

FSMA Produce Safety Rule: Documentation Requirements for Commercial Soil Amendment Suppliers

*Donna Clements, Laura Acuña-Maldonado, Connie Fisk, Don Stoeckel, Gretchen Wall, Kristin Woods, and Elizabeth Bihn
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The Food Safety Modernization Act (FSMA) Produce Safety Rule, a regulation intended to reduce the number of foodborne illness outbreaks associated with fruits and vegetables, sets requirements for certain agricultural inputs ([FDA Final Rule fact sheet](#))¹. These inputs include biological soil amendments of animal origin (BSAAOs) such as untreated manure and composted manure. Growers subject to the FSMA Produce Safety Rule and those using BSAAOs should be aware of these requirements as they may be legally required or impact the ability to market fruits and vegetables.

BSAAOs, especially those which have not been treated to reduce or eliminate human pathogens, may serve as a potential source of contamination to produce crops. The FSMA Produce Safety Rule requires growers to implement specific practices to prevent BSAAOs from contaminating fresh produce ([FDA BSAAO fact sheet](#))². Growers using a treated BSAAO, such as compost, are required to keep documentation that the amendment was properly treated, handled, and stored before being applied to a produce field. This documentation is especially important as growers prepare for FSMA Produce Safety Rule compliance and inspections. Though FDA does not have jurisdiction over companies that supply treated BSAAOs, suppliers should be prepared to provide this documentation to growers as needed.

What is required of growers purchasing BSAAOs from third-party suppliers?

Growers purchasing BSAAOs from third-party suppliers are required to document that the soil amendment has been treated, handled, and stored in a safe manner. These requirements include:

1. The treatment is a scientifically valid process that was carried out with appropriate process monitoring (§ 112.60(b)(1)(i)) (see sidebar on page 2 for more information); and



A biological soil amendment of animal origin (BSAAO) is 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.

Additional soil amendment definitions can be found in the [Produce Safety Alliance Glossary](#)³.

2. The BSAAO has been handled, conveyed and stored in a manner and location to minimize the risk of contamination by an untreated or in process soil amendment (§ 112.60(b)(1)(ii)).

The FSMA Produce Safety Rule requires that this documentation be updated at least annually. The FDA states in the codified regulation and in draft guidance that a Certificate of Conformance would meet the above recordkeeping requirements. If a grower cannot obtain the appropriate documentation, one practical solution is to handle and apply the soil amendment as if it were untreated.

What documentation should commercial BSAO suppliers provide to satisfy FSMA Produce Safety Rule recordkeeping requirements?

Third-party soil amendment providers should supply a Certificate of Conformance to buyers as documentation stating that the BSAO meets the treatment and handling requirements in the FSMA Produce Safety Rule. A model Certificate of Conformance can be found at the end of this fact sheet.

Commercial BSAO suppliers with pre-existing Certificates of Conformance might consider adding an attestation statement to their existing documentation, if requested. The [FSMA Produce Safety Rule draft guidance](#)⁴ provides a sample attestation statement that may apply to, for example, Heat Treated Poultry Pellets: “A scientifically valid thermal treatment was applied and carried out with appropriate process monitoring to satisfy the microbial standard in 21 CFR 112.55(a). The BSAO has been handled, conveyed, and stored in a manner and location to minimize the risk of contamination.”

Commercial BSAO suppliers should consider including documentation to support the Certificate of Conformance so that anyone reviewing the documentation can evaluate the treatment process and handling. Examples of additional documentation may include:

- Description and records of the treatment process, including relevant process controls (e.g., time, temperature, number and timing of turnings). An example of a basic treatment record from the [PSA Required Records fact sheet](#)⁵ can be found in Figure 1.
- Validation studies demonstrating treatment effectiveness conforming to one of the microbial standards in § 112.55. Two methods (see sidebar on this page) have already been validated to meet the criteria in § 112.55(b). These specific methods, if used, do not require additional validation. Documentation in support of treatment effectiveness should be provided for other treatment processes that may be used.
- Written description of how the BSAO is handled, cured, transported, and stored. Emphasis should be placed on minimizing risk of cross-contamination between treated and untreated BSAOs.

References

1. U.S. Food and Drug Administration. [Key Requirements: Final Rule on Produce Safety](#). Accessed 8/27/19.
2. U.S. Food and Drug Administration. [FDA Fact Sheet Produce Safety Rule \(21 CFR 112\) Biological Soil Amendments of Animal Origin](#). Accessed 8/27/19.
3. Produce Safety Alliance. [Glossary](#). Accessed 8/27/19.
4. U.S. Food and Drug Administration. [Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: Guidance for Industry](#). Accessed 8/27/19.
5. Produce Safety Alliance. [Records Required by the FSMA Produce Safety Rule](#). Accessed 8/27/19.

What is a scientifically valid treatment process?

The FSMA Produce Safety Rule establishes two treatment levels, each with an associated microbial standard. The BSAO treatment level determines how and when growers can apply the BSAO to produce fields (§ 112.56).

