December 15, 2014

TO: **Division of Dockets Management [HFA-305]**
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: **Docket No. FDA-2011-N-0921** **RIN 0910—AG35**
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

Thank you for the opportunity to provide comments on FDA's Supplemental Proposed Produce Safety Rule.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America, representing organic businesses across 49 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect the growth of organic trade to benefit the environment, farmers, the public and the economy.

As expressed in our earlier comments, the organic industry takes food safety seriously, and we fully embrace FDA's efforts and the intended outcome of a safer food supply. We believe that **every** food producer has a legal obligation to supply safe food to the public. As an early supporter of food safety reform, OTA was fully engaged in the legislative process that resulted in the enactment of the Food Safety Modernization Act (FSMA). One key provision we advocated for was that the produce safety rule must not duplicate or conflict with the U.S. Department of Agriculture's (USDA) National Organic Program (NOP) standards[1].

Since the draft rules were released in January 2013, OTA's Food Safety Task Force, with support of our membership, has worked to raise awareness on the issue throughout the organic sector, and develop comments to proposing solutions to align with the organic regulations without a reduction in food safety. The supplemental proposals clearly indicate that FDA listened to the feedback from OTA and other organic producers and handlers. OTA applauds FDA's work and its extensive outreach to organic stakeholders across the country. We expressly thank you for listening and responding to the concerns you have heard.

OTA is largely supportive of the changes made to the Proposed Produce Safety Rule. Although we are pleased with most of the revisions, we still have a few concerns that deserve additional attention. Directly below is a summary of our comments. Our more detailed comments and suggestions for improvement follow thereafter.

Summary:

- ***Definition of a "farm:"*** OTA agrees with FDA's revised definition of a "farm." We recognize, however, that a farm may have multiple sites located in "one general physical location" and one or more

[1] FSMA Section 105 Standards for Produce Safety (A)(3)(E) - The proposed rulemaking under paragraph (1) shall in the case of production that is certified organic, not include any requirements that conflict with or duplicate the requirements of the national organic program established under the Organic Foods Production Act of 1990, while providing the same level of public health protection as the requirements under guidance documents, including guidance documents regarding action levels, and regulations under the FDA Food Safety Modernization Act.

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of these sites may be designated for packing operations. OTA requests that FDA issue guidance to clarify the boundaries intended by the phrase "one general physical location," and clarify the extent to which this would apply to holding or packing operations located within the close proximity of a farm and under its ownership, but not on the farm itself.

- ***Farms that pack or hold food from other farms:*** OTA supports FDA's revisions to the following definitions: "farm," "harvesting," "holding," and "packing." Specifically, we agree that a farm should not be required to register as a food facility merely because it packs or holds raw agricultural commodities (RACs) grown on another farm under a different ownership. We agree that on-farm packing and holding of produce should be subject to the Proposed Produce Safety Rule, not the Preventive Controls Rule, provided RACs are not transformed into a processed product. Farms that conduct additional processing or manufacturing should be subject to the preventive controls rule for those activities. FDA's revision supports a collaborative approach to local and regional agriculture. It clarifies the rules, and reduces unwarranted burdens for farming operations that pack and distribute produce on their own farms as well as produce from neighboring farms.

- ***Operations that pack and hold produce but are not growing produce:*** OTA recognizes that many off-farm produce operations pack and hold produce but they do not grow the produce. The activities carried out by such operations are no different than the post-harvest activities described under the proposed definition of a "farm" and the definitions of "packing" and "holding." The only difference is that the off-farm operation is devoted to packing and holding and is not involved in growing produce. Regardless, as the proposed rule is now written, the off-farm operation would be subject to the Preventive Controls Rule for Humans, and would therefore be subject to additional requirements that a farm performing the same activities would not. This creates an un-level playing field and causes unnecessary burden to the off-farm operation. OTA suggests that off-farm operations that perform the same post-harvest activities (packing and holding) as an on-farm operation be subject to the Preventive Controls Rule for Humans (and therefore required to register under the Bioterrorism Act), BUT only be subject to the specific preventive requirements that are consistent with packing and holding activities described under the Produce Safety Rule.

- ***Biological Soil Amendments of Animal Origin:*** FSMA mandates that FDA develop rules that do not duplicate or conflict with existing organic regulations. As confirmed by the survey results[2] from 310 of the estimated 8,100[3] organic producers certified for crop production in the United States, the initial proposed requirements for **biological soil amendments of animal origin** would have conflicted with organic fertility and crop rotation practices required under USDA's NOP standards. This would have placed undue economic hardship on many organic producers by requiring overly prescriptive requirements not adequately supported by science, and may not be necessary to achieve food safety. Scientific literature cited in the proposed produce safety rule supports concerns that manure and compost pose a food safety risk, but do not support the waiting periods proposed by FDA.

  OTA is pleased to see that the supplemental proposed rule recognizes the potential regulatory conflict with organic regulations and the lack of scientific support for a 9-month minimum application interval

[2] **See Appendix A** – Impact of Input Application Intervals on Organic Crop Rotation

[3] National Organic Program Website: http://apps.ams.usda.gov/nop/

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following the use of untreated manure. FDA's proposes to defer a final decision on proper waiting times for untreated manure for 5 to 10 years until research and risk assessment focused on pathogen persistence provide a scientific basis for a specific interval. In the interim, organic producers will continue to comply with organic standards which require either 90 or 120 days minimum application interval following untreated manure use depending on the crop's contact with the soil. We recognize the concern expressed by others that deferring a decision on a minimum application interval for untreated manure will not restrict non-organic producers' use of this material and may pose an unacceptable risk to public safety.

To address these concerns, FDA could consider drawing from other food safety programs and include an interim standard based on USDA's Good Agricultural Practices (GAP) guidelines. Using this approach, FDA could reference GAP and require a 120-day minimum application interval for untreated manure that contacts covered produce during application or has the potential for contact with covered produce after application. An interim standard of a 120-day minimum application interval would also be consistent with and supported by the findings of the Scientific Literature Survey OTA conducted in response to the 2013 proposed produce safety rule.

OTA is eager to support FDA in its effort to conduct research on pathogen persistence in soils from untreated manure. We offer our network of organic farmers and partners at land-grant universities to participate in the study. It is critical for FDA to evaluate pathogen persistence on both conventional and organic operations, since certified organic farmers must implement practices that maintain and improve soil health and grow their crops on biologically active soils. Biological activity in soils may have effects on pathogen persistence, and this factor should be factored into any risk assessment research FDA conducts.

OTA applauds FDA for eliminating the 45-day minimum application interval for properly made compost and for FDA's recognition of the importance of compost in sustainable agriculture. However, we remain concerned that FDA has not proposed revisions to the requirement that compost piles be insulated during curing. This is not typical industry practice at either commercial or on-farm composting facilities, and we urge FDA to align its composting procedure requirements with current industry standards and state regulations, which do not require an insulating layer on curing piles.

- ***Water:*** The proposed requirements for agricultural water will place an economic hardship on organic and conventional producers alike across the United States by requiring extensive and potentially unnecessary testing to a standard that FDA itself recognizes is "not perfect for our purposes." OTA recommends that FDA move both the testing threshold and testing frequencies out of the regulation and into guidance.

  OTA does not support including prescribed metrics ***in the regulation itself*** unless those metrics are scientifically based and proven to be appropriate for any given situation. There are many growing situations across the country, all of which are unique to a particular growing region and site location, and there are many ways in which a farmer can prevent and/or minimize food safety risks. If the science behind a specific standard or testing metric is inconclusive, yet it potentially offers a target range of usefulness, the provision should be added to guidance.

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OTA agrees with FDA's proposed revisions to provide for the use of a pathogen die-off rate as a mechanism for farmers to mitigate food safety risk from utilizing water that may exceed the established or recommended microbiological thresholds.

- ***Domesticated and Wild Animals in the Growing Area:*** OTA fully supports the revisions made to this section of the supplemental proposed rule. Organic producers must manage their farms in a manner that supports biodiversity, and a misinterpretation of FDA's intent behind the proposed rules could jeopardize organic farmers' full compliance with NOP regulations. By including language in the regulation clearly stating that the regulation does not authorize or require farms to take actions that would constitute the "taking" of a threatened or endangered species in violation of the Endangered Species Act or destroy animal habitats that would harm wildlife, FDA clarifies its intention and alleviates the concern for a potential regulatory conflict. OTA commends FDA for including this language in the rule itself, and for communicating the agency's commitment to environmental stewardship and resource conservation.

