

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

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Table of Contents: Compost Tea Field Guide

Acknowledgements Background and grant focus Pg. 3 Food Safety Modernization Act and compost tea Pg. 5 **Good Agricultural Practices** Produce Safety Rule **Microbial Standards** Validation Process Pg. 7 Pathogen Prevention Testing Water quality testing Pg. 8 Pathogen testing Compost tea quality testing Compost tea basics Pg. 9 Part One: Farmer Self Assessment Pg. 11 Part Two: Farm Infrastructure Development Pg. 13 Part Three: Step-by-Step Compost Tea Production Pg. 22 Brewing trials at our farm Pg. 26 Process specifications at North Valley Organics Pg. 28 Conclusion Pg. 30 40 gallon brewer design Pg. 31 **Useful Websites** Pg. 34 Appendices A: FSMA Final Rule on Produce Safety B: FDA, Frequently Asked Questions on Produce Rule C: Test results, compost and compost tea, Primus Labs D: Test results, compost and compost tea, Soil Control Laboratory

- E: Test results, well water quality, Hall Environmental Laboratory
- F: Earthfort compost testing form
- G: Soil Food Web compost testing form
- H: Farmer self assessment
- I: Step-by-Step: Preparation
- J: Step-by-Step: Mailing tea for testing
- K: Air volume conversion factor (for calculating pump capacity)
- L: General information on dissolved oxygen

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John Garlisch is the County Agent for the Bernalillo County Cooperative Extension Service, the extension agency for New Mexico State University. John has acted as Technical Advisor and has many years in supporting agricultural producers in New Mexico, as well as being a farmer himself.

Walter Dods has worked for Soilutions for 15 years. Soilutions is the largest company in New Mexico to produce compost approved for use in certified organic gardens and farms and has been doing so for 20 years. Walter is THE expert in organic compost in New Mexico and is knowledgeable in compost and compost tea production. We used Walter's commercial aerating compost tea brewer for all compost tea production.

Fred Koster, raised on a farm, a lifelong gardener and recently a commercial farmer is a retired physician and microbiologist. As a commercial farmer using sustainable and organic practices, Fred is committed to helping develop a compost tea production process that is both effective, safe and in compliance with FSMA Standards.

Matthew Draper has been a partner at North Valley Organics for the past three years and has been a mainstay in the day-to-day operations of our farm. Without his calm perseverance, focused attention and deep dedication to biological and sustainable farming, this project would never have left the ground. (or made it into the ground...)

A special note of appreciation goes to Rudy Garcia and all the staff at the New Mexico USDA NRCS office. Rudy has been a champion of Soil Health for 25 years and has recently taken a position as Regional Coordinator for the newly organized "Soil Health Division" within the NRCS. Rudy's tireless efforts to promote biological farming and the critical role of the living biosphere has been an inspiration to all of us.

Finally, I could not have completed this work without the ongoing support of my lovely wife, Sylvia. With forbearance and an amused tolerance - "Why is there a bowel of dirt in the closet?!?"- Sylvia has survived any number of planned (and accidental) events.

Background and grant focus

In January, 2011 the Food Safety and Modernization Act (FSMA) was signed into law, with a 5 year review period for receiving feedback and modifying the regulations. FSMA covers a wide range of issues regarding food safety and agricultural production and consists of thousands of pages of regulations, rulemaking, etc. FSMA was promulgated by the Food and Drug Administration (FDA) and grants broad authority to the FDA to regulate its Standards, including regulating on-farm production activities.

One part of FSMA- The Final Rule for Produce Safety- is the focus of this paper. The Final Rule was published in November, 2015 and went into effect in February, 2016. There is a timeline for beginning of enforcement activities that ranges from 2016-2020. The Produce Safety rule establishes: "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption". In subpart F of this rule, compost and compost tea is addressed.

This paper does NOT discuss whether a particular farm is exempt from FSMA. The question of who is covered by FSMA, farm size, produce sales, timeframe for compliance, specific exemptions under FSMA- these are all important questions, but not addressed here. Our focus is providing information to farmers who have decided they wish to comply with FSMA Standards.

<u>Disclaimer</u>: Although we have made our best efforts to understand the FSMA rules and Standards, we cannot guarantee that following the processes outlined in this paper will guarantee compliance under FSMA. The law is too new, with too many questions for us to make this claim. We have outlined what we believe to be a thorough and well documented process for making compost tea that complies with FSMA, but make no guarantees that any regulatory body will accept our process as valid.

In the last few years there has been a resurgence in interest in biological farmingmaximizing the natural biologically based processes that occur on a farm, to the benefit of the farmer and the farm ecosystem. Elaine Ingham, the Rodale Institute, Cornell University College of Agriculture and the Sustainable Agriculture Research and Education program (SARE), to name a few, have long championed the critical role microbes play in soil health and improving the farm eco-system.

New research is emerging about how these microbes are present at every level of plant production and play a critical role in plant growth, carbon cycling, pathogen suppression and a healthy environment. This report, however, does NOT address the effectiveness of compost tea in improving plant health, yield, pathogen suppression, etc. Nor does it address how to properly make compost that complies with FSMA or the National Organic Plan (NOP) Standards for making compost.

The specific focus of this report is how to implement an on-farm process for making aerated compost tea that meets the newly promulgated Standards for "biological soil amendment of animal origin" under the Food Safety and Modernization Act (FSMA). We outline what a farmer must do on his own farm to meet FSMA standards for compost tea safety.

Food Safety Modernization Act (FSMA)

In recent years food safety on farms has become increasingly important. Many vendors are moving in the direction of requiring farmers to be certified in "Good Agricultural Practices" (GAP). There are many excellent programs for on-farm food safety. The USDA website is a good place to start: https://www.ams.usda.gov/services/auditing/gap-ghp.

Making pathogen free compost tea on-farm is a subset of an overall program to minimize food safety concerns on the farm. Many of the steps needed to make safe compost teawashing hands, material storage, etc- are also good general practices for ensuring farms comply with GAP.

Under the Produce Safety rule "biological soil amendment of animal origin" is defined as: "A 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, 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))."

The rule makes a distinction between raw manure and compost:

"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."

See Attachment "A" for a summary of the Final Rule on Produce Safety. (also called the Final Rule or Produce Safety Rule). The Final Rule sets Microbial Standards listing the quantity of pathogens allowed for "biological soil amendment of animal origin". i.e. compost. These Microbial Standards are:

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.

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:

<mark>Listeria monocytogenes</mark>	Not detected using a method that can detect one (1) CFU per five gram	
	analytical portion	
<mark>Salmonella species</mark>	Less than three (3) MPN per four grams of total solids (dry weight basis)	
E. coli O157:H7	Less than 0.3 MPN per one gram analytical portion	
<mark>Fecal coliforms</mark>	Less than 1,000 MPN fecal coliforms per gram of total solids (dry	
	weight basis).	

Definitions: "CFU" means "colony forming unit" and "MPN" means "most probable number"

Using a "Validated Process"

In the Final Rule, the FDA does not specifically discuss compost tea although it is clearly a "biological soil amendment of animal origin". As such, it would be covered under the Microbial Standards. One can argue that a compost tea made from a compost that has no animal products in it and which does not receive any kind of additives as food during the brewing process does not meet this definition. However, we have opted to apply the Microbial Standards to all compost tea we produce for the following reasons:

- 1. How can one be certain that the source of compost has no "animal" products?
- 2. "Animal products" include such food additives used during brewing as fish emulsion, worm compost and bone meal, all potentially useful.
- 3. Even in 100% vegetable based compost, can you be absolutely certain that no fecal or animal matter has entered the compost stream? bird droppings? Insects?

The FDA is sensitive to the question of whether or not the Final Produce Rule requires ongoing testing of compost or compost tea in order to meet compliance. The Final Rule itself does not address this, but in a monograph titled:

"Frequently Asked Questions and Answers for Proposed Rule: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" (see appendix B)

The FDA responds:

" 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."

<u>Our Interpretation:</u> The explanation above by the FDA is confusing. Our understanding of this clause is as follows:

1. For compliance purposes, compost tea must meet the Microbial Standards as "a biological soil amendment of animal origin".

2. An on-farm process for producing compost tea that has been validated, would be acceptable proof that the microbial Standards are met- without batch-by-batch testing.

3. The best way, however, to validate an on-farm brewing process is... microbial testing.

In other words, if a farm develops a process for brewing and using a compost tea, documents this process, then tests the results to demonstrate compliance with the microbial standards, *as long as this same process is followed, it is not necessary to test each batch.* This is why we have developed such detailed documentation of every step in brewing tea. The one-time documentation of every step in brewing becomes our "validating" process. Having tested our compost tea once and demonstrating there are no pathogens, we feel on solid ground that every subsequent batch will be pathogen free.

How long is our "validated" process good for? In our interpretation, as long as the process steps have not been altered, the validation is open ended. Of course, if any of the process steps change, this would require a new "validation" test (i.e. microbial testing) to then validate the "new" process. What constitutes a change in process? We are applying a "common sense" standard to this question. Major changes such as source of compost, source of water, different food additives used or different brewer - these would all constitute "new" steps requiring validation. Temperature changes, brew time, and storage location are examples of variations that would not require new validation.

Pathogen Prevention

The intention behind the FSMA is to keep our food supply safe and prevent pathogens from getting into the food stream. On the farm, pathogens can be introduced into the food stream primarily by two vectors: introduction of pathogens from outside the farm and failing to prevent natural pathogens that are present on the farm from entering the food stream. Both of these vectors can occur while brewing compost tea. By being aware of every step involved in tea brewing and understanding how pathogens move in the farm ecosystem, we are demonstrating a larger commitment to food safety. For our farm, this is the primary reason for documenting our tea brewing process and "validating" our process through testing: the confidence and certainty that we are doing everything possible to deliver to the public a safe product. Even if not required by FSMA, we would implement the exact same steps in brewing compost tea.

There is another great benefit to becoming immersed in the details of compost tea brewing: a farmer becomes much more aware of the microbial life on the farm in all its aspects. Once you start "thinking like a microbe" it begins to affect how you see many operations on the farm.

Being aware of overall farm food safety practices, we can list several factors that will help minimize the possibility of pathogens in compost tea:

1. Personal hygiene and worker health. Washing hands, not handling food products or compost when sick and wearing safety gear are no-brainers for food safety.

2. Assure that the component parts of compost tea contain no pathogens. The compost itself, water used and any materials added during brewing should all be pathogen free.

3. Cleaning and sanitizing are critical. During the brewing process we take precautions to assure that pathogens do not proliferate, but when brewing is complete, it is critical to clean and sanitize all areas that came into contact with compost tea.

4. Assure that the tea has enough oxygen. Pathogens tend to grow in environments with low oxygen (anaerobic) so assuring that our tea is properly aerated can go a long way to preventing pathogen growth.

Testing:

In order to assure that the finished compost tea is pathogen free it is important to begin with components that are pathogen free.

Water:

Water source is an important consideration in compost tea brewing. If municipal water is used, it is possible to obtain a water quality report to verify water quality.

For well water it is recommended to test for safe drinking standards as well as other parameters important in understanding how water affects microbes. For our validation process we tested our water for the following:

Bernalillo County water quality analysis: total coliform, E. Coli, total Kjeldahl nitrogen, ammonia, nitrate, nitrite, sodium, potassium, calcium, magnesium, chlorine, bicarbonate, total dissolved solids, pH and sulfate.

In addition we tested for: arsenic, lead, iron and chloride

See Appendix E for test results. We used the following lab:

Hall Environmental Analysis Laboratory 4901 Hawkins, NE Albuquerque, New Mexico 87109 (505) 345-3975 www.hallenvironmental.com Attention: Andy Freeman

Compost/compost tea pathogen testing:

When we began this project, we assumed it would be straightforward to locate a laboratory capable of testing compost and compost tea with the Standards required under FSMA. This has turned out to be quite challenging. Many laboratories test for E Coli, but very few have the capability to test for all 4 pathogens listed in FSMA. We have identified 2 laboratories- both in California- with full capabilities.

Primus Labs is a specialist in food safety testing. This work is an extension of their testing, auditing and quality control work around food safety. They are not a specialist in compost testing, but have the full laboratory capabilities to test compost and compost tea.

Control Laboratories in Watsonville, California, is a specialist in compost and are members of the US Composting Council. While food safety is not their specialty, pathogen testing for compost and compost tea is.

Primus Laboratories 2810 Industrial Parkway Santa Maria, California 93455 (805) 922-0055 www.primuslabs.com Attention: Adam Hughes Control Laboratories 42 Hangar Way Watsonville, California 95076 (831) 724-5422 www.compostlab.com Attention: Mike Galloway

See appendix C and D for copies of test results.

Compost/compost tea quality testing:

Although this paper addresses the safety of compost tea, it is important to understand how the process of brewing tea affects the overall quality of the tea. Our goal in using compost tea is to inoculate our crops with the full diversity of microbes that perform beneficial functions. Elaine Ingham has been researching soil microbes for over 40 years and has developed excellent resources for evaluating the quality of compost tea. Through her seminars, writings, publications and webinars, she actively educates farmers in how to evaluate for themselves the quality of their compost tea. Information can be found at: www.soilfoodweb.com

Matt Slaughter worked with Dr. Ingham for many years and has developed testing protocols for compost/compost tea quality. Information at: www.earthfort.com

Appendix F and G have information on these 2 laboratories.

