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Food Safety Modernization Act Produce Safety Rule: Soil Amendments

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Overview

The Produce Safety Rule is one of seven major food safety regulations authorized by the Food Safety Modernization Act (FSMA). The rule, found in the Code of Federal Regulations Title 21 Part 112, sets standards for the safe growing, harvesting, packing, and holding of produce grown for human consumption (U.S. FDA 2015). Similar to the other FSMA rules, the Produce Safety Rule is proactive rather than reactive by focusing on high-risk practices and identifying hazards within individual operations. The rule sets standards for agricultural water; soil amendments; sprouts; domesticated and wild animals; worker training; health and hygiene; and equipment, tools, and buildings. Here, we describe the Produce Safety Rule standards for soil amendments.

Biological Soil Amendments

The Produce Safety Rule describes the minimum requirements for using different types of soil amendments to reduce the risk of contaminating produce. Growers should refer to the rule's "Subpart F—Biological Soil Amendments of Animal Origin and Human Waste" for detailed requirements to determine if biological soil amendments of animal origin are treated or untreated and how to handle them. Subpart F also addresses the use of human waste, treatment of the biological soil amendments, application methods and intervals, and recordkeeping.

Definitions

(Source: 21CFR Part 112.3)

- **Soil amendment:** "Soil amendment means any chemical, biological, or physical material intentionally added to the soil to improve the chemical or physical condition of soil in relation to plant growth or to improve the capacity of the soil to hold water."
- **Biological Soil Amendment:** "Any soil amendment containing biological materials such as stabilized compost, manure, non-fecal animal byproducts, peat moss, preconsumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea, or yard trimmings, alone or in combination."
- **Biological Soil Amendment of Animal Origin:** "A biological soil amendment which consists, in whole or in part, of materials of animal origin, such as manure or nonfecal 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."

Assessing the Risks of Biological Soil Amendments

Managing soil amendments is an important element in reducing food safety risks. The type of amendment being applied, the crop it will be applied on, the application method, and the timing of application can all affect the risk of using soil amendments (Produce Safety Alliance 2016).

One of the most commonly used soil amendments, manure, is associated with food safety risks. However, if managed according to the FSMA Produce Safety Rule standards, manure can be a valuable resource. Using Good Agricultural Practices (GAPs) can help reduce soil amendment-related risks. These GAPs include treating soil amendments, extending time between amendment application and harvest, preventing contamination of adjacent crops, storing amendments in a way that reduces runoff, handling amendments properly, and keeping records.

Part 112.3 of the Produce Safety Rule also describes different types of soil amendments:

Raw Manure

- Animal excreta, alone or in combination with litter (such as straw and feathers used for animal bedding) for use as a soil amendment.
- May contain human microbial pathogens that come from the intestines of animals.

Composted Manure

- Organic material that has been decomposed by the actions of microorganisms under thermophilic conditions.
- Heat from proper composting destroys human microbial pathogens.

Chemical

- Non-biological soil amendments such as elemental fertilizers that are not commonly associated with human microbial pathogens.
- Can harm humans if applied improperly.

Pre-consumer Vegetative Waste

- Solid waste that is purely vegetative in origin, not considered yard trash, and derived from commercial, institutional, or agricultural operations without coming in contact with animal products, byproducts or manure, or with an end user (consumer).
- Includes material generated by farms, packinghouses, canning operations, wholesale distribution centers and grocery stores; products that have been removed from their packaging (such as out-of-date juice, vegetables, condiments, and bread); and associated packaging that is vegetative in origin (such as paper or cornstarch-based products).

Human Waste and Biosolids

- Untreated human waste may not be used as a soil amendment.
- May contain high levels of human pathogens.
- Biosolids may only be used if they meet Environmental Protection Agency requirements.

Non-Manure Based Amendments of Animal Origin

- Solid waste (other than manure) that is animal in origin (such as meat, fat, dairy products, eggs, carcasses, blood meal, bone meal, fish meal, shellfish waste (such as crab, shrimp, and lobster waste), fish emulsions, and offal, and is generated by commercial, institutional, or agricultural operations.

