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Soil amendments are commonly used in the production of fresh fruits and vegetables. The focus of this section is on assessing risk and ways to reduce risks associated with soil amendment use.

The majority of the standards related to soil amendments can be found within Subpart F—Standards Directed to Biological Soil Amendments of Animal Origin and Human Waste § 112.51(a)–§ 112.60(b).

In this module, the term ‘soil amendments’ is used for brevity, however, there are multiple definitions outlined in the FSMA Produce Safety Rule that are included below in the notes. They will be discussed later in this module.

- Soil amendment means any chemical, biological, or physical material (such as elemental fertilizers, stabilized compost, manure, non-fecal animal byproducts, peat moss, perlite, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea and yard trimmings) 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. The term soil amendment also includes growth media that serve as the entire substrate during the growth of covered produce (such as mushrooms and some sprouts) (§ 112.3(c)).
• Biological soil amendment means any soil amendment containing biological materials such as stabilized compost, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea, or yard trimmings, alone or in combination (§ 112.3(c)).

• Biological soil amendment of animal origin means 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 (§ 112.3(c)).

It is important to consider the types of soil amendments being used on the farm (if any) and understand the risks they may pose to produce.

In general, the biggest risk is from soil amendments that contain manure or other biological components of animal origin that have not been treated to reduce microbial risks.

Biological soil amendments may contain biological components of animal origin that are not manure-based (e.g., blood meal, bone meal). Risks associated with these types of amendments will be discussed later in the module.

§ 112.51(a) defines a treated soil amendment as having been processed to completion to reduce microorganisms of concern in accordance with §§ 112.54(a) and (b) (which references § 112.55 microbial criteria), or in the case of agricultural tea, the biological materials used to make the tea have been processed and the water has no detectable generic E. coli/100 mL water.

§ 112.51(b) defines a biological soil amendment of animal origin as untreated if it:

1) Has not been processed to completion in accordance with § 112.54, or in the case of agricultural tea, the biological materials used to make the tea have not been so processed or the water used to make the tea is untreated surface water, or the water used to make the tea has detectable generic E. coli in 100 mL of water.
2) Has become contaminated after treatment
3) Has been recombined with an untreated biological soil amendment of animal origin
4) Is or contains a component of untreated waste that you know or have reason to believe is contaminated with a hazard or has been associated with foodborne illness
5) Is an agricultural tea that contains an agricultural tea additive

- Agricultural tea additive means a nutrient source (such as molasses, yeast extract, or algal powder) added to agricultural tea to increase microbial biomass (§ 112.3(c)).
- Chemical and synthetic soil amendments can also impact food safety, if not prepared and applied properly. The Environmental Protection Agency and Federal Insecticide, Fungicide, and Rodenticide Act regulates the use of chemical and synthetic soil amendments. The preparation of chemical and synthetic soil amendments is also an important factor in mitigating risk.

Types of soil amendments include raw manure, composted manure, chemical, green waste, and biosolids.

Soil amendment management can reduce food safety risks. This includes assessing risks from the soil amendment being used, selecting low risk crops for application (e.g., agronomic), and reviewing the application method (incorporated, injected, or surface applied) and timing (days to harvest; season of application) to reduce risks.

- For example, if soil amendments are applied to agronomic crops, there is lower risk of direct produce contamination.
- Excessive use of soil amendments can be a problem (i.e., when used as a ‘disposal’ mechanism or when applied beyond crop nutrient demand) and this may affect the safety of agricultural water sources or lead to runoff into produce fields.
- The rule has requirements for application method and application to harvest interval that will be discussed later in the module.
- Each of the bullets highlighted in this slide will be discussed in greater detail throughout this module.
Chemical and synthetic fertilizers usually do not present microbial risks because they either 1) do not support the growth of human pathogens or 2) are processed in such a way that eliminates pathogens.

However, chemical amendments should not be considered 100% safe. Though rare, chemical amendments have been linked to outbreaks in the past (see Additional Resource).

Chemical and synthetic fertilizers can pose chemical risks to humans, including food safety risks to the crop (if applied improperly) as well as health hazards to those who apply and handle the chemicals.

Additional Resource:


§ 112.53 states that you may NOT use untreated human waste, except biosolids used in accordance with the requirements of 40 CFR part 503, subpart D, or equivalent regulatory requirements for growing covered produce.

