



July 19, 2016

Division of Dockets Management (HFA-305)
Food and Drug Administration
5631 Fishers Lane, Rm. 1061
Rockville, MD 20852

Docket: FDA-2016-N-0321

RE: Risk Assessment of Foodborne Illness Associated with Pathogens from Produce Grown in Fields Amended with Untreated Biological Soil Amendments of Animal Origin; Request for Comments, Scientific Data, and Information

The Organic Trade Association (OTA) is pleased to submit comments on FDA's efforts to gather information relating to their risk assessment of the use of untreated biological soil amendments of animal origin used on produce covered by the Produce Safety Rule.

OTA is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing organic businesses across 50 states. Its members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's Board of Directors is democratically elected by its members. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

As expressed in our earlier comments on the Proposed Produce Safety Rule (Appendix A), 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) standards¹.

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. FDA has clearly heard from the organic sector that excessively long preharvest intervals following the application of untreated manure will interrupt typical crop rotation and soil fertility strategies, which could conflict with federal organic regulations (7 CFR 205). FDA has also acknowledged a lack of scientific research to support specific preharvest intervals, and OTA applauds FDA's decision to defer

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.

the establishment of a specific preharvest interval for untreated manure for 5 years until a risk assessment can occur.

With regards to FDA's request for additional information to inform their own risk assessment of the use of untreated biological soil amendments of animal origin on produce farms, OTA, in partnership with The Organic Center (TOC) and University of California Davis received a planning grant through USDA's Organic Research and Extension Initiative in 2015 to gather information about the use of soil amendments, including rotational grazing of livestock and poultry, in organic agriculture with a focus on produce commodities covered under the Produce Safety Rule. Included in this research planning grant, partners conducted a comprehensive survey of organic farmers on their use of untreated manure and compost as well as convening a summit of key stakeholders to discuss how to best design a long-term research study of pathogen risks from untreated manure used on covered produce at certified organic research farms.

The complete results of the comprehensive survey will be made publically available upon publishing of the study. Highlights from the study are described below.

Use Patterns of Untreated Manure on Organic Farms

Many organic producers rely on untreated manure for crop nutrients in their organic systems. USDA's National Agricultural Statistics Service (NASS) reported in their 2014 Organic Producer Survey² that 8,400 of the nation's 14,048 organic farms use green or animal manures in their production systems. Over ½ of the 595 respondents to the survey conducted by UC Davis, TOC, and OTA, who indicated that they grow produce covered by the Produce Safety Rule, report using animal manure. Of those using untreated manure, approximately 2/3 follow the preharvest interval required under the USDA organic regulations of 90/120 days depending on crop contact with soil. Less than 30% of respondents report annual sales of less than \$25,000 in covered produce, which indicates the vast majority of producers surveyed would be subject to the preharvest intervals included in the Produce Safety Rule.

Barriers to Composting

FDA has indicated their effort to encourage producers to compost manure prior to use on produce farms. OTA strongly supports this effort. However, there are a number of barriers to producers engaging in scientifically validated composting processes including infrastructure, education, and timely availability of compost feedstocks. Similarly, compost and untreated manure typically serve different functions in an organic production system, compost being primarily used for soil quality improvement, and manure for plant nutrients. The two soil amendments cannot be interchanged. The recent survey results indicate that only 40% of respondents rely entirely on compost for their fertility management. It is not practical at this time for producers to convert entirely from untreated manure to composted manure, therefore development of an appropriate, scientifically supported preharvest interval is essential.

Developing a Sound and Appropriate Standard

OTA has been concerned that the unique production practices on organic farms will not be fully incorporated into a risk assessment of untreated manure. To alleviate this concern, OTA, again in partnership with TOC and UC Davis, submitted a full grant proposal to USDA Organic Research and

² https://www.agcensus.usda.gov/Publications/2012/Online_Resources/Organics/

Extension Initiative to study pathogen persistence from untreated manure on produce crops grown under certified organic conditions. The overall objective of this grant proposal is to develop a customized risk assessment based on good agricultural practices, rigorous microbial testing, self-assessment of soil health, economic impacts (cost/benefit) and environmental factors to maintain the value of untreated manure soil amendments while limiting food safety risks. The risk assessment will be conducted in three produce-growing regions in the United States (West, Midwest, and Northeast) on certified organic farms growing produce commonly consumed raw and using typical organic production methods; it will evaluate pathogen die-off rates based on time and climatic conditions; and, ultimately, it will provide data that should support the establishment of an appropriate preharvest interval for produce grown on certified organic farms. We encourage FDA to consider the grant proposal's experimental design in the development of its own risk assessment.

CONCLUSION

OTA is supportive of FDA's effort to gather information on the risks that untreated biological soil amendments of animal origin pose to food safety. We appreciate FDA's willingness to listen to the unique needs of the organic sector as it promulgates rules to enforce the Food Safety Modernization Act, and we view ourselves as one of FDA's partners in ensuring America's organic food supply is safe. To accomplish this important task without overly burdening organic farmers with excessively long preharvest intervals, we encourage FDA to look at the data in the survey of organic producers and the experimental design that organic stakeholders helped to develop in order to best model actual use patterns and pathogen risks of untreated biological soil amendments of animal origin on organic farms.

On behalf of our members across the supply chain and the country, OTA thanks the FDA for the opportunity to comment. We invite FDA to reach out to us directly in order to obtain data from the comprehensive survey conducted of organic producers and to learn about the experimental model our partners have designed in the grant proposal to USDA Organic Research and Extension Initiative.

Respectfully submitted,



Nathaniel Lewis
Farm Policy Director
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association

Appendix A: November 18, 2013, OTA comments on the Proposed Produce Safety Rule – Docket No. FDA-2011-M-0921



November 18, 2013

**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 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.

First and foremost, OTA would like to express that the organic industry fully embraces FDA's efforts and the intended outcome of a safer food supply. We believe that every food producer has an obligation to supply safe food to the public.

Second, 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 not duplicate or conflict with the U.S. Department of Agriculture's (USDA) National Organic Program (NOP) standards:

FSMA Section 105, Standards for Produce Safety (A)(3)(E) provides that the Produce Safety Rule 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.

While OTA supports the overall efforts of FDA to ensure a safer food supply and we agree with many sections of the proposed rule, we are concerned that several key sections conflict with requirements under the NOP or otherwise should be changed. The following is a summary of the key issues we have identified that need additional consideration and revision. Our more detailed comments and suggestions for improvement follow thereafter.

- We are pleased to see that the proposed rule does not require duplicative trace-back and record-keeping systems, and *in most cases* does not conflict with or duplicate the organic standards. However, the proposed requirements for **biological soil amendments of animal origin in proposed Subpart F** are inconsistent with FSMA Section 105(A)(3)(E) because they conflict with organic fertility and crop rotation practices required under USDA's NOP standards. In

addition, these inconsistent requirements will place undue economic hardship on many organic producers by imposing overly prescriptive requirements that are not adequately supported by science, and are not necessary to achieve food safety.

Scientific literature cited in the proposed produce safety rule support concerns that manure and compost pose a food safety risk, but do not support the waiting periods proposed by FDA. Aligning with USDA organic regulations concerning the use of manure and expanding options for compost use patterns and quality testing will eliminate regulatory conflict without a reduction in food safety.

- The proposed requirements for **agricultural water in proposed Subpart E** will place undue economic hardship on organic producers and other producers across the United States by requiring extensive and potentially unnecessary testing in order to ensure water is safe according to water quality criteria that has not been proven applicable to consumed produce. OTA recommends that FDA move testing requirements to guidance where they can initially be used as part of a risk assessment carried out by each individual operation. The regulation itself should support a performance and outcome risk-based approach.
- For both the proposed requirements for **biological soil amendments of animal origin** and the requirements for **agricultural water**, OTA does not support including prescribed metrics *in the regulation itself* unless those metrics are scientifically established and proven to be appropriate for a variety of growing situations. There are many growing situations across the country, each of which is 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.
- OTA appreciates FDA’s efforts to allow farms to use alternative practices and to allow states and foreign countries to request variances from the produce safety rule. We request that FDA extend the use of alternative practices to apply to any prescribed metrics included in the final rule in order to increase the flexibility for each operation. We also request that FDA provide better guidance on what constitutes “adequate scientific data or other information.”
- The list of produce under section § 112.2 that is considered by FDA to NOT be commonly consumed raw includes several produce items that are commonly consumed raw, particularly as raw juice, salads, or in raw food diets. We suggest that the list be revised to remove some items (i.e., kale) and add additional other items (i.e., coffee), or, that the list be non-exhaustive and combined with criteria that would need to be met in order to qualify as “produce that is not covered.”
- OTA does not agree that a farm or farm mixed-type facility that places others’ Raw Agricultural Commodities (RACs) into consumer containers should be classified as packaging (manufacturing/process), and therefore subject to the Preventive Control Rule. Rather than focusing on the ownership of the product, we suggest FDA focus on “risk” and supplier verification. Farms should be required to assess their suppliers and accept produce from farms under different ownership provided they are receiving produce that was grown and harvested in a safe manner, either under the Produce Safety Rule, or a similar food safety program deemed acceptable by FDA.