OTA respectfully submits the following more specific comments:

Subpart A	GENERAL PROVISIONS
§ 112.3	**What definitions apply to this part?** ***FDA's proposed revisions to definitions:*** FSMA mandates that FDA issue regulations clarifying on-farm manufacturing, processing, packing, and holding activities that trigger the requirement to register with FDA. The Preambles to both the proposed Preventive Controls Rule and the proposed Produce Rule provide perspective on the applicability of the regulation based on whether or not a facility is required to register with FDA under Section 415, and where the facility falls within the definitions of "farm," "mixed-type facility," "harvesting," "holding," "packing," "packaging," and "manufacturing/processing." In response to comments expressing concern about farms that pack or hold food from other farms, FDA has made the following revisions to the definition of "farm," "harvesting," "packing," and "holding," *Farm* The revised proposed rule defines "farm" as: Farm means an ~~facility~~ establishment under one ownership in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term "farm" includes establishments that, in addition to these activities: (1) ~~Facilities that p~~ Pack or hold raw agricultural commodities; (2) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same ownership, or is processed food identified in paragraph (3)(ii)(A) of this definition; and (3) Manufacture/process food, provided that: (i) All food used in such activities is consumed on that farm or another farm under the same

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ownership; or
(ii) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same ownership consists only of:
(A) Drying/dehydrating raw agricultural commodities to create a distinct commodity, and packaging and labeling such commodities, without additional manufacturing/processing; and
(B) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing.

Harvesting
The revised proposed rule defines "harvesting" as:

> "*Harvesting* applies to farms and farm mixed-type facilities, and means activities that are traditionally performed on ~~by~~ farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities on ~~the~~ a farm ~~on which they were grown or raised, or another farm under the same ownership~~. Harvesting does not include activities that transform a raw agricultural commodity, as defined in Section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in Section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Gathering, field coring, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm or another farm under the same ownership are examples of harvesting."

Holding
The revised proposed rule defines "holding" as:

> Holding means storage of food and also includes activities performed incidental to storage of a food [e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets)] ~~Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks. For farms and farm mixed-type facilities, holding also includes activities traditionally performed by farms for the safe or effective storage of raw agricultural commodities grown or raised on the same farm or another farm under the same ownership~~, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Packing
The revised proposed rule defines "packing" as:

> Packing means placing food into a container other than packaging the food, and also includes activities performed incidental to packing a food [e.g., activities performed for the safe or effective packing of that food (such as sorting, culling and grading)], but does not include

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activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. ~~For farms and farm mixed-type facilities, packing also includes activities (which may include packaging) traditionally performed by farms to prepare raw agricultural commodities grown or raised on the same farm or another farm under the same ownership for storage and transport, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.~~

OTA's Comments:

The definition of a "farm"

OTA agrees with FDA's revised definition of a "farm." We agree that a farm means "an establishment under one ownership in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both." We recognize, however, that a farm may have multiple sites located in "one general physical location," and one or more of these sites may be designated for packing and holding operations. For example, it's not uncommon for a farm devoted to the growing and harvesting of crops to establish packing operations (warehouses, cold storage facilities, etc.) located "down the road" from the farm/growing fields. We assume that the designation of "one general physical location" would cover this type of scenario, provided that the packing and holding locations fall under the "farm" ownership devoted to the growing and harvesting of crops. Guidance may be necessary to clarify the term "general."

OTA recommendation: OTA recommends that FDA issue guidance that will clarify and further designate the boundaries of "one general physical location."

Farms that pack or hold food from other farms

OTA agrees that farms that pack or hold food from other farms are not subject to the preventive control rule. We agree that a farm or farm mixed-type facility that places others' Raw Agricultural Commodities (RACs) into consumer containers should NOT be subject to the Preventive Control Rule provided the activity does not change the "status" of the RAC into a processed product. Placing a farm's own RACs or a neighbor's RACs into consumer containers that contact the food (*e.g.*, a strawberry farm placing strawberries in clamshell packages, an apple farm placing apples into bags) should be considered "packing" within the "farm" definition. The effect of the revised definitions would be that a farm would no longer be required to register as a food facility merely because it packs or holds RACs grown on another farm not under the same ownership. A farm operating in compliance with the Produce Safety Rule will be able to ensure the safe production, harvesting, **holding and packing** of raw fruits and vegetables regardless of the ownership of the farm the produce was grown on.

OTA also agrees that drying and dehydrating raw agricultural commodities to create a distinct commodity, and packaging and labeling such commodities without additional manufacturing/processing are both activities that should fall under the "farm" definition. Operations carrying out such activity should not be subject to the Preventive Controls Rule for Human Food.

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	Operations that pack or hold produce but do not grow produce OTA recognizes many off-farm produce facilities simply perform packing and holding activities. The activities carried out by such operations are no different than the post-harvest activities described under the proposed definition of a "farm." The only difference is that the off-farm operation is devoted to packing, holding and storage rather than growing produce. If, however, the off-farm packing operation were subject to the Produce Safety Rule only, and packing and/or holding produce from several different farms all under different ownerships, traceability could become an issue since the Produce Safety Rule does not require supplier verification and traceability records. ***OTA recommendation:*** To remedy the traceability concern described above, while recognizing the unfair burdens that would be incurred by off-farm operations subject to the Preventive Controls Rule engaged exclusively in the holding and packing of RACs, OTA suggests that off-farm operations that perform the same functions as an on-farm operation be subject to the Preventive Control Rule (and therefore required to register under the Bioterrorism Act), BUT only be subject to the subparts of the Produce Safety Rule that apply to those activities, such as Subparts C, D, K, L and O. To accomplish this, a new subpart under Subpart 117 of the Preventive Controls Rule could be created permitting registered establishments (that only hold, store or pack RACs) to meet their obligation by compliance with subparts of the Produce Safety Rule applicable to holding and packing. Finally, USDA's National Organic Program (NOP) requires every certified organic operation (organic farms and organic handlers/processors) to maintain records allowing complete traceability from each field of crop production to the point of retail sale. Whether subject to the Produce Safety Rule or the Preventive Control Rule, organic farms packing or holding produce will be able to provide records allowing complete traceability back to the farm (and field) where the produce was grown.
Subpart E	**STANDARDS DIRECTED TO AGRICULTURAL WATER**
§ 112.41	**What requirements apply to the quality of agricultural water?** The requirements that apply to the quality of safe and sanitary agricultural water have been revised to reflect a more realistic risk-based approach. This approach has less potential to impose economic hardship on organic farmers, while supporting the safest food supply in the world. However, OTA is still concerned that the revised rules are not science-based. OTA does not support including prescribed metrics **in the regulation itself** unless those metrics are scientifically established **and** proven to be appropriate for any given situation. The problem is that there are many growing situations across the country, all of which are unique to a particular growing region and site location, and there are many ways in which a farmer can prevent and/or minimize food safety risks. If the science behind a specific standard or testing metric is inconclusive, yet it potentially offers a target range of usefulness, the provision should be added to **guidance.**
§ 112.42	**What measures must I take with respect to my agricultural water sources, water distribution system, and pooling of water?** OTA agrees with the intent expressed in 112.42(a) – (e) which in summary states that a farm must: 1) inspect the entire agricultural water system and identify conditions that are reasonably likely to

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	introduce microbiological hazards into or onto covered produce or food-contact surfaces; 2) maintain agricultural water sources and distribution systems to ensure that neither becomes a source of contamination; 3) discontinue use of a source of water if there is reason to believe or if it is determined that it's not safe and of adequate sanitary quality until the situation is changed or the water is treated; and 4) implement measures to reduce the potential for contamination with covered produce. In short, a farm must assess the agricultural water system, identify hazards, and take appropriate steps to correct the situation so the water is safe. OTA agrees, and we strongly believe this is the most critical step in establishing a regulation that is science-based and flexible. **Regulatory actions should be based on risk assessment, and the appropriate action taken should be based on science.**
§ 112.44	**What testing is required for agricultural water, and what must I do based on the test results?** ***FDA Proposed revision:*** FDA is proposing various revisions to the microbial standard for water directly applied during the growing of produce (other than sprouts). The agency is updating the microbial quality standard to reflect data that support the 2012 Environmental Protection Agency (EPA) recreational water quality criteria rather than EPA's criteria established in 1986, which had been referenced in the previous proposed rules. Farmers with agricultural water that do not initially meet the proposed microbial standard would have additional means by which they could meet the standard and then be able to use the water. These options include establishing a sufficient interval of days between last irrigation and harvest to allow time for potentially dangerous microbes to die off. They could also apply an interval of days between harvest and the end of storage using appropriate microbial die-off or removal rates, provided there is adequate supporting data. And there is an option to calculate and apply appropriate pathogen removal rates for activities such as commercial washing. ***OTA Comments:*** Consistent with the comments OTA submitted in November 2013 on the initial proposed rule, OTA disagrees with the application of EPA's Recreational Water Standards **in the rule itself** since there is inadequate scientific basis for those standards as they relate to produce production. The microbial standards specified in these provisions are currently used to set health-based standards to protect swimmers at beaches from harmful bacteria. These standards were not designed for produce safety, and are not appropriate for water used to irrigate, spray or pack food crops. Generic *E. coli* bacteria are used as an indicator of fecal contamination to correlate with largely viral GI illnesses, not for identifying the bacterial pathogens that have caused most produce outbreaks, serious illnesses or deaths (nor with more serious viral illnesses). OTA recognizes and agrees with FDA that the use of EPA's water standard would serve to minimize risk when used as a standard for agricultural water. For this reason, and in the absence of sufficient information to support a pathogen-based microbial standard for water used in the production of produce, the generic *E. coli* criteria is best placed in guidance. In order to place such criteria in the rule itself, further analysis and scientific justification are needed regarding the indicator organisms used and the microbial limits being set, particularly for irrigation water. FDA