Compost tea basics

This paper describes a validating process for brewing "actively aerated compost tea (aact)". AACT is distinguished from other liquid compost products by 2 characteristics:

- 1. Compost is suspended in water, either free floating or in a mesh bag, and is then subject to air bubbles that simultaneously add oxygen to the water and by their aggressive movement, dislodge the variety of microbes- bacteria, fungi, protozoa and nematodes- from the surfaces of the compost.
- 2. Once these microbes are free in the water, they begin to feed and reproduce. The feeding and reproduction depends on several factors: available food sources, temperature, oxygen in the water and the proportion of various microbes.

Typically, bacteria reproduce at a faster rate than fungi. Probiotic bacteria thrive in an oxygen rich (aerobic) environment whereas pathogenic bacteria such as E coli. 0157:H7 thrive in an oxygen poor (anaerobic) environment. As microbes begin to reproduce, if there is adequate food sources and oxygen, the probiotic microbes dominate, consuming the pathogenic microbes and creating a rich broth of microbes that benefit plants and soil. If either the oxygen level drops OR the available food supply becomes inadequate, the pathogenic microbes can dominate. A simple "smell test" is a good indicator: a rich earthy smell is probiotic; a rotting putrid smell indicates pathogens.

The brewing process amplifies the microbes that already exist in the compost. Both probiotic and pathogenic microbes exist in any compost but a high quality compost that has reached 131 degrees F will have a preponderance of probiotic microbes. The single most important factor in making good compost tea is starting with high quality compost. Next in importance is maintaining at least 6 mg/L (milligrams per liter) of oxygen dissolved in the water. Oxygen consumed is proportional to the amount of biological activity, which in turn is affected by available food supply and temperature. Typical food sources that are added to tea that favor bacterial growth are simple sugars such as molasses and protein sources such as kelp and fish hydrolysate. Soybean, garbanzo bean and to a lesser degree oats are a protein source that favor fungal growth.

With experience (and testing and microscope work) you can begin to develop the expertise to brew tea that favor bacterial growth or fungal growth. Traditional wisdom is that annual plants benefit from bacterial dominant teas whereas perennial plants such as trees benefit from fungal dominant teas. Recent thinking, however, favors a "balanced" tea with high counts of both bacteria and fungi.

Brewing tea without additional food sources slows down the metabolic process and variations in oxygen level are less likely to favor the pathogenic microbes. Adding food speeds up metabolism yielding much higher microbe counts, but also making it critical that the brew never becomes anaerobic. For our validation process, we measured the dissolved oxygen level every 4 hours, based on a fixed amount of food additives. Many tea brewers have moved away from simple sugars such as molasses due to a concern that the rate of bacterial reproduction with this readily available sugar can outstrip the aerating pump's ability to supply adequate oxygen. Seaweed, kelp, humic acid- these food sources break down much slower thus giving a wider range of microbes the opportunity to feed and reproduce, and modulating the amount of oxygen consumed.

A note on temperature. Some brewers strive to brew at temperatures between 70-80 degrees F, regardless of the ambient air temperature, as this mildly warm environment favors microbe growth. It is possible to multiply the microbe population at a much faster rate at higher temperatures- assuming food source and oxygen level are maintained. This can shorten the brew time to 12-24 hours. However, there is a high rate of die off of microbes brewed at 80 degrees F sprayed into an ambient temperature of 55 degrees F, such as might be the case in early spring or fall. To avoid this issue, we brew at the ambient temperature we are applying at, but modify the brew time for colder weather, sometimes brewing as long as 48-72 hours. The critical measurement is dissolved oxygen level.

Compost Tea Brewing Process at our farm

Outlined below are the steps we followed at our farm to brew compost tea. In dealing with microbes, small differences in process can make a big difference in outcome. The process of brewing compost tea is similar to what microbiologists do in million dollar labs. They just do it with more precision, controlling for more variables. In order for an on-going brewing process to be considered "valid", each step as outlined in the validation process needs to be followed every time a new batch of tea is made. The degree to which this process is more or less specific reflects the degree of specificity the farmer agrees to follow in the

day-to-day brewing of compost tea. As a rule of thumb don't make your validation process more complicated than you are prepared to follow in the daily brewing of compost tea. On the other hand, if you become inspired and enamored of how small changes affect tea quality, by all means take as much time and energy to explore this. The hidden world of microbes is infinitely fascinating and the more deeply you become involved, the better understanding you will gain about the overall functioning of your farm ecosystem. Our validation process is more detailed than what the average farmer will probably follow, so feel free to simplify. In the end, there are 2 criteria that determine whether your compost tea brewing process is "validated":

- 1. That you routinely follow the steps outlined in your validation process and
- 2. The test results for your compost, water source and finished compost tea fall below the microbial standards issued by FSMA.

Part One: Farmer Self Assessment

Yes

As we began to study the factors that can potentially affect the safety of compost tea, we began to expand the parameters we tracked. Each farmer that contemplates documenting and validating their on-farm brewing process can benefit from familiarizing themselves with the variety of details that can affect the process of brewing. Outlined below is a self assessment that will guide the farmer in deciding what level of detail to track in creating their own validation process. The completed self assessment also becomes part of the documentation required in the validation process.

This section reviews the reasons for using compost on the farm, and asks the farmer to think through the logistics of production, storage, transportation and impact on organic certification. Attachment H is the full Self Assessment.

Compost: 1. Do I plan to use compost in my farm operation? Yes No If No, skip to Compost Tea section. If Yes, continue 2. How do I plan to use compost on my farm operation? 3. What are the outcomes I expect to see using compost? 4. Is my farm certified organic, or plan to be certified organic? _____Yes No 5. What is the source of the compost I plan to use: _____ made on the farm. Following organic standards? ____Yes ____No ____NA _____ purchased from off-farm. Approved for organic use? ____Yes ____No ____NA _ obtained free off-farm. Approved for organic use? _____Yes _____No ____NA both farm made and purchased 6. If purchased/obtained off-farm, name, address and phone of supplier(s): - Does supplier have any credentials or documentation of compost quality? (i.e. member of US Composting Council, organic certification, compost test results, etc)

No

Page **11** of **34**

- Do I have copies of c	locuments? _	Yes	<u>No</u>	
- How is compost transported	to farm?			
- Is transport vehicle/container	inspected befor	re loading for possil	ole contamination?	
Yes	No			
- Is compost covered during tra	ansportation?	Yes	No	
arrival to farm, is compost used	l immediately c	or stored on-farm?		
			both	
If stored, location and manner	<mark>of storage:</mark>			
Is stored compost covered: _	Yes	No		
If yes, manner and type of cove	ering:			
ored compost, what is maximur	n length of time	e before compost is t	used as compost or fo	r making compost to
Days	Weeks	Months		
· · · · ·				
your compost making process,	including inpu	<mark>its, timeframes, proc</mark>	<mark>cess and storage:</mark>	
· · · · · · · · · · · · · · · · · · ·	•	U U		
•			No	
If yes, manner and type of cove	ering:			
rm produced compost certified	0		No	
rm produced compost certified farm produced compost, what Days	0			mpost or for making
	- Is transport vehicle/container Yes - Is compost covered during tra arrival to farm, is compost used used immediately If stored, location and manner Is stored compost covered:If yes, manner and type of cove ored compost, what is maximumDays	Is transport vehicle/container inspected befo YesNo Is compost covered during transportation? arrival to farm, is compost used immediately c used immediatelystor If stored, location and manner of storage: Is stored compost covered:Yes If yes, manner and type of covering: ored compost, what is maximum length of time DaysWeeks farm produced compost: your compost making process, including input e location of on-farm produced compost and m	 Is transport vehicle/container inspected before loading for possilYesNo Is compost covered during transportation?Yes arrival to farm, is compost used immediately or stored on-farm?used immediatelystored and used later If stored, location and manner of storage: Is stored compost covered:YesNo If yes, manner and type of covering:No If yesNo Is stored compost:YesNo 	 Is transport vehicle/container inspected before loading for possible contamination? YesNo Is compost covered during transportation?YesNo arrival to farm, is compost used immediately or stored on-farm? used immediatelystored and used laterboth If stored, location and manner of storage: Is stored compost covered:YesNo If yes, manner and type of covering: pred compost, what is maximum length of time before compost is used as compost or forDaysWeeksMonths farm produced compost; your compost making process, including inputs, timeframes, process and storage: Is stored compost covered:YesNo

This section addresses use of compost tea and requires the farmer to identify the source of the compost, water, and type of brewer. Details on testing are also required.

<u>Compost Tea:</u>

1. Do I plan to use compost tea in my farm operation?	Yes]	No	
2. How do I plan to use compost tea on my farm operation?				
2A. Do I plan to use a bacterial dominant, fungal dominant	<mark>or balanc</mark>	ed tea? W	<mark>hy?</mark>	
3. What are the outcomes I expect to see using compost tea?				
4. Is my farm certified organic, or plan to be certified organi	ic?	_Yes		No
5. What is the source of the compost I plan to use in making made on the farm. Following organic standa purchased from off-farm. Approved for orga obtained free off-farm. Approved for organi both farm made and brought in	irds? anic use?	_Yes Yes	No	_NA NA _NA
- Have I tested the compost for pathogens?	Yes]	No	
6. What is the water source for making compost tea?				
 7. Have you tested the water using drinking water standard - if Yes, name and address of laboratory: 	ls?	_Yes	No	

- What was water tested for/what Standards were used?

- Were test results positive for pathogens or prohibited materials? ____Yes ____No If Yes, explain:

8. In making compost tea I will use compost that has been:

_____ Brought to farm fresh with each batch of tea, i.e. not from farm-stored compost

_____ From compost previously brought/made at farm and stored on-farm.

- maximum length of time stored compost will be used for tea:_

 I will be using the following brewer (include make, model, description, gallon capacity, air pump capacity):

At the completion of the brewing cycle, I will be using the compost tea within_______
 hours and _______ minutes from the time I stop aerating the tea.

The final section outlines some of the application methods.

Application:

I will use the following methods for applying the compost tea:

Application method	Application Equipment	Water dilution ratio
Spray foliar feed plants	<mark>4 gal backpack sprayer</mark>	<mark>3:1</mark>
side dress at base of plants	<mark>5 gal bucket with pail</mark>	<mark>5:1</mark>
liquid drench of soil	40 gal. tractor mounted sprayer	<mark>5:1</mark>
injection through drip lines	Injector	Not diluted (1:1)
root soak for greenhouse transplant	<mark>5 gal bucket with pail</mark>	Not diluted (1:1)
starts		
other application method		

Part Two: Infrastructure Preparation

Once the farmer has reviewed their use of compost on the farm and decided they want to move forward with making compost tea, there are many preparatory steps necessary prior to beginning the brewing process. Attachment I is the full Step-by-Step Preparation. Photos below illustrate each section.

1. The most important factor in determining the quality and safety of compost tea is the compost. High quality compost, free of pathogens and properly cured is essential. The brewer used is also a critical component. The air pump and diffuser on the brewer must be able to deliver adequate oxygen to the water such that the dissolved oxygen level never falls below 6 mg/L, and preferably stays at 8mg/L or above all during brewing. Even with a good pump if the diffuser becomes clogged, air distribution can be restricted.

Decide on type and model of brewer to be used.

- what brand of tea brewer will you use?
- what are the components of the brewer?
- what is the air pump capacity in cubic feet/minute (cfm)?
- what type of diffuser is being used?
- turbidity level: is pump able to move brew around sufficiently to dislodge microbes?

Page 13 of 34

- is turbidity level adequate to assure no "low oxygen" zones

- is the brewer easy to clean?
- what type of strainer will you use?
 - what is mesh size of strainer?
- can you obtain more strainers as needed?
 - who is your supplier for strainers?
- besides the brewer, what additional implements are used in the brewing process?



Growing Solutions 10 gallon brewer

2. Maintaining clean and uncontaminated brewing equipment is essential. A stable power source for the pump is important. A brew can become anaerobic very quickly if the aerating pump goes out.

Decide on location where brewer and supplies will be located.

- where is the brewer stored?
 - is storage in the open or closed area?
 - is the brewer stored covered or uncovered?
 - is the brewer stored in the same location at all times?
- during brewing, what is the location of the brewer?
 - is the brewer covered during brewing
- what is the power source for the aerator motor?
 - could you lose power from this power source?
 - how would you know if you lost power?
- what is elevation of your brewing location?



indoor storage area for equipment

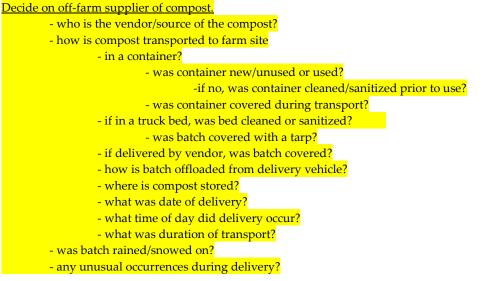


covered brewing area

3. For those farmers using compost they themselves produce it is critical to assure a high quality product. If the operation is certified organic, then very specific records are required.