- As written, the rule will have significant impact on farms throughout the country. Considering the number of questions asked in the preamble of the proposed rule and the number of tentative conclusions, the quality and legitimacy of a final rule would be improved if FDA were to consider and respond to the extensive comments received, and then issue a second proposed rule.

OTA respectfully submits the following more specific comments:

General	OTA’s comments on the proposed rule are guided by three critical factors: 1) FDA’s mandate to establish science-based and risk-based minimum standards that will minimize the risk of serious adverse health consequences or death; 2) FDA’s mandate to develop rules that do not duplicate or conflict with existing organic regulations; and 3) FDA’s intention to create a flexible regulation that will accommodate future changes in science and technology and the particularities of local growing conditions and commodities.
General	OTA applauds FDA's decision to take an integrated approach to the produce safety standards, rather than attempting to establish a unique standard for each type of agricultural commodity covered by the proposed rule. Thousands of farmers across the United States grow more than one type of agricultural commodity, with many growing ten or more commodities. For the most part, the proposed produce safety rule takes a common sense approach focusing on common actions that will be effective in achieving the goal of safe produce. Farmers will be required to achieve the outcomes of safe, unadulterated food with some flexibility in how that goal is achieved.
General	Many growers currently use and understand voluntary auditing programs such as USDA’s GAP and GHP (Good Agriculture Practices and Good Handling Practice) programs. Producers will likely not stop requesting these audits because it is what customers and produce buyers recognize, and markets currently demand. It is neither operationally sound nor efficient to create a separate inspection framework for a FSMA program without taking steps to provide integration with GAP and GHP programs. FDA can enhance (or further the goals of) FSMA by building on the existing foundation of GAP and GHP programs. OTA recommends that FDA re-evaluate the proposed rules, compare them with existing programs, and identify where current programs may be adequate and where programs need upgrading.
General	Imports should be regulated in the same manner as domestic products. Consumers need to know that imported products are as safe as those from the U.S.A. Also, unless imported products are held to the same standards as domestic products, domestic firms would be placed at an unfair disadvantage. Requirements for imports and domestic products should be consistent, and the method of enforcement for imports is important for ensuring both food safety and market fairness. Adequate oversight and certification of third-party inspection firms are vital, and variances for imports must be as strictly controlled as those for states.
General	FDA has requested comments on its decision to focus squarely on microbiological hazards related to the growing, harvesting, packing, and holding of produce. Consumer concerns regarding safety of the food supply are broader than microbial contamination. They include heavy metals, pesticide residues, the use of synthetic hormones, antibiotics in livestock production, and various other substances. A full assessment of the safety of the food supply should address non-microbial contamination as well as microbial contamination as they relate to public health. For future rulemaking, OTA urges FDA to look beyond the acute food safety risks associated with the presence of microorganisms, and also look at the long-term food safety health risks due to exposure to pesticides and other agricultural chemicals.
General	To follow the rule, farmers and packers need to understand what is expected of them. Those

	<p>enforcing the rule need to know what compliance looks like. A phased-in approach to education and enforcement—having guidance before the rule is to be implemented—can help remove uncertainty for both producers and regulators. It is not enough to simply develop and distribute guidance materials. Ongoing education, outreach and compliance assistance also will be needed to make the rule effective. Guidance documents should be timely and written in plain language. Multiple formats will be needed for different uses and audiences. Communication may best be accomplished by locally based efforts. This will require considerable coordination and adequate funding.</p>
General	<p>OTA thanks FDA for its thoughtful approach and inclusion of specific questions for comments throughout the preamble. However, the numerous questions and tentative conclusions expressed reflect a very tentative rule. To avoid unintended consequences, we respectfully request FDA to consider the extensive comments submitted by thousands of stakeholders across the country, make changes accordingly, and release a second proposed rule. An additional comment opportunity will prompt further discussion and exchange of information, and ultimately result in a better final product.</p>
Subpart A	GENERAL PROVISIONS
§ 112.1 Pg. 3629	<p>What food is covered by this part? OTA agrees that food produced within the meaning of this part that is a raw agricultural commodity (RAC) should be covered by this regulation, and this includes a produce RAC grown domestically <i>and a produce RAC imported</i> or offered for import in any state with the United States, the District of Columbia, or the Commonwealth of Puerto Rico.</p>
§ 112.2 Pg. 3630	<p>What produce is not covered by this part? OTA agrees that some produce items do not need to be covered under the Produce Safety Rule because they are rarely consumed raw. However, the list of items proposed includes several produce items that are commonly consumed raw, particularly as raw juice or in raw food diets. The list also DOES NOT INCLUDE other items such as coffee and hops that ARE rarely consumed raw. OTA suggests that this list be eliminated altogether, or revised to eliminate the following: kale, beets, collard greens, bok choy, ginger root, parsnips, rhubarb, sweet corn, figs, and turnips. All of these produce items are commonly consumed raw – in salads, dressings, fresh juice and/or eaten as fresh snacks. Kale, in particular, is one of the hottest produce commodities on the market, and is increasingly being used in juice bars across the nation. It’s also harvested young and included in fresh salad mixes. We request that coffee and hops be added to the list.</p> <p>In order to avoid the probability of inadvertently leaving out produce items that may or may not be rarely consumed raw, another approach could include a non-exhaustive list of “example” produce that would rarely be consumed raw, along with a list of criteria that must be met in order for produce to fall outside the definition of covered produce. To be considered “rarely consumed raw,” any produce falling under this category would necessitate a processing step (i.e., heating or cooking) that would convert the produce into consumable condition. Such processing would need to adequately reduce the presence of microorganisms of public health significance.</p>
§ 112.3	<p>What definitions apply to this part?</p> <p>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.”</p>

Our comments below discuss our position on the definition of a farm and the kinds of activities that should fall outside the definition of a “farm,” and would therefore be subject to the proposed Preventive Controls Rule.

Farm

The proposed rule defines “farm” as:

Farm means a facility (as defined in § 1.227 of this chapter) 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 same ownership.

We recognize that FDA has adopted the definition of “farm” from § 1.227 in the Section 415 registration regulations in order to position the requirements of the proposed Produce Rule within a complex regulatory framework that already exists under Chapter 4 of the FD&C Act, including Section 415 (Bioterrorism Act) and proposed Section 418 (Hazard analysis and risk-based preventive controls).

As explained in the Preamble in the proposed Preventive Controls Rule, a farm is considered an “establishment” within the definition of “facility.”

Although the definition of “farm” proposed by FDA for use in the proposed Produce Rule and Preventive Controls Rule may be appropriate in the legal context of the existing regulatory framework, the description of a “farm” as a “facility” on a practical level is potentially confusing because industry typically understands a “farm” to be an area of land and its buildings.

OTA recommendation: OTA recommends that FDA, within the constraints of the FD&C Act, clarify the proposed Produce Rule’s definition of a “farm” by adding “an area of land and its buildings” to its definition.

Farm means a facility (as defined in § 1.227 of this chapter), **typically an area of land and its buildings**, 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 same ownership.

Mixed-Type Facility

As proposed:

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under Section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d) and activities that require the establishment to be registered. An example of such a facility is a “farm mixed-type facility,” which is an establishment that grows and

harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered.

OTA agrees with this definition, and the fact that an establishment may engage in activities that are within the definition of “farm” (and therefore are exempt from FDA registration) and activities outside the definition of a “farm” (and therefore require FDA registration).

Manufacturing/Processing

As proposed:

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. For farms and farm mixed-type facilities, manufacturing/ processing does not include activities that are part of harvesting, packing, or holding.

OTA agrees with this definition, particularly that “for farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.”

Harvesting

As proposed:

“*Harvesting* applies to farms and farm mixed-type facilities, and means activities that are traditionally performed 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 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, 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.”

We agree with the definition of “harvesting” except for the condition that the RACs be grown on the farm or another farm under the same ownership. At first glance, this requirement is perfectly logical because it would follow that “harvesting” should only happen on a farm where a RAC is grown, and harvesting is “for the purpose of removing raw agricultural commodities from the place they are grown or raised and preparing them for use as food.” However, advanced farming practices, unique crop harvesting methods, and the incredible expenses of such systems make the sole ownership of such equipment not possible in all situations. As a result, it is common to perform job sharing and equipment sharing for harvesting functions.

OTA Recommendation: OTA requests that FDA consider removing the sentence “[h]arvesting is

limited to activities performed on raw agricultural commodities on the farm on which they were grown, raised, or another farm under the same ownership” from the definition of harvest. Removing this limitation will allow “harvesting” activities to remain part of “farm” activities.

Holding and Packing

Consistent with FDA’s proposed definition of “harvesting,” the proposed definitions for “holding” and “packing” include two conditions that must be met if those activities are to fall under the definition of a “farm” (and are therefore not subject to FDA registration and the Preventive Controls Rule):

- 1) Limited to activities that are performed on raw agricultural commodities grown or raised on the same farm or another farm under the same ownership; and
- 2) Does not include activities that transform an RAC, 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.

Under the proposed revisions to part 1, FDA explains that there would be a change in how FDA considers the act of placing RACs into consumer containers (1) off-farm and (2) on a farm or farm mixed-type facility with respect to others’ RACs. Off-farm, the expanded definition of packing would not apply, so this activity would now be classified as packaging (and, therefore, manufacturing/processing). Off-farm, this change should have no practical impact because off-farm establishments that conduct this activity are already required to register under Section 415 of the FD&C Act, and therefore already are subject to Section 418 of the FD&C Act, whether this activity is classified as packing or manufacturing/processing.

