Southeastern Soil Summit – Georgia
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FSMA Produce Safety Rule Standards for Soil Amendments: Clarification on Requirements and Future Guidance

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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
FDA’s Produce Safety Network

Roles and Responsibilities

• Technical assistance
• Outreach and training
• Work planning
• Outbreak investigations
• Inspections *(particularly foreign)*
• Enforcement
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Draft Guidance

This guidance is being distributed for comment purposes only.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can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance within ___ days of publication in the Federal Register of the notice announcing the availability of the draft guidance.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.
# Soil Amendments

<table>
<thead>
<tr>
<th>Type</th>
<th>Least</th>
<th>Non-Animal Origin</th>
<th>Animal Origin</th>
<th>Most</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Non-Biological (e.g., elemental)</td>
<td></td>
<td></td>
<td>Human waste</td>
</tr>
</tbody>
</table>

And where contamination is known to exist, the likelihood of contamination is a function of the following factors:

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Pasteurized (heat, chemical, physical)</th>
<th>Composted</th>
<th>Untreated/Raw; Partially treated; Re-contaminated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application timing</td>
<td>Further from harvest</td>
<td></td>
<td>Close to harvest</td>
</tr>
<tr>
<td>Application method</td>
<td>No contact with harvestable portion</td>
<td>Effort made to minimize contact</td>
<td>Contact with harvestable portion</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?

BSAAO

Chemical
(i.e. elemental fertilizers)

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

Physical
(i.e. perlite, rock dust, sand)

Soil Amendments
What is a BSAAO?

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

**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

§ 112.3(a) “…. Agricultural teas are held for longer than one hour before application”
§ 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>Salmonella species</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>Fecal coliforms</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 – **Zero days-to-harvest interval**.

- **Treated BSAAO** – **Zero days-to-harvest interval** 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?