Biological Soil Amendments of Animal Origin (BSAAO) in Fresh Fruit and Vegetable Production: A Regulatory Perspective

David T. Ingram, Division of Produce Safety
Fresh Produce Branch
Division of Produce Safety, CFSAN
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
Produce Safety Regulation Compliance Dates

Publication of Final Rule
Nov 27, 2015

Sprouts - All Others
All Provisions
Jan 26, 2017

Sprouts - Very Small
All Provisions
Jan 26, 2019

Farms - Small
Except Water *
Jan 26, 2019

Farms - Small
All Provisions
Jan 26, 2021

Farms - All Others
Except Water *
Jan 26, 2018

Farms - All Others
All Provisions
Jan 26, 2020

Farms - Very Small
All Provisions
Jan 26, 2022

Full Implementation & Transition to Operational Mode
2022

Effective
Jan 26, 2016

* 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
Preventive Controls **Scientific & Technical** Questions from Industry – submit a web form at: [www.iit.edu/ifsh/alliance](http://www.iit.edu/ifsh/alliance)

**FSMA Regulation & Policy Interpretation**
Questions – submit a web form at: [www.fda.gov/fsma](http://www.fda.gov/fsma)

**FSMA Technical Assistance Networks**

Produce **Scientific & Technical** Questions from Industry

Produce Technical Assistance Network

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**FSMA Technical Assistance Network**

- **CVM**
- **CFSAN**
- **ORA**
- **OIP**

**FDA FSMA Technical Assistance Network**

**Extension Specialists**

- Land Grant Universities
- International Partners

**FSPCA Technical Assistance Network**

**PSA**

**SSA**

**KMS**

**ORI**

**OIP**

**CFSAN**

**CVM**

**International Partners**

- FDA-NIFA/ National & Regional Centers
- States/ NASDAQ

**Land Grant / Extension Specialists**

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[Image 647x462 to 696x521]
[Image 12x-8 to 102x69]
[Image 27x450 to 649x459]
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
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.
## Soil Amendments

<table>
<thead>
<tr>
<th>Type</th>
<th>Least</th>
<th>Non-Biological (e.g., elemental)</th>
<th>Non-Animal Origin</th>
<th>Animal Origin</th>
<th>Most</th>
<th>Human waste</th>
</tr>
</thead>
<tbody>
<tr>
<td>And where contamination is known to exist, the likelihood of contamination is a function of the following factors:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Treatment</strong></td>
<td></td>
<td>Pasteurized (heat, chemical, physical)</td>
<td></td>
<td></td>
<td>Untreated/Raw; Partially treated; Re-contaminated</td>
<td></td>
</tr>
<tr>
<td><strong>Application timing</strong></td>
<td></td>
<td>Further from harvest</td>
<td></td>
<td></td>
<td>Close to harvest</td>
<td></td>
</tr>
<tr>
<td><strong>Application method</strong></td>
<td></td>
<td>No contact with harvestable portion</td>
<td></td>
<td></td>
<td>Contact with harvestable portion</td>
<td></td>
</tr>
</tbody>
</table>
Part 112 – Subpart F – Biological Soil Amendments of Animal Origin and Human Waste

§ 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?
What is a BSAAO?

Soil Amendments

Chemical
(i.e. elemental fertilizers)

Biological (BSA)
(i.e. organic matter)

Physical
(i.e. perlite, rock dust, sand)
What is a BSAAO?

- Manure
- Non-fecal animal byproducts
- Table waste

BSAAO

BSA

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.
§ 112.51 – Determine whether your BSAAO is “Treated” or “Untreated”

• 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
§ 112.51 – Determine whether your BSAAO is “Treated” or “Untreated”

- **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
§ 112.54 / § 112.55 –BSAAO Treatment processes and associated microbiological standards

• 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>
§ 112.54 / § 112.55 – Acceptable treatment processes and associated microbiological standards

<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>
</tbody>
</table>

- **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
§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
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
Any Questions?