However, on a farm or farm mixed-type facility that places others’ RACs into consumer containers, this activity would now be classified as packaging and therefore manufacturing/processing, because the expanded definition of packing would only apply to a farm’s own RACs. This change in classification would impact a farm or farm mixed-type facility that conducts such activities if it is not currently required to register.

OTA does not agree that a farm or farm mixed-type facility that places others’ RACs into consumer containers should be classified as packaging (manufacturing/process), and therefore subject to the Preventive Controls Rule. Foodborne pathogens do not care about the ownership of a farm. It’s the farm activities that matter. A farm operating in compliance with the Produce Safety Rule will be able ensure the safe production, **harvesting and packing** of raw fruits and vegetables regardless of the ownership of the farm on which the produce was grown.

Placing a farm’s own RACs OR a neighbor’s RACs into consumer containers that contact the food should be considered “packing” within the “farm” definition.

To restrict otherwise would negatively impact community-based food systems such as farmers’ markets, food hubs, and community supported agriculture farms (CSAs). Many farmers and ranchers are challenged by the lack of distribution and processing infrastructure of appropriate scale that would give them wider access to retail, institutional, and commercial foodservice markets, where demand for local and regional foods continues to rise. Many farmers and ranchers are challenged on how to best move product from the farm to the marketplace. This is especially

	<p>crucial for small and mid-size farmers who may not have enough capital to own their own trucks, their own refrigeration units, or their own warehouse space.</p> <p>It's not uncommon for several smaller farms to send their produce to a larger farm with on-site packing sheds where the produce is packed for distribution. These kinds of situations offer a combination of production, aggregation, distribution, and marketing services, and make it possible for producers to gain entry into new and additional markets that would be difficult or impossible to access on their own. The proposed Produce Safety Rule includes standards directed to harvesting, packing, and holding activities that will adequately ensure safe food regardless of the ownership of the farm on which the produce was grown. In this type of situation, records must clearly document the farm from which the produce was received, including a lot number or some system of easily allowing traceability back to the farm of origin.</p> <p>OTA Recommendation: OTA recommends that FDA revise the criteria for applicability of the proposed Produce Rule and proposed Preventive Controls Rule such that, regardless of ownership of the RACs, all activities (including harvesting) would be treated consistently under either the proposed Produce Rule or the proposed Preventive Controls Rule.</p> <p>It is the view of OTA that the activities described under harvesting, holding, and packing more appropriately fit under the Produce Safety Rule and not the Preventive Controls Rule, provided RACs are not transformed into a processed product.</p> <p>Rather than focusing on the ownership of the product, we suggest FDA focus on “risk” and supplier verification. Farms should be required to assess their suppliers and accept produce from farms under different ownership provided they are receiving produce that was grown and harvested in a safe manner, either under the Produce Safety Rule, or a similar food safety program deemed acceptable by FDA.</p>
<p>Subpart B</p>	<p>GENERAL REQUIREMENTS</p>
<p>112.12 Pg. 3633</p>	<p>Are there any alternatives to the requirements established in this part? FDA proposes that farms and or farm mixed-type facilities covered by this rule may establish alternatives to the requirements for: 1) testing water and taking action based on test results (§ 112.44); 2) composting treatment processes established in § 112.54(c)(1) and (c)(2); 3) the minimum application interval established in § 112.56(a)(1)(i) for an untreated biological soil amendment of animal origin that is reasonably likely to contact covered produce after application or for a compost agricultural tea that contains compost agricultural tea additives; and (4) The minimum application interval established in § 112.56(a)(4)(i) for a biological soil amendment of animal origin treated by a composting process that is reasonably likely to contact covered produce after application.</p> <p>OTA supports the establishment of alternatives and the flexibility it may provide. However, as explained further below in our comments, we ultimately do not support including prescribed metrics in the regulation itself. Should FDA decide to leave prescribed metrics for agricultural water and/or biological soil amendments of animal origin in the rule, rather than moving the metrics to guidance as we suggest, we request that alternatives to the requirements apply in all instances (microbial standards, testing frequency and application intervals).</p> <p>The objective is safe food. If a farm operation is able to achieve the same outcome through means that are not provided for in the practice standards, the farm operation should be granted the</p>

	<p>opportunity to establish alternative practices provided adequate scientific data or information supports the conclusion that the alternative would provide the same level of public health protection as the applicable requirement established in the regulation.</p> <p>OTA also urges FDA to create a pre-approval process for commodity groups that would like to establish an alternative. In the 6/25/13 Fact Sheet titled “Alternatives and Variances: What is the Difference Under the Proposed Produce Safety Rule?,” FDA clarifies that “farms would not need to ask permission or petition FDA in order to use alternative measures, provided they have adequate scientific data and documentation used to support those alternatives.” Farms, particularly if there is a regional effort where many farmers rely on one study, may want the added assurance of knowing that the scientific data being used is in fact acceptable to FDA.</p> <p>The fact sheet also goes on to explain that documentation could be as simple as a peer-reviewed journal, a State Extension bulletin, or a process developed or made available to the grower by a third-party. The proposed regulation also allows an alternative to be developed by the farm. OTA requests that FDA provide additional clarification on acceptable forms of scientific data and documentation, especially in the case of an alternative practice developed by a farm based on its own research.</p> <p>We also suggest amending Section 112.12 to provide a clear safe harbor for farms using alternative procedures as follows:</p> <p style="padding-left: 40px;">(d). Use of alternative procedures does not require prior approval. No farm using alternative procedures shall be deemed to be in violation of the requirements of the subpart unless it continues to use an alternative procedure after receiving written notice from FDA that the alternative procedure in question is not consistent with the provisions in Subpart R.</p>
<p>Subparts C & D</p>	<p>STANDARDS DIRECTED TO PERSONNEL QUALIFICATIONS AND STANDARDS DIRECTED TO HEALTH AND HYGIENE</p>
<p>Pgs. 3633 - 3623</p>	<p>No Comments</p>
<p>Subpart E</p>	<p>STANDARDS DIRECTED TO AGRICULTURAL WATER</p>
<p>§ 112.41 Pg. 3634</p>	<p>What requirements apply to the quality of agricultural water? OTA does not support including prescribed metrics (numeric specifications) <i>in the regulation itself</i> unless those metrics are scientifically established <u>and</u> proven to be appropriate for a variety of growing situations. The problem is that there are many growing situations across the country, each of which is 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 <u>guidance</u>.</p> <p>The final rule should be written to allow flexibility within the agricultural water section to allow a risk-based modeling approach when an appropriate model has been designed. OTA urges FDA to revise Subpart E to include regulatory actions <u>based on risk assessment</u>. In drafting the proposed testing and treatment requirements, FDA has essentially already conducted the risk assessment for the entire industry, and is proposing a blanket requirement to all operations across the country regardless of their individual risk level. This does not allow adequate flexibility, and will place undue economic hardship on organic producers and other producers across the United</p>

	<p>States. Compliance with water quality standards promulgated in the proposed rule will be the greatest obstacle produce growers will face. Many farms that use surface water have indicated that the water quality testing intervals proposed in the rule will put their farms out of business.</p>
<p>§ 112.42 Pg. 3634</p>	<p>What measures must I take with respect to my agricultural water sources, water distribution system, and pooling of water?</p> <p>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 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 is 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.</p> <p>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 believe this is the most critical step in establishing a regulation that is science-based and flexible. <u>Regulatory actions should be based on risk assessment, and the appropriate action taken should be based on science.</u></p> <p>From this perspective, we <i>disagree</i> with the prescribed frequency of FDA’s proposed testing requirements, and with the limited option requirement to treat water in accordance with § 112.43. Testing and treatment protocols should be determined according to a risk-assessment conducted by each farm.</p>
<p>§ 112.43 Pg. 3635</p>	<p>What treatment of agricultural water is required, and what requirements apply to treating agricultural water?</p> <p>The proposed requirements to treat agricultural water with an EPA-registered antimicrobial pesticide, as specified in § 112.43, conflicts with the organic standards because of the limited number of antimicrobial pesticides allowed under NOP regulations. In the preamble, FDA acknowledges that currently there are NO antimicrobial pesticides in the United States that would be allowed for this use (label restrictions), and therefore the implementation period was designed to allow for the time needed for product registration.</p> <p>It is critical to understand that in addition to the time needed for product registration, for organic producers, antimicrobial pesticides would need to be on the NOP National List of Allowed and Prohibited substances. In order to be on the National List, a substance must be petitioned for placement, and that process can take anywhere from two to six years, or more. There is no guarantee that a petitioned material would be approved for addition to the National List because of the strict environmental criteria that must be met for a pesticide to be allowed in organic production. Therefore, it is entirely possible that organic producers would be faced with an absolute inability to treat agricultural water in accordance with FSMA regulations, without finding themselves in violation of NOP (USDA) regulations.</p> <p>To the best of our knowledge, currently there are NO antimicrobial pesticides that would be effective, allowed for use per label instructions, AND allowed under the National Organic Program.</p> <p>NOP organic standards allow the following materials to be used as algaecides, disinfectants and</p>

sanitizers in organic crop production (as restricted below):

§ 205.601 Synthetic substances allowed for use in organic crop production.

