FSMA Facts

FDA FOOD SAFETY MODERNIZATION ACT

Biological Soil Amendments: Subpart F

The proposed rule identifies possible routes of microbial contamination of produce and sets requirements to prevent or reduce the introduction of pathogens. Biological soil amendments of animal origin, such as composted manure, are one identified route of contamination because they may contain pathogens of public health concern.

Background

"Soil amendments" are any chemical, biological, or physical material intentionally added to the soil to improve the chemical or physical condition of the soil in relation to plant growth or to improve the capacity of the soil to hold water. "Biological soil amendments of animal origin" are biological soil amendments which consist, in whole or in part, of materials of animal origin, such as manure or non-fecal animal byproducts, or table waste, alone or in combination. The FDA-issued proposed rule focuses on biological soil amendments of animal origin because of the potential for these types of soil amendments to contaminate produce with pathogens of public health concern. Currently, within the U.S., composting of animal manure is not specifically regulated by any federal agency with respect to the safety of its use in the broad production of all produce. Instead, state and local regulations in some cases provide oversight, but this varies in scope and complexity.

Requirements:

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The FDA-issued proposed rule focuses on biological soil amendments of animal origin because of the potential for these types of soil amendments to contaminate produce with pathogens of public health concern. Currently, within the U.S., composting of animal manure is not specifically regulated by any federal agency with respect to the safety of its use in the broad production of all produce. Instead, state and local regulations in some cases provide oversight, but this varies in scope and complexity

- Establishes requirements for determining the status of a biological soil amendment of animal origin as treated or untreated, and for their handling, conveying, and storing (proposed §§ 112.51, 112.52);
- Prohibits the use of human waste for growing covered produce except in compliance with EPA regulations for such uses, or equivalent regulatory requirements (proposed § 112.53);
- Establishes requirements for treatment of biological soil amendments of animal origin with scientifically valid, controlled, physical and/or chemical processes or composting processes that meet or exceed specific microbial standards (proposed §§ 112.54 and 112.55);
- Establishes application requirements and minimum application intervals for untreated and treated biological soil amendments of animal origin (proposed § 112.56); and
- Requires certain records, including documentation of application and harvest dates relevant to application intervals; documentation from suppliers of treated biological soil amendments of animal origin, and scientific data or information relied on to support any permitted alternatives to requirements (proposed § 112.60).

Alternatives

You may establish and use alternatives to the composting treatment processes established in §112.54(c)(1) and (c)(2), and for the minimum application intervals established in § 112.56(a)(1)(a) and in § 112.56(a)(4)(a), provided you have adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection as the composting treatment processes and the minimum application intervals established in the proposed rule and would not increase the likelihood that your covered produce will be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

Microbial Standards for Treatment Processes (Proposed §§ 112.54 and 112.55)

The following treatment processes would be acceptable for biological soil amendments of animal origin used in the growing of covered produce under the proposed rule. The choice of treatment process used affects the application options available under proposed §112.56 [see next section below].

1. (Proposed §§ 112.54(a) and 112.55(a)) Scientifically valid controlled physical processes (for example, thermal), chemical processes (for example, high alkaline pH), or combinations of scientifically valid controlled physical and chemical processes that have been demonstrated to satisfy each of the following microbial standards:

L. monocytogenes	Not detected using a method that can detect one CFU per five gram analytical portion
Salmonella species	Less than three (3) MPN per four (4) grams of total solids (dry weight basis)
E. coli O157:H7	Less than 0.3 MPN per one gram analytical portion

2. Proposed §§ 112.54(b) and 112.55(b)) Scientifically valid controlled physical processes, chemical processes, or combinations of scientifically valid controlled physical and chemical processes that have been demonstrated to satisfy each of the following microbial standards:
    - Less than three MPN *Salmonella* species per four grams of total solids (dry weight basis); and
    - Less than 1,000 MPN fecal coliforms per gram of total solids (dry weight basis).
3. (Proposed §§ 112.54(c) and 112.55(b)) Scientifically valid controlled composting processes that have been demonstrated to satisfy each of the following microbial standards:
    - Less than three MPN *Salmonella* species per four grams of total solids (dry weight basis); and
    - Less than 1,000 MPN fecal coliforms per gram of total solids (dry weight basis).

The proposed rule identifies two scientifically valid controlled composting processes that meet these microbial standards, and allows farms to establish alternative composting processes if they meet the same microbial standards and provide the same public health protection as the proposed rule and do not increase the risk of adulteration. The two identified composting processes are:

- Static composting that maintains aerobic (i.e., oxygenated) conditions at a minimum of 131°F (55 °C) for 3 days and is followed by adequate curing, which includes proper insulation; or
- Turned composting that maintains aerobic conditions at a minimum of 131°F (55 °C) for 15 days, with a minimum of five turnings, and is followed by adequate curing, which includes proper insulation.

Application Requirements and Minimum Application Intervals for Untreated and Treated Biological Soil Amendments of Animal Origin (Proposed § 112.56)

The following chart describes the application options available (application methods and application intervals), depending on the treated/untreated status of the biological soil amendment of animal origin and treatment process used.

If the biological soil amendment of animal origin is:	Then the biological soil amendment of animal origin must be applied:	And then the minimum application interval is:
Untreated …	In a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application ...	9 months
Untreated …	In a manner that does not contact covered produce during or after application ...	0 days
(2) Treated by a scientifically valid controlled physical or chemical process, or combination of scientifically valid controlled physical and chemical processes, in accordance with the requirements of § 112.54(a) to meet the microbial standard in § 112.55(a) [see number 1 in previous section above]...	In any manner (i.e., no restrictions) ...	0 days
(3) Treated by a scientifically valid controlled physical or chemical process, or combination of scientifically valid controlled physical and chemical processes, in accordance with the requirements of § 112.54(b) to meet the microbial standard in § 112.55(b) [see number 2 in previous section above]...	In a manner that minimizes the potential for contact with covered produce during and after application ...	0 days
(4)(a) Treated by a composting process in accordance with the requirements of § 112.54(c) to meet the microbial standard in § 112.55(b) [see number 3 in previous section above]...	In a manner that minimizes the potential for contact with covered produce during and after application ...	45 days
(4)(b) Treated by a composting process in accordance with the requirements of § 112.54(c) to meet the microbial standard in § 112.55(b) [see number 3 in previous section above]...	In a manner that does not contact covered produce during or after application ...	0 days