

Biological Soil Amendments of Animal Origin (BSAAO)

Food Safety Modernization Act (FSMA) Fact Sheet for Produce Growers

What is a BSAAO?

Any soil amendment intentionally added to the soil to improve the chemical or physical condition that contains an animal ingredient (manure, fish emulsion, egg shells, blood meal, bone meal, etc.). If it comes from an animal in any way, shape, or form, it's a BSAAO. This fact sheet is intended for growers using a BSAAO.

Is it OK to use BSAAO?

Absolutely! This fact sheet discusses how to properly use treated and untreated soil amendments of animal origin.

When is a BSAAO considered treated?

If the treatment was a scientifically valid controlled process. This process can be physical (e.g. thermal), chemical (e.g. high alkaline pH), biological (e.g. composting), or a combination of those. The treatment process must be validated to satisfy the microbial standard of 21 CFR Part 112, described on page 2.

Can I do the composting myself?

Yes. Just remember you must use a scientifically valid controlled process for composting and record your conditions. Aged or stacked manure is not considered a valid treatment process.

If I am doing the composting, do I have to send samples for testing?

No. You must keep a record documenting process controls (e.g. time, temperature, and turnings).

What if I am purchasing a treated soil amendment of animal origin?

To be considered a treated BSAAO, you will need an annual Certificate of Conformance from the supplier.

- Treatment process is a scientifically valid process that has been carried out with appropriate process monitoring; and

- The amendment has been handled, conveyed and stored in a manner and location to minimize the risk of contamination.

Are there minimum time intervals from applying a BSAAO to harvesting of produce?

The treatment status determines the time interval from application to harvest (21 CFR Part 112 Subpart F). See Page 2 for a detailed breakdown of guidelines.

Treatment Type	Application Method	Time Interval
Untreated	Does not contact produce during and minimizes the potential for contact after application	Under review current best practice is NOP 90/120-day rule
Untreated	Does not contact produce during or afterwards	Unrestricted
Treated § 112.54(a)	Unrestricted	Unrestricted
Treated § 112.54(b)	Minimizes potential for produce contact during and after	Unrestricted

What about biosolids?

You may not use human waste for growing covered produce, except sewage sludge biosolids used in accordance with the requirements of 40 CFR part 503, subpart D, or equivalent regulatory requirements. Know your local and state regulations for potential restrictions outside the FSMA Produce Safety Rule.

What are the requirements for applying, handling, transporting and storing your BSAAO?

The goal is to minimize the potential for contamination of the following: 1) agricultural water and distribution systems, 2) food contact surfaces, 3) other soil amendments, 4) other covered produce, and 5) growing, holding, and packing areas. Each farm has unique topography and weather patterns. Be conscious of how and where you are storing BSAAOs, equipment cleanliness, and weather during/immediately

after application. Be diligent to avoid cross-contamination. Establish measures that minimize the potential for contamination (for example having procedures for cleaning and sanitizing equipment between uses or having dedicated equipment for handling untreated BSAAOs). Personnel should understand potential routes of contamination and how to report problems.

21 CFR Part 112 guidelines for treatment validation requirements and application intervals

If BSAAO is treated to § 112.54(a)

- Applied in any manner with no restrictions
- 0 day harvest interval

L. monocytogenes	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.
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Salmonella spp	Not detected using a method that can detect three most probable numbers (MPN) per 4 grams of total solids (or milliliter, if liquid is being sampled).
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E. coli 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.
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If BSAAO is treated to § 112.54(b)

- Applied in manner minimizing potential for produce contact during/after application.
- 0 day harvest interval.

Salmonella spp	Not detected using a method that can detect three most probable numbers (MPN) per 4 grams of total solids (or milliliters, if liquid is being sampled).
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Fecal Coliforms	<1,000 MPN fecal coliforms per gram of total solids (dry weight basis).
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Two options under § 112.54(b) are 1) static composting that maintains aerobic conditions at a minimum of 131°F for 3 consecutive days and is followed by adequate curing; and 2) turned composting that maintains aerobic conditions at a minimum of 131°F for 15 days (do not have to be consecutive), with a minimum of five turnings, and is followed by adequate curing.

Is it possible to grow produce in or on the ground so that contact with produce is minimized after application? This is a discussion you could have with your local extension agent and inspection authority.

Untreated BSAAO

Applied in a manner that does not contact produce during or after application = 0 day harvest interval.

Untreated BSAAO carries a high risk for pathogens, Can you be certain the untreated BSAAO will never contact produce during or after application? Consider rain, wind, traffic, runoff, topography, application method, etc. Are there any circumstances on your farm where it is safe to make this decision?

Untreated BSAAO

Applied in a manner that does not contact covered produce during application and **minimizes the potential for contact** with produce after application = Under FDA review.

Current best practice is to use the National Organic Program (NOP) 90/120 day rule - see 7 CFR Part 205.203(c).

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