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

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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

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

Soil Amendments

| | | | | | |
|---|--|-------------------|---------------------------------|---|------|
| |  | | | Least | Most |
| Type | Non-Biological (e.g., elemental) | Non-Animal Origin | Animal Origin | Human waste | |
| <p>And where contamination is known to exist, the likelihood of contamination is a function of the following factors:</p> | | | | | |
| Treatment | Pasteurized (heat, chemical, physical) | | Composted | Untreated/Raw; Partially treated; Re-contaminated | |
| Application timing | Further from harvest | | | Close to harvest | |
| Application method | No contact with harvestable portion | | Effort made to minimize contact | Contact with harvestable portion | |

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?

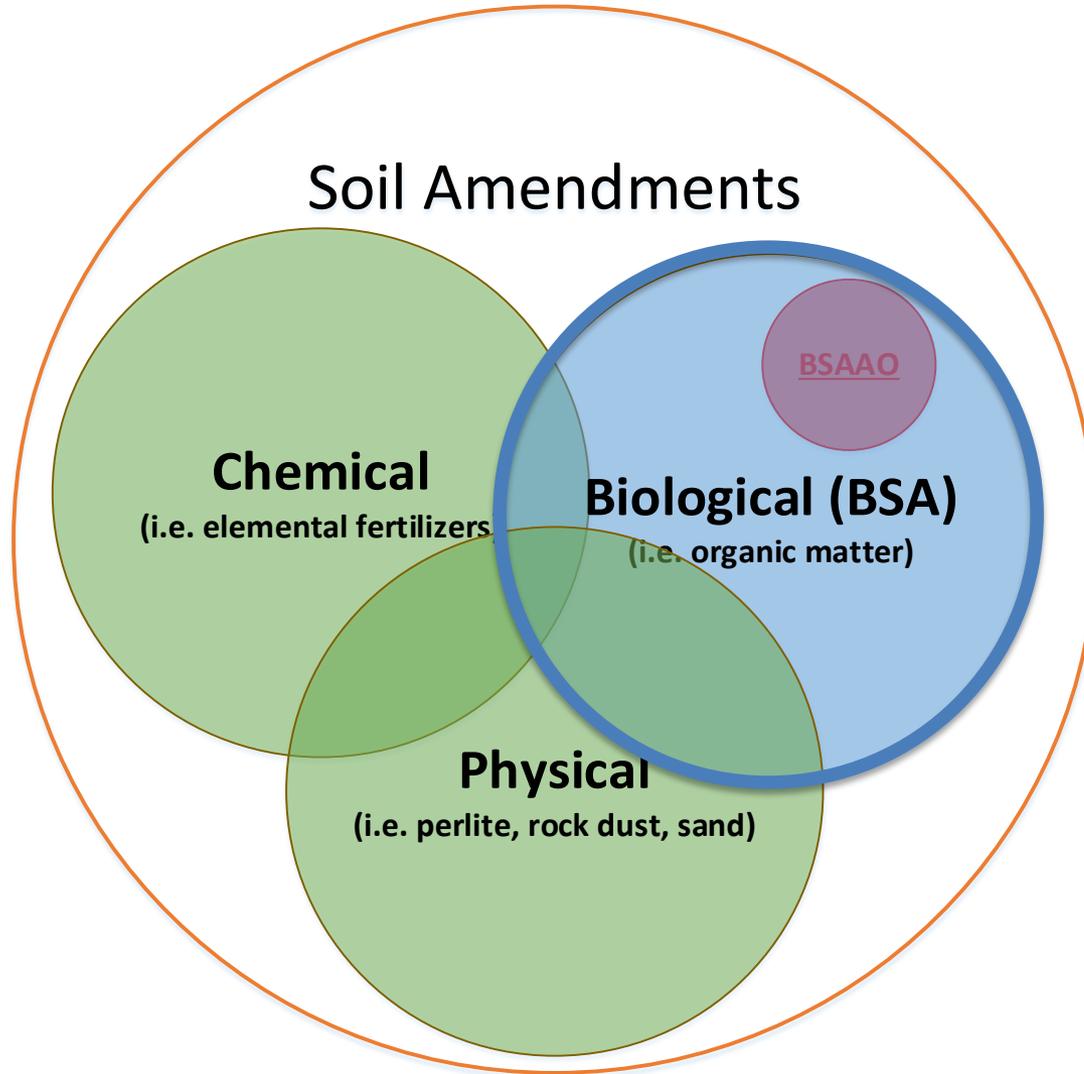
§ 112.54 – What treatment processes are acceptable for a BSAAO that I apply in the growing of covered produce?