- For most purposes 40 CFR part 503, subpart D, limits application for land growing covered produce to Class A biosolids.
- Untreated human waste may contain high levels of human pathogens.
Biosolids may also contain high levels of heavy metals or other contaminants such as pharmaceuticals.

- Some States regulate the metals content of soil amendments, including Class A biosolids.
- Management of biosolids is not discussed in detail in this module because its use is infrequent in fruit and vegetable production.
- If using biosolids, review the regulatory sections that apply to ensure biosolids are used properly.

**Additional Resource:**
- Standards for the Use or Disposal of Sewage Sludge, Subpart D—Pathogens and Vector Attraction Reduction, 40 CFR 503 (2015).

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In § 112.3(c), **pre-consumer vegetative waste** means 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). Pre-consumer vegetative waste 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 corn-starch based products). Pre-consumer vegetative waste does not include table waste, packaging that has come in contact with materials (such as meat) that are not vegetative in origin, or any waste generated by restaurants.

- Pre-consumer vegetative waste could contain chemical hazards such as pesticides and physical hazards such as glass.
- Table wastes (leftovers) or wastes that could be contaminated by domesticated animals (e.g., cats or dogs) feces are considered untreated biological soil amendments of animal origin.
- Table wastes can also be contaminated with saliva or by contact with hands.

Notes:
Additional Resources:


In the FSMA Produce Safety Rule, §§ 112.54(a) and (b) provides treatment processes which are acceptable for biological soil amendments of animal origin used in the growing of covered produce. These options will be covered in greater detail later in the module.

All biological soil amendments of animal origin treatment processes, including mortality composting, must meet the microbial standards in §§ 112.55(a) and (b) or must be considered untreated.

The rest of this module will focus on reducing risks associated with biological soil amendments containing animal manure.

Additional Resources:


Non-Manure Based Soil Amendments of Animal Origin

- Should be processed to eliminate pathogens or must be considered untreated biological soil amendments of animal origin

- Bone meal
- Blood meal
- Feather meal
- Fish emulsion
Manure is a valuable resource on farms. Adding manure as a soil amendment can increase soil tilth, fertility, and water holding capacity.

There are food safety risks associated with using manure, but if managed properly, these risks can be minimized.

Additional Resources:
- Cornell Waste Management Institute.

The reason manures present food safety risks is because they can carry and spread human pathogens. Manures especially present a food safety risk to the crop if they are not applied or treated properly. Additional information is provided below, but the key is to know that raw manures represent a microbial risk.

Different animals tend to be reservoirs for different pathogens, though all animals have the potential to shed pathogens. For example, birds (chickens) often shed Salmonella and Campylobacter and ruminants (cows, sheep) often shed toxigenic E. coli (EHEC/STECs).

There are many factors that contribute to whether an animal will shed human pathogens in their feces including season, diet, rearing practices, and age. For example, younger cattle tend to shed more toxin-producing pathogens in their manure than older animals.
Additional Resources:


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- As a reminder, § 112.51(b) defines **untreated** soil amendments.
- Raw manure, aged manure (meaning no specific process, such as composting, has been followed), untreated slurry, agricultural teas from raw manure, and other raw or incompletely treated products (such as untreated bone meal and blood meal) are examples of higher risk soil amendments.
- If a treated soil amendment is mixed with raw manure or incompletely treated manure by accident (or intentionally), or if you have reason to suspect a finished compost has become contaminated, it must be handled as a raw, untreated soil amendment (§ 112.52).
- There are treatment options, such as composting or heat treatments, that will reduce food safety risks. The FSMA Produce Safety Rule standards for composting processes will be outlined in the next slides.

**Additional Resources:**

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- Implementing Good Agricultural Practices (GAPs) on the farm can help reduce risks associated with the use of soil amendments.

- GAPs for soil amendments could include:
  - Selecting soil amendments which have been treated (instead of using raw)
  - Extending the application to harvest interval
  - Assuring application methods do not put adjacent crops at risk (such as from wind drift on a dry day or runoff)
  - Proper storage to reduce runoff risks into produce fields (§ 112.52)
  - Handling practices to reduce cross-contamination from soil amendments to equipment and tools (§ 112.52)
  - Recordkeeping to monitor soil amendment application
  - Recordkeeping to monitor soil amendment treatment (§ 112.60)

Notes:

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Composting is defined in § 112.3(c) 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 (e.g., 3 days) at a designated temperature (e.g., 131°F (55°C)), followed by a curing stage under cooler conditions.