Decide whether on-farm or off-farm compost will be used. If on-farm compost:
- do you plan to use the compost as compost on the farm, or just to make tea?
- do you have a written log documenting your steps for making compost?
- are you certain that the minimum temperature is reached?
- how do you measure this?
- how do you document this?
- are you certain that the minimum temperature timeframes are met?
- how do you measure this?
- how do you document this?
- Is your operation certified organic?
- if yes, do you follow the NOP Standards for producing compost?
- do you have documentation to demonstrate compliance with NOP Standards?
- If not certified organic, do you follow the FSMA standards for making compost?
- which Standard do you follow?
Acceptable treatment processes include any scientifically valid controlled physical, chemical, or
biological process – or a combination – that is validated to satisfy certain microbial standards.
Composting is considered a common biological process, and validated composting methods include:
1. Static composting that maintains aerobic (<i>i.e.,</i> oxygenated) conditions at a minimum of 131 °F (55 °C)
for 3 consecutive days and is followed by adequate curing; and
2. Turned composting that maintains aerobic conditions at a minimum of 131 °F (55 °C) for 15 days
(which do not have to be consecutive), with a minimum of five turnings, and is followed by adequate
curing.
Per FDA's definitions, curing may or may not involve insulation, depending on environmental
conditions.

4. Many farms may choose to purchase certified organic compost for the purpose of making compost tea. If so keeping accurate records is important.



- was sample from batch tested for microbes by supplier?
- was sample from batch tested for pathogens by supplier?
- do you have a written receipt from supplier for purchase?
 - does receipt show:
 - date purchased
 - date delivered
 - amount purchased/delivered
 - cost?
 - vendor name, address, phone #?
 - description of compost/product name?
 - organic designation?
 - other information?
 - is receipt stored in a safe place?
 - what is location of stored receipt?
 - how long do you keep the receipt?
 - is this batch being used in a certified organic operation?
 - do you have documentation approving this product for organic use?
 - what is location of this documentation?





Buying compost and transporting to farm

5. Storage of the compost is important. Compost needs to be covered to prevent contamination from animals but also in such a manner that air can circulate around the compost.

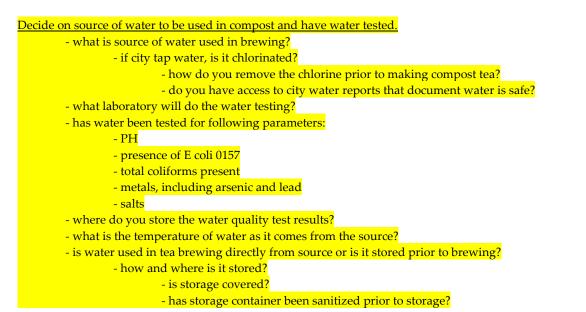
Compost storage at the farm what is the location where compost used for compost tea is stored? is it always stored in the same location? is storage out in the open or in a contained building/structure? is the compost covered? how is the compost covered, with what material? is the covering applied in such a manner to allow access to air? what assurance is there covering will not be removed/blown away? is the compost covered or partially covered? do you use the same stored batch as direct applied compost and for compost tea?

- what is the longest timeframe that tea will be made from a batch of compost?



covered compost storage at the farm

6. Assuring pathogen free, chlorine free water is critical to quality compost. Special Note: well water coming directly from the ground is often at 4 mg/L or less of dissolved oxygen when first pumped out. Running the aerator pump for 1-2 hours prior to brewing will usually solve this problem.





Water quality test bottles provided by testing lab



water source- 200' deep well

7. Being able to test the dissolved oxygen (DO) level in the brew is a critical step in the validation process. Dissolved oxygen meters range in cost from \$400-up, whereas DO test strips cost as little as \$15.

Decide on testing methodology for dissolved oxygen (DO) and acquire supplies.

- will you acquire a DO meter?
 - make and model of meter?
 - has meter been calibrated?
 - has meter been compensated for elevation?
- if using test strips, who is supplier of test strips?
 - do test strips have adequate range indicators? (0 mg/L through 12 mg/L)

- have you completed a "static test" using water only with your brewer to measure DO levels at beginning of aeration and after one hour of aeration to assure that aeration is actually occurring?



Salifort brand DO test kit

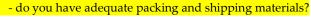


Extech brand DO meter

8. For purposes of creating a validated process it is necessary to test at least one batch of finished compost tea. Most farmers will also want to have their compost tea tested for microbial levels. Dedicated enthusiasts will purchase a quality microscope and learn how to recognize the variety of microbes.

Choose which laboratories for pathogen and quality testing.

- will you do both pathogen testing and quality testing?
- which laboratory will you use for pathogen and quality testing?
 - is it necessary to open an account?
 - do you know exactly where to send the sample?
 - do you understand packing and shipping protocols to assure an accurate test?





Compost tea and packing supplies



Packed up and ready for overnight mailing

Page 18 of 34

9. For those seeking a high fungal compost tea, pretreating compost assures that fungal microbes have a chance to get a jumpstart on growth.

Decide on pretreatment additives and supplier.

- will you be pretreating compost prior to making compost tea
- what additives will you be adding to compost as a pretreatment?
 - what is the proportion of compost, additives and water?
 - who is the supplier or source of additives?
- how long will you pretreat compost?
- where will you store compost during pretreatment?
 - will temperature be adequate for pretreatment? (65-80 degrees F.)
 - will pretreatment be covered, in the dark and undisturbed?



pretreating compost with oat flour



compost after 7 days- white is fungal growth

10. Adding food sources to the brew will greatly increase the microbial population BUT it is critical to assure that the DO level never falls below 6mg/L. Pathogen microbes are more likely to develop in an anaerobic brew. There are an endless number of food sources that can be added. There are also many premixed additives on the market.

Decide on brewing additives to be used and supplier

- will you be adding supplemental foods to brew?
- what materials will you be adding as food during brewing?
- what is the source/supplier of additives?
- what are the proportions of additives used during brewing?
- at what point in brewing cycle are foods added?



food sources for microbes- Brand X blend and unsulphured molasses

11. For best results application of tea should be as soon after brewing as possible, preferably within 1 hour. As soon as brewing stops the brew no longer is being aerated and pathogenic microbes could begin to grow. Also microbes are susceptible to UV radiation, so timing of application is important.

Determine application equipment and methods - what method of application will you use? - side dress, foliar spray, drip tape/sprinkler injection, greenhouse starts - has your application vessel been used with any product that might inhibit microbe growth? - was vessel thoroughly cleaned prior to using with tea? - will tea be diluted or applied at full strength? - what is temperature of water used for dilution? - is source for dilution water the same as water for brewing? - will any additional materials be added to tea after brewing is complete? - if foliar spray, is the spray orifice large enough to pass microbes? - does the sprayer have a built-in filter that might restrict tea flow? - is the filter finer than 400 micron mesh? - does the tea liquid make any 90 degree turns during spraying? - do you add any wetting agents to your spray mix? - are the wetting agents compatible with living microbes? - is the exit pressure from any nozzle greater than 20 PSI? - if foliar spraying, is application during early morning or later afternoon to avoid strong UV radiation?



filling sprayer for foliar application

12. Cleaning of equipment is perhaps the most overlooked aspect of brewing tea. Most brewers have spaces that come into contact with tea that are hard to clean. Careful consideration of the cleaning and sanitizing process will minimize potential for pathogens.

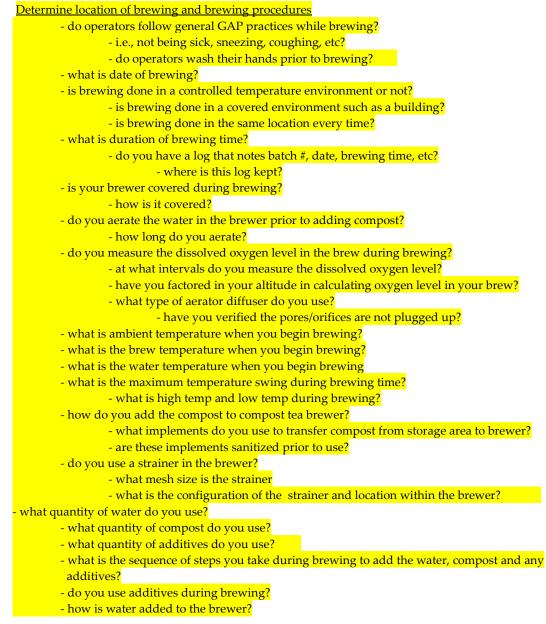
Acquire cleaning materials and equipment

- how do you assure tea liquid does not get into air line?
- do you clean all components with water and detergent prior to sanitizing?
- are all implements used in cleaning labeled for compost cleaning only?
- are all cleaning implements stored in a central location?
- are all implements used for compost cleaning only
- after cleaning components of brewer, are all components sanitized?
 - what brand and type of sanitizer do you use?
 - are brewer components allowed to air dry prior to placing in storage
- are you able to reach and clean all parts of brewer that come into contact with tea?
 - are there invisible or difficult to reach parts of brewer?
 - for membrane diffusers, do you disassemble diffuser?
 - for air stones, do you soak stone in sanitizer?
- do you maintain a "cleaning/sanitizing log"?
- do you clean the brewer and equipment within one hour of completing brewing?



cleaning supplies including StarSan sanitizer

13. Brewing process. Once everything has been prepared you are ready to start brewing.



14. Finally do you keep accurate records and record information for each batch brewed?

Part Three: Brewing Tea

Outlined below are the specific steps we take at North Valley Organics for brewing compost tea.

<u>1. Pre-treat compost.</u> Seven days prior to brewing we add oat flower and water to the compost, lightly cover and place in a dark area, usually inside the house to maintain a consistent 70 degree F temperature. This allows the slow growing fungal microbes to fully develop. When this compost is brewed we obtain a more balanced compost tea.



oat, soybean and garbanzo flour are good pretreatment food sources

after 7 days growth

2. Operator health check. As with all activities related to handling food crops, we only work when we are healthy and always wash our hands prior to brewing compost tea.

3. <u>Prepare brewing area</u>. We set up the brewer such that we will not need to move it after we add water and begin brewing. All equipment and materials are prepared. Note that brewing occurs in a covered area out of direct sunlight.



covered brewing area

<u>4. Fill brew tank with water.</u> Since we use well water that comes out of the ground at a uniform 55 degrees F. and a DO level of 4mg/L, we let the water sit for at least 8 hours to reach ambient air temperature of approximately 70 degrees F.



Well water initially at 4 mg/L DO- too low to brew

5. Prepare dilution water. If we plan to dilute the tea with water, we draw the water from the well at this point to allow it to warm up



letting dilution water sit- temperature and DO level rise

<u>6. Aerate water for 2 hours.</u> We turn the air pump on approximately 2 hours prior to brewing to raise the DO level from 4 mg/L to 10-12 mg/L. This also allows us to test our pump, assure that air diffuser is working correctly and verify our power source. If using municipal water, aerating will dissipate the chlorine.



raising the DO level by aerating Page 23 of 34

<u>7. Test DO at beginning of brew cycle.</u> We test the water for DO level prior to beginning brewing to assure level is 8 mg/L or higher.



DO level in brew water is raised to 10 mg/L

<u>8. Add compost.</u> We add the compost to our 1000 micron basket after the pump is turned on. This assures that no tea ever gets into the air line. The air line is harder to clean and can be overlooked. Pathogens can build up in the air line if it comes into contact with tea.



adding compost to brewer- note that basket is not too tightly packed

<u>9. Add any food additives.</u> We add food additives after 15 minutes of brew time to allow the compost microbes to disperse throughout the tea.



food additives during brewing

Page **24** of **34**

<u>10. Allow to brew.</u> We brew 24-48 hours, mostly based on ambient air temperature. In summer when temp is 80 degrees F we brew 24 hours typically. In fall or early spring with temp at 60 degrees F we often brew 36-48 hours. Experience (and testing) will be your guide to brew time.



Foam after 24 hours brewing- indicates good microbe growth

<u>11. Check DO level during brewing.</u> Particularly when you are brewing to validate your process, you want to check the DO level while brewing to document that the oxygen level never falls below the 6 mg/L level.

<u>12. Decant brew into applicator.</u> Note that we keep the pump running while decanting in order to prevent the tea from back flowing into the air tube.



backpack sprayer

<u>13. Dilute brew if necessary.</u> We use the water that has been sitting, not fresh from the well.

<u>14. Apply tea.</u> If used as a foliar feed, we try to avoid spraying midday. UV sunlight will kill the microbes. If using tea as a soil drench, root drench, side dress or transplant boost, time of day application is less critical. We have discontinued the practice of injecting tea through drip lines, as we don't want the possibility of creating a toxic biofilm inside the drip lines. Flushing followed by sanitizing the drip lines is too much work.

<u>15. Clean all equipment</u>. It is important to clean and sanitize all surfaces that have come into contact with tea, including hidden spaces and hard to reach areas. We use an acid based sanitizer used in the beer brewing industry. This material does not need to be rinsed off after application and is food surface compatible. The other major advantage of this product is that you can mix up a batch in a five gallon bucket and keep it stored for up to a month or more without it losing its sanitizing power.

<u>16. Store equipment.</u> Particularly when you are documenting your process for validation purposes, you will want to note where and how your equipment is stored.

<u>17. Complete record-keeping.</u> Complete records of each brew, particularly while validating your brewing process.

Brewing trials at our farm

For the purposes of this study, we worked with three sources of compost, representing three common sources small scale farmers might use for their composting operations:

1. On-farm produced compost using mixed inputs including plant residue, vegetable culls, grass clippings and most significantly, poultry manure and poultry bedding gathered from the chicken pen. This compost was created using a process of active turning and watering over a one year period to achieve thermal breakdown of plant matter. Scale is small with 2 piles approximately 1 cubic yard each.

