Aerated Compost Tea: A Field Guide to Production Methods, Formulas and Application Protocols- Appendices Only

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Attachment A: FSMA Final Rule on Produce Safety

FSMA Final Rule on Produce Safety

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

Produce Safety Standards under the FSMA Main Page (/Food/GuidanceRegulation/FSMA/ucm304045.htm)

View the Final Rule Contents in the Federal Register Notice (https://www.federalregister.gov/articles/2015/11/27/2015-28159/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption)

Below is a fact sheet provided by FDA.

About the Final Rule

- Federal Register Notice (https://www.federalregister.gov/articles/2015/11/27/2015-28159/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption)
- Docket Folder FDA-2011-N-0921 (http://www.regulations.gov/#!docketDetail;D=FDA-2011-N-0921)
- Questions & Answers (/Food/GuidanceRegulation/FSMA/ucm247559.htm#Produce_Rule)
- Coverage and Exemptions/Exclusions Flowchart (Color PDF: 95KB) (/downloads/Food/GuidanceRegulation/FSMA/UCM472499.pdf)
- Coverage and Exemptions/Exclusions Flowchart (Black & White PDF: 67KB) (/downloads/Food/GuidanceRegulation/FSMA/UCM479592.pdf)
- How Did FDA Establish Requirements for Water Quality and Testing of Irrigation Water? (/Food/GuidanceRegulation/FSMA/ucm472501.htm)
- What the Produce Safety Rule Means for Consumers (/Food/GuidanceRegulation/FSMA/ucm472503.htm)
- Print-Friendly Fact Sheet (PDF: 405KB) (/downloads/Food/GuidanceRegulation/FSMA/UCM472887.pdf)

Related Guidance

- Draft Guidance for Industry: Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing FSMA (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm524553.htm)

The Produce Safety Network Wants You (/Food/GuidanceRegulation/FSMA/ucm510261.htm)

The FDA is seeking eight experts with backgrounds in science and policy to help build the Produce Safety Network that will support the implementation of the produce safety rule that became final last November.

Public Meetings & Webinars

- Webinar on the Final Rule (/Food/GuidanceRegulation/FSMA/ucm471649.htm) November 2015

- Supplemental Notices of Proposed Rulemaking (/Food/GuidanceRegulation/FSMA/ucm418878.htm) November 13, 2014
- Environmental Impact Statement for the Proposed Rule (/Food/GuidanceRegulation/FSMA/ucm428460.htm) February 10, 2015

Supporting Material

- Final Environmental Impact Statement (EIS) (/Food/GuidanceRegulation/FSMA/ucm396564.htm)
- Final Regulatory Impact Analysis (/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/ucm472310.htm)
- Record of Decision (/downloads/Food/GuidanceRegulation/FSMA/UCM470746.pdf)
- Additional Information on Raw Manure (/Food/GuidanceRegulation/FSMA/ucm482426.htm)
- Testing Methodologies for *E. coli* O157:H7 and *Salmonella* species in Spent Sprout Irrigation Water (or Sprouts) (PDF: 622KB) (/downloads/Food/FoodScienceResearch/LaboratoryMethods/UCM467055.pdf)
- Testing Methodology for *Listeria* species or *L. monocytogenes* in Environmental Samples (PDF: 109KB) (/downloads/Food/FoodScienceResearch/LaboratoryMethods/UCM467056.pdf)
- Final Qualitative Assessment of Risk to Public Health From On Farm Contamination of Produce (PDF: 986 KB) (/downloads/Food/FoodScienceResearch/RiskSafetyAssessment/UCM470780.pdf)

Additional Information

- Audio of the Industry Call Concerning the Final Rule - November 13, 2015 (MP3: 12MB) (/downloads/Food/GuidanceRegulation/FSMA/UCM473502.mp3)
- Constituent Update: FDA Provides $21.8 Million to States for Produce Safety (/Food/NewsEvents/ConstituentUpdates/ucm519760.htm)
- Transcript of the Industry Call Concerning the Final Rule - November 13, 2015 (PDF: 109KB) (/downloads/Food/GuidanceRegulation/FSMA/UCM473503.pdf)
- Constituent Update: FDA Releases Groundbreaking Rules on Produce and Imported Foods to Modernize and Strengthen Food Safety System (/Food/NewsEvents/ConstituentUpdates/ucm472505.htm)
- Consumer Update: 5 Ways New FDA Rules Will Make Your Foods Safer (/ForConsumers/ConsumerUpdates/ucm459072.htm)
- Sprout Safety Alliance (/Food/GuidanceRegulation/FSMA/ucm293429.htm)
- Produce Safety Alliance (http://producesafetyalliance.cornell.edu/) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)
- Video Blog: Coming Together to Talk About FSMA (http://blogs.fda.gov/fdavoice/index.php/2015/06/coming-together-to-talk-about-fsma/)

Contact Us

- How to Contact FDA about FSMA (/Food/GuidanceRegulation/FSMA/ucm459719.htm)(Technical Assistance Network)

Translations of this Fact Sheet

- Arabic (PDF: 218KB) (/downloads/Food/GuidanceRegulation/FSMA/UCM480534.pdf)
- Chinese (Simplified) (PDF: 358KB) (/downloads/Food/GuidanceRegulation/FSMA/UCM480536.pdf)
- Chinese (Traditional) (PDF: 515KB) (/downloads/Food/GuidanceRegulation/FSMA/UCM482189.pdf)
- French (PDF: 143KB) (/downloads/Food/GuidanceRegulation/FSMA/UCM480538.pdf)
  - French Exemptions/Exclusions Flowchart (PDF: 75KB) (/downloads/Food/GuidanceRegulation/FSMA/UCM487250.pdf)
  - French Exemptions and Variance (PDF: 74KB) (/downloads/Food/GuidanceRegulation/FSMA/UCM490299.pdf)
- Hindi (PDF: 211KB) (/downloads/Food/GuidanceRegulation/FSMA/UCM480540.pdf)