The length of time will depend on management parameters including aeration, turning, cover, feedstock make-up, moisture levels, and many other potential variables at a designated temperature. For example, not less than 131°F (55°C) for 3 days, followed by a curing stage.

§ 112.54 provides more information on scientific validation including examples involving composting. The next slide contains more information about this, but is an optional slide for growers using these types of amendments.

Curing, as defined by § 112.3(c) means the final stage of composting, which is conducted after much of the readily metabolized biological material has been decomposed, at cooler temperatures than those in the thermophilic phase of composting, to further reduce pathogens, promote further decomposition of cellulose and lignin, and stabilize composition. Curing may or may not involve insulation depending on environmental conditions.

There are many more methods of composting. Examples of thermophilic composting are provided in the FSMA Produce Safety Rule that are designed to meet § 112.55(b). Non-thermophilic methods may be acceptable (e.g., vermicomposting, anaerobic digestion, etc.). Processes must be validated to meet the treatment required (§ 112.55(a) or (b)) for intended application (§ 112.56). Process monitoring to meet the microbial standard and record keeping are critical to ensuring the compost is adequately treated.

Additional Resources:


16 Additional Information

- This slide is optional.

- Treating soil amendments which contain ingredients of animal origin, such as manure and other animal byproducts, is the best method for reducing the risk of contamination.

- §§ 112.54(b)(1) and (2) of the FSMA Produce Safety Rule provides two processes, static and turned composting, as examples of validated options for treating manure and other soil amendments.

- In § 112.54, other methods are allowed if they are scientifically valid, controlled processes supported by adequate scientific information and that have been validated to achieve the microbial standards outlined in § 112.55.

- The microbial standards outlined in § 112.55 are not meant to be lot-by-lot testing requirements. Process monitoring must be documented to support the expectation of adequate pathogen reduction (§ 112.60(b)(2)).
For more information, review the response to comment 145 of the FSMA Produce Safety Rule Preamble: “FDA does not intend § 112.55 to require that farms test their treated biological soil amendments for compliance with the microbial standards. Rather, FDA intends these provisions to provide the standards against which treatment processes described in § 112.54 must be validated. Farms would be able to use treatment processes that are validated to meet the relevant microbial standard in § 112.55 without the need to test the end products of their treatments to confirm that the microbial standard was achieved”.

There is not sufficient time in this module to cover composting in detail. Those interested in composting as a method of pathogen reduction should be encouraged to contact a professional who has experience in composting processes.

Additional Resources:
- Cornell Waste Management Institute.
- Frankenfield, A. Compost: How to make it and how much to use. Pennsylvania State University Extension.
- Natural Resources Conservation Service. Field Office Technical Guides.
One simple risk reduction strategy is to apply manure during non-produce (e.g., cover crops, grains, or hay) field rotations.

Pathogens can survive in manure, compost, and soil for long periods of time. Therefore, maximizing time between application of the manure and harvest of produce can help minimize risks.

Keep untreated soil amendments from touching the edible portions of the crop—this is easy to achieve in tree fruit, but more difficult for crops grown on or close to the soil. This is also a requirement of the FSMA Produce Safety Rule which will be discussed in the next few slides.

**Side-dressing** should only be utilized if properly composted or treated soil amendments are used and applied in a manner consistent with § 112.56.

Application methods can impact safety. If field spread, be aware of adjacent fields or waterways that could be contaminated and take steps to reduce risks.

Steps should include:
- Not spreading in high winds and leaving a buffer area to prevent manure from entering adjacent fields.
- Not applying when ground is saturated or frozen to reduce the risk of runoff.

**Additional Resources:**


**Note:** This resource provides a research framework for preventive control practices using a ‘good, better, best’ approach and validates the equivalency of alternative methods that growers may utilize.
• The FSMA Produce Safety Rule does not currently establish intervals for the application of treated and untreated soil amendments. It is anticipated that FDA will revise this standard in the future upon completion of risk assessments and a more in-depth research agenda. The application interval for untreated soil amendments that may contact covered produce after application is listed as “reserved” in § 112.56(a)(1)(i)). This does not mean that there is zero risk associated with applying these amendments or that FDA is suggesting a zero day application interval.

