

Biological Soil Amendments of Animal Origin (BSAAO) Factsheet:

Manner of Application Requirements & Examples

| Type of BSAAO | Untreated | Treated (less strict)* | Treated (more strict)* |
|----------------------------------|--|--|--|
| Manner of Application | An untreated or partially treated BSAAO. | A treatment process that meets Salmonella species and fecal coliform microbial standards. E.g., turned or aerated composted animal manure. See 21 CFR §112.54(b). | A treatment process that meets Listeria monocytogenes, Salmonella species, and E. coli O157:H7 microbial standards. E.g., scientifically valid heat-treated animal by-product. See 21 CFR §112.54(a). |
| Examples of Acceptable Practices | <p>The BSAAO must be applied in a manner that does not contact the harvestable part of covered produce during application; AND, does not contact the harvestable part of covered produce after application, OR, minimizes the potential for contact with the harvestable part of covered produce after application.</p> <p><u>Example: Melons grown on plasticulture</u></p> <p>An untreated BSAAO (such as partially composted animal manure) applied during or prior to field preparation for a covered crop with the harvestable portion that grows on the ground (such as melons) where plasticulture (e.g. “black plastic”) is used to minimize potential contact with the BSAAO after application.</p> <ul style="list-style-type: none"> All BSAAOs must be handled, conveyed, and stored in a manner and location to minimize the risk of contamination. See 21 CFR §112.52. For additional examples see FDA Draft Guidance, Chapter 4: https://go.usa.gov/xEA2r | <p>The BSAAO must be applied in a manner that minimizes the potential for contact with the harvestable part of covered produce during application; AND, minimizes the potential for contact after application.</p> <p><u>Example: Turned composted animal manure</u></p> <p>Composted animal manure that maintains aerobic conditions at a minimum of 131 °F for 15 days (not necessarily consecutive), with a minimum of five turnings, and followed by adequate curing. Similar to National Organic Program (NOP) guidelines. Cannot be used to grow a covered crop with the harvestable part that grows in the soil (e.g. a root crop).</p> | <p>The BSAAO can be applied in any manner (i.e., no restrictions).</p> <p><u>Example: Heat-treated animal by-product</u></p> <p>A scientifically valid heat-treated animal by-product that is applied and carried out with appropriate process monitoring. Documentation such as a Certificate of Conformance is required from the product supplier. See record requirements on the reverse side for further details.</p> |
| Application Interval | <p>Does not contact covered produce during or after application: 0 days.</p> <p>Does not contact covered produce during application and minimizes contact after application: Reserved; no application interval at this time.</p> | <p>0 days.</p> <p>*Treated BSAAOs must maintain record requirements (see reverse side for details).</p> | <p>0 days.</p> |

Questions? Contact the Vermont Agency of Agriculture at AGR.FSMA@vermont.gov or (802) 522-3132.

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Definitions

21 CFR part 112, Subpart A, § 112.3 (<https://go.usa.gov/xEA2C>)

Agricultural tea means a water extract of biological materials (such as stabilized compost, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, table waste, or yard trimmings), excluding any form of human waste, produced to transfer microbial biomass, fine particulate organic matter, and soluble chemical components into an aqueous phase. Agricultural teas are held for longer than one hour before application. Agricultural teas are soil amendments for the purposes of this rule.

Agricultural tea additive means a nutrient source (such as molasses, yeast extract, or algal powder) added to agricultural tea to increase microbial biomass.

Biological soil amendment of animal origin (BSAAO) means a biological soil amendment which consists, in whole or in part, of materials of animal origin, such as manure or non-fecal animal byproducts including animal mortalities, or table waste, alone or in combination. The term “biological soil amendment of animal origin” does not include any form of human waste.

Covered produce means produce that is subject to the requirements of this part in accordance with §§ 112.1 and 112.2. The term “covered produce” refers to the harvestable or harvested part of the crop.

“Minimize the potential for contact” means there is no intended contact between the BSAAO and covered produce during the relevant time period, but some unintentional contact is likely due to incidental or environmental action. See FDA 2018, *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: Guidance for Industry Draft Guidance*, page 68 (<https://go.usa.gov/xEA2r>).

Determining the status of a BSAAO

21 CFR part 112, Subpart F, § 112.51 (<https://go.usa.gov/xEA2g>)

(a) A biological soil amendment of animal origin is treated if it has been processed to completion to adequately reduce microorganisms of public health significance in accordance with the requirements of §112.54, or, in the case of an agricultural tea, the biological materials of animal origin used to make the tea have been so processed, the water used to make the tea is not untreated surface water, and the water used to make the tea has no detectable generic *Escherichia coli* (*E. coli*) in 100 milliliters (mL) of water.

(b) A biological soil amendment of animal origin is untreated if it:

- (1) Has not been processed to completion in accordance with the requirements of §112.54, or in the case of an agricultural tea, the biological materials of animal origin used to make the tea have not been so processed, or the water used to make the tea is untreated surface water, or the water used to make the tea has detectable generic *E. coli* in 100 mL of water;
- (2) Has become contaminated after treatment;
- (3) Has been recombined with an untreated biological soil amendment of animal origin;
- (4) Is or contains a component that is untreated waste that you know or have reason to believe is contaminated with a hazard or has been associated with foodborne illness; or
- (5) Is an agricultural tea made with biological materials of animal origin that contains an agricultural tea additive.

BSAAO Record Requirements

21 CFR part 112, Subpart F, § 112.60 (<https://go.usa.gov/xEA22>)

(a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.

(b) For any biological soil amendment of animal origin you use, you must establish and keep the following records:

(1) For a treated biological soil amendment of animal origin you receive from a third party, documentation (such as a Certificate of Conformance) at least annually that:

(i) The process used to treat the biological soil amendment of animal origin is a scientifically valid process that has been carried out with appropriate process monitoring; and

(ii) The biological soil amendment of animal origin has been handled, conveyed and stored in a manner and location to minimize the risk of contamination by an untreated or in process biological soil amendment of animal origin; and

(2) For a treated biological soil amendment of animal origin you produce for your own covered farm(s), documentation that process controls (for example, time, temperature, and turnings) were achieved.

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