- Italian (PDF: 159KB) (/downloads/Food/GuidanceRegulation/FSMA/UCM480543.pdf)
- Japanese (PDF: 566KB) (/downloads/Food/GuidanceRegulation/FSMA/UCM480544.pdf)
- Korean (PDF: 317KB) (/downloads/Food/GuidanceRegulation/FSMA/UCM480545.pdf)
- Portuguese (PDF: 163KB) (/downloads/Food/GuidanceRegulation/FSMA/UCM480546.pdf)
- Russian (PDF: 206KB) (/downloads/Food/GuidanceRegulation/FSMA/UCM480547.pdf)
- Spanish (PDF: 74KB) (/downloads/Food/GuidanceRegulation/FSMA/UCM480548.pdf)
  - Spanish Exemptions/Exclusions Flowchart (PDF: 75KB) (/downloads/Food/GuidanceRegulation/FSMA/UCM487283.pdf)
  - Spanish Exemptions and Variance (PDF: 74KB) (/downloads/Food/GuidanceRegulation/FSMA/UCM490298.pdf)
- Thai (PDF: 304KB) (/downloads/Food/GuidanceRegulation/FSMA/UCM480549.pdf)

In this fact sheet:

Introduction

The FDA Food Safety Modernization Act (FSMA) Produce Safety rule is now final, and the earliest compliance dates for some farms begin one year after the effective date of the final rule (see "Compliance Dates" below). The rule establishes, for the first time, science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption.

This rule was first proposed in January 2013. In response to input received during the comment period and during numerous public engagements that included public meetings, webinars, listening sessions, and visits to farms across the country, the FDA issued a supplemental notice of proposed rulemaking in September 2014. The proposed revisions were designed to make the originally proposed rule more practical, flexible, and effective.

The final rule is a combination of the original proposal and revisions outlined in the supplemental proposal, with additional changes as appropriate. The definition of "farm" and related terms were revised in the final Preventive Controls for Human Food rule (/Food/GuidanceRegulation/FSMA/ucm334115.htm), and the same definitions of those terms are used in this rule to establish produce safety standards. Operations whose only activities are within the farm definition are not required to register with FDA as food facilities and thus are not subject to the preventive controls regulations.

For operations that meet the farm definition, exemptions and modified requirements for the Produce Safety are explained in "Exemptions and Variances" and in the Coverage and Exemptions/Exclusions flowchart (PDF: 95KB) (/downloads/Food/GuidanceRegulation/FSMA/UCM472499.pdf).

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Key Requirements

1. Agricultural Water

- **Water quality**: The final rule adopts the general approach to water quality proposed in the supplemental rule, with some changes. The final rule establishes two sets of criteria for microbial water quality, both of which are based on the presence of generic *E. coli*, which can indicate the presence of fecal contamination.
  - No detectable generic *E. coli* are allowed for certain uses of agricultural water in which it is reasonably likely that potentially dangerous microbes, if present, would be transferred to produce through direct or indirect contact. Examples include water used for washing hands during and after harvest, water used on food-contact surfaces, water used to directly contact produce (including to make ice) during or after harvest, and water used for sprout irrigation. The rule establishes that such water use must be immediately discontinued and corrective actions taken before re-use for any of these purposes if generic *E. coli* is detected. The rule prohibits use of untreated surface water for any of these purposes.
  - The second set of numerical criteria is for agricultural water that is directly applied to growing produce (other than sprouts). The criteria are based on two values, the geometric mean (GM) and the statistical threshold (STV). The GM of samples is 126 or less CFU of generic E.coli per 100 mL of water and the STV of samples is 410 CFU or less of generic E.coli in 100 mL of water.
    - The GM is an average, and therefore represents what is called the central tendency of the water quality (essentially, the average amount of generic *E. coli* in a water source).
    - STV reflects the amount of variability in the water quality (indicating *E. coli* levels when adverse conditions come into play—like rainfall or a high river stage that can wash waste into rivers and canals). Although this is an over simplification, it can be described as the level at which 90 percent of the samples are below the value.
    - The FDA is exploring the development of an online tool that farms can use to input their water sample data and calculate these values.
    - These criteria account for variability in the data and allow for occasional high readings of generic E.coli in appropriate context, making it much less likely (as compared to the originally proposed criteria for this water use) that a farm will have to discontinue use of its water source due to small fluctuations in water quality.
    - These criteria are intended as a water management tool for use in understanding the microbial quality of agricultural water over time and determining a long-term strategy for use of water sources during growing produce other than sprouts.
  - If the water does not meet these criteria, corrective actions are required as soon as is practicable, but no later than the following year. Farmers with agricultural water that does not initially meet the microbial criteria have additional flexibility by which they can meet the criteria and then be able to use the water on their crops. These options include, for example:
    - Allowing time for potentially dangerous microbes to die off on the field by using a certain time interval between last irrigation and harvest, but no more than four consecutive days.
    - Allowing time for potentially dangerous microbes to die off between harvest and end of storage, or to be removed during commercial activities such as washing, within appropriate limits.
    - Treating the water.
- **Testing**: The final rule adopts the general approach to testing untreated water used for certain purposes proposed in the supplemental notice, with some changes. The rule still bases testing frequency on the type of water source (i.e. surface or ground water).
  - In testing untreated surface water—considered the most vulnerable to external influences—that is directly applied to growing produce (other than sprouts), the FDA requires farms to do an initial survey, using a

minimum of 20 samples, collected as close as is practicable to harvest over the course of two to four years. The initial survey findings are used to calculate the GM and STV (these two figures are referred to as the "microbial water quality profile") and determine if the water meets the required microbial quality criteria.

- After the initial survey has been conducted, an annual survey of a minimum of five samples per year is required to update the calculations of GM and STV.
- The five new samples, plus the previous most recent 15 samples, create a rolling dataset of 20 samples for use in confirming that that the water is still used appropriately by recalculating the GM and STV.