2. Our second source of compost was a mid size commercial horse stable composting operation that utilized specially designed air injection piping and an automatic watering system with tractor turning of piles over an 18 month period. Inputs for this compost are primarily horse manure, alfalfa and hay used as bedding and feed, and a small amount of plant residue. This mid size operation produces approximately 30 cubic yards per year of compost.

3. Our third source of compost is a large scale commercial operation (Soilutions in Albuquerque, New Mexico, www.soilutions.net) whose primary input is plant residue with some horse manure. Temperature, moisture, process and curing time, chip size and other parameters are strictly monitored. Soilutions is the only source in Albuquerque for compost approved for use on organic farms.

Compost source	Pathogen test results	Comments
Chicken manure	Failed	fecal coliform greater than 1000 MPN
Horse manure	Failed	fecal coliform greater than 1000 MPN
Soilutions	Passed	4 pathogens below microbial standard

Pathogen test results for compost:

Because the chicken and horse manure based compost exceeded the standard for fecal coliforms, we eliminated these 2 composts for making compost tea. As a side note, however, we were curious whether the brewing process might have an effect on the total

coliforms, possibly reducing them to below the standard for food safety. We did brew compost tea and in both cases the total fecal coliform count came down below the 1000 MPN, indicating the tea was safe. Even so, we will not use these compost sources for tea.

The table below indicates the results of brewing compost tea with the Soilutions compost. We used 2 batches of Soilutions compost. The first batch was purchased on 10/19/15 and the second batch purchased on 7/14/16. From these 2 batches we ran tests with each batch- compost tea brewed with no additives, tea brewed with Brand X Tea Catalyst as food additives, and unsulphured molasses as food additive. All of our brewing followed the same protocols. We were evaluating 2 variables:

- 1. Whether or not the compost sitting idle for one year made any difference, and
- 2. Whether adding a food source affected the safety level of the tea.

The reason we made tea from a batch one year old is that we wanted to demonstrate in our validation process that we could make safe tea from compost produced off-farm, but stored on-farm for up to a year. This follows our farm practice of purchasing one load of compost per season, storing it properly and using it throughout the season to make compost tea. In addition we tested the Soilutions compost after one year, to verify that the compost had not developed any pathogens in the one year period stored at our farm.

Compost purchase date	Test Date	Pathogen Test Results
10/19/15	10/22/15	Passed
10/19/15	9/1/16	Passed
7/14/16	8/30/16	Passed

Test results for Soilutions brand compost:

Test results for compost tea brewed from Soilutions brand compost:

Compost purchase date	Compost Tea brewing Date	Microbe Food additives used	Pathogen Test Results
10/19/15	1/23/17	organic unsulphured molasses	Passed
10/19/15	1/21/17	None	Passed
10/19/15	1/23/17	Brand X Tea Catalyst	Failed
7/14/16	7/22/16	None	Passed
7/14/16	1/25/17	organic unsulphured molasses	Passed
7/14/16	1/17/17	None	Passed

CONCLUSION: We had passing test scores for both the old and new Soilutions compost tea when no food sources were added. We also had no problems when we added molasses. The only compost that failed was when we added Brand X mix. <u>Therefore,</u> we have validated that we can use Soilutions brand compost that has been stored on-farm for up to one year either without additives or by adding molasses.

Process Specifications for brewing compost tea at North Valley Organics			
Albuquerque, Ne	w Mexico		
Category	Parameter	Value	
Drower	brower make and model	Crowing Solutions	
Brewer	brewer make and model	Growing Solutions	
	capacity	10 gallon	
	pump make and model	Ecoplus model 728455	
	pump flow rate at 0 PSI	2.3 cfm (cubic feet/min)	
	storage location	container shelf	
	mesh type	nylon basket	
	mesh size	#18 mesh, 1000 microns	
	bubbler type	3/4" pvc with 1/4" holes	
	amount of compost per 10 gal batch	10 cups	
	compaction level of compost in basket	low	
water	water source	farm well	
	initial water temp	55 degrees F	
	initial water dissolved oxygen level (DO)	4.0 mg/L	
	water ph	7.54	
compost	compost source	purchased from Soilutions	
	on-farm compost storage location	next to orchard	
	compost pile age range	1-12 months	
	is compost pile covered?	Yes	
	delivery date of compost	7/14/2016	
pre-activation	compost batch amount pre-activated	10 cups	
	preactivation time	7 days	
	preactivation temp	70 degrees F	
	additive 1, per batch	fine oat flour	
	Source	La Montanita Coop	
	amount additive 1,per batch	1.5 cups	
	additive 2, per batch	mined humates powder	
	amount additive 2, per batch	1 cup	
	Source	Mesa Verde Resources	
	additive storage location	compost storage area	
	amount water added	2 cups	
	mixing process	in plastic bowl	

The following Table lists the parameters for each step in our brewing process:

Albuquerque, Nev	w Mexico	
Category	Parameter	Value
tea brewing	water aeration time, pre brew	2 hours
	DO level in water at beginning of brewing	10 mg/L
	minimum DO level during brew cycle	8 mg/L
	maximum DO level during brew cycle	12 mg/L
	water temp at beginning of brewing	60 degrees
	minimum brew temp during brew cycle	60 degrees
	maximum brew temp during brew cycle	90 degrees
	total brew time	24-48 hours
	food additives used	yes
	when food added	after 15 minutes of brewing
Additives	ingredients	humic acid/seaweed extract
	brand	Peaceful Valley Farm Supply
	rate	1/2 cup per 10 gallons
	ingredients	unsulfured molasses
	brand	Wholesome organic molasses
	rate	1/2 cup per 10 gallons
dilution	dilution water source	well water
anation	water aeration time	12 hours
	DO level at dilution	10 mg/L
	water temp at dilution	70 degrees F
	dilution ratio: foliar feed	2:1
	dilution ratio: side dress	4:1
	dilution ratio: soil drench	4:1
	dilution ratio: starts drench	1:1
application	boom sprayer T-Jet nozzle type	AIXR
	boom sprayer T-Jet nozzle #	04
	boom sprayer T-Jet nozzle color	red
	micron size opening	600 microns
	filter removed from nozzle?	yes
	boom sprayer maximum psi	15 psi
	was spray application during low UV?	yes
cleaning	cleaner material	dawn dishwashing soap
	sanitizing material	star-san brand sanitizer
	storage location	compost tea storage area
	cleaning/sanitizing timeframe	within 1 hour after brewing complet
documentation	brewing log completed	yes
testing	laboratory used	Primus Labs, California
testing	shipping method	overnight USPS
	shipping timeframe	within 1 hour of brew completion
	tea shipping container	1 Qt. plastic water bottle, 1/2 full
	shipping packaging	styrofoam with ice packs
	test results location	3 ring binder in office

Conclusion- Rules for brewing pathogen free compost tea

1. Assure that compost used in tea contains no pathogens.

2. Assure that water used in brewing tea contains no pathogens.

3. Assure that equipment used in brewing has been adequately cleaned and sterilized prior to every batch of tea.

4. Clean equipment and material immediately after brewing to prevent buildup of biofilm on brewer surfaces.

5. Use brewing equipment that is easy to clean and does not contain sharp corners where pathogens can accumulate and grow.

6. Assure that all parts including hidden parts of brewer are able to be cleaned and sanitized.

7. Assure that dissolved oxygen level in all parts of the brewer never falls below 6 mg/L.

8. Apply tea within one hour after completion of brewing.

9. Assure that brewer air pump has adequate and stable power supply to not shut off during brewing.

10. Assure that operators wash their hands prior to brewing and are not sick (coughing, sneezing, etc)

11. Do not use compost tea with any equipment that cannot be easily cleaned and sanitized, i.e. drip lines.

40 Gallon Brewer Design

Based on our experiences with a variety of brewers, we designed our own low cost 40 gallon brewer. Our brewer has the following characteristics:

1. A robust air pump that is designed for continuous use, producing 5.5 cfm air flow.

2. Quick release air tube that allows you to remove the pump while cleaning and also prevents tea from getting into air line.

3. Air line easily removed from diffuser for easy cleaning.

4. Custom made diffuser that sits on the bottom of the tank providing aeration over entire bottom of tank.

5. Diffuser parts easily disassembled for easy cleaning with a bottle brush.

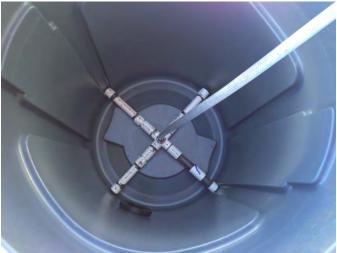
- 6. Diffuser fits snugly into bottom of tank, yet is easily removable.
- 7. Tank is a 45 gallon heavy duty garbage can.
- 8. Custom attached spigot attached 8" from bottom of tank to allow settling of compost after brewing completed.
- 9. Compost floats free in tank- no strainer used.
- 10. Diffuser on bottom continuously agitates compost, preventing compost from settling on bottom of tank.
- 11. When air pump turned off, compost settles to bottom of tank within 5 minutes BELOW level of spigot.
- 12. Large (2") low torque spigot for easy cleaning.
- 13. Super easy to clean: disconnect air hose, take out diffuser and wash out compost.
- 14. Diffuser parts and air line fit into a premixed 5 gal. bucket of sanitizer. After cleaning with dishwashing soap, dunk the parts in the sanitizing bucket, remove and let dry. Easy!
- 15. Low cost- entire setup approximately \$300.



Brewer consists of 1) 45 gallon garbage can with spigot, 2) quick release air line, 3) pvc diffuser, 4) heavy duty air pump.



Diffuser assembled and attached to air line



Diffuser in bottom of garbage can



Robust aeration and agitation

Page **32** of **34**



Unit assembled and ready to go!

Conclusion-Validation process for brewing compost tea under FSMA

The FSMA is vague on what the exact requirements are regarding use of compost tea. It appears that teas fall under the generic category "treated soil amendments of animal origin" and therefore can be regulated by the FDA. At our farm we have chosen to adhere to the microbiology Standards as a precaution and to demonstrate a deeper commitment to food safety at the farm. Ultimately our motivation is to create a "culture of safety" at our farm to assure our customers we are doing everything possible to bring them a safe product.

Having "bitten the bullet" and decided to take the extra time and trouble to document our tea brewing process and create a "validated" set of practices, we have discovered many important lessons along the way, lessons we would not have learned if we had not decided to go down this path. Lessons not only about safe farm practices, but a deeper appreciation for the "life in the soil" that is the true richness of the farm. We are now experimenting with "designer" composts where we hope to isolate and multiply the probiotic microbes that are plant specific. We will use teas made from these composts to inoculate plants in the same family. We are learning about bacteria that exist on the leaf surface that help plants process nitrogen from the air (Azotobacter Vinelandii) and bacteria that exists in the soil that help roots process phosphorous (Azotobacter Chroococcum).

Is it possible to discover a microbe on the leaf surface that... repels squash bugs?!?

Who knows!

Useful Websites:

1. Elaine Ingham-	www.soilfoodweb.com
2. Elaine Ingham/Matt Slaughter-	www.earthfort.com
3. Tim Wilson-	www.microbeorganics.com
4. Tad/Leon Hussey-	www.kisorganics.com
5. Tad Hussey-	www.gardeningwithmicrobes.com
6. Elaine Ingham on-line classes-	www.environmentcelebration.com
7. Marc Remillard-	www.compostteamaking.com
8. General info on compost tea-	www.sare.org -use search function for compost tea www.calrecycle.ca.gov - go to compost tea home page www.biodynamics.com
9. compost tea blog-	www.compostjunkie.com
10. Information on brewers-	www.livingsoilsorganics.com www.growingsolutions.com www.willametteorganics.com www.composttealab.com

Websites addressing Food Safety, GAP, FSMA and compost/compost tea:

https://gaps.cornell.edu/educational-materials/decision-trees/soil-amendments http://sustainableagriculture.net/fsma/learn-about-the-issues/manure-and-compost/ http://www.ffscn.net/blog/2016/2/28/compost-tea-in-the-age-of-food-safety http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334552.htm https://www.farmcrediteast.com/sitecore/content/FCE%20Home/knowledgeexchange/Blog/todays-harvest/fsma-produce-safety-rule https://www.ams.usda.gov/sites/default/files/media/Compost_FINAL.pdf http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm 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 <u>Federal Register Notice</u> (<u>https://www.federalregister.gov/articles/2015/11/27/2015-28159/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption</u>)

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-thegrowing-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)
- <u>Coverage and Exemptions/Exclusions Flowchart (Color PDF: 95KB)</u> (/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

Food Safety Modernization Act (FSMA) > FSMA Final Rule on Produce Safety

- 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)
- <u>Testing Methodology for Listeria species or L. monocytogenes in Environmental Samples (PDF: 109KB)</u> (/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

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

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)

http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm

- 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
- Key Requirements
- Exemptions
- Variances
- Compliance Dates
- Environmental Impact Statement
- Assistance to Industry

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).

back to top

http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm

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.
 Required measures to prevent contamination of covered produce and food contact surfaces include, for example, appropriate storage, maintenance and cleaning of equipment and tools.

back to top

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.

back to top

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.

back to top

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 <u>Compliance Date Extensions and Clarifications for FSMA Final Rules</u> (/Food/GuidanceRegulation/FSMA/ucm517545.htm).

back to top

Environmental Impact Statement

The FDA has also released the Final Environmental Impact Statement (EIS)

<u>(/Food/GuidanceRegulation/FSMA/ucm396564.htm)</u>, 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

http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm

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.

back to top

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.

back to top

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

http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.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)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 11, 16, and 112

[Docket No. FDA-2011-N-0921]

RIN 0910-AG35

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: To minimize the risk of serious adverse health consequences or death from consumption of contaminated produce, the Food and Drug Administration (FDA or we) is establishing science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption. FDA is establishing these standards as part of our implementation of the FDA Food Safety and Modernization Act. These standards do not apply to produce that is rarely consumed raw, produce for personal or on-farm consumption, or produce that is not a raw agricultural commodity. In addition, produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance is eligible for exemption from the requirements of this rule. The rule sets forth procedures, processes, and practices that minimize the risk of serious adverse health consequences or death, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce and to provide reasonable assurances that the produce is not adulterated on account of such hazards. We expect the rule to reduce foodborne illness associated with the consumption of contaminated produce.