In accordance with restrictions specified in this section, the following synthetic substances may be used in organic crop production: *Provided*, That, use of such substances do not contribute to contamination of crops, soil, or water.

As algacides, disinfectants, and sanitizers, including irrigation system cleaning systems:

- Alcohols (Ethanol & Isopropanol)
- Chlorine materials—For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions (Calcium hypochlorite, Chlorine dioxide. & Sodium hypochlorite).
- Hydrogen peroxide
- Ozone gas—for use as an irrigation system cleaner only
- Peracetic acid—for use in disinfecting equipment, seed, and asexually propagated planting material. Also permitted in hydrogen peroxide formulations as allowed in § 205.601(a) at a concentration of no more than 6% as indicated on the pesticide product label.

In addition to our regulatory conflict concern outlined above, we are also concerned about the large-scale use and release of antimicrobial pesticides into the environment that may be used to comply with the proposed microbial standards and treatment requirements. By requiring treatment of water to meet microbial standards that are inappropriate for produce safety, FDA may in effect increase the release of antimicrobial pesticides into the environment while alternative mitigation practices may be available.

OTA requests that the section addressing treatment of agricultural water be included in the scope of the Environmental Impact Statement being prepared on the effects of this proposed rule. [Federal Register Notice: Notice of Intent to Prepare an Environmental Impact Statement for the Proposed Rule - Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.](#)

OTA recognizes that FDA has provided alternatives and variances to this part of the regulations. However, we strongly urge FDA to revise this section of the regulation to allow other mitigation and/or treatment practices that could result in agricultural water that is safe and of adequate sanitary quality for its intended use.

**§ 112.44
Pg. 3635**

What testing is required for agricultural water, and what must I do based on the test results?

OTA disagrees with the application of EPA’s Recreational Water Standards to a food safety regulation since there is no 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 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).

	<p>The proposed standards do not take into account the pathogen reduction that occurs from the time irrigation water is used to the time produce is consumed. Several mitigation steps typically occur during harvest and post-harvest practices, not to mention the time that occurs between irrigation and consumption. Further analysis and scientific justification are needed regarding the indicator organisms used and the microbial limits being set, particularly for irrigation water.</p> <p>Furthermore, since the time the proposed rule was released, EPA has updated its standard. As a result, the proposed microbial standards are already out of date. http://water.epa.gov/scitech/swguidance/standards/criteria/health/recreation/index.cfm</p> <p>More research specifically targeted at agricultural use is needed—both for an appropriate standard and for appropriate treatment alternatives. 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.</p> <p>We also recommend that all numeric specifications related to water testing currently in Section 112.44 be placed in guidance in order to facilitate current updates as new science is developed, and that such guidance specify limits on foodborne pathogens and incorporate a new, consistently reliable indicator organism that is relevant to fresh produce.</p>
<p>§ 112.45 Pg. 3635</p>	<p>How often must I test agricultural water that is subject to the requirements of § 112.44? Testing requirements should reflect the level of risk for each unique operation. The water testing frequency requirements in Section 112.45(a)(b) should be moved to guidance. 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.</p> <p>Risk-assessment needs to be conducted by each operator. Measures that need to be taken and testing frequency will depend on the outcome of the risk analysis. OTA recommends that after two years of data collection, a testing frequency should be set by each operation to reflect the risk at that farm. The regulation itself should support a performance and outcome-based approach based on risk-assessment, and should require that procedures and monitoring protocols be established to demonstrate that agricultural water is safe and of adequate sanitary quality for its intended use.</p>
<p>Subpart F</p>	<p>F—STANDARDS DIRECTED TO BIOLOGICAL SOIL AMENDMENTS OF ANIMAL ORIGIN AND HUMAN WASTE</p>
<p>§ 112.51 Pg. 3636</p>	<p>What requirements apply for determining the status of a biological soil amendment of animal origin? OTA generally agrees with the requirements set forth in this section describing the processes that define whether a biological soil amendment of animal origin is processed to completion so that the microorganisms of public health significance are adequately reduced. However, we recommend that an additional process be added for compost that: 1) meets the time and temperature requirements specified in §112.54(c)(1) and (c)(2); and 2) has been demonstrated via testing to satisfy the microbial standard in 112.55(a). See Appendix B for suggested revisions to Section 112.54.</p>
<p>§ 112.52 Pg. 3636</p>	<p>How must I handle, convey, and store biological soil amendments of animal origin? OTA agrees with the requirements proposed in this section. However, additional guidance would improve its usefulness. Guidance could provide several examples of the manner and locations that reflect proper handling and storage of biological soil amendments of animal origin. We urge FDA to draft guidance to support this section of the rule.</p>
<p>§ 112.54</p>	<p>What treatment processes are acceptable for a biological soil amendment of animal origin</p>

<p>Pg. 3636-3637</p>	<p>that I apply in the growing of covered produce?</p> <p>OTA agrees with the <u>treatment processes</u> proposed in the section with the exception of the <u>requirement</u> to insulate compost piles while they are curing.</p> <p>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 reintroduce contamination.</p> <p>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.</p> <p>We also recommend an additional treatment process be added for compost that: 1) meets the time and temperature requirements specified in §112.54(c)(1) and (c)(2); and 2) has been demonstrated through testing to satisfy the microbial standard in 112.55(a). A scientifically validated composting process meeting the microbial standards in 112.55(a) would allow for a 0-day application interval provided the compost is applied in a manner that minimizes the potential for contact with the harvestable or harvested part of the crop during or after application.</p> <p>See our more detailed comments directly below and Appendix B for suggested revisions to the proposed rule.</p>
<p>§ 112.56 Pg. 3637</p>	<p>What application requirements and minimum application intervals apply to biological soil amendments of animal origin?</p> <p>Organic production (the fastest growing sector in U.S. agriculture, generating \$31.5 billion in sales each year) relies on compost and manure as part of the foundation for soil health and fertility. Creating a rule that limits the organic sector's ability to use compost and manure for soil health and fertility could negatively impact the continued growth of organic agriculture, and agriculture in general. Therefore, it is essential that any proposed FSMA regulations regarding compost and manure be supported by science and risk assessments.</p> <p>The proposed regulations under Subpart F §112.56 require a 9-month minimal application interval for <u>untreated manure</u> that contacts or potentially contacts covered produce. This requirement is more stringent than the existing NOP regulations requirement of a 120 (4-month)- or 90 (3-month)-day application interval for untreated manure, depending on whether the edible portion has direct or indirect contact with the soil in which the manure was incorporated.</p> <p>For a biological soil amendment of animal origin treated by a <u>composting process</u> that has been demonstrated to satisfy the microbial standard in § 112.55(b), and used in a manner that minimizes the potential for contact with covered produce during and after application, a 45-day minimum application interval is required. This is more stringent than the existing NOP regulations, which do not require any application interval for composted manure.</p>

FDA explains in the preamble¹ that compliance with the provisions of the proposed rule would not preclude compliance with the requirements for organic certification. OTA agrees with FDA that when placing the application interval numbers from each rule side-by-side, the application intervals in the organic regulations could run concurrently with the proposed application intervals in the proposed produce safety rule. However, this does not take into account NOP regulations as a whole. When you consider the organic requirements for soil fertility and pest management, it becomes clear that a regulatory conflict exists.

Certified organic producers are required to use biologically based fertilizers as the major nutrient sources in crop production (205.203(b)) and they are required to manage soil fertility in a manner that maintains or improves soil quality and that prevents contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited materials (205.203(a)(c)). Organic producers are also required to implement crop rotation practices as part of a preventative pest, weed, and disease management plan and to manage for soil erosion, excess plant nutrients, and soil organic matter (§ 205.205). FDA's proposed application intervals will make compliance with these requirements impossible for many organic producers.

For a number of regions of the country, a 9-month interval would mean that both application and harvest would occur during winter and, therefore, outside of the growing season. If growers wanted to do the application or harvest during the growing season, under the proposed regulations, those growers would be forced to fallow the field for an entire growing season. This would seriously disrupt crop production schedules and rotations, because vegetable growers in these regions commonly grow two, three, or even four crops in succession. For farmers who use compost, enactment of the proposed 45-day interval would severely limit crop rotations for short-season crops and significantly restrict the use of compost during the growing season for side-dressing.

FSMA mandates that FDA develop rules that do not duplicate or conflict with existing organic regulations. FSMA also mandates that FDA develop a science- and risk-based rule. In an effort to further understand the effects the proposed application intervals would have on organic crop producers, OTA and Washington State Department of Agriculture (WSDA) conducted a survey of organic producers. Those producers were asked a number of questions related to the impact the proposed rule would have on their organic fertility and crop rotation practices. **See Appendix A.** Additionally, OTA contracted with a researcher to conduct a scientific literature survey to address the scientific basis of the proposed rule. **See Appendix D.** A summary of the findings are as follows:

Producer Survey

The survey conducted by WSDA and OTA was circulated to producers who grow produce that would be covered by the proposed regulation, and who are certified under USDA's organic regulations. Responses were received from over 300 of the approximately 8,100 certified organic producers in the U.S.