- For untreated ground water that is directly applied to growing produce (other than sprouts), the FDA requires farms to do an initial survey, using a minimum of four samples, collected as close as is practicable to harvest, during the growing season or over a period of one year. The initial survey findings are used to calculate the GM and STV and determine if the water meets the required microbial quality criteria.
  - After the initial survey has been conducted, an annual survey of a minimum of one sample per year is required to update the calculations of GM and STV.
  - The new sample, plus the previous most recent three samples, create a rolling dataset of four samples for use in confirming that that the water is still used appropriately by recalculating the GM and STV.
- For untreated ground water that is used for the purposes for which no detectable generic *E. coli* is allowed, the FDA requires farms to initially test the untreated ground water at least four times during the growing season or over a period of one year. Farms must determine whether the water can be used for that purpose based on these results.
  - If the four initial sample results meet the no detectable generic *E. coli* criterion, testing can be done once annually thereafter, using a minimum of one sample. Farms must resume testing at least four times per growing season or year if any annual test fails to meet the microbial quality criterion.
- There is no requirement to test agricultural water that is received from public water systems or supplies that meet requirements established in the rule (provided that the farm has Public Water System results or certificates of compliance demonstrating that the water meets relevant requirements), or if the water is treated in compliance with the rule's treatment requirements.

2. Biological Soil Amendments

- **Raw Manure**: The FDA is conducting a risk assessment and extensive research on the number of days needed between the applications of raw manure as a soil amendment and harvesting to minimize the risk of contamination. (A soil amendment is a material, including manure, that is intentionally added to the soil to improve its chemical or physical condition for growing plants or to improve its capacity to hold water.)
  - At this time, the FDA does not object to farmers complying with the USDA's National Organic Program standards, which call for a 120-day interval between the application of raw manure for crops in contact with the soil and 90 days for crops not in contact with the soil. The agency considers adherence to these standards a prudent step toward minimizing the likelihood of contamination while its risk assessment and research is ongoing.
  - The final rule requires that untreated biological soil amendments of animal origin, such as raw manure, must be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered prdouce after application.
- **Stabilized Compost**: Microbial standards that set limits on detectable amounts of bacteria (including *Listeria monocytogenes*, *Salmonella* spp., fecal coliforms, and *E. coli* 0157:H7) have been established for processes used to treat biological soil amendments, including manure. The rule includes two examples of scientifically valid composting methods that meet those standards. Stabilized compost prepared using either of these

methods must be applied in a manner that minimizes the potential for contact with produce during and after application.

3. Sprouts

- The final rule includes new requirements to help prevent the contamination of sprouts, which have been frequently associated with foodborne illness outbreaks. Sprouts are especially vulnerable to dangerous microbes because of the warm, moist and nutrient-rich conditions needed to grow them.
  - Between 1996 and 2014, there were 43 outbreaks, 2,405 illnesses, and 171 hospitalizations, and 3 deaths associated with sprouts, including the first documented outbreak of *Listeria monocytogenes* associated with sprouts in the United States.
- Requirements specific to sprouts include, for example:
  - Taking measures to prevent the introduction of dangerous microbes into or onto seeds or beans used for sprouting, in addition to treating seeds or beans that will be used for sprouting (or relying on prior treatment by the seed/bean grower, distributor, or supplier with appropriate documentation).
  - Testing of spent sprout irrigation water from each production batch of sprouts, or in-process sprouts from each production batch, for certain pathogens. Sprouts cannot be allowed to enter commerce until it is ascertained that these required pathogen test results are negative.
  - Testing the growing, harvesting, packing and holding environment for the presence of Listeria species or *Listeria monocytogenes*.
  - Taking corrective actions if spent sprout irrigation water, sprouts, and/or an environmental sample tests positive.
- Sprout operations will have less time to come into compliance with the rule than farms growing other produce. They will have one to three years to comply based on the size of their operation, with no additional time to meet the water requirements.

4. Domesticated and Wild Animals

- The rule addresses concerns about the feasibility of compliance for farms that rely on grazing animals (such as livestock) or working animals for various purposes. It establishes the same standards for these animals as it does for intrusion by wild animals (such as deer or feral swine). Farmers are required to take all measures reasonably necessary to identify and not harvest produce that is likely to be contaminated.
  - At a minimum, this requires all covered farms to visually examine the growing area and all covered produce to be harvested, regardless of the harvest method used.
  - In addition, under certain circumstances the rule requires farms to do additional assessment during the growing season, and if significant evidence of potential contamination by animals is found, to take measures reasonably necessary to assist later during harvest. Such measures might include, for example, placing flags outlining the affected area.
- Although the final rule does not require establishing waiting periods between grazing and harvest, the FDA encourages farmers to voluntarily consider applying such intervals as appropriate for the farm's commodities and practices. The agency will consider providing guidance on this practice in the future, as needed.
- As was stated in the supplemental notice, farms are not required to exclude animals from outdoor growing areas, destroy animal habitat, or clear borders around growing or drainage areas. Nothing in the rule should be interpreted as requiring or encouraging such actions.

5. Worker Training and Health and Hygiene

- Requirements for health and hygiene include:

- Taking measures to prevent contamination of produce and food-contact surfaces by ill or infected persons, for example, instructing personnel to notify their supervisors if they may have a health condition that may result in contamination of covered produce or food contact surfaces.
- Using hygienic practices when handling (contacting) covered produce or food-contact surfaces, for example, washing and drying hands thoroughly at certain times such as after using the toilet.
- Taking measures to prevent visitors from contaminating covered produce and/or food-contact surfaces, for example, by making toilet and hand-washing facilities accessible to visitors.

- Farm workers who handle covered produce and/or food-contact surfaces, and their supervisors, must be trained on certain topics, including the importance of health and hygiene.
- Farm workers who handle covered produce and/or food contact surfaces, and their supervisors, are also required to have a combination of training, education and experience necessary to perform their assigned responsibilities. This could include training (such as training provided on the job), in combination with education, or experience (e.g., work experience related to current assigned duties).

6. Equipment, Tools and Buildings

- The rule establishes standards related to equipment, tools and buildings to prevent these sources, and inadequate sanitation, from contaminating produce. This section of the rule covers, for example, greenhouses, germination chambers, and other such structures, as well as toilet and hand-washing facilities. o Required measures to prevent contamination of covered produce and food contact surfaces include, for example, appropriate storage, maintenance and cleaning of equipment and tools.

