

**Chapter 4: Biological Soil Amendments of
Animal Origin and Human Waste
and
Chapter 5: Domesticated and Wild Animals**

(Subparts F and I)

Chapter 4: Biological Soil Amendments of Animal Origin and Human Waste Overview



1. Determine Whether your Soil Amendment is a BSAAO
2. Determine Whether your BSAAO is “Treated” or “Untreated”
3. Determine the Appropriate Treatment Process and Associated Microbial Standard for your Treated BSAAO
4. Determine How to Apply your BSAAO
5. Determine the Requirements for Handling, Transporting, and Storing your BSAAO
6. Determine What Records to Keep for your Treated BSAAO

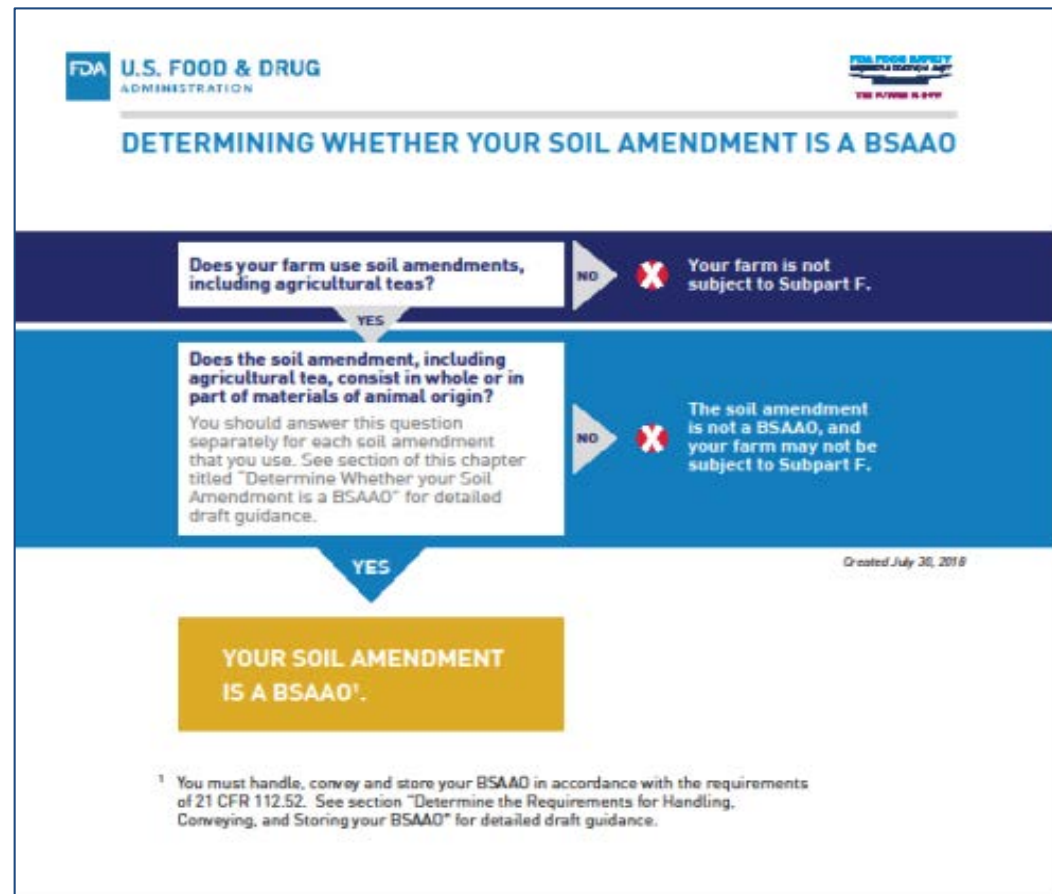
1. Determine Whether Your Soil Amendment is a BSAAO



- Defined terms, including:
 - Soil amendment, Biological soil amendment, Agricultural tea, Curing, Non-fecal animal by-products, Table waste, and Yard trimmings

- Examples

- Figure



2. Determine Whether Your BSAAO is “Treated” or “Untreated”



- Treated BSAAO
 - BSAAOs
 - Agricultural Teas that are BSAAOs
 - The rule does not require you or your supplier to conduct lot-by-lot microbial testing of treated BSAAOs
- Untreated BSAAO
 - Examples
 - Options for management