DATES: This rule is effective January 26, 2016. The effective date of §§ 117.5(k)(2), 117.8, 117.405(c), 117.410(d)(2)(ii), 117.430(d), and 117.475(c)(13) published September 17, 2015 (80 FR 55908), is January 26, 2016. The effective date of §§ 507.12(a)(1)(ii), 507.105(c), 507.110(d)(2)(ii), 507.130(d), and 507.175(c)(13) published September 17, 2015 (80 FR 56170), is January 26, 2016. See section XXIV of this document for the compliance dates. The incorporation by reference of certain publications listed in this rule is

approved by the Director of the Federal Register as of January 26, 2016.

FOR FURTHER INFORMATION CONTACT: Samir Assar, Center for Food Safety and Applied Nutrition (HFS-317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1636

SUPPLEMENTARY INFORMATION:

Table of Contents

Executive Summary

I. Background

- A. FDA Food Safety Modernization Act
- B. 2013 Proposed Produce Safety Rule
- C. Draft Qualitative Assessment of Risk
- D. Produce Safety Supplemental Notice
- E. List of Federal Register Publications Regarding the Proposed Produce Safety Rule
- F. Public Comments
- II. Legal Authority
 - A. Relevant Statutory Authorities Other Than Section 419 of the FD&C Act and Section 105 of FSMA
 - B. Legal Authority for Records Requirements
 - C. Intrastate Activities
- D. Application of Section 112.2(b)(6) to Entities Other Than Covered Farms
- III. General Comments on the 2013 Proposed Rule
 - A. General Comments
 - **B.** Intentional Adulteration
 - C. Registration
 - D. Consistency With USDA's National Organic Program
 - E. Consideration of Environmental Standards
 - F. Product Testing as a Strategy To Control Pathogens
- G. Aquaponic and Hydroponic Operations
- IV. Comments on the Regulatory Approach
 - A. Commodity-Specific Versus Integrated Approach
 - B. Use of Quantitative Metrics
 - C. Scientific Support for the Rule
 - D. Market Channels
- E. Guidance in Lieu of the Produce Safety Regulation
- F. Existing Industry Guidelines and **Certification Programs**
- G. Reducing Burden on Small Farms H. Estimated Produce Outbreaks and
- Associated Illnesses 1. Impact on Traditional Farming Methods
- J. Other Comments
- V. Final Qualitative Assessment of Risk
- VI. Comments on Non-Biological Hazards VII. Comments on Farm-Specific Food Safety
- Plans
- VIII. Comments Related to Foreign Farms IX. Subpart A-Comments on Definitions and **General** Provisions
- A. Food That Is Covered and That Is Not Covered (§§ 112.1 and 112.2, and Definition of "Produce" in § 112.3(c))
- B. Definitions Other Than Small Business, Very Small Business, Produce (§ 112.3(c))
- C. Small Businesses, Very Small Businesses, and Farms That Are Not Covered or Are Eligible for a Qualified Exemption

- X. Subpart B—Comments on General Requirements
 - A. General Requirement in §112.11
 - B. General Comments About Alternatives in §112.12
 - C. Alternatives for Additional or All Requirements D. Additional Clarification
- E. Prior Approval of Alternatives XI. Subpart C—Comments on Personnel
 - Qualifications and Training A. General Comments

 - B. Qualification and Training for Personnel Who Handle (Contact) Covered Produce
 - or Food-Contact Surfaces (§ 112.21) C. Training Personnel Who Conduct a
 - Covered Activity (§ 112.22) D. Records Related to Personnel
- Qualifications and Training (§ 112.30) XII. Subpart D-Comments on Health and
 - Hygiene
 - A. General Comments
 - B. Ill or Infected Persons (§ 112.31) C. Personnel Hygienic Practices (§ 112.32)
 - D. Visitors (§ 112.33)
- XIII. Subpart E-Comments on Agricultural Water
 - A. General Comments
 - B. General Agricultural Water Quality Requirement (§ 112.41) and **Corresponding Corrective Measures** (§112.45(a))
 - C. Agricultural Water Sources, Water Distribution Systems, and Pooling of Water (§112.42)
 - D. Treatment of Agricultural Water (§112.43)
 - E. Microbial Quality Criterion for Agricultural Water Used for Certain Specified Purposes (§ 112.44(a)) and **Corresponding Corrective Measures** (§ 112.45(a))
- F. Microbial Quality Criteria for Agricultural Water Used for Direct Application During Growing Activities of Produce (Other Than Sprouts) (§ 112.44(b)) and Corresponding Corrective Measures (§ 112.45(b))
- G. Testing of Agricultural Water (§ 112.46)
- H. Sharing of Water Testing Data (§ 112.47(a))
- I. Agricultural Water Used During Harvest, Packing, and Holding Activities (\$112.48)
- J. Records Related to Agricultural Water (§ 112.50)
- K. Compliance Periods Related to Agricultural Water XIV. Subpart F—Comments on Biological

Soil Amendments of Animal Origin and Human Waste

- A. General Comments
- B. Determining the Status of a Biological Soil Amendment of Animal Origin (§112.51)
- C. Handling, Conveying, and Storing Biological Soil Amendments of Animal Origin (§ 112.52)
- D. Prohibitions Regarding Use of Human Waste (§ 112.53)
- E. Treatment Processes (§ 112.54) Microbial Standards Applicable to the Treatment Processes in § 112.54
- (§112.55) G. Application Requirements and Minimum Application Intervals
- (§112.56)

- H. Records Related to Biological Soil Amendments of Animal Origin (§ 112.60) I. Other Comments
- XV. Subpart I-Comments on Domesticated and Wild Animals
 - A. Subpart I and Prevention of Contamination
 - B. Limited Scope of Applicability of Subpart I (§ 112.81)
 - C. Grazing and Working Animals (§ 112.83)
 - D. Animal Intrusion (§ 112.83) E. List of "Animals of Concern"
- XVI. Subpart K-Comments on Growing, Harvesting, Packing, and Holding Activities
 - A. Growing, Harvesting, Packing, or Holding Both Covered and Excluded Produce (§ 112.111)
 - B. Harvesting Covered Produce (§ 112.112) C. Handling Harvested Covered Produce
 - (§112.113)
 - D. Dropped Covered Produce (§112.114)

 - E. Packaging Covered Produce (§ 112.115) F. Food-Packing (Including Food
- Packaging) Material (§ 112.116) XVII. Subpart L-Comments on Equipment,
- Tools, Buildings, and Sanitation A. Types of Buildings That Are Subject to
- the Requirements of Subpart L (§112.122)
- B. Equipment and Tools (§ 112.123) C. Instruments and Controls Used To
- Measure, Regulate, or Record (§ 112.124) D. Equipment Used in the Transport of
- Covered Produce (§112.125)
- E. Buildings (§ 112.126)
- F. Toilet Facilities (§ 112.129) and Hand-Washing Facilities (§112.130)
- G. Controlling Animal Excreta and Litter From Domesticated Animals (§ 112.134)
- XVIII. Subpart M-Comments on Sprouts A. General Comments
 - B. Seeds or Beans Used To Grow Sprouts (\$112.142)
 - C. Growing, Harvesting, Packing, and Holding Sprouts (§ 112.143) D. Testing During Growing, Harvesting,
 - Packing, and Holding Sprouts (§ 112.144)
 - E. Environmental Testing for Listeria Species or L. monocytogenes (§ 112.145)
 - F. Follow-Up Actions for Positive Environmental Testing Results $(\S 112.146)$
 - G. Collection and Testing of Samples of Spent Sprout irrigation Water or Sprouts (§ 112.147
- H. Actions if Spent Sprout Irrigation Water or Sprouts Test Positive for a Pathogen (§112.148)
- I. Records Related to Sprouts (§ 112.150)
- J. Compliance Periods for Covered Activities Involving Sprouts
- K. Other Comments
- XIX. Subpart N-Comments on Analytical
- Methods
- A. Responses to Comments
- B. Other Revisions
- C. Incorporation by Reference
- XX. Subpart O-Comments on Records A. General Comments
 - B. General Requirements Applicable to Records Required Under Part 112 §112.161)
 - C. Storage of Records (§ 112.162)
 - D. Use of Existing Records (§ 112.163)
 - E. Length of Records Retention (§ 112.164)

- F. Acceptable Formats for Records
- (§ 112.165)
- G. Disclosure of Records Submitted to FDA (§ 112.167)
- XXI. Subpart P-Comments on Variances A. Requesting a Variance (§§ 112.171 and
 - 112.172)B. The Statement of Grounds in a Variance
 - Petition (§112.173) C. Process for Requesting a Variance
 - \$112.176] D. Permissible Types of Variances (§112.182)
 - E. Other Comments
- XXII. Subpart Q-Comments on Compliance and Enforcement
 - A. General Comments on Compliance and Enforcement Strategy
 - B. FDA Enforcement Decisions
 - C. Coordination of Education and
 - Enforcement (§112.193)
 - **D.** On-Farm Inspections
- E. Third-Party Audits, Inspections, and Other Arrangements
- XXIII. Subpart R-Comments on Withdrawal of Qualified Exemption
 - A. Circumstances That May Lead FDA To Withdraw a Farm's Qualified Exemption (§112.201)
 - B. Contents of an Order To Withdraw a Qualified Exemption (§ 112.203)
- C. Compliance With, or Appeal of, an Order To Withdraw a Qualified Exemption (§§ 112.204, 112.205, and 112.206)
- D. Procedure for Requesting an Informal Hearing (§ 112.207) E. Informal Hearing (§ 112.208)
- F. Circumstances Related To Reinstatement of a Qualified Exemption That Is Withdrawn (§ 112.213)
- G. Other Comments
- H. Conforming Amendment to 21 CFR Part 16
- XXIV. Comments on Effective and
 - **Compliance** Dates A. Effective and Compliance Dates for Part 112
 - B. Effective Dates for Conforming Changes C. Effective Date for Certain Provisions in
- the PCHF Regulation D. Effective Date for Certain Provisions in the PCAF Regulation
- XXV. Executive Order 13175
- XXVI. Economic Analysis of Impacts

XXVII. Analysis of Environmental Impact XXVIII. Paperwork Reduction Act of 1995 XXIX. Federalism XXX. References

Executive Summary

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353) requires FDA to conduct a rulemaking to establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables that are raw agricultural commodities (RACs) for which we have determined such standards minimize the risk of serious adverse health consequences or death. Further, FSMA requires FDA to adopt a final regulation based on known safety risks, setting forth procedures, processes, and

practices that we determine to minimize the risk of serious adverse health consequences or death, including those that are reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into produce and to provide reasonable assurances that produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). FDA published a proposed rule entitled, "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," which would establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption (78 FR 3504, January 16, 2013). The comment period for the proposed rule closed on November 22, 2013. In response to information we heard at public meetings, and based on a preliminary review of written comments submitted to the docket for the 2013 proposed rule, information available at that time, and our subsequent analysis of the proposed provisions in light of such information, FDA issued a supplemental notice of proposed rulemaking and reopened the comment period to seek public comment on specific issues and amended and new proposed provisions (79 FR 58434; September 29, 2014). The comment period for the supplemental notice of proposed rulemaking closed on December 15, 2014. We are now finalizing this rule entitled, "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption."

The final rule focuses on biological hazards related to produce growing, harvesting, packing, and holding. We conducted a "Qualitative Assessment of Risk to Public Health from On-Farm Contamination of Produce" and considered the findings of this assessment in finalizing this rule. While we acknowledge the potential for nonbiological (physical or chemical (including radiological)) hazards in produce, we are not addressing such hazards in this rule.

Scope of Coverage of the Rule

The final rule applies to both domestic and imported produce. However, as explained in the remainder of this document, the rule contains several exemptions and limitations:

 The rule does not apply to certain specified produce commodities that are rarely consumed raw.

 The rule also does not apply to produce that is used for personal or onfarm consumption, or that is not a RAC.