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Exemptions

The rule does not apply to:

- Produce that is not a raw agricultural commodity. (A raw agricultural commodity is any food in its raw or natural state)
- The following produce commodities that FDA has identified as rarely consumed raw: asparagus; black beans, great Northern beans, kidney beans, lima beans, navy beans, and pinto beans; garden beets (roots and tops) and sugar beets; cashews; sour cherries; chickpeas; cocoa beans; coffee beans; collards; sweet corn; cranberries; dates; dill (seeds and weed); eggplants; figs; horseradish; hazelnuts; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; winter squash; sweet potatoes; and water chestnuts
- Food grains, including barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (e.g. cotton seed, flax seed, rapeseed, soybean, and sunflower seed)
- Produce that is used for personal or on-farm consumption
- Farms that have an average annual value of produce sold during the previous three-year period of $25,000 or less

The rule provides an exemption for produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, under certain conditions.

The rule also provides a qualified exemption and modified requirements for certain farms.

- To be eligible for a qualified exemption, the farm must meet two requirements:
  - The farm must have food sales averaging less than $500,000 per year during the previous three years; and

- The farm's sales to qualified end-users must exceed sales to all others combined during the previous three years. A qualified end-user is either (a) the consumer of the food or (b) a restaurant or retail food establishment that is located in the same state or the same Indian reservation as the farm or not more than 275 miles away.

- A farm with the qualified exemption must still meet certain modified requirements, including disclosing the name and the complete business address of the farm where the produce was grown either on the label of the produce or at the point of purchase. These farms are also required to establish and keep certain documentation.
- A farm's qualified exemption may be withdrawn as follows:
  - If there is an active investigation of an outbreak of foodborne illness that is directly linked to the farm, or
  - If FDA determines it is necessary to protect the public health and prevent or mitigate an outbreak based on conduct or conditions associated with the farm that are material to the safety of the farm's produce that would be covered by the rule.
- Before FDA issues an order to withdraw a qualified exemption, the agency:
  - May consider one or more other actions to protect public health, including a warning letter, recall, administrative detention, refusal of food offered for import, seizure and injunction.
  - Must notify the owner, operator, or agent in charge of the farm, in writing, of the circumstances that may lead FDA to withdraw the exemption, provide an opportunity for response within 15 calendar days of receipt of the notification, and consider actions taken by the farm to address the issues raised by the agency.
- A withdrawn exemption may be reinstated if (as applicable):
  - The FDA determines that the outbreak was not directly linked to the farm, and/or
  - The FDA determines that the problems with conduct or conditions material to the safety of the food produced or harvested at the farm have been adequately resolved, and continued withdrawal of the exemption is not necessary to protect public health or prevent or mitigate an outbreak of foodborne illness.

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Variances

The rule also permits states, tribes, or foreign countries from which food is imported into the U.S. to submit a petition, along with supporting information, to FDA requesting a variance(s) from one or more of the requirements of this rule.

- The rule enables a state, tribe, or country, if it concludes that meeting one or more of the rule's requirements would be problematic in light of local growing conditions, to request variances to those requirements. The state, tribe, or foreign country must demonstrate that the requested variance is reasonably likely to ensure that the produce is not adulterated and provides the same level of public health protection as the corresponding requirement(s) in the rule.
- The final rule makes it clear that federally recognized tribes may submit a variance petition.
- The request for a variance must be submitted by a competent authority, meaning a person or organization that is the regulatory authority for food safety for the state, tribe, or foreign country.
- A foreign government does not need to have a systems recognition arrangement or equivalence agreement with the FDA to obtain a variance.
- The variance request must include relevant and scientifically valid information specific to the produce or activity. Information could relate to crops, climate, soil, geography or environment, as well as the practices of that particular region.

- Examples of types of variances that may be granted include a variance from the agricultural water microbial quality criteria for water used during growing covered produce (other than sprouts) using a direct water application method, a variance from the microbial die-off rate used to determine the time interval between the last irrigation and harvest and/or the accompanying maximum time interval; and a variance from the approach or frequency for water testing for water uses subject to the rule's microbial quality criteria.

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Compliance Dates

Compliance dates for covered activities, except for those involving sprouts, after the effective date of the final rule are:

- Very small businesses, those with more than $25,000 but no more than $250,000 in average annual produce sales during the previous three year period : four years
- Small businesses, those with more than $250,000 but no more than $500,000 in average annual produce sales during the previous three year period: three years
- All other farms: two years
- The compliance dates for certain aspects of the water quality standards, and related testing and recordkeeping provisions, allow an additional two years beyond each of these compliance dates for the rest of the final rule

Compliance dates for modified requirements for farms eligible for a qualified exemption are:

- For labeling requirement (if applicable): January 1, 2020
- For retention of records supporting eligibility for a qualified exemption: Effective date of the final rule
- For all other modified requirements:
  - Very small businesses, four years after the effective date of the final rule
  - Small businesses, three years after the effective date of the final rule

Compliance dates for covered activities involving sprouts after the effective date of the final rule are:

- Very small businesses: three years
- Small businesses: two years
- All other farms: one year

For more information, see **Compliance Date Extensions and Clarifications for FSMA Final Rules (/Food/GuidanceRegulation/FSMA/ucm517545.htm)**.

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Environmental Impact Statement

The FDA has also released the **Final Environmental Impact Statement (EIS) (/Food/GuidanceRegulation/FSMA/ucm396564.htm)**, which places the Produce Safety rule in the context of its likely impact on the environment, including human health and socioeconomic effects. The Draft EIS was published in January 2015. The FDA considered public comments submitted in the two months that followed in drafting the Final EIS. The FDA considered the findings of the Final EIS in finalizing the produce rule.

- The EIS evaluated actions that FDA proposed in the original and supplemental rules, as well as a number of alternative actions for each of the provisions identified as having the potential to result in significant

environmental impacts. The provisions of the final rule represent FDA's preferred alternatives, which are detailed in a Record of Decision (ROD). The ROD addresses how the EIS findings were incorporated into decisions about the final rule. The agency's preferred alternatives are those that the FDA believes best fulfill the agency's statutory mission and responsibility, giving consideration to economic, environmental, technical and other factors.