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	recognizes in the *Federal Register* Notice for these revisions to the proposed rule that the change to microbial standards in this section were largely due to the issuance of EPA's 2012 Recreational Water Quality Criteria. The very standards to which FDA had aligned its proposed rules changed prior to the release of the first proposed Produce Safety Rule. Maintaining these numerical microbiological standards within the regulation does not provide FDA with adequate flexibility as emerging science continues to drive how we evaluate the safety of our water resources. Placing these numerical standards into guidance will give FDA the flexibility to ensure its rules and oversight of produce farms are based on current sound science. OTA agrees with FDA's proposed revisions to provide the use of a pathogen die-off rate as a mechanism for farmers to mitigate food safety risk from utilizing water that may exceed the established microbiological thresholds. It is critical that farmers have an option in these situations, and FDA's proposed revisions satisfy this need.
§ 112.45	**How often must I test agricultural water that is subject to the requirements of § 112.44?** ***FDA Proposed Revision:*** Recognizing that water sources have different levels of contamination risk, FDA is proposing a tiered and more targeted approach to testing each source of untreated water that will be less burdensome on farmers while still protective of public health. The revisions reduce how often the water is tested, with the frequency depending on the water source (i.e., surface or ground water) and on the results of prior tests. ***OTA Comments:*** OTA agrees that testing water sources when agricultural water is used during growing activities for covered produce is only necessary when there is a reasonable likelihood of direct water contact of the harvestable portion of covered produce, but we believe this belongs in guidance with the proposed microbial standard. OTA agrees no water testing is necessary if the water source is municipal (and municipal records of water quality are available) or treated (and records of chemical testing are available). OTA agrees that an operation should initially test the quality of each water source to determine its baseline quality. Testing requirements should reflect the level of risk for each unique operation. The revised water testing frequency requirements are an improvement. However, they are still overly prescriptive and do not allow enough flexibility for the diversity and range of operations across the nation. Farms and water sources—surface or ground—with an established good history and a food safety plan that addresses water quality should be required to test less frequently than those identified at higher risk. Testing should be determined according to a risk-assessment conducted by each farm and recommended testing frequencies should be available to growers in guidance. <u>Metrics belong in guidance</u> Science may never provide "the right answer" to the question of how much testing is required to adequately ensure the safety of agricultural water used on produce. Because of this, OTA continues to emphasize that the proposed microbial water quality standard and proposed testing frequencies belong in guidance. More research specifically targeted at agricultural use is needed. We encourage

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	FDA to work with EPA and other appropriate research organizations to develop a scientifically valid agricultural water standard for fresh produce that appropriately addresses foodborne pathogens. This will allow FDA to effectively and efficiently facilitate updates as new science is developed. If the science behind a specific standard or testing metric is inconclusive, yet it potentially offers a target range of usefulness, the provision should be added to **guidance.** The regulation itself should support a performance and outcome-based approach based on risk-assessment, and should require that testing procedures and monitoring protocols be established to demonstrate that agricultural water is safe and of adequate sanitary quality for its intended use.
Subpart F	**F—STANDARDS DIRECTED TO BIOLOGICAL SOIL AMENDMENTS OF ANIMAL ORIGIN AND HUMAN WASTE**
§ 112.54	**What treatment processes are acceptable for a biological soil amendment of animal origin that I apply in the growing of covered produce?** OTA continues to agree with the **treatment processes** proposed in the section with the exception of the **requirement** to insulate compost piles while they are curing. We are supportive of FDA's commitment to encouraging composting as a safer alternative to the use of untreated biological soil amendments of animal origin. However, we are surprised to see that FDA has not removed the requirement to insulate compost piles while curing in the supplemental notice. Requiring the use of an insulation layer on curing piles is neither economically feasible nor operationally practical. The layer cannot be completely removed because it becomes part of the pile and therefore has the potential to re-introduce contamination. While multiple field tests have shown that an insulation layer may be helpful in maintaining temperatures in the outer few inches of the static pile, no correlation to pathogen kill rates has been proven to occur with any degree of certainty in the outer pile layers. Additionally, this insulation layer essentially becomes the outer layer of the static pile once applied, and an extension of the pile itself. This layer may take on the microbial character of the pile as well. Industry standards are to mix the insulation layer into the pile for the next stage of composting (be it a secondary composting process or curing). Therefore, any short-term advantage that may occur will ultimately be negated by the fact that the insulation layer has become part of the mix. We take this opportunity to reiterate our concern that the requirement to insulate compost while curing does not reflect current practices at commercial and on-farm compost facilities, will not contribute to incentivizing the use of compost instead of raw manure, and is not commiserate with FDA's proposed removal of the 45-day minimum application interval following the use of compost.
§ 112.56	**What application requirements and minimum application intervals apply to biological soil amendments of animal origin?** ***FDA Proposed Revisions:*** o FDA is removing the 9-month proposed minimum-time interval between the application of untreated biological soil amendments of animal origin (including raw manure) and crop harvesting. The agency is deferring its decision on an appropriate time interval until it

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pursues certain actions. These include conducting a risk assessment and extensive research to strengthen scientific support for any future proposal, working with the U.S. Department of Agriculture and other stakeholders. FDA expects this process will take at least five years.

- At this time, FDA does not intend to take exception 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.
- FDA is proposing to eliminate the previously proposed 45-day minimum application interval for compost (also known as humus), including composted manures. Properly treated and handled compost is safer than raw manure from a public health standpoint, and this change to the proposal would help facilitate its use while still providing an appropriate level of public health protection.

OTA Comments:

OTA is particularly pleased to see these revisions. Our extensive surveys of organic producers showed the importance of compost and manure in organic production, and demonstrated the conflict between the proposed produce safety rule and the organic regulations. Our scientific literature review[4] showed that a 9-month minimum application interval for unprocessed manure was not wholly supported by current science. We applaud FDA's recognition that its previous proposed restrictions on unprocessed manure conflict with organic production standards and are not based on sound science. FDA's removal of restrictions on properly made compost corroborates its importance in sustainable approaches to agriculture, and we resoundingly support this revision to the minimum application interval.

FDA's acknowledgement of current organic standards on the use of manure is a definite step in the right direction. However, given that FDA has chosen not to recommend a minimum application interval for manure at this time, organic operations will continue to follow the 90/120-day application-to-harvest intervals required in the organic regulations. OTA shares the concerns of other commenters about the complete elimination of required wait time between the application of untreated manure and harvest for all other operations that are not certified organic. FDA expects the risk assessment and research into pathogen persistence from raw manure may take 5 to 10 years, and some have called for FDA to establish an interim standard. To address the concern, FDA could consider drawing from other food safety programs, such as USDA's Good Agricultural Practices (GAP), which require a 120-day minimum application interval following raw manure use.[5] FDA could in the interim require a 120-day minimum application interval for untreated manure that contacts covered produce during application or has the potential for contact with covered produce after application. An interim standard of a 120-day minimum application interval would also be consistent with and supported by the findings of the Scientific Literature Survey **(Appendix B & C)** OTA conducted in response to the 2013 proposed produce safety rule.

The organic sector under OTA's leadership offers FDA assistance in its research efforts and

[4] See **Appendix B (**Scientific Literature Survey: Manure-Soil-Compost Pathogen Transfer and Survival) and **Appendix C** (Scientific papers that indicate reduction of manure and compost pathogens reduction).

[5] http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5091326

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	supports the development of an expert panel to guide FDA's work. The industry continues to invest in research on appropriate waiting times for raw manure, and OTA also supports FDA's efforts to bring together top researchers and practitioners to discuss and develop a recommendation to FDA. It is critical that FDA's risk assessment evaluate pathogen persistence over the diversity of cropping systems and climates on both organic and conventional farms. Organic farmers are required to manage their soils and crop nutrients in order to maintain and improve soil health and biological diversity. As a result, soils on organic farms are biologically active, and the impacts of soil health on pathogen persistence should be built into the research on this subject.
Subpart I	**STANDARDS DIRECTED TO DOMESTICATED AND WILD ANIMALS**
	FDA's Proposed Revision: In the preamble of the proposed rule, FDA asserts that in general, carrying out the regulation would not require total exclusion of animals from outdoor growing areas, or the destruction of animal habitats near growing areas, or the clearing of farm borders, or any action that would violate environmental laws or regulations. Several comments were received expressing concerns that growers would interpret the original proposed rule in ways that would harm wildlife, including taking measures to exclude animals from outdoor growing areas or destroying animal habitats. FDA's clarification is intended to relieve those concerns. FDA states in the proposed revisions that the proposed produce regulation does not authorize or require farms to take actions that would constitute the "taking" of a threatened or endangered species in violation of the Endangered Species Act. This regulation does not require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages. ***OTA Comments:*** In our comments to FDA on the first proposed Produce Safety Rule, OTA requested that these principles so clearly expressed in the preamble become part of the actual text of the final rule. Organic producers must manage their farms in a manner that supports biodiversity, and a misinterpretation of FDA's intent behind the proposed rules could jeopardize organic farmers' full compliance with NOP regulations. By including this language in the regulation, FDA clarifies its intention and alleviates the concern for potential regulatory conflict. OTA commends FDA for including this language in the rule itself, and for communicating the agency's commitment to environmental stewardship and resource conservation.

