

AT A GLANCE: KEY POINTS IN THE PRODUCE SAFETY RULE DRAFT GUIDANCE

CHAPTER 4: BIOLOGICAL SOIL AMENDMENTS OF ANIMAL ORIGIN AND HUMAN WASTE (SUBPART F)

What is the goal of this chapter?

To help farmers comply with requirements for minimizing the risk of produce contamination from certain soil amendments, which are materials added to the soil to help plant growth or to improve the capacity of the soil to retain water. The materials that the requirements focus on are called biological soil amendments of animal origin (BSAAOs). They are materials that come from animals, such as manure or non-fecal animal byproducts.

The use of unsafe agricultural practices, particularly ones involving an untreated BSAAO, could lead to a foodborne illness from the consumption of contaminated produce.

References to “you” in this document (as well as in the Produce Safety Rule and draft guidance) mean the owner, operator, or agent in charge of a covered farm that is subject to some or all of the requirements of the rule. In addition, unless otherwise specified, we’re only talking about produce covered by the rule.

Who does this most affect?

Farms that use biological soil amendments of animal origin.

Is it a BSAAO?

Farmers should first determine whether materials they’re adding to their soil would be classified as BSAAOs. Examples of BSAAOs include treated compost or compost ingredients containing materials that come from animals, manure, straw or grass that are known to include significant animal waste, non-fecal animal byproducts (i.e., eggs, fat, milk, meat, shellfish waste, fish emulsions, and fish, bone or blood meal), and leftover scraps from the kitchen (table waste).

This includes water extracts, known as agricultural teas, from biological materials like manure and compost that contain materials that come from animals.

Note that you cannot use human waste for growing produce, except sewage sludge biosolids that are used following certain requirements.

Is the BSAAO treated or untreated?

The treatment status of your BSAAO determines what application restrictions apply in the Produce Safety Rule. A treated BSAAO has been processed using a treatment that has been confirmed to adequately reduce the potentially dangerous microorganisms that are often



linked to outbreaks of foodborne illness. An agricultural tea is considered treated if the biological materials that come from animals meet the treatment requirements, the water used is not untreated surface water, there are no detectable generic *E. coli* in 100 ml of water used to make the tea, and no agricultural tea additives are used (such as molasses).

“Untreated” means exactly that – the BSAAO has not been treated in accordance with the Produce Safety Rule requirements.

For more information and examples, see the “Determine Whether your BSAAO is ‘Treated’ or ‘Untreated’” section in Chapter 4 of the draft guidance, specifically the subsection on untreated BSAAO.

Even if a BSAAO is treated, if it comes in contact with an untreated BSAAO, or is contaminated after treatment, it is then considered untreated. This could happen, for example, if treated compost comes in contact with runoff from untreated cow manure or bedding materials containing animal feces are added to the BSAAO after treatment.

What treatment processes can be used?

The Produce Safety Rule describes acceptable treatment processes that, when done properly, will result in BSAAOs that meet the specified microbial standards. You are not required to conduct microbial testing of your treated BSAAOs, but farms should ensure that the treatment processes they use – if not the example treatments given in the Produce Safety Rule – are valid and meet the rule’s standards. You could, for example, work with technical assistance resources, such as your suppliers, academia, extension services, and industry associations to assist you with evaluating validation studies and your practices.

- There are two levels of treatment described in the rule, one of which has a more rigorous microbial standard and specifies microbial standards for *L. monocytogenes*, *E. coli* O157:H7, and *Salmonella* species. The other treatment level specifies microbial standards for *Salmonella* species and fecal coliforms. The treatment level you choose will affect the application method allowed under the Produce Safety Rule.
- Treatment options include: physical (e.g., heat); chemical (e.g., high alkaline pH), and biological (e.g., composting) processes, or a combination of these. You have the flexibility to determine the treatment process that you use, but it must be scientifically valid, meaning based on scientific information, data, or results published in a scientific journal, references, text books, peer-reviewed literature, or in proprietary research.