- A significant beneficial impact on public health is expected due to the anticipated decrease in the number of illnesses tied to produce contamination.
- As in the Draft EIS, the Final EIS notes that any produce regulation that causes a farmer to use ground water instead of surface water could exacerbate existing groundwater shortages, although added flexibility in the water provisions make such a management decision unlikely.
- The Final EIS also concludes that Native American farmers may be disproportionately affected by any increases in operating costs necessitated by the produce rule since their average income is 30 percent less than that of other farmers.

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Assistance to Industry

The FDA is developing several guidance documents on subjects that include:

- General guidance on implementation and compliance.
- A Small Entity Compliance Guide that explains the actions a small or very small business must take to comply with the rule.
- Other documents, including guidance on sprouts, are being considered and prioritized.

Plans for training and technical assistance are well under way. They include:

- Establishing the FDA FSMA Food Safety Technical Assistance Network, already operational, to provide a central source of information to support industry understanding and implementation of FSMA.
- The FDA is developing a comprehensive training strategy that includes collaboration with:
  - The Produce Safety Alliance;
  - The Sprout Safety Alliance;
  - The National Institute of Food and Agriculture in the U.S. Department of Agriculture (to administer a grant program to provide food safety training, education and technical assistance to small and mid-size farms and small food processors, beginning farmers, socially disadvantaged farmers, and small produce merchant wholesalers); and
  - Cooperative agreement partners (to develop training programs for sustainable agriculture and tribal operations).
- The FDA also plans to work with cooperative extension units, land grant universities, trade associations, foreign partners, the Joint Institute for Food Safety and Applied Nutrition (JIFSAN), and other stakeholders to develop a network of institutions that can provide technical assistance to the farming community, especially small and very small farms.
- FDA has entered into a cooperative agreement with National Association of State Departments of Agriculture (NASDA) to help with the implementation of the produce safety regulations.

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More in Food Safety Modernization Act (FSMA) (/Food/GuidanceRegulation/FSMA/default.htm)

The Law, Rules & Guidance (/Food/GuidanceRegulation/FSMA/ucm359436.htm)

How to Comment on FSMA (/Food/GuidanceRegulation/FSMA/ucm261689.htm)

Fact Sheets & Presentations (/Food/GuidanceRegulation/FSMA/ucm247546.htm)

Frequently Asked Questions on FSMA (/Food/GuidanceRegulation/FSMA/ucm247559.htm)

FDA Actions and Meetings (/Food/GuidanceRegulation/FSMA/ucm359450.htm)

FSMA Training (/Food/GuidanceRegulation/FSMA/ucm461513.htm)

Contact FDA About FSMA (/Food/GuidanceRegulation/FSMA/ucm459719.htm)

Archive (/Food/GuidanceRegulation/FSMA/ucm412613.htm)

Attachment B: FDA, Frequently Asked Questions on Produce Rule

FDA FOOD SAFETY
MODERNIZATION ACT

Frequently Asked Questions and Answers

Proposed Rule: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

March, 2013

A: General

A.1 What does the proposed produce safety rule establish?

The proposed rule would establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce on farms. To that end, the rule proposes new standards in the following major areas:

- Worker Training and Health and Hygiene
- Agricultural Water
- Biological Soil Amendments of Animal Origin
- Domesticated and Wild Animals
- Equipment, Tools, and Buildings
- Sprouts

A.2 What kind of produce does the proposed produce safety rule apply to?

The proposed rule covers most fruits and vegetables while they are in their raw or natural (unprocessed) state. It would not apply to raw agricultural commodities that are rarely consumed raw, those produced for personal or on-farm consumption, and (with certain documentation) those destined for commercial processing, such as canning, that will adequately reduce microorganisms of public health concern.

A.3 How would the proposed rule define "farm"?

The proposed rule would define "farm" to mean a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood) or both. "Farm" includes (i) facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and (ii) facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.

A.4 How would the proposed rule define "mixed-type facility" and "farm mixed-type facility?

The proposed rule would define "mixed-type facility" to mean an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility" which is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to register with FDA under section 415 of the FD&C Act.

A.5 Where can I find out more about what activities are within the definition of "farm" and what activities are outside that definition?

Table 3 in the proposed produce rule preamble (in section V.A.2.b.i, at 78 FR 3543-4) provides examples of activities and their classification. For more information, we

encourage you to read section V.A.2.b.i of the proposed produce rule preamble (starting at 78 FR 3539), and section VIII of the proposed preventive controls rule preamble (starting at 78 FR 3674), which includes the most detail on this topic.

A.6 When would packing produce be subject to the rule and when would it not be subject to the rule? What is the reason for the difference?

Produce packing that does not occur on a farm would not be subject to the proposed rule because the proposed rule would only apply to covered farms as defined in the rule (see proposed § 112.4).

Packing produce for consumption on the farm would not be covered by the rule because the rule would not apply to produce for on-farm consumption (see proposed § 112.2(a)(2)).

When a covered farm packs produce grown on that farm (or another farm under the same ownership) for distribution into commerce, that activity would be covered by the rule because the activity is within the definition of "farm" in the rule (see proposed §112.3(c) definition of farm: "'Farm' includes (i) facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership").

When a covered farm packs produce that was not grown on that farm (or another farm under the same ownership) for distribution into commerce, that activity would not be subject to the proposed rule because it would not be within the definition of "farm" in the rule (see proposed §112.3(c) definition of farm: "'Farm' includes (i) facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership").

The definition of "farm" and related definitions in the proposed rule are based in part on FDA's tentative conclusions that:

- the basic purpose of farms is to produce raw agricultural commodities (RACs) and RACs are the essential products of farms;
- activities that involve RACs and that farms traditionally do for the purposes of growing their own RACs, removing them from the growing areas, and preparing them for use as a food RAC, and for packing, holding and transporting them, should all be within the definition of "farm"; and
- activities farms may perform on others' RACs should appropriately be classified as manufacturing/processing, packing, or holding in the same manner as these activities are classified off-farm when the RACs are to be distributed into commerce.

A.7 Who would be a "covered farm" under the proposed rule?