- Ninety-four percent of organic producers are using either untreated manure or compost for soil fertility.
- Ninety-five percent of organic producer responses indicate that FDA's proposed application

¹ 78 FR 3584

interval for untreated manure (9-months) will prevent or restrict organic producers' ability to improve soil biodiversity and rotate crops as required under USDA's organic regulations.

- Seventy-three percent of organic producer responses indicate that FDA's proposed application interval for compost (45-days) will prevent or restrict organic producers' ability to improve soil biodiversity and rotate crops as required under USDA's organic regulations.

Failure to adhere to soil fertility and crop nutrient requirements and implement crop rotation would force organic producers out of compliance with USDA Organic Regulations and prompt organic certifiers to pursue adverse action. It could lead to producers losing their organic certification.

See **Appendix C** for NOP regulatory text sections 205.203 through 205.505: 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.

For untreated manure, specific examples of regulatory conflict include, but are not limited to:

- **Crop Rotation Standard:** For diversified livestock and crop farms, early season covered produce could not follow a late harvested feed crop.
- **Crop Rotation Standard:** For intensively managed mixed vegetable operations, rotations between various plant families (cucurbits, brassicas, etc.) would be severely restricted if not impossible.
- **Crop Nutrient Management Standard:** The 9-month application interval necessitates the application of untreated manure at times when the risk of runoff, nutrient loss, and damage to soil quality are the greatest. This would conflict with the requirements in the organic regulation to manage soil fertility in a manner that improves its quality and prevents contamination of soil and water.

For compost, examples of regulatory conflict include, but are not limited to:

- **Crop Rotation Standard:** For short season greens often harvested 20-45 days after planting (lettuce, spinach, arugula, etc.), rotations would be severely restricted if not impossible.
- **Crop Nutrient Management Standard:** Side dressing heavy feeders and leafy greens during the growing season (summer squash, kale, chard, cucumbers) would be severely restricted, if not eliminated.
- **Pest, Weed and Disease Management Standard:** Many producers side-dress with compost as a part of their integrated pest management plan, with the goal of enhancing soil biological activity and thereby improving nutrient availability and suppressing certain crop diseases. This cultural approach to pest management is required under the regulations and must prove to be ineffective prior to use of pest control materials on the NOP National List of Allowed and Prohibited Substances (§ 205.206(e))
- **Crop Rotation Standard:** For smaller diversified operations in short season northern climates, the number of crops that could be grown would be severely limited if they were to accommodate the 45-day application interval and follow an adequate crop rotation cycle.

Scientific Literature Survey

In addition to the organic producer survey, OTA also contracted for a scientific literature survey to address the scientific basis of the proposed application-harvest intervals. **See Appendix D.**

Approximately 40 scientific studies were examined concerning pathogen survival in field application of manure and pathogen reduction during composting. The objective was to extract best-case/ worst-case scenarios as reported from actual field and lab trials on survival of bacteria, and from this data construct a best/worst case summary suggesting the risk after application of soil of contaminated material. 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 depending on study conditions and the ecosystem environment.

Manure

The 18 soil-manure studies that were examined largely support as safe the existing 90-120 day application interval already incorporated into the NOP rule, but which the FDA proposed regulations would significantly extend. It appears that the range in days of survival of pathogens after application is 50 – 94 days (best/worst case). In order to determine this number, a risk model was used where a standard error (deviations) from the data was added on top of the data to create an upper margin of best-worst case. The results provide a realistic target for restrictions of planting into soil affected by pathogen containing materials. This number is 131-days, very close to the 120-day application interval included in the NOP regulations. **See Appendix E.**

Compost

With regard to composting, a number of issues emerge. The studies examined reveal wide variances in findings. Although the reduction times for pathogens are shorter than manure application ranges, they are on average considerably longer than the 3/15-day limits used in the NOP regulations. 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.

One resolution is to focus on the maturity of the compost when it is applied to the field. FDA could provide a more specific definition of “curing” along with guidance that would help ensure the pathogen stability of finished compost. This approach could effectively result in adequate pathogen reduction (maturity/stability of compost) prior to field application.

Required testing, as we have suggested below, would validate whether the composting process used reliably meets the pathogen standards proposed under §112.55(a). Under this option, there would be no minimum time limit between application and harvest. This resolution is discussed in further detail below under solutions for safe organic produce.

FDA’s Proposed Alternatives

While FDA has allowed for “alternatives” to certain requirements in Subpart F in accordance with § 112.12, the limited scope and unclear, burdensome requirements for an alternative do not make them a realistic option for farmers. The alternatives apply very narrowly and not to the entire standard. Additionally, the burden of proof is on the farmer to have adequate scientific data or information to show that the alternative would “provide the same level of public health protection as the applicable requirement” in the proposed standards.² In other words, FDA is placing the

² § 112.12(b)

burden on farmers and private entities to conduct research on public health risks generally – a research and investigative task that FDA has been challenged to fulfill.

SOLUTIONS FOR SAFE ORGANIC PRODUCE

The scientific literature cited in the proposed produce safety rule supports concerns that manure and compost pose a food safety risk, but does not support the proposed application interval. Considering the regulatory conflict and the economic impact this part of the proposed regulation will have on organic farmers, OTA urges FDA to accept the following solutions that we believe will eliminate regulatory conflict without a reduction in food safety.

Untreated Manure

FDA has tentatively concluded that nine months may be a longer application interval than is needed under certain circumstances. OTA agrees. In addition to the regulatory conflict the proposed regulation presents, the results of the scientific literature survey demonstrate that there is virtually no data supporting a 9-month application interval, and there is little ground for going beyond the 90/120-day setback precaution with soil spread manure, as is found in the NOP rule.

The scientific justification for a 9-month application interval for untreated manure was based on worst-case scenario studies. While using worst-case scenarios to assess pathogen risk from manure is a cautious approach, it risks using selective science, which is inconsistent with FDA’s mandate to develop science-based produce safety rules. Numerous studies on pathogen persistence in soil align more with the existing USDA organic regulations. The range of reduction times reported in the scientific literature examining manure applications appears consistent with, if not slightly more lenient than, existing NOP requirements.

OTA’s Proposed Solution

OTA urges FDA to recognize USDA’s widely used and accepted existing standards on the use of untreated manure and issue a rule consistent with waiting periods in USDA’s NOP organic standards. For untreated biological soil amendments of animal origin (manure), the application method and intervals would read as follows (**See Appendix B for suggested changes to the proposed rule**):

- **120 Days:** For covered produce whose edible portion has direct contact with the soil surface or soil particles, applied in a manner that does not contact the harvestable or harvested part of the crop during application, and minimizes the potential for contact after application.
- **90 Days:** For covered produce whose harvestable portion does not have direct contact with the soil surface or soil particles, applied in a manner that prevents potential contact with the harvestable or harvested part of the crop during or after application.

Compost

As demonstrated in the survey, the proposed 45-day waiting period from application to harvest of treated compost from an animal origin severely limits organic farmers’ ability to rotate crops, as they are required to do under NOP regulations. Thus, it creates a regulatory conflict between existing USDA requirements and the proposed FSMA regulations.

FDA acknowledges that controlled composting suitably destroys pathogens to a minimal risk factor, and, therefore, the 45-day application interval is incongruous with FDA’s assessment.

Inconsistency in any pathogen mitigation process can lead to the use of soil amendments that pose a public health risk.

Also, FDA references the rules under California's Leafy Greens Marketing Agreement (LGMA) as a factor in developing waiting times outlined in the proposed rule. This type of arrangement has proven successful to mitigate food safety risks in the unique leafy greens production areas of California and Arizona. However, we caution FDA when using industry standards developed for a production system unlike most of the rest of the United States. LGMA is an example of industry- and region-specific concerns prompting producers and handlers to take additional food safety measures. These concerns should be evaluated and addressed for each specific industry and region, and FDA should develop and enforce a rule that sets a minimum standard for food safety acceptable nationwide.

Application-to-harvest intervals should be determined using science-based knowledge about pathogen levels in and transfer from compost. If a monitored and validated composting process reliably meets pathogen standards of §112.55(a), there should be no minimum time limit between application and harvest.

However, given the uncertainty in the scientific literature, the liabilities to compost manufacturers and food producers, and the mandate for public safety, we acknowledge that a 45-day application-to-harvest interval is prudent in certain circumstances until further research better defines what, if any, the proper interval should be. We also recognize that a validated composting process meeting the pathogen standards proposed for physical and chemical treatment should sufficiently minimize the risk of pathogen transfer. We therefore urge FDA to include a third option in Section 112.56 that would allow for a zero-day application interval.

OTA's Proposed Solution

A 45-day minimum application-to-harvest interval shall be required when using a biological soil amendment of animal origin that:

- a) Is treated by a composting process as per §112.54(c);
- b) Has been demonstrated to satisfy the microbial standard in §112.55(b);
- c) Is used on covered produce whose edible portion has direct contact with the soil surface or soil particles; and
- d) Is applied in a manner that minimizes the potential for contact with the harvestable or harvested part of the crop during and after application.

