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Food

Fact Sheets on the Subparts of the FSMA Proposed Rule for Produce: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

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FDA's proposed rule, *Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption*, would establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce on farms. Below is information on individual subparts of the rule.

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[Equipment, Tools, Buildings, and Sanitation: Subpart L](#)

The proposed rule identifies possible routes of microbial contamination of produce and sets requirements to prevent or reduce the introduction of pathogens. Equipment, tools, and buildings are one identified route of contamination because they may contaminate covered produce with pathogens of public health concern, and adequate sanitation is an important way of minimizing the risk of such contamination.

Background

The potential for contamination by undesirable microorganisms or other contaminants is increased if the equipment and tools that are intended to, or likely to, come in contact with the produce, as well as the building in which growing, harvesting, packing, or holding activities take place are not sanitary. Making sure that equipment, tools, and buildings are clean and that they are also of adequate design and construction to be adequately cleaned and properly maintained, can minimize contamination of the produce.

Requirements

Equipment and tools subject to the requirements of this subpart of the proposed rule are those that are intended to, or likely to contact covered produce, and those instruments and controls used to measure, regulate, or record conditions to control or prevent the growth of undesirable microorganisms or other contamination. Examples include: knives, implements, mechanical harvesters, waxing machinery, cooling equipment (including hydrocoolers), grading belts, sizing equipment, palletizing equipment, and equipment used to store or convey harvested covered produce (such as containers, bins, food-packing material, dump tanks, or flumes).

Some of the key requirements for equipment and tools are:

- You must use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained
- Equipment and tools must be stored and maintained to protect covered produce from being contaminated with known or reasonably foreseeable hazards and to prevent the equipment

and tools from attracting and harboring pests.

- You must inspect, maintain, and clean and sanitize, when necessary and appropriate, all food-contact surfaces of equipment and tools used in covered activities as frequently as reasonably necessary to protect against contamination of covered produce
- Instruments or controls used to measure, regulate, or record temperatures, hydrogen ion concentration (pH), sanitizer efficacy or other conditions, in order to control or prevent the growth of undesirable microorganisms or other contamination must be accurate and precise as necessary and appropriate in keeping with their purpose; adequately maintained; and adequate in number for their designated uses.

Buildings subject to the requirements of this subpart include: any fully- or partially-enclosed building used for covered activities, including minimal structures that have a roof but do not have any walls; and storage sheds, buildings, or other structures used to store food-contact surfaces (such as harvest containers and food-packing materials).

Some of the key requirements that apply to buildings are:

- Buildings must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for covered activities to reduce the potential for contamination of covered produce or food-contact surfaces.
- Buildings must provide sufficient space for placement of equipment and storage of materials; permit proper precautions to be taken to reduce the potential for contamination of covered produce, food-contact surfaces, or packing materials; be constructed in such a manner that floor, walls, ceilings, fixtures, ducts and pipes can be adequately cleaned and kept in good repair, and that drip or condensate does not contaminate covered produce, food-contact surfaces, or packing materials; and provide adequate drainage in all areas where normal operations release or discharge water or other liquid waste on the ground or floor of the building.
- You must take reasonable measures to protect against contamination of covered produce from domesticated animals and pests.
- You must provide adequate, readily accessible toilet and hand washing facilities and properly dispose of sewage, trash, litter and waste.
- Your plumbing systems must be properly designed, installed and maintained.

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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:

“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

- 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:

<i>L. monocytogenes</i>	Not detected using a method that can detect one CFU per five gram analytical portion
<i>Salmonella</i> species	Less than three (3) MPN per four (4) grams of total solids (dry weight basis)
<i>E. coli</i> 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 §	In a manner that minimizes the potential for contact with covered produce during and after application ...	0 days

112.55(b) [see number 2 in previous section above]...

(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

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Domesticated and Wild Animals: Subpart I

The proposed rule identifies possible routes of microbial contamination of produce and sets requirements to prevent or reduce the introduction of pathogens. Domesticated and wild animals are one possible route of contamination because pathogens can be introduced into fruit and vegetable production systems via animal feces.