Conclusion

The *Organic Trade Association's 2014 Organic Industry Survey* shows the industry has grown from $3.6 billion in 1997 to $35.1 billion in 2013, with an annual growth rate of 19% from 1997-2008. As our country has been dramatically affected by the worst economic downturn in 80 years, the organic industry has remained in positive growth territory, and has come out of the recession hiring employees, adding farmers, and increasing revenue. The latest data indicate that 78% of organic farms report planning to maintain or increase organic production levels over the next five years. The organic sector will continue to play a contributing role in revitalizing America's rural economy through diversity in agriculture.

As a federally regulated and certified process, the organic food industry is uniquely positioned to respond to food safety requirements in ways that are not in effect in other food sectors. The organic foods industry has legally mandated safeguards that contribute to food safety for consumers, including full food product traceability, accountability of food production methods, and strict controls on known potential sources of food

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contamination. Organic producers and handlers are already familiar with planning, regulatory oversight, third-party certification, and independent inspections. Certified organic growers follow strict guidelines for organic food production and, as with all food producers, must comply with local, state and federal food safety and health standards. Familiarity with these requirements positions the organic sector well in terms of complying with a regulation to improve food safety systems in the United States.

In closing, OTA appreciates the opportunity to provide comments on behalf of our members across the supply chain and the country. We respectfully request that FDA accept the following recommendations:

- OTA recommends that FDA issue guidance that will clarify and further designate the boundaries of "one general physical location" as used in the definition of a "farm."

- OTA recommends that off-farm operations that perform the same functions as an on-farm operation be subject to the Preventive Control Rule (and therefore required to register under the Bioterrorism Act), BUT only be subject to the subparts of the Produce Safety Rule that apply to those activities, such as Subparts C, D, K, L and O. To accomplish this, a new subpart under Subpart 117 of the Preventive Controls Rule could be created permitting registered establishments (that only hold, store or pack RACs) to meet their obligation by compliance with subparts of the Produce Safety Rule applicable to holding and packing.

- Science may never provide "the right answer" to the question of how much testing is required to adequately ensure the safety of agricultural water used on produce. Because of this, OTA continues to emphasize that the proposed microbial water quality standard and proposed testing frequencies belong in guidance. More research specifically targeted at agricultural use is needed. We encourage FDA to work with EPA and other appropriate research organizations to develop a scientifically valid agricultural water standard for fresh produce that appropriately addresses foodborne pathogens. This will allow FDA to effectively and efficiently facilitate updates as new science is developed.

- The organic sector under OTA's leadership offers FDA assistance in its research efforts on untreated manure and supports the development of an expert panel to guide FDA's work. The industry continues to invest in research on appropriate waiting times for untreated manure, and OTA supports FDA's efforts to bring together top researchers and practitioners to discuss and develop a recommendation to FDA. OTA recommends that FDA's risk assessment evaluate pathogen persistence over the diversity of cropping systems and climates on both organic and conventional farms. Organic farmers are required to manage their soils and crop nutrients in order to maintain and improve soil health and biological diversity. As a result, soils on organic farms are biologically active, and the impacts of soil health on pathogen persistence should be built into the research on this subject.

OTA thanks FDA again for its extensive outreach to organic stakeholders and for taking these comments into consideration as it moves forward with its programs for assuring the safety of the U.S. food supply. We look forward to a final rule that will ensure the success and safety of this segment of the food supply.

Respectfully submitted,

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Appendix A: Producer Survey: Impact of Proposed Application Intervals on Organic Crop Rotation
Appendix B: Scientific Literature Survey: Manure-Soil-Compost Pathogen Transfer and Survival
Appendix C: Scientific papers that indicate reduction of manure and compost pathogens reduction

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FDA Food Safety Modernization Act

OTA-WSDA Organic Producer Survey Results

Biological Soil Amendments of Animal Origin

Impact of FDA's Proposed Application Intervals on Organic Fertility and Crop Rotation Requirements

Impact of FDA's Proposed Application Intervals on Organic Fertility and Crop Rotation Requirements

Background

In an effort to further inform the effects of the proposed application intervals would have on organic crop producers, the Organic Trade Association (OTA) and the Washington State Department of Agriculture (WSDA) conducted a survey of organic producers asking a number of questions related to the impact the FDA proposed produce safety rule would have on their organic fertility and crop rotation practices. The survey was circulated to organic producers via email and hardcopy (August 30 – October 4, 2014) and was limited to producers certified under the USDA organic regulations, and therefore legally subject to the requirements outlined in 7 CFR 205.205 (Crop rotation practice standard).

Rate of survey response

The NOP website lists approximately 8,100 producers certified for crop production in the United States. This was considered the target population for the purposes of this survey, as organic crop producers are the group of farmers who may be subject to both the crop rotation requirements under USDA organic regulations as well as the application interval requirements outlined in FDA's proposed produce safety rule. The survey received 310 responses, which constitutes a response rate that provides a 95% confidence level with a confidence interval of 5.5%.

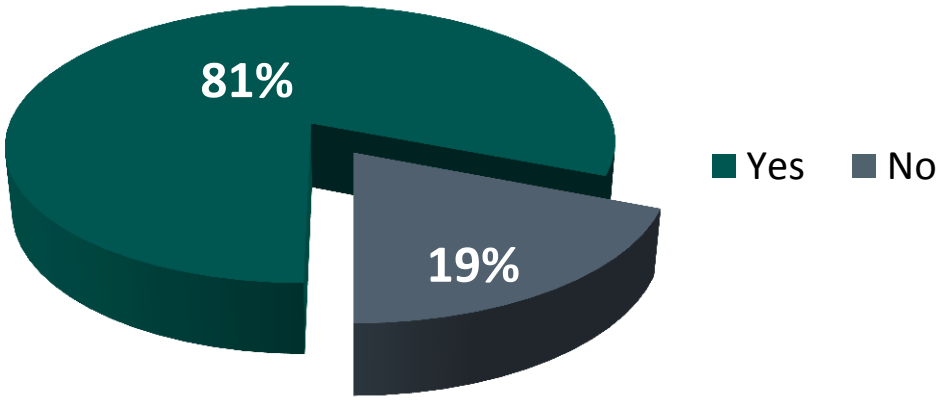
Survey conclusions

94% of organic producer responses indicate the use of compost or manure as a soil fertility input with organic covered produce. The survey results indicate that FDA's proposed waiting periods between application and harvest for compost and untreated manure will restrict organic producers' ability to rotate crops as part of preventive pest and disease control and to comply with the established UDSA Organic Regulations at 7 CFR 205.203, 205.205, and 205.206 (Soil Fertility and Crop Nutrient Management Practice Standard & Crop rotation practice standard; Crop Rotation Practice Standard; and Crop Pest, Weed, and Disease Management Practice Standard). Failure to implement crop rotation as part of a preventative pest management program will force organic producers out of compliance with current USDA Organic Regulations and prompt organic certifiers to pursue adverse action. Results also indicate that the majority of producers using compost obtain their compost from commercial sources.

Biological Soil Amendments

Organic Producer Survey Results

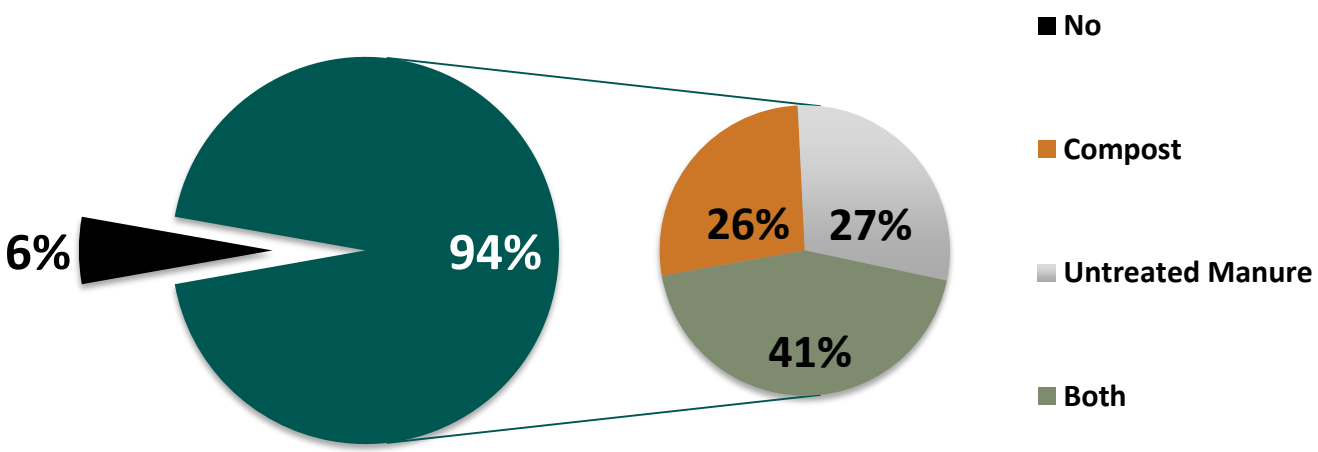
Does your operation grow any organic produce commonly consumed raw?



