

Frequently Asked Questions: Biological Soil Amendments of Animal Origin under the FSMA Produce Safety Rule

What are Biological Soil Amendments of Animal Origin (BSAAO)?

- Biological soil amendment[s] of animal origin are biological soil amendments which consist, 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.
- Biological soil amendments are any soil amendments containing biological materials such as stabilized compost, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea, or yard trimmings, alone or in combination.
- Biological soil amendments of animal origin include untreated: cattle manure; poultry litter; swine slurry; or horse manure.

Does the Produce Safety Rule prohibit the use of untreated biological soil amendments of animal origin?

No. The Produce Safety Rule does not prohibit farms from using untreated BSAAO, including manure produced as part of a sustainability or co-management program, nor does it prohibit farms from producing or storing compost on site. Covered farms must conduct relevant activities in accordance with the provisions of the Produce Safety Rule, such as handling, conveying, and storing untreated BSAAO such that they do not contaminate treated BSAAO and do not become a potential source of contamination to covered produce, food-contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems. When utilized for produce production, untreated BSAAO must not be applied in a manner that contacts covered produce during application ([21 CFR § 112.56\(a\)\(1\)](#)).

Where in the Produce Safety Rule can I find the requirements on biological soil amendments of animal origin?

Requirements for biological soil amendments of animal origin can be found in Subpart F ([21 CFR §§ 112.50-60](#)), in the Produce Safety Rule ([21 CFR Part 112](#)).

What is the difference between treated and untreated biological soil amendments of animal origin?

- A biological soil amendment of animal origin is **treated** if it has been processed to completion to adequately reduce microorganisms of public health significance (i.e.

Listeria monocytogenes, *Salmonella* spp., and *E. coli* O157:H7) in accordance with the requirements of § 112.54.

- A biological soil amendment of animal origin is **untreated** if it:
 - Has not been processed to completion in accordance with the requirements of § 112.54;
 - Has become contaminated after treatment;
 - Has been recombined with an untreated biological soil amendment of animal origin; or
 - 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.

Does the Produce Safety Rule require testing for treated biological soil amendments of animal origin?

No. FDA does not require microbial testing of any biological soil amendments of animal origin. Instead, we have provided the microbial standards to which treatment processes described in §112.54 must be validated. Farms can use any controlled treatment process or processes that have been scientifically validated to meet the relevant microbial standards in § 112.55 without the need to test the end products. For static and turned composting processes, we have codified in §§112.54(b)(1) and (b)(2), respectively, two scientifically validated BSAAO treatment processes that have already been validated to meet the microbial standards in §112.55(b). If your operation follows one of these two examples of a biological treatment process (i.e., turned or static composting), then you would not have to do any process validation.

How will FDA establish application intervals for untreated biological soil amendments of animal origin to my field?

We have deferred action on an application interval (or intervals) until we have completed certain steps. We have recently completed a risk assessment and supporting research to supplement science on understanding what effectiveness the integration of an appropriate interval or intervals may have on protecting public health. Now that this research and risk assessment activity has been finalized, we intend to:

- (1) Provide stakeholders with data and information gathered from scientific investigations and risk assessment;
- (2) Consider such data and information to develop policy decisions from the science-based conclusions;
- (3) Follow traditional rulemaking procedures which will provide an opportunity for public comment on our tentative decisions; and

(4) Consider public input before the Agency finalizes the provision(s) establishing an appropriate minimum application interval(s).

What documents do I need if I use treated biological soil amendments of animal origin in accordance with §112.56(a)(2) and/or §112.56(a)(3) (application restrictions) for covered produce?

If you receive treated biological soil amendments of animal origin from a third party, § 112.60(b)(1)(i) requires covered farms to:

- Receive and maintain documentation, at least annually, demonstrating that 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.
- Receive and maintain documentation, at least annually, that 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.

If your farm produces its own treated biological soil amendment of animal origin, § 112.60(b)(2) requires your farm to have documentation that process controls for the validated treatment process you use were achieved during treatment, such as time, temperature, and turnings. Any form of documentation is acceptable, provided that it includes the information required in § 112.60(b)(1) and also follows the general record keeping requirements in § 112.161 (Subpart O).

Should FDA establish application intervals greater than zero days for any uses of biological soil amendments of animal origin at a later date, we may also establish appropriate recordkeeping requirements related to those intervals.