Background

The proposed rule balances the need to prevent contamination with the need to be practical and flexible with the diversity of operations and ensure that prevention measures are in harmony with resource and wildlife conservation efforts whenever possible. The proposed rule is consistent with sustainable conservation practices; it does not require animals to be harmed, farms to be fenced, animal habitats to be destroyed or farm borders to be cleared.

Requirements

- (Proposed § 112.82) If animals are allowed to graze or are used as working animals in fields where produce is grown, and under the circumstances there is a reasonable probability that grazing or working animals will contaminate covered produce, you would be required to do the following:
 - Wait an adequate amount of time between grazing and harvesting any growing area that was grazed to ensure the safety of the harvested crop, and
 - Implement measures to prevent the introduction of hazards onto covered produce from working animals if working animals are used in a growing area where a crop has been planted. For example, if you use draft horses, you could establish and use horse paths that are segregated from the produce.
- (Proposed §§ 112.83 and 112.112) If under the circumstances there is a reasonable probability that animal intrusion will contaminate covered produce, you would be required to monitor for evidence of animal intrusion immediately prior to harvest and, as needed, during the growing season. If you see evidence of animal intrusion, such as significant quantities of animals, animal excreta, or crop destruction via grazing, you must evaluate whether the covered produce can be safely harvested. For example, if you see evidence of bird excreta on a head of lettuce, you would not be allowed to harvest it.

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Personnel Qualifications, Training, and Health and Hygiene: Subparts C and D

The proposed rule identifies routes of microbial contamination of produce and sets requirements to prevent or reduce the introduction of pathogens. Bacteria, viruses, and parasites are frequently transmitted from person to person and from person to food, particularly through the fecal-oral route. The proposed rule would require that farm personnel use hygienic practices, including hand washing and maintaining adequate personal cleanliness.

Background

Those who work on farms play a key role in ensuring the safety of the produce they grow, harvest, pack, and hold. In prior food borne illness outbreaks, poor worker health and hygiene were often identified as potential contributing factors in the contamination of the product. The proposed rule would require personnel who work in operations in which covered produce or food-contact surfaces are at risk of contamination to use proper hygienic practices to protect against contamination.

Requirements

Some of the key requirements for personnel qualifications, training, health and hygiene are:

- Requires personnel who handle covered produce or supervise such personnel to receive training including principles of food hygiene and food safety, health and personal hygiene, and other topics as applicable (proposed §§ 112.21 and 112.22).
- Requires measures to prevent contamination of covered produce and food-contact surfaces from any person with an applicable health condition, such as a communicable illness, infection, open lesion, vomiting, or diarrhea (proposed § 112.31).
- Requires personnel who work in operations in which covered produce or food-contact surfaces are at risk of contamination with known or reasonably foreseeable hazards to use hygienic practices to the extent necessary to protect against such contamination. This includes maintaining adequate personal cleanliness, avoiding contact with animals other than working animals, minimizing contact with covered produce when in direct contact with working animals, washing hands thoroughly before or after certain activities and at other times, and maintaining gloves appropriately (if gloves are used) (proposed § 112.32).
- Requires measures to ensure that visitors are aware of policies and procedures to protect covered produce and food-contact surfaces from contamination, ensure they comply with the policies and procedures, and make toilet and hand-washing facilities accessible to visitors (proposed § 112.33.)

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Agricultural Water: Subpart E

The proposed rule identifies routes of microbial contamination of produce and sets requirements to prevent or reduce the introduction of pathogens. Agricultural water is one identified route of contamination; water can be a carrier of many different microorganisms of public health concern and water used for produce production presents different microbial quality demands depending on its use.

Background

The proposed rule defines agricultural water as water used in covered activities on covered produce where it is intended to, or is likely to, contact covered produce or food-contact surfaces, including: water used in growing (including irrigation water directly applied, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding (including water used for washing or cooling harvested produce and water used to prevent dehydration) (proposed § 112.3(c)). Agricultural water has been identified as one probable route of produce contamination with pathogens that can cause human illness. How and when water is applied on the farm is dependent on the type of produce being grown.