The minimum application-to-harvest interval should be zero when using a biological soil amendment of animal origin that:

- a) Is treated by a composting process as per §112.54(c);
- b) Has been demonstrated to satisfy the microbial standard in §112.55(b);
- c) Is used on covered produce whose edible portion does not have direct contact with the soil surface or soil particles; and
- d) Is applied in a manner that prevents contact with the harvestable or harvested part of the crop during and after application.

We also request that FDA include an additional option and allow a 0-day application interval for compost that meets the composting process described in §112.54(c) AND meets the following testing, curing, handling, and record keeping criteria:

- a) *Testing of the finished compost to satisfy the microbial standard in § 112.55(a), the same as with physical and chemical treatment processes (§ 112.54(a) and (b));
- b) Applied in such a way that minimizes the potential for contact with covered produce during and after application (as per 112.52);
- c) Storage and handling requirements (as per § 112.52);
- d) **Curing (FDA Guidance to be developed on a measurement for stability/maturity)
- e) Records to support the testing, established protocols, monitoring and training (as per §112.60(b)(4)).

The combination of meeting time and temperature, stability (curing), and microbial standards assures the risk of transmitting viable pathogenic organism is sufficiently minimized.

**Testing:* OTA urges FDA to issue guidance for manufacturing compost for use on “covered crops” that details proper monitoring and sampling procedures for testing, along with training requirements and other Best Management Practices that would result in a “scientifically validated controlled composting process.”

***Curing and age of compost:* The preamble explains that the 45-day application interval serves as an additional step to ensure adequate pathogen reduction in compost prior to contact with covered produce. However, the proposed regulations are void of any mention of the age of compost when it is applied to the field. Furthermore, the proposed rule’s definition of curing is vague.

Per FDA proposed rule: Curing means the maturation stage of composting, which is conducted after much of the readily metabolized biological material has been decomposed, at cooler temperatures than those in the thermophilic phase of composting, to further reduce pathogens, promote further decomposition of cellulose and lignin, and stabilize composition.

OTA urges FDA to issue guidance that will define “curing” with more specificity in order to adequately promote reduction of pathogens. OTA has determined from a review of science literature that compost aging may be the single-most important factor for positive hygiene; therefore, better definitions of “aging”, “curing” and “maturity” are needed. Areas of research that are likely to be very helpful include examining the relationship of mass loss (level of organic matter degradation) to that of pathogen reduction; examining the relationship of pathogen regrowth to maturity indicators; and examining the use of multiple test factors “triangulation” to better pinpoint maturity that also correlates closely to mass-loss and hygiene.

The following definitions could also be included in the regulation (or in guidance) to help guide a process that results in adequately “cured” compost:

"Active Compost" means compost feedstock that is in the process of being rapidly decomposed and is unstable. Active compost generates temperatures that exceed ambient temperatures measurably for an extended period of time during decomposition, and releases carbon dioxide at a rate measurably elevated over background rates.

"Stabilized Compost" means any organic material that has undergone a curing process involving time past the active composting phase. In curing, compost has reached a stage of reduced biological

<p>Related Definitions</p>	<p>activity as indicated by reduced temperature and rate of respiration measurably below that of active compost.</p> <p>In order to avoid confusion with the meaning of terms as they are commonly understood in the produce and composting sectors, OTA’s proposes revisions to several definitions.</p> <p>Compost <i>FSMA Proposed Definition:</i> Composting means a process to produce humus in which organic material is decomposed by the actions of microorganisms under thermophilic conditions for a designated period of time (for example, 3 days) at a designated temperature [for example, 131°F (55 °C)], followed by a curing.</p> <p><i>OTA Comment:</i> Composting does not produce “humus” (see next comment). Specific time and temperature conditions can be required for manufacturing compost destined for crops covered by this Act, but should be included in the broad definition of composting.</p> <p><i>OTA suggested definitions:</i> “Composting” means the controlled biological decomposition and stabilization of organic material to a point where it is beneficial to plant growth.</p> <p>"Compost" means a biologically stable material derived from the composting process.</p> <p>Also, to avoid confusion, use “composting” when referring to the verb, the act of making compost, and “compost” to refer to the noun, the product of the controlled biologic decomposition of organic material and stabilized to a point that it is beneficial to plant growth.</p> <p>Humus <i>FSMA Proposed Definition:</i> stabilized (i.e., finished) biological soil amendment produced through a controlled composting process.</p> <p><i>OTA Comment:</i> This is a definition of compost. Compost, the product of composting, contains many constituents, including humus. The term humus is most commonly used to refer to very stable organo-mineral complexes, part of the long-term organic matter of soil and a common chemical constituent of compost. It is neither commonly used nor appropriate as a general term for compost.</p> <p><i>OTA suggestion:</i> We recommend that the term “stabilized compost” be used in the proposed Produce Rule, rather than the term “humus.” In support of, and consistent with our comments above on the subject of “curing,” OTA proposes the following definition:</p> <p>"Stabilized Compost" means any organic material that has undergone a curing process involving time past the active composting phase. In curing, compost has reached a stage of reduced biological activity as indicated by reduced temperature and rate of respiration measurably below that of active compost.</p> <p>Static Composting Static composting includes passively aerated systems, which are likely to have cold spots due to uneven aeration.</p>
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	<p>OTA recommends changing “Static Composting” to “Aerated Static Composting,” which is a process in which decomposing organic material is placed in piles or a vessel with an air supply system that can be used to provide oxygen and control temperature for the purpose of producing compost. The piles or vessel must be insulated to ensure that all parts of the decomposing material reach and maintain temperatures at or above 55°C for a minimum of 3 days. Insulating material may not include biological materials of animal origin unless they have been treated per the requirements of these regulations. See Appendix B for suggested changes to the rule.</p>
Subpart I	STANDARDS DIRECTED TO DOMESTICATED AND WILD ANIMALS
<p>§ 112.82 Pg. 3638</p>	<p>What requirements apply regarding domesticated animals that I allow to graze in fields or use as working animals where I grow covered produce?</p> <p>The proposed regulations at § 112.82(a) state, “At a minimum, if you allow animals to graze or use them as working animals in fields where covered produce is grown, and under the circumstances there is a reasonable probability that grazing or working animals will contaminate covered produce, you must take the following measures:</p> <ul style="list-style-type: none"> • An adequate waiting period between grazing and harvesting for covered produce in any growing area that was grazed to ensure the safety of the harvested crop. <p>In the preamble on Page 3587, FDA addresses § 112.82(a) and states:</p> <p>“We would not expect it to be necessary for such time periods to exceed 9 months, which is the application interval we propose for use of raw manure as a soil amendment in proposed § 112.56(a)(1)(i).”</p> <p>Several OTA members have expressed concern that if animals are used as working animals or graze where covered produce is grown, a 9-month waiting period between grazing and harvesting would apply.</p> <p>However, at the FDA Public Meeting in Portland, Oregon, FDA was asked this specific question and the response was that FDA had no intention of requiring a 9-month waiting period. The 9-month application interval was intended for situations where significant amount of manure (tonnage) would be applied and contact or potentially contact covered produce. FDA clarified that the 9-month application interval was not intended for animal excreta that could result from working or grazing domesticated animals. OTA requests clarification be provided in the Final Rule.</p>
<p>§ 112.83 pg. 3638</p>	<p>What requirements apply regarding animal intrusion?</p> <p>In the preamble the FDA asserts that in general, carrying out the regulation by minimizing risks to food safety would not require the 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 (78 Fed. Reg. 3552).</p> <p>In discussing the management of on-farm ponds, the preamble makes clear that FDA is not proposing that vegetation surrounding a pond be cut back or removed or that fencing be used to prevent wild and domesticated animals from having access (78 Fed. Reg. 3560). FDA states that in maintaining agricultural water sources, persons are not to manage animal habitat in a way that would result in “taking” an endangered species, which would violate the Endangered Species Act (78 Fed. Reg. 3565).</p> <p>Finally, in its discussion in the preamble of proposed § 112.83, the requirement to monitor for</p>

	<p>possible contamination due to the intrusion of wild animals, FDA states explicitly that the presence of “animals,” whether they are domesticated or wild, is not, in and of itself, a significant food safety risk (78 Fed. Reg. 3587). OTA therefore recommends that these principles expressed so clearly in the preamble should become part of the actual text of proposed § 112.83.</p> <p>Therefore, § proposed 112.83 should be amended as follows:</p> <p>Re-designate existing subsection (a) as subsection (b), and add a new subsection (a), so that § 112.83 would read as follows:</p> <p>(a) <u>The presence of wild animals in a production field, in and of itself, is not a significant food safety risk.</u> If significant wild animal intrusion occurs, and steps are needed to address that issue, you must not include measures to <u>destroy wild animal habitat or otherwise clear farm borders around outdoor growing areas, ponds, or drainages.</u> You must not “take” <u>endangered species.</u> If <i>significant</i> intrusion of wild animals occurs, you must focus measures on excluding those specific animals, for instance, fencing out feral pigs, and not use this as a reason to exclude all wild animals.</p> <p>(b) If under the circumstances there is a reasonable probability that animal intrusion will contaminate covered produce, you must monitor those areas that are used for a covered activity for evidence of animal intrusion:</p> <p>(1) As needed during the growing season based on:</p> <p>(i) Your covered produce; and</p> <p>(ii) Your observations and experience; and</p> <p>(2) Immediately prior to harvest.</p> <p>(b) If animal intrusion, as made evident by observation of significant quantities of animals, animal excreta or crop destruction via grazing occurs, you must evaluate whether the covered produce can be harvested in accordance with the requirements of § 112.112.</p>
<p>Subpart O</p>	<p>REQUIREMENTS APPLYING TO RECORDS</p>
<p>§ 112.161 pg. 3642</p>	<p>What general requirements apply to records required under this part?</p> <p>OTA recognizes the value for farms to conduct operational assessments and develop written food safety plans. We believe that the most effective approach to produce safety would be one that incorporates food safety plans developed at the operational level. We also realize that for some operations, a written food safety plan may be unnecessary. OTA agrees with FDA’s decision not to require a written food safety plan. However we urge FDA to recommend operational assessments and written food safety plans and to do so through guidance.</p>

Conclusion

OTA’s 2013 Organic Industry Survey shows the organic industry has grown from \$3.6 billion in 1997 to \$31.5 billion in 2012, with an annual growth rate of 19% from 1997-2008. As our country has been 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 contribute to 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 the same as other food sectors. The organic foods industry has federally-mandated safeguards that result in food safety for consumers, including full food product traceability, accountability of food production methods, and strict controls on known potential sources of food 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, they 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 thank FDA for taking these comments into consideration as it moves forward with its programs for assuring the safety of the U.S. food supply.