• Untreated biological soil amendments of animal origin must not be applied in a manner that directly contacts the harvestable portion of the crop and must be applied in a manner that minimizes the potential for contact with covered produce after application (§ 112.56(a)(1)(i)).

• Additionally, if an untreated biological soil amendment of animal origin is applied in a manner that does not contact covered produce during or after application, then the minimum application interval is zero days (§ 112.56(a)(1)(ii)).

• § 112.56 requires that biological soil amendments of animal origin treated to the microbial standards in § 112.55(b) be applied in a manner that minimizes the potential for contact with covered produce during and after application, while biological soil amendments of animal origin treated to the microbial standards in § 112.55(a) may be applied in any manner.

• The National Organic Program guidelines outlined in 7 CFR 205.203 (c)(1) can help minimize the likelihood of contamination since the probability of pathogen survival decreases as the interval between application of raw manure and harvest increases. Growers may continue to follow these standards, but they are not currently required for the FSMA Produce Safety Rule.

• The NOP Regulation states that raw animal manure must be composted unless it is: (a) Incorporated into the soil not less than 120 days prior to the harvest of a product whose edible portion has direct contact with the soil surface or soil particles; or (b) Incorporated into the soil not less than 90 days prior to the harvest of a product whose edible portion does not have direct contact with the soil surface or soil particles.

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Additional Resource:


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- These examples represent ways growers might achieve the FSMA Produce Safety Rule requirements outlined below.

- To minimize the potential for cross-contamination, specific equipment and tools can be designated for use in handling soil amendments. If tools and equipment that contact soil amendments will also be used in produce fields, a **Standard Operating Procedure (SOP)** should be developed to clean them before entering the field (e.g., rakes for turning compost piles are also used in produce fields).

- One way to reduce the risk of cross-contamination is to direct farm traffic away from soil amendment handling and loading areas to reduce the chances of tracking contamination from the manure/compost pile to other areas of the farm or packinghouse.

- If equipment is used for handling soil amendments, it should not serve as a source of cross-contamination to the produce.

- § 112.123(b)(1) states that equipment and tools must be installed and maintained as to facilitate cleaning of the equipment and of all adjacent spaces.

- § 112.123(d)(2) states that all non-food-contact surfaces of equipment and tools used during harvesting, packing, and holding must be maintained and cleaned as frequently as reasonably necessary to protect against contamination of covered produce.

- § 112.123(e) requires that if equipment such as pallets, forklifts, tractors, and vehicles are used, such that they are intended to or likely to contact produce, they must be used in a manner to minimize the potential for contamination.

- § 112.52(a) requires that those on covered produce farms must handle, convey and store any biological soil amendment of animal origin in a manner and location such that it does not become a potential source of contamination to covered produce, food contact surfaces, areas used for a covered activity, water sources, water distribution systems, and other soil amendments.
§ 112.52(a) requires that those subject to the rule handle, convey, and store any biological soil amendment of animal origin in a manner and location such that it does not become a potential source of contamination to covered produce, food contact surfaces, areas used for a covered activity, water sources, water distribution systems, and other soil amendments.

§ 112.52(b) requires that those subject to the rule handle, convey, and store any treated biological soil amendment of animal origin in a manner and location that minimizes the risk of it becoming contaminated by an untreated or in-process biological soil amendment of animal origin.

§ 112.52(c) requires that treated soil amendments that come into contact with untreated soil amendments must be handled as if they were untreated or raw.

This slide contains examples of things growers can do to minimize risks.

- Keep finished compost piles covered and separated from raw manure piles.
- Keep both domesticated animals and wildlife away from compost piles so as not to cross-contaminate the amendment with fecal material. For example, fencing compost piles to prevent free-range chickens from contaminating the piles with their feces.
- Store soil amendments away from produce growing and handling areas as well as high foot traffic areas to reduce risks of unintended cross-contamination of equipment, footwear, or packing facilities.