The proposed rule would define "farm" and "mixed-type facility" (see above). Farms and farm mixed-type facilities that have an average annual monetary value of food sold

during the previous 3-year period of more than $25,000 (on a rolling basis) would be "covered farms" under the proposed rule, unless they are eligible for the qualified exemption (see below) and FDA has not withdrawn their qualified exemption.
The proposed rule would not apply to farms that have an average annual value of food sold during the previous 3-year period of $25,000 or less. FDA notes, however, that these farms are and will continue to be covered under the adulteration provisions and other applicable provisions of the FD&C Act, whether or not they are included within the scope of this proposed rule.

A.8 What food would count in calculating the average annual monetary value of food sold during the previous three-year period (for the purposes of proposed §§ 112.4, 112.5, and the definitions of small and very small business in proposed § 112.3(b))? For example, would the value of peaches I sold to a commercial cannery be calculated when determining the average monetary value of food sold during the previous 3-year period?

In the term "average annual monetary value of food sold," the word "food" means "food as defined in section 201(f) of the FD&C Act and includes seeds and beans used to grow sprouts" (see proposed § 112.3(c)). In section 201(f) of the FD&C Act, "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article. Thus, all food would count in calculating the average annual value of food sold, even if that food is not covered produce. In the example, the value of peaches sold to a commercial cannery would be included in the calculation to determine the average monetary value of food sold during the previous 3-year period.

B. Qualified exemption and modified requirements

B.1 What qualified exemption is being proposed for certain farms under the proposed rule?

As required by FSMA, certain farms would be exempt from most of the requirements of the proposed rule and would instead be subject to modified requirements. This qualified exemption could be withdrawn under certain circumstances. The following farms would be eligible for the qualified exemption:

Farms for which, during the previous 3-year period preceding the applicable calendar year:

The average annual monetary value of the food sold directly to qualified end-users during such period exceeded the average annual value of the food sold to all other buyers during that period; AND

The average annual monetary value of all food sold during such period was less than $500,000, adjusted for inflation.

B.2 What modified requirements would the proposed rule establish for farms eligible for the qualified exemption? (proposed § 112.6)

Farms eligible for the qualified exemption would be subject to proposed subparts A, Q, and R. The proposed rule would also require a farm eligible for the qualified exemption to do the following:

- When a food packaging label **is required** on food that would otherwise be covered produce under the FD&C Act or its implementing regulations, the farm must include prominently and conspicuously on the food packaging label the name and the complete business address of the farm where the covered produce was grown;
- When a food packaging label **is not required** on food that would otherwise be covered produce under the FD&C Act or its implementing regulations, the farm must prominently and conspicuously display, at the point of purchase, the name and complete business address of the farm where the produce was grown on a label, poster, sign, placard, or documents delivered contemporaneously with the produce in the normal course of business, or, in the case of Internet sales, in an electronic notice.

The complete business address would be required to include the street address or post office box, city, state, and zip code for domestic farms, and comparable full address information for foreign farms.

B.3 If some of the produce that I grow is not covered by the proposed rule or is eligible for exemption from most requirements under certain conditions, could my farm still be covered by this rule?

Yes. The exemptions in proposed § 112.2 are only applicable to the produce specified in the exemption. In other words, a covered farm may not rely on these exemptions for all of its covered produce simply because a subset of that produce is rarely consumed raw; is for personal or on-farm consumption; is not a RAC; or will receive the requisite commercial processing; in those instances, only the subset that meets the relevant exemption criteria would be exempt from the proposed rule. For example, if you own or operate a farm that produces both tomatoes that will be processed into tomato paste, and tomatoes that will not receive any commercial processing to adequately reduce pathogens, and you do not qualify for any other exemption, you would be subject to the rule when you grow, harvest, pack or hold those tomatoes that will not be processed to adequately reduce pathogens. Likewise, if you produce both artichokes and lettuce, you would be subject to the rule when you grow, harvest, pack or hold lettuce, but you would not be subject to the rule when you grow, harvest, pack, or hold artichokes.

B.4 Are there circumstances in which FDA could withdraw a qualified exemption?

Yes. The proposed rule would allow FDA to withdraw a qualified exemption:

- In the event of an active investigation of a foodborne illness outbreak that is directly linked to your farm; or
- If FDA determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with your farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed or held at your farm (see proposed § 112.201).

B.5 What are examples of the types of conduct or conditions that could trigger the withdrawal of a qualified exemption?

As an example, we may receive reports to the Reportable Food Registry under section 417 of the FD&C Act about contamination of a food, and the reports may lead us to investigate a farm that grew, harvested, packed or held the food. If our investigation finds conduct or conditions associated with the farm that are material to the safety of the food that would otherwise be covered produce subject to proposed subparts B through O of the proposed rule (for example, conduct or conditions that likely led to the contamination of the food), we would consider withdrawing the qualified exemption applicable to the farm if doing so would be necessary to protect the public health and prevent or mitigate a foodborne illness outbreak. Likewise, if during a routine inspection of a farm to which the qualified exemption applies, we discover conditions and practices that are likely to lead to contamination of food that would otherwise be covered produce with microorganisms of public health significance, we would consider withdrawing the

qualified exemption provided to the facility if doing so would be necessary to protect the public health and prevent or mitigate a foodborne illness outbreak.

B.6 How would the proposed rule define "qualified end-user"?

The proposed rule would define "qualified end-user" to mean, with respect to a food:
The consumer of the food; OR
A restaurant or retail food establishment that is located in the same state as the farm that produced the food, or not more than 275 miles from such farm.

B.7 Would establishments like community sponsored agriculture (CSA) farms, "U-pick" farms, or farms that sell at farmers markets be covered by the proposed rule?

CSA farms, U-pick farms, and farms that sell at farmers markets, like all farms, would need to analyze their individual situations to determine if they would be covered by the proposed rule. In particular, these operations would need to analyze their sales under the terms of proposed § 112.5 to determine their eligibility for the qualified exemption and modified requirements.

For example, if a U-pick operation has an average annual monetary value of food sold during the relevant 3-year period of less than $500,000, and all of its sales were to individuals who come to the farm to pick their own produce, all of its sales would be sales to consumers (who are qualified end-users, regardless of location) for the purpose of determining the proportion of the sales that are to qualified end-users. In this example, the U-pick farm would be eligible for the qualified exemption and modified requirements.