Biological Soil Amendments

Organic Producer Survey Results

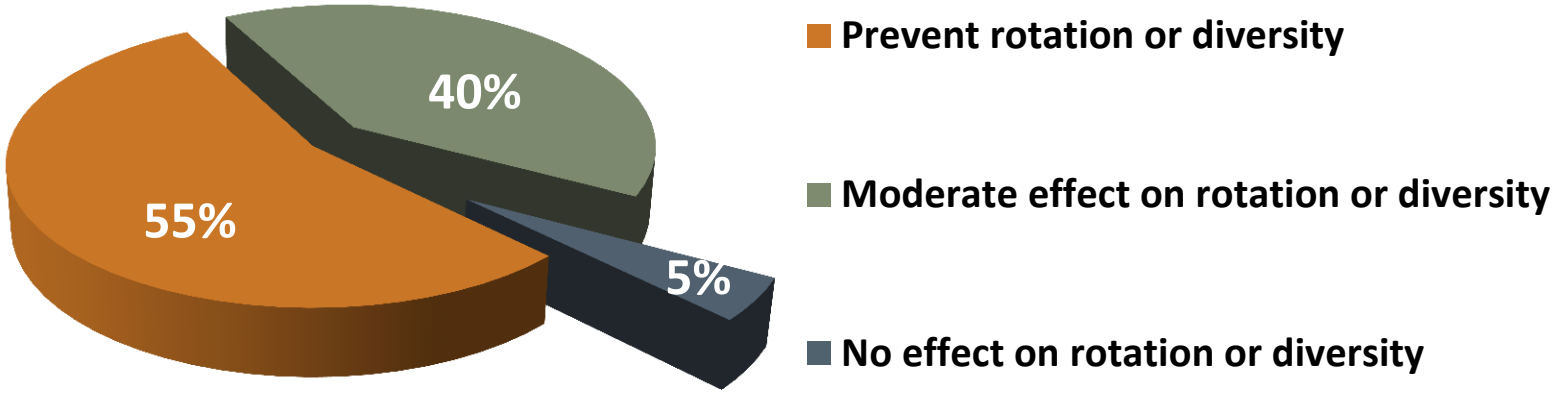
Does your operation use either untreated manure or compost for soil fertility?



Biological Soil Amendments

Organic Producer Survey Results

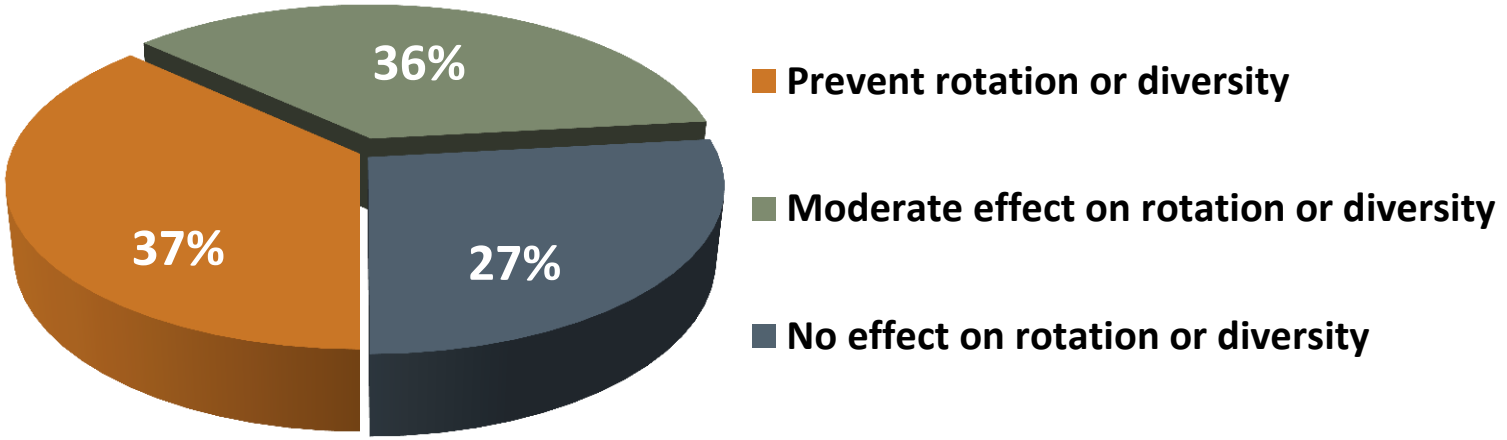
If a nine (9) month waiting period was required after applying untreated manure, how would this impact your operation's ability to rotate crops or introduce biological diversity?



Biological Soil Amendments

Organic Producer Survey Results

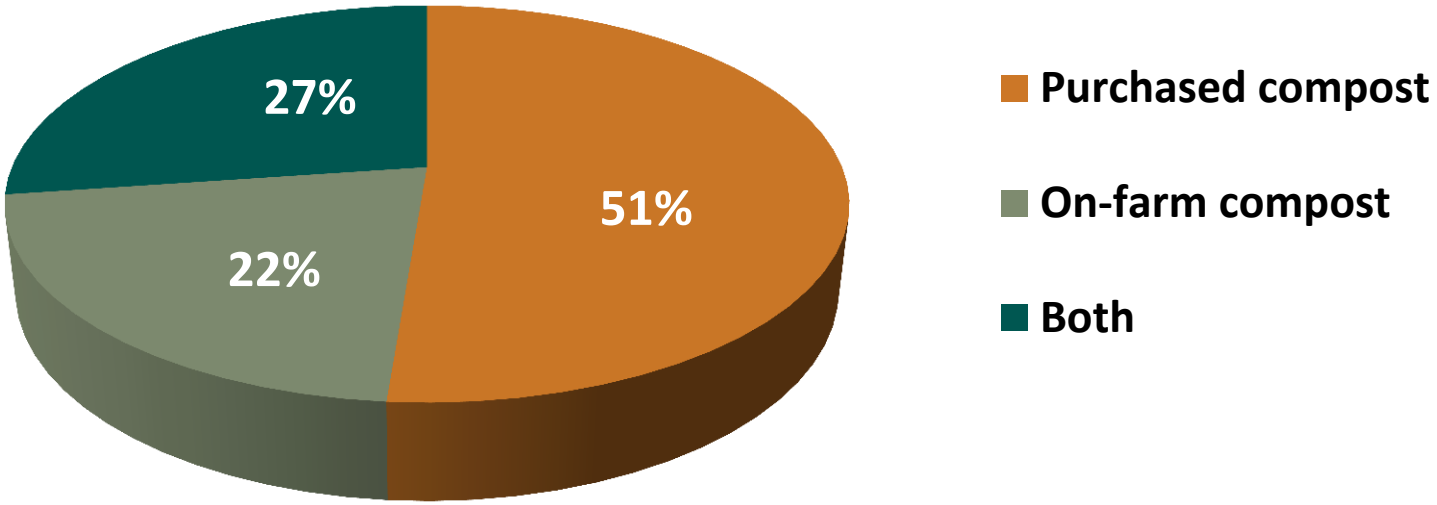
If a forty-five (45) day waiting period was required after applying compost, how would this impact your operation's ability to rotate crops or introduce biological diversity?



Biological Soil Amendments

Organic Producer Survey Results

What are the sources of compost used on organic farms?