3. Determine the Appropriate Treatment Process and Associated Microbial Standard for Your Treated BSAAO



- Treatment processes validated to meet the relevant microbial standard
- Recommendations to process your BSAAO to completion
 - Establish procedures to deliver the scientifically valid, controlled process throughout the BSAAO;
 - Administer the treatment process in a controlled manner to ensure treatment parameters are achieved throughout the BSAAO material;
 - Ensure that the treatment parameters are achieved in areas of the material where delivery of the process could be more challenging to achieve



4. Determine How to Apply Your BSAAO

- Factors to Consider
 - Treatment Status, Level of Treatment and Application Restrictions
 - The application methods that you could use and the likelihood of contact between the BSAAO and the harvestable or harvested part of the crop
 - The type of covered produce and maturity at the time of application
 - Location of the growing area and environmental conditions
- Recommendations, Examples and Figures for Application of Untreated and Treated BSAAOs

4. Determine How to Apply Your BSAAO, continued



Figure 4f. Microbial Standards and Application Requirements for Treated BSAAOs.

BSAAO Treatment Process (§ 112.54)	BSAAO Microbial Standards (§ 112.55) for <i>L. monocytogenes</i>	BSAAO Microbial Standards (§ 112.55) for <i>Salmonella</i>	BSAAO Microbial Standards (§ 112.55) for <i>E. coli</i> O157:H7	BSAAO Microbial Standards (§ 112.55) for Fecal Coliforms	BSAAO Application (§112.56)	BSAAO Application (§112.56) Minimum Interval
§ 112.54(a) – Scientifically Valid Treatment Process to meet § 112.55(a) ⁵	Not detected ¹	Not detected ²	Not detected ³	Not Applicable	Any manner (no restrictions) (§ 112.56(a)(3))	0 Days
§ 112.54(b) – Scientifically Valid Treatment process to meet § 112.55(b) ⁶	Not Applicable	Not detected ²	Not Applicable	<1,000 MPN per gram (total solids) ⁴	Minimizes potential contact during and after application (§ 112.56(a)(2))	0 Days

¹Using a method that can detect 1 CFU per 5 grams (or milliliter, if liquid is being sampled) analytical portion.

²Using a method that can detect 3MPN *Salmonella* species per 4 grams (or milliliter, if liquid is being sampled) of total solids.

³Using a method that can detect 0.3 MPN per 1 gram (or milliliter, if liquid is being sampled) analytical portion

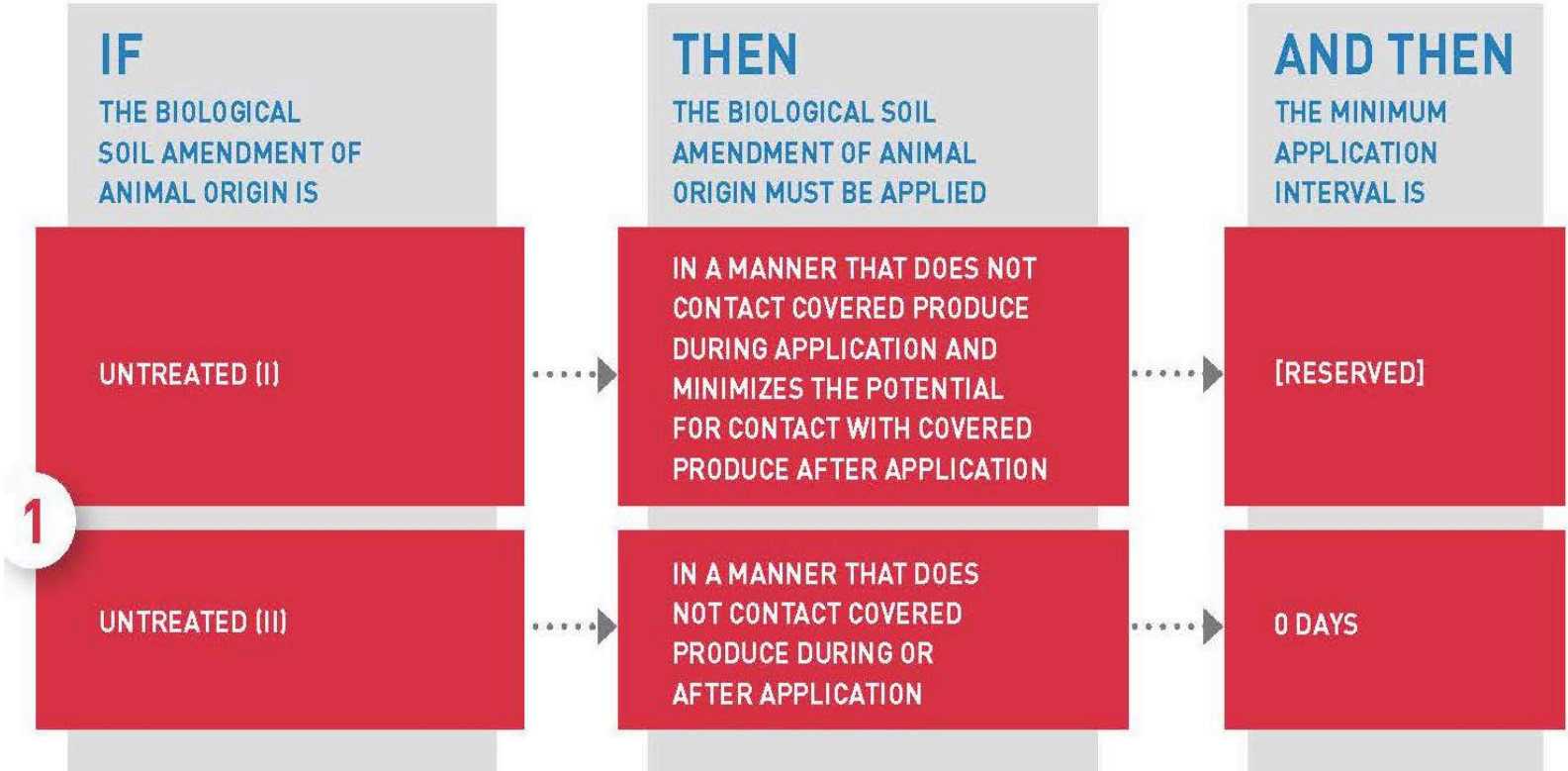
⁴Per milliliter (if liquid is being sampled) of total solids (dry weight)