Our suggested revisions and recommendations for improvement are summarized as follows:

- OTA urges FDA to consider and respond to the extensive comments received and issue a second proposed rule with opportunity for comment.
- OTA requests that FDA provide a pre-approval process for commodity groups that would like to establish alternatives.
- Prescribed metrics should not be included *in the regulation itself* unless those metrics are scientifically based and proven to be appropriate for a variety of growing situations. 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.
- OTA urges FDA to extend the use of alternative practices to apply to any prescribed metrics retained in the rule in order to increase the flexibility for each operation.
- Agricultural Water: OTA requests that testing requirements be moved to guidance where they can initially be used as part of a risk assessment carried out by each individual operation. The regulation itself should support a performance and outcome risk-based approach.
- Proposed requirements for agricultural water, particularly the proposed treatment options, should be included in the scope of the Environmental Impact Statement being prepared on the effects of this proposed rule. [Federal Register Notice: Notice of Intent to Prepare an Environmental Impact Statement for the Proposed Rule - Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption](#).
- Compost & Manure: FDA should align with USDA's organic regulations for the use of manure and expand options for compost to include a zero day application interval based supported by quality testing.
- Proposed requirements for biological soil amendments of animal origin, particularly the proposed application harvest intervals, should be included in the scope of the Environmental Impact Statement being prepared on the effects of this proposed rule. [Federal Register Notice: Notice of Intent to Prepare an Environmental Impact Statement for the Proposed Rule - Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption](#).
- Domesticated and wild animals: Clarification is needed on any intended waiting periods between animal use/intrusion and harvest. The principles expressed regarding conservation practices in the preamble should become part of the actual text of proposed § 112.83.

We also request that FDA issue guidance in the following areas in order to further the goals of FSMA, improve implementation of the rule and increase consistent practice:

- Compost Curing (maturity/stability index for compost)
- Acceptable forms of scientific data and documentation that would support an alternative practice developed by a farm based on its own research.
- Manufacturing compost for use on “covered crops” that details proper monitoring and sampling procedures, training requirements and other Best Management Practices to be considered a “scientifically validated controlled composting process.”
- Handling and storage of biological soil amendments of animal origin, particularly the manner and locations that reflect proper handling and storage.
- Microbial standard and risk-assessment/risk-based modeling for water evaluation to determine testing frequency and mitigation practices.
- OTA urges FDA to **recommend** operational assessments and create guidance that will help operators develop written food safety plans.

And finally, we request FDA prioritize the following research topics:

- Agricultural Water: Further analysis and scientific justification are needed regarding the indicator organisms used and the microbial limits being set for testing agricultural water.
- Compost: Examine the relationship of mass loss (level of organic matter degradation) to that of pathogen reduction; the relationship of pathogen regrowth to maturity indicators; and the use of multiple test factors “triangulation” to better pinpoint maturity that also correlates closely to mass-loss and hygiene.

We thank you for carefully considering our comments and look forward to a final rule that will ensure the success and safety of this segment of the food supply.

Respectfully submitted,



Gwendolyn Wyard
Regulatory Director of Organic Standards and Food Safety
Organic Trade Association

cc: Laura Batcha
Executive Vice President
Organic Trade Association

Appendix A: Producer Survey: Impact of Proposed Application Intervals on Organic Crop Rotation

Appendix B: Suggested revisions to § 112.54 (Biological Soil Amendments of Animal Origin)

Appendix C: USDA NOP Regulatory Text for Sections 205.203-205.205

Appendix D: Scientific Literature Survey: Manure-Soil-Compost Pathogen Transfer and Survival

Appendix E: Scientific papers that indicate reduction of manure and compost pathogens reduction

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 USDA 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.

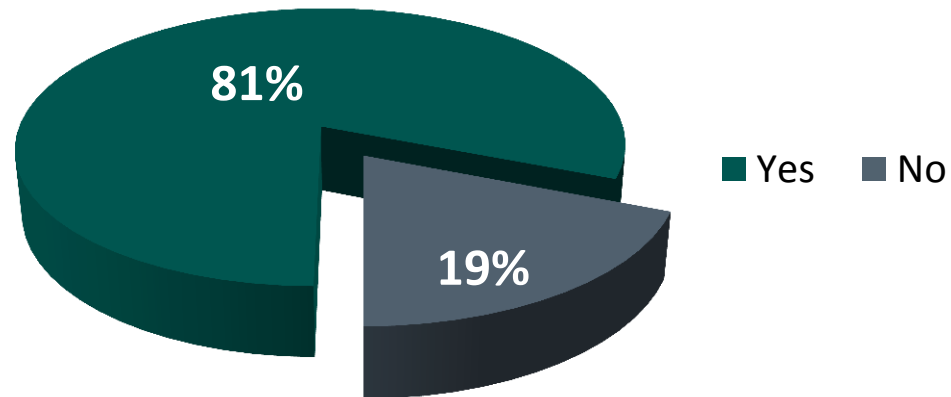


Biological Soil Amendments

Organic Producer Survey Results



Does your operation grow any organic produce commonly consumed raw?



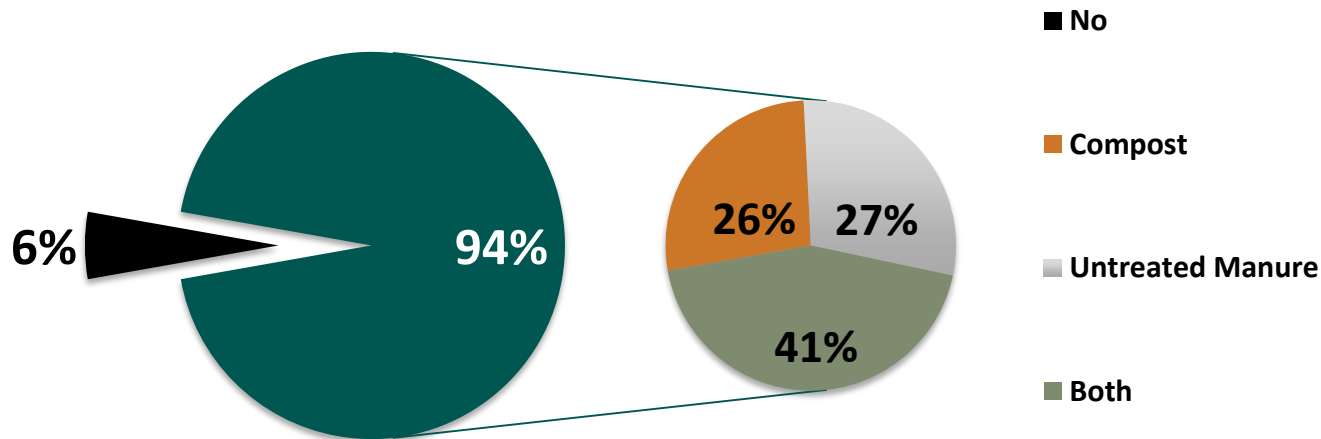


Biological Soil Amendments

Organic Producer Survey Results



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



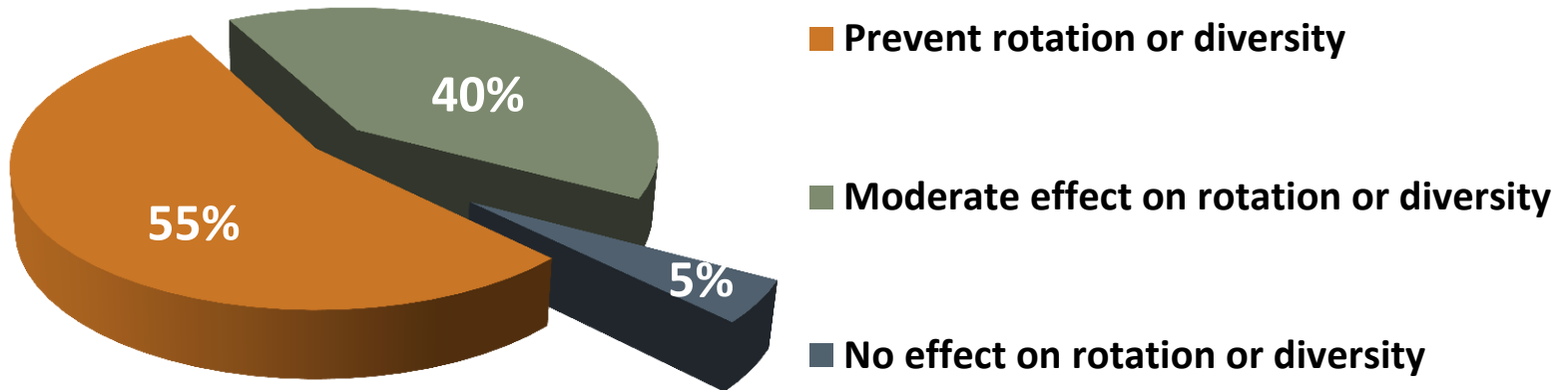


Biological Soil Amendments

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?