Attachment B: FDA, Frequently Asked Questions on Produce Rule



Frequently Asked Questions and Answers

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

March, 2013

A: General4
A.1 What does the proposed produce safety rule establish?4
A.2 What kind of produce does the proposed produce safety rule apply to? 4
A.3 How would the proposed rule define "farm"?4
A.4 How would the proposed rule define "mixed-type facility" and "farm mixed-type facility?
A.5 Where can I find out more about what activities are within the definition of "farm" and what activities are outside that definition?4
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?
A.7 Who would be a "covered farm" under the 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?
B. Qualified exemption and modified requirements7
B.1 What qualified exemption is being proposed for certain farms under the proposed rule?7

	B.2 What modified requirements would the proposed rule establish for farms eligible for the qualified exemption? (proposed § 112.6)
	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?
	B.4 Are there circumstances in which FDA could withdraw a qualified exemption?8
	B.5 What are examples of the types of conduct or conditions that could trigger the withdrawal of a qualified exemption?
	B.6 How would the proposed rule define "qualified end-user"?
ł.	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?9
c.	Alternate Approaches for Requirements
(C.1 Would the proposed rule allow the use of alternative practices?
	C.2 Where could I find scientific data and information that I would need to support the establishment and use of an alternative?
	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?
D.	Agricultural Water11
[D.1 How would the proposed rule define "agricultural water"?
	D.2 Would the proposed rule establish requirements for indirect water application (for example, drip irrigation)?
[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?
	Soil Amendments13
E	E.1 How would the proposed rule define "biological soil amendment of animal origin"?
	E.2 Does the proposed rule account for the differences between "manure" and compost"?
	E.3 How would the proposed rule categorize biological soil amendments of animal prigin as treated or untreated?
	4 Does the proposed rule establish testing requirements for soil amendments? 14
E	E.5 How do the proposed application requirements and intervals for raw manure elate to those used in the National Organic Program?
	Records

F.1 Would records maintained for the National Organic Program (NOP) meet the records requirements of the proposed rule?
F.2 Would the proposed rule permit me to use existing records to meet its requirements?
F.3 Does the proposed rule require that records be made available and accessible to FDA?
F.4 How long will the public have to comment on the proposed rule?

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 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 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 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 agroecological 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 <u>not</u> 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 EPAregistered 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 <u>www.regulations.gov</u>.

Attachment C: Test results, Primus Labs



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

Microbiological Results

2810 Industrial Parkway Santa María, CA 93455

VOICE 805.922.0055 FAX 805.922.2462 EMAIL Primus@primuslabs.com

www.primuslabs.com

......

Customer: North Valley Organics

Roberto Guzman

Approved by:

Location:

Albuquerque - New Mexico

Sampled by:

Customer

			Date Received	
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 - 0	1			
		EC 0157:H7	AOAC-RI	Negative
			011401	
		L. mono	AOAC-RI	Negative
			111301	
		Salmonella	AOAC-RI	Negative
			041303	
		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

Guzman	Uriarte	P.
	Viton 1-	E -

Analyst

Date Approved:

Aug 01, 2016

Rev. 07/05

PrimusLabs' representation of the results of laboratory analyses is limited to the analyzed samples only. PrimusLabs makes no representations of warranties about other portions of these commodities/lots. PrimusLabs' liability is limited to the cost of the laboratory tests. See also www.primuslabs.com for additional information. ANALYTICAL CHEMISTS and BACTERIOLOGISTS Approved by State of California



TEL: 831-724-5422 FAX: 831-724-3188 www.compostlab.com

Account #: 6070748-1/1-9056 Group: Jul16E #44 Reporting Date: August 9, 2016

Attachment D: Test results, Soil Control Laboratory

North Valley Organics (Albuquerque) P.O. Box 6848 Albuquerque, NM 87197 Attn: Minor Morgan

CT-50-7/26/16-7/14/16

Date Received: Sample Identification: Sample ID #:

26 Jul. 16 Soilutions Compost Tea 6070748 - 1/1

Pathogen Reduction Indicator Species

Bacteria		Results	Units	Date Tested
Fecal Coliform	Less than	7.5	MPN/10mL	26 Jul. 16
Salmonella	Less than	3	MPN/40mL	26 Jul. 16

Method (Fecal Coliform): Standard Methods 9221E Method (Salmonella): TMECC 07.02-A, EPA 1682

Analyst: Assaf Sadeh

ANALYTICAL CHEMISTS and BACTERIOLOGISTS Approved by State of California

LAB SOIL R (WATSONVILLE CALIFORNIA 95076 USA

TEL: 831-724-5422 FAX: 831-724-3188 www.compostlab.com

Account #: 6070748-1/1-9056 Group: Jul16E #44 Reporting Date: August 9, 2016

North Valley Organics (Albuquerque) P.O. Box 6848 Albuquerque, NM 87197 Attn: Minor Morgan

26 Jul. 16 Date Received: Sample Identification: Soilutions Compost Tea Sample ID #: 6070748 - 1/1

Bacteriological Examination of Material for E. coli O157:H7

Sample Identification

Soilutions Compost Tea

Sampling Date

25 Jul. 16

E. coli O157:H7 Absent

Method of Analysis: AOAC996.09

Analyst: Assaf Sadeh

ang Sabel

ANALYTICAL CHEMISTS and BACTERIOLOGISTS Approved by State of California

R LAB SOIL

ATSONVILLE CALIFORNIA 95076

USA

TEL: 831-724-5422 FAX: 831-724-3188 www.compostlab.com

Account #: 6070748-1/1-9056 Group: Jul16E #44 Reporting Date: August 9, 2016

North Valley Organics (Albuquerque) P.O. Box 6848 Albuquerque, NM 87197 Attn: Minor Morgan

Date Received: 26 Jul. 16 Sample Identification: Soilutions Compost Tea Sample ID #: 6070748 - 1/1

Bateriological Examination of Material for Listeria

Sample Identification Sampling Date

Listeria

Soilutions Compost Tea

25 Jul. 16

Absent

Method of Analysis: AOAC 997.03

Analyst: Assaf Sadeh

ang Sale

Hall Environmental Anal	ysis Labora	ntory, In	c.		La	alytical Report b Order 1612991 te Reported: 1/4/2017
CLIENT: Minor Morgan Project: Field 1 Well			C	Client Sample II		Water 2016 1:00:00 PM
Lab ID: 1612991-001	Matrix:	AQUEOUS				2016 2:13:00 PM
Analyses	Result	PQL	Qual	Units	DF	Date Analyzed
EPA METHOD 300.0: ANIONS						Analyst: LGT
Chloride	17	0.50		mg/L	1	12/20/2016 2:46:39 PM
Nitrogen, Nitrite (As N)	ND	0.10		mg/L	1	12/20/2016 2:46:39 PM
Nitrogen, Nitrate (As N)	ND	0.10		mg/L	1	12/20/2016 2:46:39 PM
Sulfate	84	10		mg/L	20	12/20/2016 2:59:03 PM
EPA METHOD 200.7: METALS						Analyst: MED
Calcium	77	1.0		mg/L	1	12/28/2016 6:35:54 PM
Iron	ND	0.020		mg/L	1	12/28/2016 6:35:54 PM
Magnesium	21	1.0		mg/L	1	12/28/2016 6:35:54 PM
Potassium	11	1.0		mg/L	1	12/28/2016 6:35:54 PM
Sodium	27	1.0		mg/L	1	12/28/2016 6:35:54 PM
EPA 200.8: METALS						Analyst: JLF
Arsenic	0.0036	0.0010		mg/L	1	12/22/2016 5:30:57 PM
Lead	ND	0.00050		mg/L	1	12/22/2016 5:30:57 PM
SM 9223B TOTAL COLIFORM						Analyst: SMS
Total Coliform	Absent	0		P/A	1	12/20/2016 4:56:00 PM
E. Coli	Absent	0		P/A	1	12/20/2016 4:56:00 PM
CHLORINE: HACH 8167						Analyst: SMS
Total Chlorine	ND	0.050	н	mg/L	1	12/27/2016 12:50:00 PM
SM 4500 NH3: AMMONIA						Analyst: CJS
Nitrogen, Ammonia	ND	1.0		mg/L	1	12/22/2016 1:22:00 PM
	ND.	1.0		iligit		
SM4500-H+B: PH	4.67	4.00	-76		4	Analyst: JRR
рН	7.54	1.68	н	pH units	1	12/21/2016 3:08:10 PM
SM2320B: ALKALINITY						Analyst: JRR
Bicarbonate (As CaCO3)	222.1	20.00		mg/L CaCO3	1	12/21/2016 3:08:10 PM
Carbonate (As CaCO3)	ND	2.000		mg/L CaCO3	1	12/21/2016 3:08:10 PM
Total Alkalinity (as CaCO3)	222.1	20.00		mg/L CaCO3	1	12/21/2016 3:08:10 PM
SM2540C MOD: TOTAL DISSOLVED						Analyst: KS
Total Dissolved Solids	478	20.0		mg/L	1	12/23/2016 6:39:00 PM
SM 4500 NORG C: TKN						Analyst: CJS
Nitrogen, Kjeldahl, Total	ND	1.0		mg/L	1	12/29/2016 10:37:00 AM

Attachment E: Test results, well water, Hall Environmental

Refer to the QC Summary report and sample login checklist for flagged QC data and preservation information.

Qualifiers:

*

- D Sample Diluted Due to Matrix
- H Holding times for preparation or analysis exceeded

Value exceeds Maximum Contaminant Level.

- ND Not Detected at the Reporting Limit
- R RPD outside accepted recovery limits
- S % Recovery outside of range due to dilution or matrix
- B Analyte detected in the associated Method Blank
- E Value above quantitation range
- J Analyte detected below quantitation limits Page 1 of 10
- P Sample pH Not In Range
- RL Reporting Detection Limit
- W Sample container temperature is out of limit as specified

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for samples from the United States and U.S. Territories



Mail Samples To Earthfort at:

635 SW Western Blvd

Corvallis OR 97333

For detailed assay descriptions and instructions on how to sample, package and ship your materials visit earthfort.com

Questions? We're here to help! Call (541) 257-2612 or email info@earthfort.com *required information	'o@earthfort.com	earinio		Ford	Corval For detailed assay descriptions and instructions on package and ship your materials visit	ons and ship you
*Primary Contact's Address (will be printed on test reports)	ill be printed on test reports)		*Billing Address	(Check here	Check here if same as primary contact's address	/ cont
*Contact Person			Contact Person			
Organization			Organization			
*Address			Address		÷	
*City, State, Zip			City, State, Zip			
*Phone Number			Phone Number	1		
*Email (send report)			Email (send receipt)	¢		
	Yes! Please add my email to Earthfort's monthly e-newsletter list for special	Earthfort's monthly e-new		deals, informative articles, and events!	icles, and events!	
Save on shipping costs! Se	Save on shipping costs! Send 10 oz (250 g) or 10 fl. oz. (300 ml) of material per sample, (double this amo)) of material per sample	, (double this amour	ıt if ordering Biolo	unt if ordering Biology Package and Crop Nutrients on same sa	Nutri
*Sample Name / Identification	*Material Type	*Date Taken Plant Type (*for soils only)	ype (*for soils only)	Notes (plant health, irrigation, etc.)	n, irrigation, etc.) *	*Test/s Requested
	soil compost liquid				_	
	soil compost liquid					
	soil compost liquid					
	soil compost liquid					
	soil compost liquid					
	soil compost liquid					
	soil compost liquid					
	soil compost liquid					
Testing Packages and Individual Assays	lual Assays		1. 1. S.		Price per Sample	e *Quantity
Basic Biology Package - Include:	Basic Biology Package - Includes total/active bacteria, total/active fungi	yi.			\$80.00	-
Essential Biology Package - Incl	Essential Biology Package - Includes total/active bacteria, total/active fungi, and protozoa.	fungi, and protozoa.			\$108.00	-
Advanced Biology Package - Inc	Advanced Biology Package - Includes total/active bacteria, total/active fungi, protozoa, and nematodes	e fungi, protozoa, and ner	natodes.		\$144.00	_
Crop Specific Nutrient Package	Crop Specific Nutrient Package - Send an extra 2 cups (10 oz) of material. Includes pH, N, P, K, Ca, Mg, B, Mn, Cu, Zn, S, Cl, soluble salts, humus.	I. Includes pH, N, P, K, Ca, M	lg, B, Mn, Cu, Zn, S, Cl,	soluble salts, humus.	\$75.00	-
Mycorrhizal Colonization [VAM]	Mycorrhizal Colonization [VAM] - This test is for SOILS ONLY and MUST include 10 inches (26 cm) of fine, young	UST include 10 inches (26	i cm) of fine, young rc	roots in sample.	\$42.00	-
E. coli					\$30.00	-

Attachment G: Soil food Web compost testing form



Foodweb Biology

Submission Form (22 April 2016 revision) Report will be sent by email Submit Samples to: Environment Celebration Institute 13193 Oroville Quincy Highway Berry Creek, CA 95916 530-589-9947 info@environmentcelebration.com

Send 1/4 cup of material per sample, by Next Day Air. Take the sample the same day you ship it. Samples must be shipped on a Monday, Tuesday, or Wednesday to arrive in our lab in time for testing. If samples arrive on a Friday afternoon after 3 PM, there is not enough time for testing since there is no one in the lab after 5 PM on Friday until Monday at 9 AM. If you have liquid fill a plastic water bottle about 1/8 full and then ship it overnight so it arrives before noon the next day so we can be sure to have time to test.