Two thermophilic composting processes are listed in the FSMA Produce Safety Rule as validated to achieve the microbial standard in § 112.55(b):

- Aerated static compost (maintained in aerobic conditions at a minimum of 131°F for three consecutive days, followed by adequate curing) (§ 112.54(b)(1))
- Turned (windrow) composting (maintained in aerobic conditions at a minimum of 131°F for 15 days, with a minimum of five turnings, followed by adequate curing)(§ 112.54(b)(2))

Compost manufacturers following a different treatment process should research whether the method is validated to achieve the appropriate microbial standard. More details on validation and the microbial standards can be found in the FSMA Produce Safety Rule draft guidance (page 64).

Compost Treatment Record Template

Name and address of farm: _____

Type of compost method: Windrow Date piled: 9-15-2016 Date finished: _____ Row number: 2

List all ingredients added to compost: Poultry litter, kitchen scraps, dried leaves, straw

Use this record for on farm composting. Record the date piled, turning dates, and the temperatures maintained. Use one sheet for each pile or row.

Date Turned	Temp/Time Test Area 1	Temp/Time Test Area 2	Temp/Time Test Area 3	Temp/Time Test Area 4	Initials
9-25-2016	135 F/ 2:00 PM	138 F/2:01 PM	140 F/ 2:03 PM	135 F/ 2:04 PM	EAB
9-26-2016	137 F/ 2:15 PM	137 F/2:18 PM	138 F/ 2:19 PM	137 F/ 2:25 PM	EAB

Proper compost production requires a minimum temperature of 131°F be maintained for 3 days using an enclosed system OR a temperature of at least 131°F for 15 days using a windrow system, during which the materials must be turned 5 times (FSMA Produce Rule, 2015, Rule 21 CFR part 112.54(b)).

Reviewed by: _____ Title: _____ Date: _____

FSMA PSR reference § 112.60(b)(2) Confidential Record
Modified from On-Farm Decision Tree Project: Soil Amendments—v5 7/16/2014
 E.A. Bihn, M.A. Schemmann, A.L. Wozniak, G.L. Wall, and S.K. Amundson, 2014 www.gaps.cornell.edu

Figure 1

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Third-Party Soil Amendment Suppliers

Food Safety Modernization Act (FSMA) Produce Safety Rule

Model Certificate of Conformance

{Date, to be renewed annually}

To whom it may concern;

{Company and product name} meets the definition of a treated biological soil amendment of animal origin¹ in the FSMA Produce Safety Rule. This product has undergone a scientifically valid treatment, with appropriate process monitoring, to conform to one of the following microbial standards. {Select one of the following}

- §112.55(a): No detectable *L. monocytogenes*, *Salmonella spp.*, and *E. coli* O157:H7
 - For *L. monocytogenes*, detection limit 1 CFU in 5 g or 5 mL
 - For *Salmonella*, detection limit 3 MPN in 4 g (total solids) or 4 mL (if liquid is being sampled)
 - For *E. coli* O157:H7, detection limit 0.3 MPN in 1 g or 1 mL analytical portion
- §112.55(b): No detectable *Salmonella spp.*, and fecal coliforms <1000 CFU in 1 g or 1 mL total solids
 - For *Salmonella*, detection limit 3 MPN in 4 g (total solids) or 4 mL (if liquid is being sampled)

{If final product was tested, attach a copy of the analysis to this document²}

The process used to achieve this treatment status was: {Select one of the following}

- Aerated static composting with 3 or more days at temperature followed by adequate curing
- Turned (windrow) composting with 15 or more days at temperature and 5 or more turnings, followed by adequate curing
- Other: {Write in brief name and description of process. Insert a reference for the validation study(ies) that support this process}

Appropriate control parameters {e.g. time, temperature, pH, moisture, number and timing of turnings, carbon:nitrogen ratios²} were monitored throughout the treatment process.

This product 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. Practices used to minimize contamination risk include: {Select all that apply²}

- Physical separation of in-process product from finished product
- Storm water and runoff were directed away from finished product
- Different equipment was used for handling finished product
- Equipment was cleaned and sanitized before handling finished product
- Other: {write in description}

{Insert authorized signature/name of company representative}

Download a [Word document file of the above model certificate of conformance](#)

Notes:

¹ For soil amendments that do not contain materials of animal origin, state regulations may require a separate statement specifying that the product does not meet the definition of a biological soil amendment of animal origin (BSAAO). Soil amendments that do not meet the definition of a BSAAO are not covered by the FSMA Produce Safety Rule. For this reason, it may be useful to describe the compost feedstock in the first paragraph. The FSMA Produce Safety Rule definitions do not include, for example, human waste and pre-consumer vegetative waste as a BSAAO.

² FDA's draft guidance for industry (docket number FDA-2018-D-3631) states that:

“A farm that receives a treated BSAAO from a third party could keep a record that includes a statement such as: ‘A scientifically valid thermal treatment was applied and carried out with appropriate process monitoring to satisfy the microbial standard in 21 CFR 112.55(a). The BSAAO has been handled, conveyed, and stored in a manner and location to minimize the risk of contamination.’ In addition, other information related to producing or managing the BSAAO, such as the BSAAO materials used, process parameters monitored and their results, and any applicable test results could be included.” (page 72)

In addition to the FDA requirements, industry representatives have indicated that the FSMA-optional language may be beneficial or required by state regulations, buyer requirements, organic audits, or other programs.