Additional Resource:

21

- The success of a food safety program is in the hands of those who work on the farm, so be sure everyone receives training.
- Workers need to understand the risks that handling and applying soil amendments may present.
- Workers should be trained so that soil amendment management steps will be completed properly.
- Resources should be provided so workers can do their jobs properly. Some examples include, additional clothing worn during produce handling activities such as gloves, overalls, or aprons should be kept clean, or changed if they are dirty, prior to entering packing and produce handling areas. While many farm activities are inherently likely to cause clothing to become soiled, it is important to pay special attention when activities involve handling raw animal manures, which could cross-contaminate food contact surfaces or produce.

22

- Developing and keeping logs of soil amendment use and handling practices will help record what has been done and allow for the process to be reviewed from year to year.
- Recordkeeping should document the type and source of soil amendment used, when it was applied, how much was applied, and any analysis or testing that was done.
- The source of the soil amendment should be documented if it does not come from the farm where it is being used.
- If growers are already keeping these types of records for other purposes, such as organic certification, they can also use them here.

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• §112.163 states that existing records (e.g., records that are kept to comply with other Federal, State, or local regulations, or for any other reason) do not need to be duplicated if they contain all of the required information and satisfy the requirements of this part.

• § 112.60 outlines the recordkeeping requirements for Subpart F related to biological soil amendments of animal origin. Recordkeeping requirements specific to on-farm composting and third-party supplied treated biological soil amendments of animal origin are in additional Recordkeeping slides.

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• If a grower plans to treat or compost soil amendments on their farm, they must establish and keep records that document the process controls (for example, time, temperature, and turnings) were achieved (§ 112.60(b)(2)).

• This includes the length of time materials are composted, the temperature compost reaches (including the ‘come-up’ time), how often it is turned, and any additional steps in the process to show that the appropriate validated process has been correctly followed.

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• Purchased, treated biological soil amendments must have documentation that indicates what process was used to treat the soil amendment, that the treatment process is a scientifically valid process that has been carried out with appropriate process monitoring (e.g., achievement of appropriate time and temperatures if composting according to § 112.54) and that the soil amendment has been handled and stored in a way that minimizes contamination from untreated amendments (§ 112.52(a)).

Notes:
For biological soil amendments of animal origin that are received from a third party, documentation must be provided and kept by the grower to show the process used to treat the soil amendment is a scientifically valid process that has been carried out with appropriate process monitoring and prove that it has been handled in a way that minimizes the risk of contamination (§ 112.60(b)(1)).

- The documentation must be renewed at least annually (§ 112.60(b)(1)).

- As a best practice, the process should be periodically verified through testing.

- Some suppliers may not have documentation of the treatment process (e.g., certificate of conformance). If they do not, there is no way to know the process they have used. Those subject to the rule must handle these soil amendments the same as they would an untreated amendment, or consider finding another supplier who can supply the appropriate documentation.

In the case of soil amendments, a corrective action plan could outline actions to be taken if raw manure or other untreated soil amendments are applied too close to harvest. This might include retreatment/composting options if soil amendments were cross-contaminated.

A corrective action plan does not need to be complicated, it just needs to be documented so it is clear that growers have considered actions to reduce risks if they happen on their farm.

**Corrective Action Plan**

- Outline steps that could be taken if soil amendments:
  - Pose a microbial risk to the crop
  - Were improperly treated
  - Accidentally contacted the edible portion of the crop
- Think of alternative market options
  - Processing markets that involve a “kill” step
- Document in your plan

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When dealing with soil amendments on the farm, there are three primary ways to reduce risks:

1) Apply raw/untreated soil amendments to fields that are not planted with produce, thereby avoiding direct contact with fresh produce.

2) Treat or process the raw soil amendment to reduce or eliminate pathogens (e.g., composting).

3) Maximize the time between application of the soil amendment and harvest of the produce.

Be sure to monitor manure and compost storage areas so that they do not contaminate packing areas, produce fields, or water sources.

Always train workers who handle soil amendments in proper sanitation and/or segregation of tools and equipment used to handle soil amendments and to practice appropriate hygienic practices, such as washing hands or changing clothes to reduce the chances of cross-contamination.

Keep records of soil amendment applications, treatment processes, and sources (if purchasing) to ensure tasks are being done properly and that the soil amendment does not serve as a source of contamination to fresh produce.