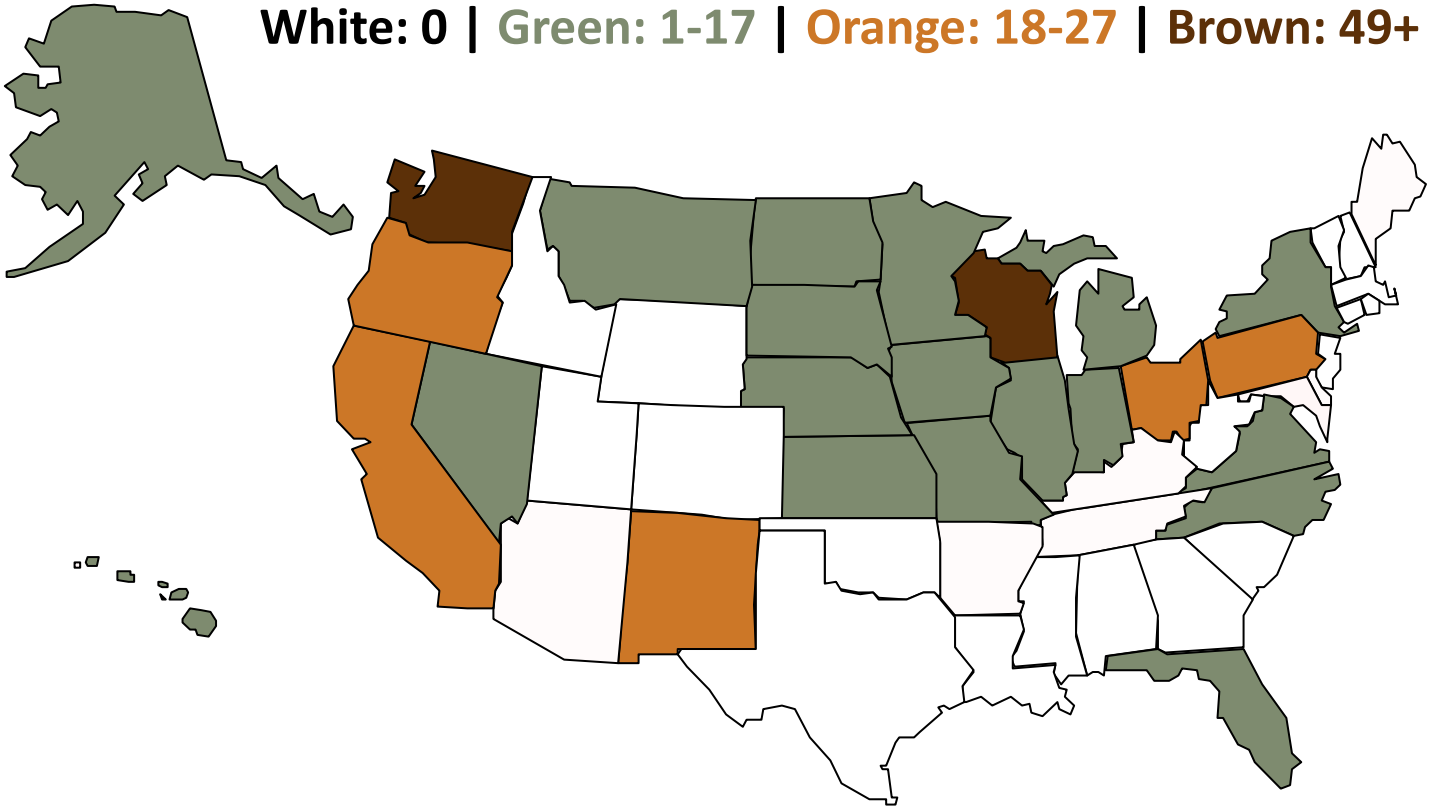


Biological Soil Amendments

Organic Producer Survey Results

310 responses received from 32 states

White: 0 | Green: 1-17 | Orange: 18-27 | Brown: 49+



Manure-Soil-Compost Pathogen Transfer and Survival – Review of Science Literature/OTA

ABSTRACT

This survey addresses the scientific basis of proposed rule changes potentially affecting organic growers due to the FDA Food Safety Modernization Act. Approximately 40 scientific studies were examined concerning pathogen survival in field application of manure and pathogen reduction during composting. The procedure used was to tabulate the average and standard deviation of best/worst case results (in days) from all the studies, divided according to manure vs. composting. These data provide clear evidence of a very wide range in reported pathogen reduction times in dependence on study conditions and the ecosystem environment. The soil-manure studies examined largely support as safe the existing 90-120 day range already incorporated into the NOP rule, but which FDA desires to significantly extend. Scientific data for compost studies also reveal wide variances in findings and although the reduction times for pathogens are shorter than manure application ranges they are on average considerably longer than the 3/15-day limits from EPA CFR40-Chap 503 material which are presently used as NOP guidance. At current level of practice in the NOP standard composting therefore appears to pose a much greater risk based on scientific evidence than does manure.

INTRODUCTION

In order to adequately summarize scientific studies regarding pathogen survival in soil and manure environments it is very important to select from as wide a list as possible of published reports. Current research increasingly reveals very broad ranges in time for reduction of pathogens such as E. coli O157:H7 after transfer or application of manure to soils. This also now appears to be the case for pathogen reduction reported during composting environments. The explanation for this variability in findings is partly the manner in which the scientific studies have been conducted. However, the chief weight of the variability is surely due to the complexity of the ecosystem into which organisms are being introduced and measured. Scientists increasingly cite specific factors such as season, moisture, temperature and indigenous microflora as influential of survival of pathogens. Consequently, arriving at recommendations for safe-margins for manure and compost timeframes may be very dependent on selectivity used in data review. This white paper examines some of the issues and facts based on closely examining a range of recently published scientific data and makes some recommendations for manure-soil systems and composting. This is a work in progress and no paper or study may claim completeness.

OVERVIEW: MANURE-SOIL STUDIES

The wide variance in observations on pathogen reduction time may be illustrated by taking two excellent studies with nearly opposite findings. In August 2006 Mukherjee et al. (Dept Food Sci., University of Minnesota – Ref#18) reported on a situation definitively linked to a child encountering E. coli from crops harvested from soil to which contaminated manure had been applied. The authors reproduced several E.coli-O157 scenarios under the specific circumstances of recently applied manure. They found that, in 3 of 4 soil test plots, E. coli O157 was completely absent *after 69 days* and only one plot had detectable presence up to 92 days. Interpreting this suggests a fairly long infectivity period for potential transfer of a pathogen to plant surfaces (it did not prove the transfer happened). If these data are applied to define set-backs, then the current NOP rule of 90/120 days would appear reasonably safe (§205.203,NOP 2000).

A second study by Johannessen et al. (2004 - Ref #5) of the Norwegian Food Research Institute attempted to create the circumstances of how many growers handle lettuce by transplanting seedlings into field soil, a practice that is also widely used by organic growers in the USA especially in northern regions. Greenhouse-grown lettuce was *directly transplanted* into soil freshly contaminated with manure-inoculated with E.coli O157:H7, and harvested and tested at 50 days. The plants showed no detectable presence of the bacterium in any of the edible parts including none found on the roots of the plants. Examination of soil identified *Pseudomonas fluorescens* in the rhizosphere, a natural soil organism known to inhibit pathogens including E. coli O157:H7 in vitro. If the findings from this study are used to define a safe-margin it would suggest that given a normal healthy soil virtually no set-back time after manure application is required – other than that of the ordinary length of time it takes to grow a relatively short-season plant to edible harvest (e.g. 50 days).

The Johannessen study may be interpreted as providing proof for strong ecosystem barriers operating in pathogen transfer. Further, it may help explain the relatively low incidence of reported outbreaks due to manure-soil contamination, considering that in the USA nearly 1-billion tons of fresh manure are produced each year and ultimately soil applied. One of the most extensive reviews of the complexity of factors influencing the fate of introduced microorganisms is by van Veen (1997).

DISCUSSION

The pathogen reductions times reported by Mukherjee et al (2006) are convenient as they closely corroborate existing NOP standards. In examining a range of published scientific reports it is possible to obtain a nearer estimate of reasonable standards. As indicated in the appendix to this paper, in taking a group of best case/worst case results and averaging, then adding the mean margin of error from all studies (itself quite large) a fairly solid estimate for a safe setback range is 47 to 88 days (survival of raw manure pathogens in soil systems).

One of most worst-case reports to our knowledge is a 2001 study by LeJeune et al. (WSU Veterinary School- Ref# 11) showing 245 days reduction time of E. coli O157 in water trough sediments contaminated with feces from cattle excreting E. coli O157. Under these circumstances the E. coli were clearly not being exposed to a normal aerobic soil environment. This suggests that long reduction times may be associated with unusual or abnormal environments and should not alone be used to construct set-back standards.

Contrast this with studies reporting on cattle environments typical for regions of the USA. Davis et al of the Dept. of Microbiology, University of Idaho (REF #13) stress in 2005 the interaction of on-farm ecology and pathogen survival. They reported declines in E. coli O157-positive (inoculated) cattle manure during routine bedding before soil application. Therefore, even in an environment where animals were artificially inoculated with E coli O157, the total survival time was not longer than 34 days in the bedding. Bedding is clearly not held in a barn for 45 days but the authors point out it is held for a week so that the suggested setback time after removal would only be another 3-weeks (and this without any soil application, which may reduce the hold time even more quickly). Using a very similar approach of inoculating cattle with E. coli O157 and following the manure but under very differing ecosystem variables, Hutchison et al (2005- Microbiological Research Division, United Kingdom – Ref# 14) reported

the infected cattle manure when spread on fescue plots showed no detection of pathogens past 64 days regardless of solid or liquid phase applications.