Address			
Contact Person			
Organization			
Address			
City, State			
Zip, Country			
Phone			
Fax			
email			
Sample ID			
Sample Type (Soil or Other)			
Intended Crop			
Date Taken			
Tests Ordered			
Notes	ckage Includes Assays	Price Per Sample	Subtotal
Qty Testing Pac	kage includes Assays		oubtotai
Full Foodweb	TB-TF-Prot-Nem	\$60.00	
QT Individual A	Asssays	Price Per Sample	Subtotal
TB: Total B	acteria	\$ 15.00	
TF: Total F	ungi	\$ 15.00	
Prot: Protozo	Ba	\$ 15.00	
Nem: Nema	todes	\$ 15.00	
	—	Expiration/ CVC C	§
Name on Card:	Billing Address:		
	edit card transactions are processed throug y orders made out to: ECI, 13193 Oro Qu	h the Environment Celebration Institute . incy Hwy, Berry Creek, CA 95916. 530-58	89-9947

Attachment H: Farmer self assessment

Farmer Self Assessment regarding use of compost and compost tea on the farm (produced with support from Western SARE grant # FW15-037)



Farm Name and Address:

Farm Operator Name and contact info:

Date Assessment completed:

Completed by:

Compost:

1. Do I plan to use compost in my farm operation? ____Yes ____No

If No, skip to Compost Tea section. If Yes, continue

2. How do I plan to use compost on my farm operation?

3. What are the outcomes I expect to see using compost?

4. Is my farm certified organic, or plan to be certified organic? _____Yes _____No

5. What is the source of the compost I plan to use:

_____made on the farm. Following organic standards? ____Yes ____No ____NA

_____ purchased from off-farm. Approved for organic use? ____Yes ____No ____NA

_____ obtained free off-farm. Approved for organic use? _____Yes _____No ____NA

____ both farm made and purchased

6. If purchased/obtained off-farm, name, address and phone of supplier(s):

- Does supplier have any credentials or documentation of compost quality? (i.e. member of US Composting Council, organic certification, compost test results, etc) No Yes - Do I have copies of documents? No Yes - How is compost transported to farm? - Is transport vehicle/container inspected before loading for possible contamination? No Yes No - Is compost covered during transportation? Yes 7. Upon arrival to farm, is compost used immediately or stored on-farm? used immediately stored and used later both If stored, location and manner of storage: No Is stored compost covered: Yes If yes, manner and type of covering: 8. For stored compost, what is maximum length of time before compost is used either as compost or for making compost tea? Weeks Months Days 9. For on-farm produced compost:

Describe your compost making process, including inputs, timeframes, process and storage:

- Storage location of on-farm produced compost and manner of storage:

Is stored compost covered: Yes No If yes, manner and type of covering: - Is on-farm produced compost certified organic? Yes No - For on-farm produced compost, what is maximum length of time before compost is used either as compost or for making compost tea? Days Weeks Months Compost Tea: 1. Do I plan to use compost tea in my farm operation? Yes No 2. How do I plan to use compost tea on my farm operation? 2A. Do I plan to use a bacterial dominant, fungal dominant or balanced tea? Why? 3. What are the outcomes I expect to see using compost tea? 4. Is my farm certified organic, or plan to be certified organic? _____Yes No 5. What is the source of the compost I plan to use in making compost tea: made on the farm. Following organic standards? Yes No NA purchased from off-farm. Approved for organic use? Yes No NA obtained free off-farm. Approved for organic use? _____Yes ____No ____NA _____ both farm made and brought in - Have I tested the compost for pathogens? Yes No Page 3 of 4

6. What is the water source for making compost tea?

7. Have you tested the water using drinking water standards? ____Yes ____No

- if Yes, name and address of laboratory:

- What was water tested for/what Standards were used?

- Were test results positive for pathogens or prohibited materials? _____Yes ____No If Yes, explain:
- 8. In making compost tea I will use compost that has been:

Brought to farm fresh with each batch of tea, i.e. not from farm-stored compost

From compost previously brought/made at farm and stored on-farm.

- maximum length of time stored compost will be used for tea:

9. I will be using the following brewer (include make, model, description, gallon capacity, air pump capacity):

10. At the completion of the brewing cycle, I will be using the compost tea within_____

hours and ______ minutes from the time I stop aerating the tea.

11. I will use the following methods for applying the compost tea:

Application method	Application Equipment	Water dilution ratio
Spray foliar feed plants	4 gal backpack sprayer	3:1
side dress at base of plants	5 gal bucket with pail	5:1
liquid drench of soil	40 gal. tractor mounted sprayer	5:1
injection through drip lines	injector	Not diluted (1:1)
root soak for greenhouse transplant starts	5 gal bucket with pail	Not diluted (1:1)
other application method		

Attachment I: Step-by-Step: Preparation

Step by Step Compost Tea- Preparation

(produced with support from Western SARE grant # FW15-037)



1. Complete "Compost Self Assessment" to become familiar with the issues regarding brewing compost tea.

2. Decide on type and model of brewer to be used.

- what brand of tea brewer will you use?
 - what are the components of the brewer?
 - what is the air pump capacity in cubic feet/minute (cfm)?
- turbidity level: is pump able to move brew around sufficiently to dislodge microbes?
 - is turbidity level adequate to assure no "low oxygen" zones
- is the brewer easy to clean?
- what type of strainer will you use?
 - what is mesh size of strainer?
- can you obtain more strainers as needed?
 - who is your supplier for strainers?
- besides the brewer, what additional implements are used in the brewing process?

3. Decide on location where brewer and supplies will be located.

- where is the brewer stored?
 - is storage in the open or closed area?
 - is the brewer stored covered or uncovered?
 - is the brewer stored in the same location at all times?
- during brewing, what is the location of the brewer?
 - is the brewer covered during brewing
- what is the power source for the aerator motor?
 - could you lose power from this power source?
 - how would you know if you lost power?
- what is elevation of your brewing location?

4. Decide whether on-farm or off-farm compost will be used. If on-farm compost:

- do you plan to use the compost as compost on the farm, or just to make tea?
- do you have a written log documenting your steps for making compost?
 - are you certain that the minimum temperature is reached?
 - how do you measure this?
 - how do you document this?
 - are you certain that the minimum temperature timeframes are met?
 - how do you measure this?
 - how do you document this?

Page 1 of 6

- Is your operation certified organic?
 - if yes, do you follow the NOP Standards for producing compost?
 - do you have documentation to demonstrate compliance with NOP Standards?
 - If not certified organic, do you follow the FSMA standards for making compost?
 - which Standard do you follow?

Acceptable treatment processes include any scientifically valid controlled physical, chemical, or biological process – or a combination – that is validated to satisfy certain microbial standards. Composting is considered a common biological process, and validated composting methods include:

1. Static composting that maintains aerobic (*i.e.*, oxygenated) conditions at a minimum of 131 °F (55 °C) for 3 consecutive days and is followed by adequate curing; and

2. Turned composting that maintains aerobic conditions at a minimum of 131 °F (55 °C) for 15 days (which do not have to be consecutive), with a minimum of five turnings, and is followed by adequate curing.

Per FDA's definitions, curing may or may not involve insulation, depending on environmental conditions.

5. Decide on off-farm supplier of compost.

- who is the vendor/source of the compost?
- how is compost transported to farm site
 - in a container?
 - was container new/unused or used?
 - -if no, was container cleaned/sanitized prior to use?
 - was container covered during transport?
 - if in a truck bed, was bed cleaned or sanitized?

- was batch covered with a tarp?

- if delivered by vendor, was batch covered?
- how is batch offloaded from delivery vehicle?
- where is compost stored?
- what was date of delivery?
- what time of day did delivery occur?
- what was duration of transport?
- was batch rained/snowed on?
- any unusual occurrences during delivery?
- was sample from batch tested for microbes by supplier?
- was sample from batch tested for pathogens by supplier?
- do you have a written receipt from supplier for purchase?
 - does receipt show:
 - date purchased
 - date delivered
 - amount purchased/delivered
 - cost?
 - vendor name, address, phone #?
 - description of compost/product name?
 - organic designation?
 - other information?

- is receipt stored in a safe place?

- what is location of stored receipt?
- how long do you keep the receipt?
- is this batch being used in a certified organic operation?
 - do you have documentation approving this product for organic use?
 - what is location of this documentation?

6. Compost storage at the farm

- what is the location where compost used for compost tea is stored?
 - is it always stored in the same location?
 - is storage out in the open or in a contained building/structure?
- is the compost covered?
 - how is the compost covered, with what material?
 - is the covering applied in such a manner to allow access to air?
 - what assurance is there covering will not be removed/blown away?
 - is the compost completely covered or partially covered?
- do you use the same stored batch as direct applied compost and for compost tea?
- how often is this batch replenished?
- what is the longest timeframe that tea will be made from a batch of compost?
- 7. Decide on source of water to be used in compost and have water tested.
 - what is source of water used in brewing?
 - if city tap water, is it chlorinated?
 - how do you remove the chlorine prior to making compost tea?
 - do you have access to city water reports that document water is safe?
 - what laboratory will do the water testing?
 - has water been tested for following parameters:
 - PH
 - presence of E coli 0157
 - total coliforms present
 - metals, including arsenic and lead
 - salts
 - where do you store the water quality test results?
 - what is the temperature of water as it comes from the source?
 - is water used in tea brewing directly from source or is it stored prior to brewing?
 - how and where is it stored?
 - is storage covered?
 - has storage container been sanitized prior to storage?
- 8. Decide on testing methodology for dissolved oxygen (DO) and acquire supplies.
 - will you acquire a DO meter?
 - make and model of meter?
 - has meter been calibrated?
 - has meter been compensated for elevation?
 - if using test strips, who is supplier of test strips?

- do test strips have adequate range indicators? (0 mg/L through 12 mg/L)

- have you completed a "static test" using water only with your brewer to measure DO levels at beginning of aeration and after one hour of aeration to assure that aeration is actually occurring?

9. Choose which laboratories for pathogen and quality testing.

- will you do both pathogen testing and quality testing?
- which laboratory will you use for pathogen and quality testing?
 - is it necessary to open an account?
 - do you know exactly where to send the sample?
 - do you understand packing and shipping protocols to assure an accurate test?
 - do you have adequate packing and shipping materials?
- 10. Decide on pretreatment additives and supplier.
 - will you be pretreating compost prior to making compost tea
 - what additives will you be adding to compost as a pretreatment?
 - what is the proportion of compost, additives and water?
 - who is the supplier or source of additives?
 - how long will you pretreat compost?
 - where will you store compost during pretreatment?
 - will temperature be adequate for pretreatment? (65-80 degrees F.)
 - will pretreatment be covered, in the dark and undisturbed?

11. Decide on brewing additives to be used and supplier

- will you be adding supplemental foods to brew?
- what materials will you be adding as food during brewing?
 - what is the source/supplier of additives?
- what are the proportions of additives used during brewing?
- at what point in brewing cycle are foods added?

12. Determine application equipment and methods

- what method of application will you use?
 - side dress, foliar spray, drip tape/sprinkler injection, greenhouse starts
- has your application vessel been used with any product that might inhibit microbe growth?
 - was vessel thoroughly cleaned prior to using with tea?
- will tea be diluted or applied at full strength?
 - what is temperature of water used for dilution?
 - is source for dilution water the same as water for brewing?
- will any additional materials be added to tea after brewing is complete?
- If foliar spray, is the spray orifice large enough to pass microbes?
 - does the sprayer have a built-in filter that might restrict tea flow?
 - is the filter finer than 400 micron mesh?
 - does the tea liquid make any 90 degree turns during spraying?
 - do you add any wetting agents to your spray mix?
 - are the wetting agents compatible with living microbes?

- is the exit pressure from any nozzle greater than 20 PSI?

- if foliar spraying, is application during early morning or later afternoon to avoid strong UV radiation?
- 13. Acquire cleaning materials and equipment
 - how do you assure tea liquid does not get into air line?
 - do you clean all components with water and detergent prior to sanitizing?
 - are all implements used in cleaning labeled for compost cleaning only?
 - are all cleaning implements stored in a central location?
 - are all implements used for compost cleaning only
 - after cleaning components of brewer, are all components sanitized?
 - what brand and type of sanitizer do you use?
 - are brewer components allowed to air dry prior to placing in storage
 - are you able to reach and clean all parts of brewer that come into contact with tea?
 - are there invisible or difficult to reach parts of brewer?
 - for membrane diffusers, do you disassemble diffuser?
 - for air stones, do you soak stone in sanitizer?
 - do you maintain a "cleaning/sanitizing log"?
 - do you clean the brewer and equipment within one hour of completing brewing?

14. Determine location of brewing and brewing procedures

- do operators follow general GAP practices while brewing?
 - i.e., not being sick, sneezing, coughing, etc?
 - do operators wash their hands prior to brewing?
- what is date of brewing?
- is brewing done in a controlled temperature environment or not?
 - is brewing done in a covered environment such as a building?
 - is brewing done in the same location every time?
- what is duration of brewing time?
 - do you have a log that notes batch #, date, brewing time, etc?
 - where is this log kept?
- is your brewer covered during brewing?
 - how is it covered?
- do you aerate the water in the brewer prior to adding compost?
 - how long do you aerate?
- do you measure the dissolved oxygen level in the brew during brewing?
 - at what intervals do you measure the dissolved oxygen level?
 - have you factored in your altitude in calculating oxygen level in your brew?
 - what type of aerator diffuser do you use?
 - have you verified the pores/orifices are not plugged up?
- what is ambient temperature when you begin brewing?
- what is the brew temperature when you begin brewing?
- what is the water temperature when you begin brewing
- what is the maximum temperature swing during brewing time?
 - what is high temp and low temp during brewing?