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

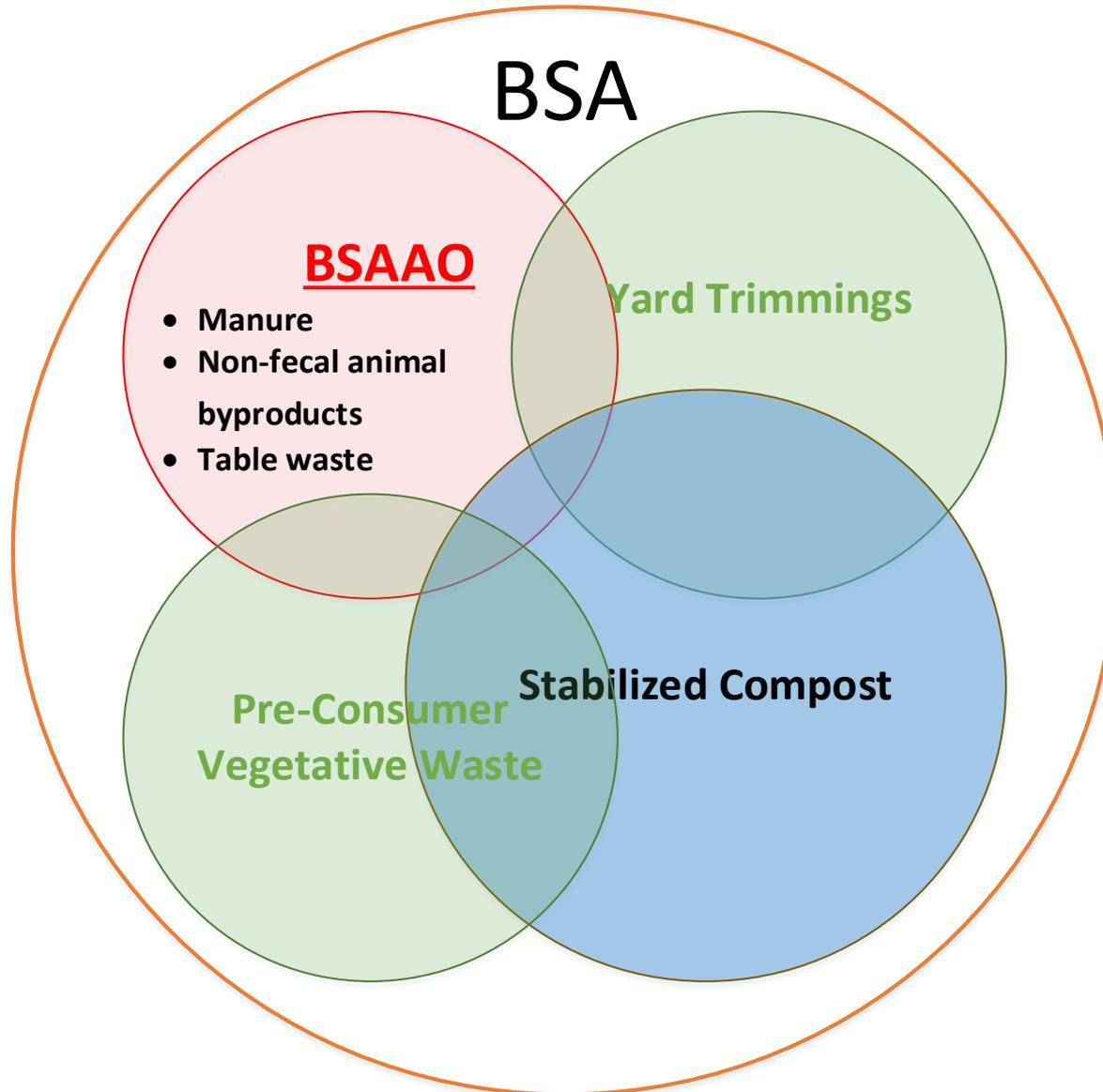
§ 112.56 – What application requirements and minimum application intervals apply to BSAAO ?

§ 112.60 – Under this subpart, what requirements apply regarding records?

What is a BSAAO ?



What is a BSAAO ?



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 – Acceptable treatment processes and associated microbiological standards

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

| 21 CFR § 112.55(a) | The microbial standard is - |
|---------------------------|--|
| <i>L. monocytogenes</i> | 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. |
| <i>Salmonella species</i> | 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. |
| <i>E. coli</i> O157:H7 | Not detected using a method that can detect 0.3 MPN per 1 gram (or milliliter, if liquid is being sampled) analytical portion. |

112.54 / 112.55 – Acceptable treatment processes and associated microbiological standards

| 21 CFR § 112.55 (b) | The microbial standard is - |
|---------------------------|--|
| Salmonella species | 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. |
| Fecal coliforms | Less than 1,000 most probable numbers (MPN) per gram (if liquid is being sampled) of total solids |

- **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)

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



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

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, South, North)

Agricultural practices (BSAAO application method, irrigation technique, etc.)

Climatic factors (temperature, rainfall, wind, moisture, etc.)

Crop type (root, low growing, stem)

Manure type (cattle, chicken, horse)

Pathogen strains



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

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:

<https://www.federalregister.gov/articles/2016/03/04/2016-04712/requests-for-information-risk-assessment-of-foodborne-illness-associated-with-pathogens-from-produce>

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>

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Any Questions ?