⁵See figure 4d.

⁶See figure 4e.

Application Requirements and Minimum Application Intervals for BSAAOs

Application Requirements and Minimum Application Intervals for BSAAOs (21 CFR 112.56)



5. Determine the Requirements for Handling, Transporting and Storing your BSAAO



- Recommendations
 - Evaluate your practices for BSAAOs (both treated and untreated) for the potential to contaminate your:
 - Growing areas;
 - Water sources;
 - Water distribution systems;
 - Other soil amendments (including treated BSAAOs); and
 - Areas used for covered activities, covered produce, and food contact surfaces.
 - Evaluate storage practices and locations
 - Evaluate use of equipment and tools
 - Ensure personnel, supervisors and responsible parties:
 - Understand the potential routes of contamination associated with BSAAOs; and
 - Understand how to take appropriate corrective measures

Chapter 5: Domesticated and Wild Animals



1. Determining Reasonable Probability That Animals Will Contaminate Covered Produce
2. Assessing Relevant Areas for Evidence of Potential Contamination of Covered Produce
3. Evaluating Significant Evidence of Potential Contamination of Covered Produce by Animals to Determine Whether Harvest Can Occur

1. Determining Reasonable Probability That Animals Will Contaminate Covered Produce



- Recommendations and Examples
 - Identify outdoor areas and partially-enclosed buildings on your farm where covered activities occur during the growing season; and
 - Determine whether, under your specific circumstances, there is a reasonable probability that animals will contaminate covered produce in these identified areas
 - Evaluate your farm's covered produce, conditions, and practices, and potential types of animals based on available historical observations and other information and factors
 - Periodically re-evaluate conditions and practices
 - Examples

2. Assessing Relevant Areas for Evidence of Potential Contamination of Covered Produce



- Developing and modifying your approach to assessment
 - Recommendation to periodically evaluate your approach and modify as needed
 - Factors to consider
 - Personnel, timing and frequency of monitoring, reporting of observations
 - Types and expected numbers of animals
 - Expected frequency of animal activity
 - Likely locations and expected time of day
 - Examples
- Performing monitoring activities

3. Evaluating Significant Evidence of Potential Contamination of Covered Produce by Animals to Determine Whether Harvest Can Occur



- If there is significant evidence of potential contamination, you must:
 - Evaluate whether the covered produce can be harvested in accordance with the requirements; and
 - Take measures reasonably necessary during growing to assist you later during harvest when you must identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard.
- Should consider the extent of the evidence
- Examples

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