Untreated Soil Amendments

- No process to reduce pathogens has been followed.
- Includes untreated soil amendments that are mixed with treated soil amendments, e.g. raw manure, aged manure, untreated slurry, agricultural teas.

Treatment of Biological Soil Amendments

In Part 112.3 of the Produce Safety Rule, composting is defined as "a process to produce stabilized compost in which organic material is decomposed by the actions of microorganisms under thermophilic conditions for a designated period of time at a designated temperature, followed by a curing stage under cooler conditions." Composting is a treatment method that is accepted under the Produce Safety Rule. Curing is the last stage of composting, and it is characterized by a greatly reduced rate of decomposition and lower pile temperature. Curing, which may last from one to 12 months, results in a further reduction of pathogen populations, breakdown of cellulose and lignin, and, ultimately, stabilized compost.

Scientifically Validated Composting Methods:

- Static composting is performed by maintaining aerobic (oxygenated) conditions at a minimum of 131°F (55°C) for three consecutive days and is followed by adequate curing.
- Turned composting maintains aerobic 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.

Application of Soil Amendments

Methods to Reduce Risk during Application

- Apply manure during non-produce seasons.
- Maximize time between manure application and harvest.
- Keep untreated soil amendments away from edible portions of the crop.
- Never side-dress with raw manure.
- Do not apply during high winds, or if the ground is saturated or frozen.

Minimum Application Intervals

- The FDA has not yet issued an application interval for untreated soil amendments.
- Untreated biological soil amendments must be applied in a manner so that they do not contact the harvestable portion of the crop.
- Growers may follow the National Organic Program (NOP) guidelines for applying raw manure to reduce the likelihood of contamination, but these guidelines are not required under the Produce Safety Rule. The NOP intervals for applying raw manure are 120 days between application (incorporation) and harvest for produce that has its edible portion directly in contact with the soil, or 90 days for produce that does not have its edible portion in contact with the soil (USDA 2015).
- Soil amendments that have been treated by a scientifically validated method (e.g., compost) may be applied with no wait time.

Handling and Storage of Soil Amendments

Handling Recommendations

- Have designated equipment to handle soil amendments.
- Develop standard operating procedures to clean equipment if used for multiple purposes.
- Direct farm traffic away from amendment storage sites.
- Consider treated soil amendments that come in contact with untreated soil amendments as raw or untreated.

Storage Recommendations

- Store biological soil amendments so that they will not contaminate produce, water sources, food contact surfaces, or other soil amendments.
- Store treated biological soil amendments in a way that they will not become contaminated by untreated biological soil amendments.
- Cover finished compost piles and separate them from raw manure.
- Prevent animals from coming into contact with compost piles.
- Store soil amendments in an area with low traffic.

Worker Training

Workers should be trained on the risks of using soil amendments and to correctly follow standard operating procedures for handling raw or composted manure. Before working with produce or entering the packing area, workers must have clean clothes and shoes. If workers wear gloves, they should be clean. Training on proper handwashing techniques should also be given to workers who handle soil amendments.

Recordkeeping

Logs should be kept to record soil amendment use and handling. Documentation on soil amendments should include:

- Type and source of biological soil amendment of animal origin used.
- Application dates.

• Amount used.

• Risk reduction practices.

If records are being kept for other regulations, these do not need to be duplicated.

Additional records must be kept if compost is made on-farm. These include:

• Length of time of composting.

• Temperatures achieved.

• Number of turnings.

• Other composting processes.

When receiving treated biological soil amendments from other suppliers, special records must be kept and renewed annually to verify that a scientifically validated process was used for treatment. These records include:

• Name and address of supplier.

• Process used for treatment.

• Type of soil amendment purchased.

• Date of purchase, amount, and lot number.

Corrective Action Plans

Corrective action plans are used to outline steps to take in the event that soil amendments pose a microbial risk to crops or if they have been improperly treated. These plans allow growers to take specific actions to reduce risk (e.g., process produce with kill step). Corrective action plans should be documented.

References

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