Both these studies - and several similar studies reported in the literature - used manure or cattle artificially inoculated with E. coli O157, a practice required to obtain sufficiently high positive titres for the pathogen so that the study will be successful. Most scientists find that the actual incidence of E. coli O157 in manures when plated out quantitatively would give much lower amounts. While the threshold of infectivity for specific pathogens remains not well-defined, and is undoubtedly fairly low for E. coli O157, it is also likely that in reality much of the fresh manure is very low to start with. Considering this fact, and the extreme circumstances of some of the studies, it is clear that several of the studies have been conducted virtually according to a worst/worst case premise.

COMPOSTING STUDIES

Composting differs from soil spreading in that composting is presumed to provide an environment for pathogen reduction as effective as or more effective than normal soil environments. These assumptions date back to the 1950's and in an early review of pathogen reduction Wiley (1962) cautioned that "these [pathogen reduction] statements are made without confirmation by actual experiments with composting and were made based only on observed temperatures and published reports of temperature lethal to pathogenic organisms". Today, the compost industry in the USA (and Canada) relies on the EPA CFR-40 Chap 503 rule (circa 1984) or versions of it for satisfactory composting conditions based on time, temperature and composting method. The pathogen reduction times are relatively short. For composting of sludge either a minimum temperature of 55°C for 3 days in *aerated static piles* or in-vessel systems is considered sufficient, and for turned-windrow systems 15 days at 55°C with 5 turnings is required. This guideline was incorporated intact into the NOP rule §205.203. There is a surprising paucity of published scientific data from this era that substantiates these short pathogen reduction times. However, a considerable effort was made under EPA to document the relationship of fecal coliform tests as surrogate for Salmonella detection, from which the modern EPA rule on testing salmonella or fecal coliform in sludge is based (see Janko 1988). In applying the EPA CFR40-503 rule to composters most states add also this component of actual analysis of fecal and/or salmonella on top of time x temperature guidelines as a premise for compliance, but the NOP incorporated only the time *x* temperature component, and therefore is a weaker guideline.

Very current scientific data from several studies examining pathogen behavior in composting environments clearly suggests that pathogen reduction time due to composting is as variable as that indicated for survival in soil environments from un-composted manures. Perhaps this should not surprise since composting is in all likelihood an ecosystem similar in most respect to soils and the microbes present in composting are largely strains found in soil.

In a recent study on pathogen-inoculated compost Singh et al (2011) of Clemson University Department of Biological Sciences (Ref # 7) stress that pathogen inactivation during composting is very complex. The authors point out that other factors in addition to time x temperature are also important for pathogen reduction including moisture, carbon/nitrogen ratio, particle size, aeration, heap size, pH, and *types and populations of indigenous microflora*. The emphasis on C/N as an added factor is also reflected in the NOP rule requiring evidence that starting CN ratios are proper for composting, a

requirement that is absent in the EPA 503 rule. This fits with the emerging line of thinking stressing multiple factors for composting beyond simple time *x* temperature.

The apparent discrepancy of scientific data for compost pathogen reduction compared to the original EPA Chap 503 guidelines has been discussed in a number of recent studies. In the Clemson study (Ref #7) the authors compared their static pile performance to EPA protocols and concluded that O157:H7 survival clearly exceeded 3 days at 55°C suggesting "inadequacy of the guidelines for composting". Other studies reflect a similar conclusion. Wichuk and McCartney (2007) of the Department of Environmental Engineering, University of Alberta, recently concluded that survival of pathogenic bacteria beyond EPA suggested guidelines occurred in a significant number of studies surveyed. Brinton et al. reported in 2009 results of examining finished composts from 94 west coast facilities across three states, two of which require compliance with the EPA CFR 40-Chap 503 rule. Only 1/3 of compost facilities in regulated states fell within the pathogen guidelines and 1/3 exceeded the guidelines by a significant margin. Around the same time, Kim et al (2009) of Clemson published compost data suggesting that regrowth of pathogens must be routinely occurring in compost piles. Reflecting a familiar theme of soil health, these authors concluded that the major factor affecting the suppression of E. coli O157:H7 regrowth in compost would be presence of indigenous microflora,- pointing to ecosystem factors.

In the aforementioned study Brinton et al. (2009) had sufficient facility data to divide composting types into categories similar to the EPA rule (static-pile versus turned windrow) and concluded that static pile methods showed the longest survival of pathogens whereas turned-windrow indicated the least, in contrast to the divisions suggested in the EPA CFR40 503 rule. Statistical analyses revealed that factors for elevated pathogen levels were large facility size, large pile size, and immaturity of compost. Application of a compost maturity index involving testing C:N and each of two other parameters distinguished compost products that had very low levels of E. coli from those with high levels. The referenced maturity index was originally developed by a panel of USA laboratory scientists familiar with analyzing composts (CalRecycle, 2001) but has not been adopted by the compost industry.

On-farm composting is a common practice for growers. A very research report (Berry et al – 2013- U.S. Meat Animal Research Center, USDA, Idaho) examines fate of pathogens in "minimally managed" compost piles. Such a form of low-management composting with infrequent turning is perhaps the most typical form of composting in America among farmer/growers. This study concluded similar to others that turned windrow-composting functions better than static-compost for pathogen reduction. The data indicated pathogen reduction of turned composts required on average a range of time from 28 to 56 days and in some instances measurable survival of E. coli O157 out to 84 days. In a similar approach, Shepherd (2011) examined minimally managed compost heaps and found survival times mostly in the range of 7 to 35 days with E. coli O157 survival on edges of composts out to 60 days.

A distinct impression gained in examining the field-oriented compost studies in comparison to lab-studies involving incubators, chambers and pouches inserted into artificially heated composts is that the lab studies generally report short reduction times (usually less than one week) and the field studies report significantly longer times (usually several months). This is not surprising as a growing body of evidence for survival mechanisms under extreme environments lends real credibility to reports on heat-

shock tolerance of bacteria observed in composts (Droffner et al 1995, Singh 2011, Gong et al 2005) and selective heat-survival and accumulation of pathogenic spore formers due to composting (Böhnel and Lube, 2000).

SUMMARY AND RECOMMENDATIONS

Based on this survey of scientific findings there is little ground for altering the 90/120-day setback precaution with soil spread manure which is part of the NOP rule. The range of reduction times reported in the scientific literature examining manure applications appear consistent with if not slightly more lenient to requirements presently used within the NOP.

With regard to composting a number of issues emerge. The chief discrepancy between science-based data and current NOP (and EPA) guidelines concerns the time constraints allowed which presently appear far too lenient. While several composting studies do show very short times for pathogen reduction several of these use simulated lab compost environments isolated from real ecosystems. Studies that are larger, based on field scales or involving more potential pathogens clearly point to much longer pathogen reduction times.

A simple resolution would be to require the overall length of time for composting be at least the same as soil setback rules for manure,- e.g. in the range of 120 days. While clearly composts have an advantage of episodic high heat that suppresses pathogens and results in faster reduction times, the margin of difference compared to soils is not large and appears to be diminishing with new studies. There are a variety of reasons for this, a chief one being that composts, unlike soil environments, provide an unusually rich array of nutrient substrates for pathogen survival and regrowth. Taken together the best precaution in view of the data is to treat the compost environment as essentially the same as ambient soil systems and to expect longer treatment times. This could be accomplished by more specific definition of “curing” which is not defined in the FDA proposals.

European countries have addressed compost pathogen concerns very recently as a result of the crisis of transmissible spongiform encephalopathy (TSE). Composting standards have been updated to be more rigorous with regard to testing, validation of heating, classification of type of technology and risk groups (end-use) (Commission 2002). The new Austrian ONORM standard for compost (2005) requires a multi-phasic combination of testing crossed with end-use (risk) categories (see attachment).

To get at the curing issues, there is evidence that scientists have described a variety of maturity index standards for compost completeness, none of which has taken hold in the USA. An index requires more than one indicator, a precautionary principle to avoid a single lab test being applied dogmatically. With more work these approaches could be cross-referenced to pathogen reduction and incorporated in future rules, including reincorporating the well-known but little used principle called “reduction of organic matter” (ROM) (Brinton 2010). Adding conditions for time *and* curing, with optional testing to validate curing if shorter than suggested times, should help escape the obvious vagueness of the present system, which in effect is transferring unnecessary risk to growers and ultimately to consumers. Finally many composters routinely use fairly long or 5-6 month composting times plus additional curing due to experience with satisfactory consumer quality (see Resource Recycling, 2002). The fact that many states have imposed by law additional “curing” times for composted biosolids even after they comply with the

basic EPA 503 time *x* temperature standard suggests two things; it is recognized that the 3/15-day approach is too basic and that "maturity" however vaguely defined is an advantage. Perhaps a variety of scientists and industry representatives can find a way to craft a more modern standard without being disruptive of existing practices.

