

FDA FACT SHEET

Produce Safety Rule (21 CFR 112)

BIOLOGICAL SOIL AMENDMENTS OF ANIMAL ORIGIN

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 waste¹.
- *Biological soil amendments* are any soil amendment 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 biological soil amendments of animal origin?

No. The Produce Safety Rule **does not prohibit** farms from using a 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, agricultural water distribution systems, or treated soil amendments.

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 (§§ 112.50-60), in the Produce Safety Rule.

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 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

¹ 21CFR §112.53 states that the use of human waste is prohibited 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.

- 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 treatment process or processes that have been validated to meet the relevant microbial standard 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.

When can I harvest my crop after I apply untreated biological soil amendments of animal origin to my field?

We are deferring action on an application interval until we have pursued certain steps. We are conducting 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. Following the completion of the risk assessment and research, we expect to:

- (1) Provide stakeholders with data and information gathered from scientific investigations and risk assessment;
- (2) consider such new data and information to develop policy decisions from the science-based conclusions;
- (3) provide an opportunity for public comment on our tentative decisions; and
- (4) consider public input to finalize 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 on 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 will also establish appropriate recordkeeping requirements related to those intervals.

When will FDA update the Produce Safety Rule with new information about untreated biological soil amendments of animal origin?

FDA, in consultation with the U.S. Department of Agriculture, is conducting a risk assessment to evaluate the risk of human illness associated with the consumption of produce grown in growing areas amended with untreated BSAAO that are potentially contaminated with enteric pathogens such as *E. coli* O157:H7 or *Salmonella*. The risk assessment will evaluate the impact of different agricultural and ecological conditions and certain interventions, such as use of a time interval or intervals between application of untreated BSAAO and crop harvest, on the predicted risk. We anticipate that these efforts will take 5 to 10 years to complete from the date of publication of the rule.

For more information:

- **FSMA Final Rule on Produce Safety.**
<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>
- **Produce Safety Network:**
ProduceSafetyNetwork@fda.hhs.gov

Have you seen our Blog? [FDA Voice](#)



The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, and products that give off electronic radiation, and for regulating tobacco products.

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
College Park, MD, 20740
www.fda.gov