Requirements

Some of the key requirements for agricultural water are:

- Require that all agricultural water must be of safe and sanitary quality for its intended use (proposed § 112.41).
- Require inspection, maintenance, monitoring, and follow-up actions related to the agricultural water sources and water distribution systems under your control and water used for growing, harvesting, packing, and holding of covered produce; including requiring inspection of the entire agricultural water system under your control at the beginning of each growing season and maintenance of the system to prevent it from becoming a source of contamination to covered produce (proposed §§ 112.42 and 112.46);
- Require treatment of agricultural water that you use if you know or have reason to believe that the water is not safe and of adequate sanitary quality for its intended use, including requirements for treatment methods, treating such water, and monitoring its treatment (proposed § 112.43);
- Establish specific requirements for the quality of agricultural water that is used for certain specified purposes, including provisions requiring periodic analytical testing of such water (with exemptions provided for use of public water supplies under certain specified conditions or treated water), and requiring certain actions to be taken when such water does not meet the quality standards (proposed §§ 112.44 and 112.45);
 - When agricultural water is used for sprout irrigation water, applied in a manner that directly contacts covered produce during or after harvest (including as ice), used to make a treated agricultural tea, used to contact food-contact surfaces (including as ice), or used for hand washing during or after harvest, you must test the water using an appropriate analytical method. If you find that there is any detectable generic E. coli in 100 ml of water, you must immediately discontinue use of that source of water and/or its distribution system for these uses and take specified follow-up actions. Follow-up actions include making changes to the system and re-testing, or treating the water.
 - When agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method you must test the quality of water using an appropriate analytical method. If you find that there is more than 235 colony forming units (CFU) (or most probable number (MPN), as appropriate) generic E. coli per 100 ml for any single sample or a rolling geometric mean (n=5) of more than 126 CFU (or MPN, as appropriate) per 100 ml of water, you must immediately discontinue use of that source of agricultural water and/or its distribution system for these uses and take specified follow-up actions. Follow-up actions include making changes to the system and re-testing, or treating the water.
- Require certain records, including documentation of inspection findings, scientific data or information relied on to support the adequacy of water treatment methods, treatment monitoring results, water testing results, scientific data or information relied on to support any permitted alternatives to requirements, and certain documentation from public water systems if applicable (proposed § 112.50).

Alternatives

You may establish and use alternatives to the requirements established in proposed § 112.44(c) for testing water, and taking action based on test results, when agricultural water is used during growing operations for covered produce (other than sprouts) using a direct water application method, 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 § 112.44(c) requirements and would not increase the likelihood that your covered produce will be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

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Sprouts: Subpart M

The proposed rule identifies routes of microbial contamination of produce and sets requirements to prevent or reduce the introduction of pathogens.

Background

Specific requirements are established for sprouts because they present a unique risk because the warm, moist, and nutrient-rich conditions required to produce sprouts are the same conditions that are also ideal for the growth of pathogens.

Requirements

Some of the key requirements for sprouts are:

- Require that if your farm grows seeds or beans for use to grow sprouts, you must take measures reasonably necessary to prevent the introduction of hazards into or onto seeds or beans; that if you have reason to believe that a lot of seeds or beans has been associated with foodborne illness, you must not use it; and that you must visually examine seeds, beans, and packaging used to ship them for signs of potential contamination. (proposed § 112.141).
- Require that growing, harvesting, packing and holding of sprouts be done in a fully-enclosed building; require that any food-contact surfaces that come in contact with sprouts, seeds, or beans must be cleaned and sanitized; and require that you must treat seeds or beans using a scientifically valid method immediately before sprouting to reduce microorganisms of public health significance and that prior treatment by a grower, handler, or distributor of seeds or beans does not eliminate your responsibility to treat seeds or beans immediately before sprouting at your covered farm. (proposed § 112.142)
- Require that you test the growing, harvesting, packing, and holding environment for *Listeria* spp. or *L. monocytogenes* and that you test spent irrigation water from each production batch of sprouts, or the sprouts themselves, for *E. coli* O157:H7 and *Salmonella* species and take appropriate follow-up actions. You must establish and implement a written environmental monitoring plan (that also includes a sampling plan that addresses *Listeria* species or *L. monocytogenes*) and a written sampling plan for sampling sprout irrigation water or sprouts. (proposed §§ 112.143, 112.144, 112.145, 112.146)
- Require certain records, including documentation of your treatment of seeds or beans for sprouting, the written environmental monitoring plan and sampling plan, test results, and certain methods used (proposed § 112.150).

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10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
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