The two specific examples for composting included in the Produce Safety Rule represent scientifically valid processes that meet one of the microbial standards:

- Static composting that maintains aerobic (i.e., oxygenated) conditions at a minimum of 131 degrees F for three consecutive days and is followed by adequate curing; and
- Turned composting that maintains aerobic conditions at a minimum of 131 degrees F for 15 days (which do not have to be consecutive), with a minimum of five turnings, and is followed by adequate curing.

You should establish procedures to ensure effective delivery of the treatment throughout the BSAAO materials, including where delivery could be more challenging, such as the bottom or edges of a BSAAO pile.

For more information and examples, see the section entitled “Determine the Appropriate Treatment Process and Associated Microbial Standard for your Treated BSAAO” in Chapter 4 of the draft guidance, specifically the subsection on processes to treat BSAAOs.

How can you apply the BSAAO?

The requirements for the application of the BSAAO are tied to whether it has been treated and what level of treatment it has received. Factors to consider include:

- How you’re applying the BSAAO and the likelihood for contact with the harvestable or harvested part of the crop. For example, a broadcast application that is applied across an entire field will usually result in contact; using a shovel to apply the material to the soil around the base of crops where the harvestable part is growing high above the ground, such as pistachios, is unlikely to result in contact.
- Practices after application that can influence the likelihood of contact (such as incorporating a BSAAO into the soil or using plastic materials to cover the ground).
- The type of produce (for example, whether the crop grows in the ground, low to the ground or high above the ground).
- The maturity of the crop at the time of application.
- The location of the growing area where the BSAAO is applied with respect to surrounding growing areas. (For example, if there is produce covered by the rule in an adjacent field.)
- Any environmental conditions that may impact movement of BSAAO particles.

For more information and examples, see the “Determine How to Apply your BSAAO” section in Chapter 4 of the draft guidance.

What are the restrictions on the application of treated BSAAOs?

- Treated BSAAOs that meet the more rigorous microbial standard may be applied in any manner and crops may be harvested immediately after the treated BSAAO is applied. There is no requirement that the application does not contact or minimizes contact with crops.
- Treated BSAAOs that meet the less rigorous microbial standard must be applied in a manner that minimizes the potential for contact with produce during and after application. Produce can be harvested immediately after this BSAAO is applied.

What are the restrictions on the application of untreated BSAAOs?

- Untreated BSAAOs may only be used if applied in a way that does not contact produce during application and it either has no contact after application or the potential contact is minimized after application.
 - For untreated BSAAOs that have no contact with produce during or after application, produce can be harvested immediately after the BSAAO is applied.
 - For untreated BSAAOs that have no contact with produce during and minimize the potential for contact after application, FDA has not provided a minimum application interval until we pursue certain steps, including a risk assessment and further research. However, the USDA's National Organic Program standard of 90-120 days from application to harvesting is a prudent step toward minimizing the potential for contamination.

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

The goal is to minimize the potential for contamination of water sources or water distribution, other soil amendments (including treated BSAAOs), growing areas or areas used for other covered activities, as well as the covered produce and food contact surfaces.

- You should evaluate the storage location of your BSAAOs and your storage practices. The BSAAOs should not be stored in an area where runoff from rain or another source could contaminate produce, water or other soil amendments.
- You should evaluate your practices, equipment and personnel involved to minimize the potential for contamination.
 - You could consider using separate storage locations and equipment for untreated and treated BSAAOs, establish procedures for cleaning and sanitizing equipment between uses, or other measures that minimize the potential for contamination.
- Personnel should understand the potential routes of contamination and when to report problems to supervisors or responsible parties.

What records do you need to keep?

For treated BSAAOs that are supplied from a third party, you are required to get documentation once a year that certifies that the BSAAO was properly treated, handled, transported, and stored.

For BSAAOs that you treat on your farm, you must have documentation to show that the process controls (for example, time, temperature and turnings) were achieved.

For further explanation of the underlined words, see the [Key Terms Glossary](#).

The [draft guidance](#) contains more details and examples of FDA's recommendations and current thinking. It is recommended that you review the draft guidance for complete information.