Manan Sharma
  - UMES: Fawzy Hashem

- Design: two soil types (silt loam, clay loam) three amendments (poultry litter, horse manure, unamended)
  - Irrigation events moderated temporarily the overall decline of gEc and attO157 populations in Silt loam soil amended with manure;
  - Overall, all E. coli populations declined more rapidly in unamended and HM-amended SL and CL than in these same soils amended with PL
2. Pathogen Survival in Manure and in Manure Amended Soil

- *Survival dynamics of generic E. coli in animal feces (poultry, cattle, horse, goat) and in soil in vegetable fields*
  - UC-Davis WCFS: Michele Jay-Russell, Peiman Aminabadi
- Design: field plots amended by surface application of cattle, chicken litter, horse, goat and no manure with 4 replications (n=40 plots) plus controls. Two spray inoculation levels (High 7Log; Low 4Log).
  - An average 7 log reduction of inoculated *E. coli* was observed across all manure types by ~60 days from time of manure application
  - However, heavy rainfall temporarily reversed these reductions (5-6 log increase) beyond 120 days post-manure application, probably due to bacterial resuscitation/regrowth
  - Survival of indicator *E. coli* was variable by the manure type and inoculum concentration with chicken litter showing the slowest die-off
2. Pathogen Survival in Manure and in Manure Amended Soil

- **Survival of non-pathogenic and attenuated O157 E.coli in multi-field site trial in the mid-Atlantic U.S.**
  - USDA-ARS-BARC: Manan Sharma, Patricia D. Millner,
  - UMES : Fawzy Hashem

- **Design**: field plots amended by surface application of dairy (liquid and solid), poultry litter, horse, and no manure. Two spray inoculation levels (High 7Log; Low 4Log).
  - Significant factors for persistence included: Site location, Year/Season, Amendment type; Management (conventional/organic); Depth of sample (surface vs/ core)
  - PL amendment supported significantly higher levels of **survival** and **persistence** of gEc or attO157 than all other BSA types, regardless of other factors
3. Pathogen Strain Survival Variability in Manure and Manure Amended Soil, and Pathogen Presence and Variability in Water

- **Determining strain survival variability of Salmonella spp., E. coli O157, STEC Non-O157 and generic E. coli in manure-amended agricultural soils.**
  - VA-Tech: Laura Strawn

- **Design**: 12 *Salmonella* strains, 12 *E. coli* (4 O157, 5 non-O157 STEC, 3 generic); two soil types (clay, sandy loam); weekly and daily moisture maintenance
  - Results will help reduce variability in models that utilize multiple and varied isolates (e.g. pathogenic vs/ non-path)
3. Pathogen Strain Survival Variability in Manure and Manure Amended Soil, and Pathogen Presence and Variability in Water

- **Salinas watershed sampling for Salmonella, STEC O157, STEC non-O157, generic E. coli, Listeria, and Campylobacter**
  - USDA-ARS-WRRC Albany CA: Michael Cooley, Lisa Gorski

- **Design**: 5 year study, moore swab sampling (+/-);
  - The pathogens are present and persist in the region
  - Persistence of subtypes over years, large variety of subtypes means several avenues of introduction into environment
  - Capacity to be spread through rains, agricultural animals, runoff, wildlife, water
4. Pathogen Transfer from Soil/Manure to Crops During Growth

- **Irrigation mediated transfer of E. coli O157:H7 from feces to lettuce**
  - UC Davis: Robert Atwill, J. Chase, M. Jay-Russell, L. Harris, R. Bond, M. Partyka

- Design: Inoculated rabbit fecal slurry (Log 8) O157:H7 in between romaine beds
  - 38% lettuce heads within 28in of scat had avg $7.4 \times 10^3$ after irrigation
  - Transfer coefficient = 0.006%
  - Capacity for transfer from scat to lettuce heads via overhead irrigation to outer leaves of lettuce
4. Pathogen Transfer from Soil/Manure to Crops During Growth

• *Irrigation mediated transfer of generic E. coli from feces to lettuce, Salinas Valley CA*
  – UC Davis: S. Jeamsripong, R. Atwill, J. Chase, M.Jay-Russell

• Design: Inoculated chicken and rabbit feces (Log 7) in furrow between Romaine lettuce beds
  – 96.7% lettuce heads had detectable *E. coli* (*mean* 4 Log)
  – Critical factors include: distance between fecal deposit and lettuce, age of feces prior to irrigation, irrigation volume
  – “splash” was evident beyond 5 feet ‘no harvest’ buffer
4. Pathogen Transfer from Soil/Manure to Crops During Growth

- **Transfer of generic E. coli from simulated wildlife feces to field-grown lettuce during foliar irrigation in Northeastern U.S.**
  - Cornell: Daniel Weller

- **Design**: Inoculated rabbit feces (Log 8) in furrow between Romaine lettuce beds
  - Significant factors include: age of feces prior to irrigation, outer vs/inner leaves; distance of lettuce from feces
  - All lettuce heads were positive within 1m of pellet
  - 65% lettuce heads were positive within 2m of pellet
  - Model predicts % transfer to lettuce 1.5m of pellet is ~3log lower than % transferred to lettuce 0.5m from pellet
5. Pathogen Survival on Crops

- **Survival dynamics of pathogens on lettuce, cilantro and basil, onions**
  - UC-Davis: Anne-laure Moyne, Linda Harris, et. al.

- **Survival of E. coli O157:H7 in fecal slurry on lettuce**
  - UC-Davis: R. Atwill, J. Chase, L. Harris, R. Bond, M. Partyka

- **Survival of E. coli on lettuce under field conditions encountered in Northeastern U.S.**

Many factors impact survival of microorganisms on growing plants:
  - humidity, precipitation (leaf wetness), probably wind (drying), temperature

**Generic E. coli** a good surrogate for pathogenic O157:H7
Acknowledgments

**BSAAO Risk Assessment Team**

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

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• Division of Produce Safety
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