As another example, if a CSA farm has an average annual monetary value of food sold during the relevant 3-year period of less than $500,000; and 25% of the monetary value of its sales comes from sales to individual consumers enrolled in the CSA, 50% of the monetary value of its sales comes from sales directly to restaurants in the same state as the farm, and 25% of the monetary value of its sales comes from sales to other buyers who are not qualified end-users; the CSA farm would be eligible for the qualified exemption and modified requirements. In this example, the CSA farm's sales to qualified end-users (consumers and in-state restaurants) make up 75% of the average annual monetary value of food sold, so the value of the farm's sales to qualified end-users exceed the value of its sales to all other buyers during the relevant time period.

C. Alternate Approaches for Requirements

C.1 Would the proposed rule allow the use of alternative practices?

We are proposing to allow for the use of alternatives to certain requirements of part 112 under certain specified conditions. Under proposed § 112.12, you may establish and use an alternative to certain specified requirements, 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 requirement and would not increase the likelihood that your covered produce will be adulterated under section 402 of the FD&C Act, in light of your covered produce, practices, and conditions, including agro-ecological conditions and application interval. The specific requirements for which alternatives may be established and used are:

- Requirements 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 (see proposed § 112.44(c));
- Composting treatment processes (see proposed § 112.54(c)(1) and (2));
- Minimum application interval for an untreated biological soil amendment of animal origin that is reasonably likely to contact covered produce after application (including compost agricultural teas that contain compost agricultural tea additives) (see proposed § 112.56(a)(1)(i)); and
- Minimum application interval for a biological soil amendment of animal origin treated by a composting process that is reasonably likely to contact covered produce after application (see proposed § 112.56(a)(4)(i));

C.2 Where could I find scientific data and information that I would need to support the establishment and use of an alternative?

Scientific data and information used to support an alternative to a requirement for which alternatives are permitted may be:

- Developed by you;
- Available in the scientific literature; or
- Available to you through a third party (see proposed § 112.12(c)).

C.3 Would I be required to have documentation to support the use of an alternative, and would I be required to submit that documentation to FDA?

We do not propose to require you to submit scientific data or information in support of an alternative to us for review or approval prior to marketing. However, we would require that you establish and maintain a record of any such scientific data or information, including any analytical information, and make such data and information available to us to evaluate upon request (see proposed §§ 112.12(c) and 112.166).

D. Agricultural Water

D.1 How would the proposed rule define "agricultural water"?

The proposed rule would define "agricultural water" to mean water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce (i.e., the harvestable or harvested part of the crop) or food-contact surfaces, including water used in growing, harvesting, packing, and holding activities. Agricultural water includes:

- Irrigation water applied using direct water application methods;
- Water used for preparing crop sprays;
- Water used for growing sprouts;
- Water used for washing or cooling harvested produce; and
- Water used to prevent dehydration of produce (see proposed § 112.3(c)).

D.2 Would the proposed rule establish requirements for indirect water application (for example, drip irrigation)?

The standards proposed in subpart E of the rule are directed to agricultural water only (see also A.19 above for proposed definition of agricultural water). Indirect water application methods where water is not intended to, and is not likely to, contact the harvestable or harvested part of the crop would not be subject to the requirements of proposed subpart E of the rule. As proposed, "agricultural water" would not include indirect water application methods used during growing. For example, generally, the water used for drip or furrow irrigation in apple orchards would not be considered agricultural water because the water is unlikely to contact the harvestable portion of the crop. FDA is proposing to distinguish between water that is intended to, or is likely to, contact produce or food-contact surfaces and water that is not intended to, and is not likely to, contact produce or food-contact surfaces based on the relative likelihood of contamination from water that contacts produce and the need for measures to minimize such likelihood.

While indirectly applied water is unlikely to contact produce or food-contact surfaces, we recognize that it presents the possibility of produce contamination. For example, use of contaminated water in drip or furrow irrigation may still serve as a vehicle for bringing contaminants into the growing environment which may potentially be transferred to produce by rain splash, workers, or equipment; use of contaminated water for dust abatement on farm roads may also be transferred to produce by run-off, rain splash, workers, or equipment.

Indirect water application methods would remain subject to Section 402(a)(4) of the FD&C Act. That is, indirect water application may adulterate produce if, considering the water quality and the manner of its application, the use of the water causes produce to be prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth or rendered injurious to health. Moreover, if a pathogen is

detected in or on produce, such produce would be considered adulterated under Section 402(a)(1) of the FD&C Act, in that it contains a poisonous or deleterious substance which may render it injurious to health. Therefore, we have tentatively concluded that indirect water application methods do not need to be covered within the scope of "agricultural water" for the purposes of the proposed rule. We are seeking public comment on our proposed limited scope of "agricultural water."

D.3 When the proposed rule would require me to treat my agricultural water, what requirements would it establish with respect to my treatment method?

The proposed rule does not specify a specific water treatment or method for treating agricultural water when treatment would be required. The proposed rule would require you to use a treatment method that is effective to make the water safe and of adequate sanitary quality for its intended use (see proposed § 112.43(b)). The proposed rule would also require you to deliver the treatment in a manner to ensure that the treated water consistently meets that standard, and to monitor the treatment at a frequency adequate to ensure that the treated water consistently meets that standard (see proposed § 112.43(c)).

Treating agricultural water with antimicrobial compounds (such as with an EPA-registered antimicrobial pesticide product) can be an effective means to eliminate pathogens if done properly, including under conditions that ensure the effectiveness of the active ingredient. Any chemicals used in the treatment of water would require EPA registration under the Federal Insecticide, Fungicide and Rodenticide Act before they can lawfully be used. We note, however, that at the present time, no such registration for chemical treatment of irrigation water exists. We anticipate that the proposed delayed implementation period for water quality testing would provide industry adequate time to address such issues. We are seeking public comment on this issue.

E. Soil Amendments

E.1 How would the proposed rule define "biological soil amendment of animal origin"?

The proposed rule would define the term "biological soil amendment of animal origin" to mean a biological soil amendment which consists, 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 term "biological soil amendment of animal origin" does not include any form of human waste (see proposed § 112.3(c)).

