OREGON DEPARTMENT OF AGRICULTURE

How to Draft a Certificate of Conformance

The Produce Safety Rule of the Food Safety Modernization Act allows farmers to use biological soil amendments of animal origin (BSAAOs) in the growing of produce. Farmers may treat their own BSAAOs or they may purchase these from third party suppliers. However, the rule requires farmers to obtain a certificate of conformance from any third-party supplier of treated BSAAOS that they use. BSAAOs that have been processed in a way that reduces pathogens of concern *such as* Listeria spp., Salmonella spp., and E. coli O157:H7 are considered treated and may be used with few/no restrictions. Note that the different treatment standards below vary by their focus on different pathogens.

Does your product contain a feedstock derived from animals?

If it does, then it is considered a BSAAO. Examples of relevant feedstocks include manure, bedding, animal carcasses, meat/dairy products, feather/blood/bone/fish/shell meals, post-consumer food waste, and biosolids.

What is a Certificate of Conformance?

A certificate of conformance is a letter provided by the manufacturer attesting that their product complies with the FDA's requirements for proper treatment of BSAAOs. We have included an example certificate of conformance that you may choose to use. The FDA requires that any certificate of conformance address three objectives:

1. **Is the process used to treat a BSAAO scientifically valid?**
2. **Does it reduce pathogen levels to meet one of the two standards below:**

§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

OR

§112.55(b): No detectable Salmonella spp. and fecal coliform levels <1000 CFU
- For Salmonella, detection limit 3 MPN in 4 g (total solids) or 4 mL (if liquid is being sampled)
- Fecal coliforms are <1000 CFU in 1 g or 1 mL total solids

3. **Once treated, has the BSAAO been handled, moved, and stored in a manner that minimizes the chance of subsequent contamination by an untreated or in-process BSAAO?**

Scientifically Valid Treatments

The FDA defines scientifically valid as "based on scientific information, data, or results published in, for example, scientific journals, references, text books, or proprietary research."*

To determine if a treatment process is scientifically valid, a manufacturer first will need to see how their particular treatment was designed. If they are following a standard procedure they obtained from a professional training course or certification program, they may cite this program's coursework. If their process is based on publicly available research, then they can offer a citation of this work to justify their approach. Some treatment procedures are the result of in-house, proprietary research—in this case, a company may cite these findings. However, this research must involve a controlled, replicated study design. For example, one could use a triplicate design where three samples of material undergo treatment and are compared to three samples that receive no treatment. Testing one's compost pile once after the company tried something new is not sufficient. **Composters that follow either a static aerated method or a turned windrow method may cite § 112.54(b)(1) and (2), respectively, as their validation.** See our factsheet on BSAAOs.

What if I cannot find the above research to support my treatment methods?

If a third-party BSAAO supplier cannot provide a certificate of conformance, they always have the option of telling their customers that the product they sell should be considered untreated. The Produce Safety Rule does not prohibit the selling or manufacture of untreated BSAAOs. Remember farmers may still use untreated BSAAOs, but with greater restrictions and precautions.

Microbial Testing

The Produce Safety Rule does not require producers of treated BSAAO to test their product. However, the FDA does require that the method used by these producers has been evaluated using microbial testing and can meet the requirements in either §112.55(a) or §112.55(b). When researching the scientific basis for one's methods, look for testing results that conform to §112.55(a) or §112.55(b). *If your treatment procedure has not been tested for the pathogens listed in these standards or did not reduce their numbers below the levels in the standard, then the treatment method is not sufficient and the resulting BSAAO must be labeled as untreated.*

Proper Handling, Moving, and Storage

Once treated, BSAAOs can later be contaminated by untreated and in-process BSAAOs or other foreign materials. Common ways this occurs is through using the same equipment to handle raw, untreated feedstocks and finished, treated product. *The same equipment can only be used if it is first cleaned between handling untreated and treated materials.* Analyze your system to decide whether your operation has minimized the possibility of cross-contamination. For example, if equipment is not cleaned between work with treated and untreated materials, then the treated materials are considered to be contaminated and revert to their untreated status. A company could not provide a certificate of conformance in this case.

Annual Update

The Produce Safety Rule requires farmers to obtain certificates of conformance from their suppliers **annually**. If your treatment process is unchanged from the previous calendar year, then updating your certificate of conformance is easy and only requires changing the date. However, if new procedures and parameters have been introduced, a more thorough revision is in order.

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