- how do you add the compost to compost tea brewer?
 - what implements do you use to transfer compost from storage area to brewer?
 - are these implements sanitized prior to use?
- do you use a strainer in the brewer?
 - what mesh size is the strainer
 - what is the configuration of the strainer and location within the brewer?
- what quantity of water do you use?
 - what quantity of compost do you use?
 - what quantity of additives do you use?
 - what is the sequence of steps you take during brewing to add the water, compost and any additives?
 - do you use additives during brewing?
 - how is water added to the brewer?

15. Create Compost tea log and other records as necessary

Attachment J: Step-by-Step: Mailing tea for testing

Step by Step Compost Tea- Mailing Tea for Testing

(produced with support from Western SARE grant # FW15-037)



Procedure for mailing brew for testing:

Preliminary steps

1.Locate clean one quart plastic bottle (empty water bottle is good) and label bottle with sample date and name

- 2. obtain and freeze ice packs
- 3. Obtain packing supplies
- 4. Fill out lab form and overnight mail address label

When brewing complete

1. Fill up quart bottle approximately half full with compost tea and secure cap

- 2. Place bottle in fridge and lower temperature to 45 degrees
- 3. Pack sample in insulated carrier and place in mailing box
- 4. Mail overnight delivery using USPS. Time overnight mailing so sample is taken to post office on a Monday or Tuesday, assuring sample is received by lab no later than Thursday morning.

Conversion Factors- Air volume ratings for aeration pumps

When evaluating pumps for use in brewing tea it is important to understand the basic concepts of pressure and air movement. The standard commercial rating for air pumps lists the volume of air in cubic feet moved in one minute, abbreviated CFM (cubic feet per minute). However this rating applies to a fixed pressure, which often is not stated. For commercial pumps, the air flow rate is listed as a function of the pressure and is illustrated through a "pump curve" graph which shows how the pump responds at different pressures. Pump graphs are usually available, if you request them.

For smaller pumps sold in the fish tank market, the CFM ratings are usually unstated and turn out to be at 0 PSI. This means that the pump will transfer XX CFM when there is no pressure resistance on the pump. This is rarely the scenario in the real world. The biggest factor influencing the pressure requirements are the porosity of the diffuser and where the diffuser is located in the tank. A diffuser at the bottom of a tank must overcome the weight of the water. Membrane diffusers and air stones that get plugged can easily require 10-20 PSI of pressure to pass air.

Typically to keep water well oxygenated you need:

5 gallon bucket:	1 CFM
10 gallon:	2 CFM
40 gallon:	6 CFM

Pumps are listed in a dizzying number of formats. All need to be converted to CFM to really know what you are getting.

Air Volume:

- GPM = gallons per minute (gal/min)

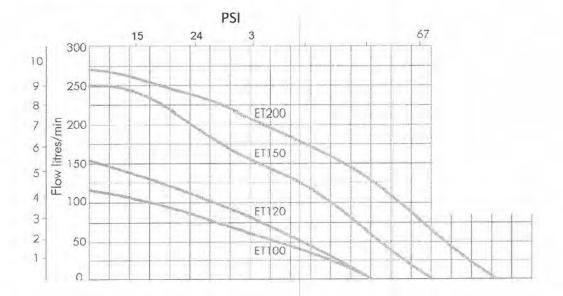
- GPH = gallons per hour (gal/hr)

- CFM = cubic feet per minute (cf/min)

1 cfm= 7.48 gpm	1 gpm= .134 cfm
1 cfm= 60 cfh	1 gph= .0167 gpm

example: How many cfm is a pump rated 1030 gph?

1 gph= .0167 gpm 1030 gph= (.0167) X 1030= 17.2 gpm 1 gpm= .134 cfm 17.2 gpm= (.134) X 17.2= 2.3 cfm The following is a "pump curve" for the Blue Diamond brand ET Series aerating pumps for ponds and septic systems.



Column on the left shows air flow rate in CFM. Numbers at top show pressure in PSI. We use a ET120 in our 40 gallon brewer and have no problem maintaining a high level of dissolved oxygen.

Attachment L: General information on dissolved oxygen

Page 1 of 4



City of Boulder/USGS Water Quality Monitoring

General Information on Dissolved Oxygen

by Sheila Murphy

DISSOLVED OXYGEN (DO)

Dissolved Oxygen (DO) is found in microscopic bubbles of oxygen that are mixed in the water and occur between water molecules. DO is a very important indicator of a water body's ability to support aquatic life. Fish "breathe" by absorbing dissolved oxygen through their gills. Oxygen enters the water by absorption directly from the atmosphere or by aquatic plant and algae photosynthesis. Oxygen is removed from the water by respiration and decomposition of organic matter.

Measurement of DO

Dissolved Oxygen can be measured with an electrode and meter or with field test kits. The electronic meter does not measure oxygen directly; rather, it uses electrodes to measure the partial pressure of oxygen in the water, which is converted to oxygen mass weight concentration. The field test kits (such as a drop bottle, a microburet, or a digital titrator) involve adding a solution of known strength to a treated sample of water from the stream. The amount of solution required to change the color of the sample reflects the concentration of DO in the sample. The amount of oxygen dissolved in water is expressed as a concentration, in milligrams per liter (mg/l) of water.



Dissolved oxygen levels are also often reported in percent saturation. Temperature affects DO concentrations, and calculating the percent saturation will factor out the effect of temperature. The "saturation level" is the maximum concentration of dissolved oxygen that would be

present in water at a specific temperature, in the absence of other factors. Scientists have determined the saturation DO level for various temperatures. Saturation levels also vary with elevation. Percent saturation is calculated by dividing the measured dissolved oxygen concentration by the saturation level and multiplying by 100.

This equation is shown as:

% Saturation = (DO / Saturation Level) x 100

Factors Affecting DO

Volume and velocity of water flowing in the water body

In fast-moving streams, rushing water is aerated by bubbles as it churns over rocks and falls down hundreds of tiny waterfalls. These streams, if unpolluted, are usually saturated with oxygen. In slow, stagnant waters, oxygen only enters the top layer of water, and deeper water is often low in DO concentration due to decomposition of organic matter by bacteria that live on or near the bottom of the reservoir.

Dams slow water down, and therefore can affect the DO concentration of water downstream. If water is released from the top of the reservoir, it can be warmer because the dam has slowed the water, giving it more time to warm up and lose oxygen. If dams release water from the bottom of a reservoir, this water will be cooler, but may be low in DO due to decomposition of organic matter by bacteria.



BASIN: General Information on Dissolved Oxygen

Climate/Season

The colder the water, the more oxygen can be dissolved in the water. Therefore, DO concentrations at one location are usually higher in the winter than in the summer.

During dry seasons, water levels decrease and the flow rate of a river slows down. As the water moves slower, it mixes less with the air, and the DO concentration decreases. During rainy seasons, oxygen concentrations tend to be higher because the rain interacts with oxygen in the air as it falls.

More sunlight and warmer temperatures also bring increased activity levels in plant and animal life; depending on what organisms are present, this may increase or decrease the DO concentration.

The type and number of organisms in the water body

During photosynthesis, plants release oxygen into the water. During respiration, plants remove oxygen from the water. Bacteria and fungi use oxygen as they decompose dead organic matter in the stream. The type of organisms present (plant, bacteria, fungi) affect the DO concentration in a water body. If many plants are present, the water can be supersaturated with DO during the day, as photosynthesis occurs. Concentrations of oxygen can decrease significantly during the night, due to respiration. DO concentrations are usually highest in the late afternoon, because

photosynthesis has been occurring all day. For an example of how DO can vary from day to night, select here .

Altitude

Oxygen is more easily dissolved into water at low altitudes than at high altitudes, because of higher atmospheric pressure.

Dissolved or suspended solids

Oxygen is more easily dissolved into water with low levels of dissolved or suspended solids. Waters with high amounts of salt, such as the ocean (which contains about 35 grams of salt for each 1000 grams of water) have low concentrations of DO. Freshwater

lakes, streams, and tap water generally contain much less salt, so DO concentrations are higher. As the amount of salt in any body of water increases, the amount of dissolved oxygen decreases. An increase in salt concentration due to evaporation of water from an ecosystem tends to reduce the dissolved oxygen available to the ecosystem's inhabitants.

Runoff from roads and other paved surfaces can bring salts and sediments into stream water, increasing the dissolved and suspended solids in the water.

Amount of nutrients in the water

Nutrients are food for algae, and water with high amounts of nutrients can produce algae in large quantities. When these algae die, bacteria decompose them, and use up oxygen. This process is called <u>eutrophication</u>. DO concentrations can drop too low for fish to breathe, leading to fish kills. However, nutrients can also lead to increased plant growth. This can lead to high DO concentrations during the day as photosynthesis occurs, and low DO concentrations during the night when photosynthesis stops and plants and animals use the oxygen during respiration. For an example of how DO can vary from day to night, select <u>here</u>.

<u>Nitrate</u> and <u>phosphate</u> are nutrients. Nitrate is found in sewage discharge, fertilizer runoff, and leakage from septic systems. Phosphate is found in fertilizer and some detergents.

Organic Wastes

http://bcn.boulder.co.us/basin/data/NEW/info/DO.html







BASIN: General Information on Dissolved Oxygen

Organic wastes are the remains of any living or once-living organism. Organic wastes that can enter a body of water include leaves, grass clippings, dead plants or animals, animal droppings, and sewage. Organic waste is decomposed by bacteria; these bacteria remove dissolved oxygen from the water when they breathe. If more food (organic waste) is available for the bacteria, more bacteria will grow and use oxygen, and the DO concentration will drop.

Directly downstream from where sewage effluent is discharged to a river, DO content often decreases, because of the increase in growth rate of bacteria that consume the organic matter contained in the effluent. The degree and extent of the DO "sag" depends on the Biological Oxygen Demand (BOD) of the effluent (how much oxygen the effluent can consume) (Giller and Malmqvist, 1998).

Riparian Vegetation

Shading tends to lower average summer temperature and reduce the daily duration of higher temperature. Removing trees reduces shade on the creek, allowing the sun to warm the water. This can affect DO concentrations in different ways. As mentioned above, in general, as water temperature increases. DO drops. Also, the bare soil exposed from removing the tree can erode, increasing the amount of dissolved and suspended solids in the water. This also leads to a decrease in DO concentrations. However, direct sunlight, along with increased nutrients can increase the growth rate of aquatic plants. These plants release oxygen to the water during the day, but then remove oxygen from the water at night. This can cause DO concentrations to become very high during the day, then very low during the night. For an example of how DO can vary from day to night, select here .

Groundwater Inflow

The amount of groundwater entering a river or stream can influence oxygen levels. Groundwater usually has low concentrations of DO, but it is also often colder than stream water. Therefore, groundwater may at first lower the DO concentration, but as groundwater cools the stream or river, the ability of the water to hold oxygen improves.

Water Quality Standards and Other Criteria Regarding DO

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Colorado Department of Public Health and Environment Water Quality Control Division (CDPHE-WOCD) regulations (5 CCR 1002-31) state that waters to be used for domestic water supply should not have DO concentrations below 3 milligrams per liter (mg/l) (Reg. 31 - Basic Standards and Methodologies for Surface Water).

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CDPHE-WQCD regulations state that waters used for recreation (both primary and secondary contact) should not have DO concentrations below 3 milligrams per liter (mg/l).

CDPHE-WQCD regulations state that waters classifed as "Class 1 Cold Water Aquatic Life" should not have DO concentrations below 6 mg/l, and not below 7 mg/l during spawning. Waters classified as "Class 1 Warm Water Aquatic Life" should not have DO concentrations below 5 mg/l. (These are 1-day minima)

Very high DO concentrations can also be harmful to aquatic life. Fish in waters containing excessive dissolved gases may suffer a condition in which bubbles of oxygen block the flow of blood through blood vessels, causing death. Abrupt changes in dissolved oxygen induce stress and subsequently make fish more susceptible to disease.

The ideal dissolved oxygen concentration for many fish is between 7 and 9 mg/l; the optimal DO for adult brown trout is 9-12 mg/l. Most fish cannot survive at concentrations below 3 mg/l of dissolved oxygen.



BASIN: General Information on Dissolved Oxygen

Other Information about DO

When dissolved oxygen concentrations drop, major changes in the types and amounts of aquatic organisms found living in the water can occur. Species that need high concentrations of dissolved oxygen, such as mayfly nymphs, stonefly nymphs, caddisfly larvae, pike, trout, and bass will move out or die. They will be replaced by organisms such as sludge worms, blackfly larvae, and leeches which can tolerate lower dissolved oxygen concentrations. Waters that have low dissolved oxygen sometimes smell bad because of waste products produced by organisms that live in low oxygen environments.

Because of the relationship between temperature, rate of photosynthesis, and DO, fish kills usually occur in late summer just before dawn.

Very low DO concentrations can result in mobilization of trace metals.

A fish that is under stress caused by low oxygen levels in the water is more susceptible to poisoning by insecticides or heavy metals (Caduto, 1990).

Select here for a list references used in the preparation of this information Select here for general information about other water quality parameters. Select here for interpretation of Dissoved Oxygen data in the Boulder Creek Watershed

INVITATION: BASIN is a community project actively seeking public participation. We appreciate all feedback and welcome comments, suggestions and contributions. To find out more about how you can be involved, <u>elick here.</u>

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