E.2 Does the proposed rule account for the differences between "manure" and "compost"?

Yes, we are proposing definitions that make the distinction clear. We are proposing to use the phrase "untreated biological soil amendments of animal origin" as a category that includes raw manure (see proposed §§ 112.3(c) and 112.51(a)). We use the term "treated biological soil amendments of animal origin" to include treatments that meet the requirements of the standards presented in subpart F of the proposed rule (see proposed § 112.51(a)). To further alleviate confusion, we use the term "compost" as a verb, to mean the act of composting, and do not use it as a noun to describe a soil amendment that was treated by a composting method. Instead, we use the term "humus" in its common agricultural meaning (see proposed § 112.3(c)).

E.3 How would the proposed rule categorize biological soil amendments of animal origin as treated or untreated?

The proposed rule would categorize a biological soil amendment of animal origin as treated if it has been processed to completion to adequately reduce microorganisms of public health significance in accordance with the proposed requirements of § 112.54, or in the case of an agricultural tea, if the biological materials used to make the tea have been so processed and the water used to make the tea satisfies the proposed requirements of § 112.44(a) (see proposed § 112.51(a)).

The proposed rule would categorize a biological soil amendment of animal origin as untreated if it:

- has not been processed to completion in accordance with the proposed requirements of § 112.54, or in the case of an agricultural tea, if the biological materials used to make the tea have not been so processed or the water used to make the tea does not satisfy the proposed requirements of § 112.44(a);
- has become contaminated after treatment;
- has been recombined with an untreated biological soil amendment of animal origin;

- is or contains a component that is untreated waste that you know or have reason to believe is contaminated with a hazard or has been associated with foodborne illness; or
- is an agricultural tea that contains an agricultural tea additive. (see proposed §112.51(b))

E.4 Does the proposed rule establish testing requirements for soil amendments?

No. The proposed microbial standards for treated biological soil amendments in § 112.55 are not meant as lot-by-lot microbial testing requirements. Rather, they are intended to provide the standard against which treatment processes would be required to be validated. A validated process, when properly implemented and monitored, would be expected to meet the listed microbial standards. The person applying the treatment process would need to monitor the physical parameters of the process (e.g., temperature of a compost pile) to ensure that they meet the conditions under which the process was validated. Farms would be able to use treatment processes that are validated to meet the relevant microbial standard without needing to test the end products of their treatments to confirm that the microbial standard was achieved.

E.5 How do the proposed application requirements and intervals for raw manure relate to those used in the National Organic Program?

The proposed rule does not include any requirements that conflict with or duplicate the requirements of the National Organic Program. Where the proposed rule and the National Organic Program would include similar or related requirements, we propose that our requirements may be satisfied concurrently with those of the National Organic Program (i.e., to the extent the requirements are the same, compliance with this proposed rule could be achieved without duplication). Certified organic farms growing produce that would be subject to this rule and that use raw manure would need to follow the application requirements and intervals in the proposed rule for untreated biological soil amendments of animal origin. The National Organic Program application intervals for raw manure would run concurrently with FDA's proposed application interval, rather than consecutively. Organic farms (like other farms) using raw manure would either need to wait 9 months between application and harvest and use application methods meeting the proposed requirements for avoiding and minimizing contact between covered produce and raw manure, or apply the raw manure in a manner that does not contact covered produce during or after application. Doing so would not jeopardize their compliance with the requirements of the National Organic Program.

We seek comment on our approach to ensuring that this proposed rule does not conflict with or duplicate the requirements of the National Organic Program while providing the same level of public health protection as required under FSMA.

F. Records

F.1 Would records maintained for the National Organic Program (NOP) meet the records requirements of the proposed rule?

The proposed rule would not require duplication of existing records if those records contain all of the information required by the proposed rule (see proposed § 112.163). USDA-certified organic growers who already maintain records of when biological soil amendments of animal origin are applied in compliance with 7 CFR 205.103 would not need to duplicate those records to meet the proposed requirements of § 112.60(b)(1).

F.2 Would the proposed rule permit me to use existing records to meet its requirements?

Yes. The proposed rule does not require duplication of existing records if those records contain all of the information required by proposed part 112 (see proposed § 112.163).

F.3 Does the proposed rule require that records be made available and accessible to FDA?

Yes. The proposed rule would require all records required by part 112 be readily available and accessible during the retention period for inspection and copying by FDA upon oral or written request (see proposed § 112.166).

F.4 How long will the public have to comment on the proposed rule?

The comment period is open for 120 days (until May 16, 2013) from the date the proposed rule is published in the Federal Register. See www.regulations.gov.

Attachment C: Test results, Primus Labs

Primus Labs™
when food safety counts

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CT-SO-7/27/16-7/14/16

Microbiological Results

Customer: North Valley Organics

Location: Albuquerque - New Mexico

Sampled by: Customer

Date Received: Jul 27, 2016

AuthorizationNumber	Sample Description	Type of Analysis	Method Used	Results
	COMPOST TEA FROM SOILUTIONS COMPOST PURCHASED 7/14/16 Grower- Soilutions Compost Tea Ranch(es)- Soilutions Compost Tea Lot- Compost Tea From Soilutions Compost Product State- Finished Product Date Time : 7/25/16, 2:00 pm			
USM16.089053 - 01		EC 0157:H7	AOAC-RI 011401	Negative
		L. mono	AOAC-RI 111301	Negative
		Salmonella	AOAC-RI 041303	Negative
		Fecal Coliform	MPN	< 3 est MPN/g

CFU = Colony Forming Unit **MPN** = Most Probable Number **L. mono** = Listeria monocytogenes
E.Coli = Escherichia coli **TPC** = Total Plate Count **TC** = Total Coliform

* Negative for E.Coli = < 10 est CFU/g ** Negative for E.Coli = < 1 est CFU/ml ** *Negative for E.Coli = < 1 est CFU/50 sq cm ** **Negative for E.Coli = < 100 est CFU/sq m

Approved by: Roberto Guzman Guzman Uriarte R. **Date Approved:** Aug 01, 2016

Analyst

Rev. 07/05