

DRAFT



**OREGON  
DEPARTMENT OF  
AGRICULTURE**



## Biological Soil Amendments of Animal Origin

The Food Safety Modernization Act's Produce Safety Rule requires farmers to minimize the risks to crops from soil amendments derived from animals. These substances like manure or fish emulsion are known as Biological Soil Amendments of Animal Origin (BSAAOs). Farms may purchase BSAAOs from third party manufacturers or may choose to process their own on-site. BSAAOs can be unique for every operation and do not just include manure.

---

*Composting can reduce pathogens of concern to levels safe for use with produce.*

The Produce Safety Rule came into effect in 2016 and farmers are now required to document the processes that they or their suppliers take to reduce pathogen risks from BSAAOs.

## Types of Biological Soil Amendments of Animal Origin

The Produce Safety Rule (PSR) sets standards for soil amendments consisting of materials of animal origin, such as manure or non-fecal animal byproducts. Non-fecal animal byproduct means solid waste (other than manure) that is animal in origin and is generated by commercial, institutional, or agricultural operations. This includes:

- ✓ Meat
- ✓ Animal carcasses
- ✓ Shellfish waste
- ✓ Dairy products
- ✓ Fat
- ✓ Blood meal
- ✓ Fish emulsion
- ✓ Bone meal
- ✓ Food waste
- ✓ Eggs
- ✓ Fish meal
- ✓ Offal

Untreated human waste is not allowed for use on produce, though biosolids are. Soil amendments made only from pre-consumer vegetative matter such as harvest culls, trimmings, or landscaping debris are not considered BSAAOs unless they are contaminated with a substance of animal origin (e.g. saliva or feces). Check with your soil amendment supplier to see if they use animal-derived feedstocks.

## Treated v. Untreated BSAAOs

The PSR distinguishes between treated BSAAOs, which have undergone a scientifically valid process that adequately reduces pathogens, and untreated BSAAOs, which have not (§112.51). Treatment processes involve following parameters specific to each process; failure to follow those parameters renders that BSAAO untreated. Subsequent mixing or contamination of a treated BSAAO with an untreated BSAAO renders the whole lot untreated. Farmers may still use untreated BSAAOs to grow produce but must do so with greater precautions. For example, a farmer may not use an untreated BSAAO if it is likely to contact a root crop.

## Microbial Standards for BSAAOs

Pathogens Tested				
Standard	L. monocytogenes	E. coli O157:H7	Salmonella	Fecal Coliforms
§112.55(a)	ND*	ND	ND	n/a
§112.55(b)	n/a	n/a	ND	<1000 CFU/g

\*No detection

## Sourcing Biological Soil Amendments of Animal Origin

### On-Farm Treatment

Any operation can treat their own BSAAO's, but one must follow certain guidelines:

- The process used to treat the BSAAO is scientifically valid
- The BSAAO has been handled, conveyed and stored in a manner and location to minimize the risk of cross-contamination by an untreated or in-process BSAAO (§ 112.60(a)).

### On-Farm Records

Farmers are required to monitor and record data to demonstrate that they have met the necessary parameters for successful treatment of their BSAAO materials. If they are not using one of the two composting methods listed in the rule, they must provide documentation on the scientific validity of their alternative method in reducing pathogen levels to the standards in §112.55(a) or §112.55(b).

### Third Party Suppliers

Farms may also source BSAAOs from off-farm manufacturers. However, growers must determine whether these products are considered treated or untreated and apply these materials in a manner to minimize risk of contamination of covered produce (§112.56).

### Third Party Records

Producers must annually request a **certificate of conformance** from their BSAAO supplier. The certificate must detail:

1. That the process used to treat the BSAAO is a scientifically valid process that has been carried out with appropriate process monitoring (§112.60(b)(1)(i)), including which microbial standard (§112.55(a) or §112.55(b)) has been satisfied **AND**:
2. That 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 BSAAO (§112.60(b)(1)(ii)).

DRAFT

## Scientifically Validated Processes

The PSR includes two pre-approved methods of treatment:

- **Static aerated composting:** Maintains oxygenated conditions at a minimum of 131°F (55°C) for 3 consecutive days and is followed by adequate curing (§ 112.54(b)(1)).
- **Turned composting:** Maintains oxygenated conditions at a minimum of 131°F (55°C) for 15 days (which do not have to be consecutive), with a minimum of five turnings, and is followed by adequate curing (§ 112.54(b)(2)).
- **Other Processes:** Contact the Produce Safety Team to discuss additional verified methods: 503-986-4620.



## FSMA and the 503 Biosolids Rule

FSMA microbial standards differ from the EPA's 503 Biosolids rule:

- FSMA's lower standard, §112.55(b), requires that processes result in NO DETECTION of Salmonella, not 3 MPN as in the 503 rule.
- FSMA does not require lot testing, but it does require that the method one uses has been validated. Whoever validated the procedure would have done testing for pathogens of concern.
- Cross-contamination is an area of focus for FSMA. 3<sup>rd</sup> party manufacturers of BSAAOs must take steps to prevent contamination between finished product and untreated feedstock by using separate equipment for handling each or by cleaning and sanitizing equipment between uses.



### Different Standards Have Different Application Requirements

Treated BSAAOs that meets the higher microbial standard §112.55(a) may be used on covered produce (including root crops) in any manner with no time restrictions (§112.56). Treated BSAAOs that meet the lower microbial standard §112.55(b) and that are applied in a manner that minimizes the potential for contact with the harvestable portion of covered produce during and after application also have no application interval between application and harvest. Untreated BSAAOs may be used without an application interval if they are applied in a manner that guarantees no contact between the BSAAO and the harvestable portion of the crop before or after application.



**OREGON  
DEPARTMENT OF  
AGRICULTURE**

635 Capitol St NE  
Salem, OR 97301-2532 USA  
503-986-4620 | Oregon.gov/ODA

*This publication is supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award U2FFD007422 totaling \$630,000 with 100 percent funded by FDA/HHS. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by FDA/HHS, or the U.S. Government.*