William Brinton
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Faculty Associate
University of Maine

See APPENDIX I with NUMBERED STUDIES #1-26

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Scientific Papers that indicate reduction of manure and compost pathogens (E.coli O157:H7; Salmonella) reduction

Color Keys: compost study | manure study

ITEM	Pub Date	Authors	Primary Institution	Focus	Days to disappearance *best case*	Days to disappearance *worst case*	
1	May-02	Jiang, Morgan, Doyle	Center for Food Safety	Manure-E.coli-O157 loss in soils	77	231	
		Fate of Escherichia coli O157:H7 in Manure-Amended Soil. APPLIED AND ENVIRONMENTAL MICROBIOLOGY, May 2002, p. 2605–2609 Vol. 68, No. 5					
2	Nov-04	Ingham et al	Univ. of Wisconsin	E. coli loss in manure fertilized soils	100	168	
		Escherichia coli Contamination of Vegetables Grown in Soils Fertilized with Noncomposted Bovine Manure: Garden-Scale Studies APPLIED AND ENVIRONMENTAL MICROBIOLOGY, Nov. 2004, p. 6420–6427					
3	Oct-03	Jiang, Morgan, Doyle	Center Food Safety	Compost inactivation of E. coli O157	6	1	
		Jiang, X., J. Morgan, and M. P. Doyle. 2003. Thermal inactivation of Escherichia coli O157:H7 in cow manure compost. J. Food Prot. 66:1771–1777					
4	Jan-05	LeJeune and Kauffman	Ohio State Ag. R & D	O157 survival cattle bedding	13	22	
		LeJune, J.T. and M.D. Kauffman. Effect of Sand and Sawdust Bedding Materials on the Fecal Prevalence pf Escherichia coli O157:H7 in Dairy Cows. Appl. Environ. Microbiol. Jan. 2005, 71.01.326-330.					
5	May-05	Johannessen et al	Natl Veterinar Inst (Oslo)	O157 in greenhouse soils and lettuce	56	84	
		Johannessen, G.S. et al. Potential Uptake of Escherichia coli O157:H7 from Organic Manure into Crisphead Lettuce. Appl. Environ. Microbiol. May 2005, 71.05.2221-2225.					
6	Jul-11	Rogers et al	Clarkson U, Pottsdam, NY	Pathogen decay in Manured Soils	55	120	*
		Rogers et al. Decay of Bacterial Pathogens, Fecal Indicators and Real-Time Quantitative PCR Genetic Markers in Manure-Amended Soils. Appl. Environ. Microbiol. Jul 2011, 77.14.4839-4848.					

ITEM	Pub Date	Authors	Primary Institution	Focus	*best case*	*worst case*	
7	Jun-11	Singh et al	Clemson U. Bio Dept		1	5	
		Singh, R. et al. Determining Thermal Inactivation of Escherichia coli O157:H7 in Compost by Simulating Early Phases of the Composting Process. Appl. Environ. Microbiol. Jun 2011, 77.12.4126-4135.					
8	Jul-96	Wang, Zhao and Doyle	Center for Food Safety	O157 fate in Bovine Feces	49	70	
		Wang, G.,T.Zhao, and M. Doyle. Fate of Enterohemorrhagic E.coli O157:H7 in Bovine Feces. Appl. Environ. Microbiol. Jul 1996, 62.07.2567-2570.					
9	Sep-98	Kudva, Blanch and Hovde	U. Idaho, Moscow, ID	O157 Fate Manure/Slurry Var. Temp	1	100	*
		Kudva, I.T., K. Blanch, A. and Hovde, C.J. Analysis of Escherichia coli O157:H7 Survival in Ovine or Bovine Manure and Slurry. Appl. Environ. Microbiol. Sep 1998. 64.09.3166-3174.					
10	Nov-99	Fukushima et al	PHI Shimane Prefecture	O157 Survival Bovine Feces	7	126	
		Fukushim, H., K. Hoshina, M. Gomyoda. Long-Term Survival of Shiga Toxin-Producing Escherichia coli O26, O111m and O157 in Bovine Feces. Appl. Environ. Microbiol. Nov 1999. 65.11.5177-5181.					
11	Jul-01	LeJeune, Besser, Hancock	WSU Vet School	O157 survival cattle troughs	180	245	
		LeJeune, J.T., T.E. Besser, D.D. Hancock. Cattle Water Troughs as Resevoirs of Escherichia coli O157. Appl. Environ. Microbiol. Jul 2001.67.07.3053-3057					
12	Sep-04	Hutchinson et al	Direct Labs. Ltd, UK	O157 decline livestock waste soil	15	60	
		Hutchinson, M.L. et al. Effect of Length of Time before Incorporation on Survival of Pathogenic Bacteria Present in Livestock Wastes Applied to Agricultural Soil. Sep 2004. Appl. Environ. Microbiol. 70.09.5111-5118					
13	Nov-05	Davis et al	U. Idaho, Moscow, ID	O157 Survival cattle bedding	35	60	
		Davis, M.A. et al.Escherichia coli O157:H7 in Environments of Culture-Positive Cattle. Nov 2005. Appl. Environ. Microbio. 71.11.6816-6822.					
14	Feb-05	Hutchinson et al	Direct Labs. Ltd, UK	Pathogen Fate spread onto Fescue	2	63	
		Hutchinson et al. Fate of Pathogens Present in Livestock Wastes Spread onto Fescue Plots. Feb 2005. Appl. Environ. Microbiol. 71.02.691-696.					

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15	May-04	Nicholson et al	ADAS Gleadthorp UK	Pathogen Survival land application	30	64
		Nicholson, F. , S.J. Groves, B.J. Chamber. Pathogen Survival During Livestock Manure Storage and Following Land Application. May 2004. Elesevier Ltd. Online.				
16	Jun-09	Erickson et al	Center Food Safety	Inactivation of Salmonella in manure	3	4
		Inactivation of Salmonella spp. in cow manure composts formulated to different C:N ratios . Bioresource Technology 100 (2009) 5898–5903				
17	Apr-07	Franz et al	Wageningen University	Manure from Organic vs Conv Farms E.coli	94	109
		Prevalence of Shiga Toxin-Producing Escherichia coli in Manure from Organic and Low-Input Conventional Dairy Farm s . APPLIED AND ENVIRONMENTAL MICROBIOLOGY, Apr. 2007, p. 2180–2190 Vol. 73, No. 7				
18	Aug-05	Mukherjee et al	Food Sci., Univ. Minn	ECO157 transfer from soil appl. Manure	69	92
		Soil survival of Escherichia coli O157:H7 acquired by a child from garden soil recently fertilized with cattle manure. Journal of Applied Microbiology 101 (2006) 429–436				
19	Jan-13	Berry et al	USDA Animal Research Ctr	Fate during Minimally Managed composting	28	84
		Fate of Naturally Occurring Escherichia coli O157:H7 and Other Zoonotic Pathogens during Minimally Managed Bovine Feedlot Manure Composting . J Food Prot., Vol. 76, No. 8				
20	Apr-10	Wei et al	Dept Food Sci Univ DE	Fate of Viruses during Manure Composting	1	9
		Fate of Human Enteric Viruses during Dairy Manure–Based Composting . Journal of Food Protection, Vol. 73, No. 8, 2010, Pages 1543–1547				
21	Dec-07	Shepherd et al	Center Food Safety		5	120
		Fate of Escherichia coli O157:H7 during On-Farm Dairy Manure-Based Composting . Journal of Food Protection 70.12: 2708-2716				
22	Apr-09	Erickson et al	Center Food Safety	Pathogen Inactivation in Composting	1	4
		Pathogen Inactivation in Composting . Compost Sci Util Vol 17:229-236				

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23	Jun-03	Larney et al.	Agriculture Canada	Fate of Coliforms in Composted Manure	7	45
		Fate of Coliform Bacteria in Composted Beef Cattle Feedlot Manure . J. Environ. Qual. 32:1508–1515 (2003).				
24	Apr-08	Franz et al	Wageningen Univ	Soil Quality Manure Amendment Pathogens	54	105
		Manure-amended soil characteristics affecting the survival of E. coli O157:H7 in 36 Dutch soils. Environmental Microbiology (2008) 10(2), 313–327				
25		Shepherd, W	Clemson Univ Doctorate	Compost Methods for Pathogen Reduction	7	60
26		Nicholson et al.	Gleadthorpe Research	Pathogen Reduction manure and compost	7	32
		Pathogen survival during livestock manure storage and following land application. Bioresource Technology 96 (2005) 135–143				

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SUMMARY OF FINDINGS

MEAN OF PATHOGEN REDUCTION DAYS (PRD)		**BEST**	**WORST**
Manure based products	**Manure Average PRD**	**46.6**	**89.6**
	standard deviation (SD) of mean, days	47.6	72.2
	1) Average worst case + one SD		**162**
	2) Average of all Best/Worst Case Scenarios		68
	3) Average margin error to estimate reduction		60
	4) Suggested safety set-back in days based on average plus SD margin of error (2 + 3)	DAYS	**128.0**
For Manure Composting	**Compost Average PRD**	**4.2**	**36.4**
soil applied and planted	standard deviation of mean, days	7.9	40.8
	1) Average worst case + one SD		**77**
	2) Average of all Best/Worst Case Scenarios		20
	3) Average margin error to estimate reduction		24
	4) Suggested safety set-back in days based on average plus SD margin of error (2 + 3)	DAYS	**44.7**