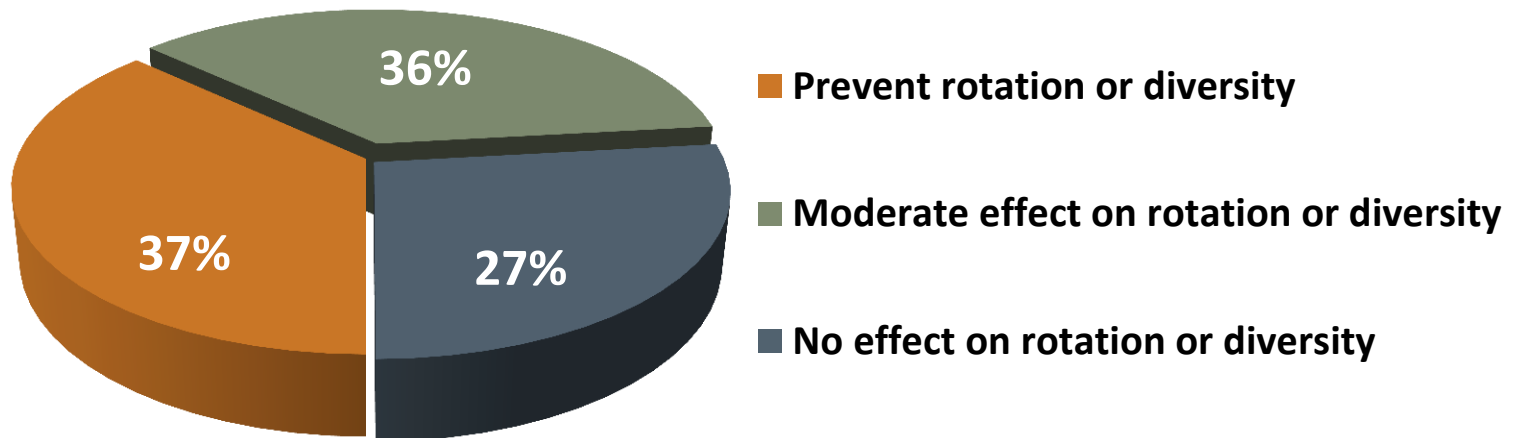


Biological Soil Amendments

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?



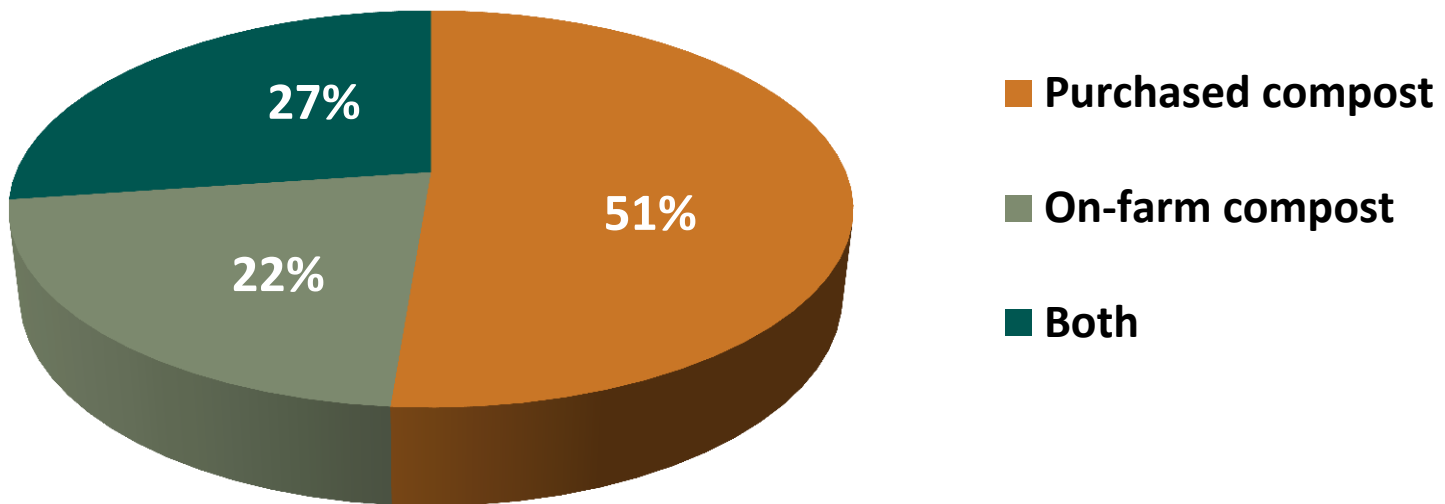


Biological Soil Amendments

Organic Producer Survey Results



What are the sources of compost used on organic farms?



APPENDIX B – OTA suggested revisions

Subpart F—Standards Directed to Biological Soil Amendments of Animal Origin and Human Waste

§ 112.51 What requirements apply for determining the status of a biological soil amendment of animal origin?

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

(b) A biological soil amendment of animal origin is untreated if it:

(1) Has not been processed to completion in accordance with the requirements of § 112.54, or in the case of an agricultural tea, 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 requirements of 112.44(a);

(2) Has become contaminated after treatment;

(3) Has been recombined with an untreated biological soil amendment of animal origin;

(4) Is or contains a component 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

(5) Is an agricultural tea that contains an agricultural tea additive.

§ 112.52 How must I handle, convey, and store biological soil amendments of animal origin?

(a) You must handle, convey and store any biological soil amendment of animal origin in a manner and location such that it does not become a potential source of contamination to covered produce, food-contact surfaces, areas used for a covered activity, water sources, and water distribution systems.

(b) You must handle, convey and store any treated biological soil amendment of animal origin in a manner and location that minimizes the risk of it becoming contaminated by an untreated or in-process biological soil amendment of animal origin.

(c) You must handle, convey, and store any biological soil amendment of animal origin that has become contaminated as if it was untreated.

§ 112.53 What prohibitions apply regarding use of human waste?

You may not use human waste for growing covered produce, except sewage sludge biosolids used in accordance with the requirements of 40 CFR part 503, subpart D, or equivalent regulatory requirements.

§ 112.54 What treatment processes are acceptable for a biological soil amendment of animal origin that I apply in the growing of covered produce?

§ 112.54 What treatment processes are acceptable for a biological soil amendment of animal origin that I apply in the growing of

covered produce?

Each of the following treatment processes are acceptable for a biological soil amendment of animal origin that you apply in the growing of covered produce, provided that the resulting biological soil amendments are applied in accordance with the applicable requirements of § 112.56:

- (a) A scientifically valid controlled physical process (for example, thermal), chemical process (for example, high alkaline pH), or combination of scientifically valid controlled physical and chemical processes that has been demonstrated to satisfy the microbial standard in § 112.55(a) for *Listeria monocytogenes* (*L. monocytogenes*), *Salmonella* species, and *E. coli* O157:H7;
- (b) A scientifically valid controlled physical process, chemical process, or combination of scientifically valid controlled physical and chemical processes, that has been demonstrated to satisfy the microbial standard in § 112.55(b) for *Salmonella* and fecal coliforms; or
- (c) A composting process that has been demonstrated to satisfy the microbial standard in § 112.55(b) for *Salmonella* and fecal coliforms. Scientifically valid controlled composting processes include:

(1) Aerated static composting that maintains aerobic (i.e., oxygenated) conditions at a minimum of 131 F (55 C) for 3 days and is followed by adequate curing, which includes proper insulation, storage, and handling practices;

(2) ~~Turned composting that maintains aerobic conditions at a minimum of 131 F (55 C) for 15 days, with a minimum of five turnings, and is followed by adequate curing, which includes proper insulation,~~ Composting that maintains a minimum average temperature of 131 °F (55 °C) or higher for 15 days or longer and is followed by adequate curing, storage and handling practices. During the period when the compost is maintained at 131 °F (55 °C) or higher, there shall be a minimum of five turnings of the windrow with a minimum of 3 days between turnings. The 15 or more days at or above 131 °F (55 °C) do not have to be continuous; or

(3) Other scientifically valid, controlled composting processes, provided you satisfy the requirements of § 112.12, including that the alternative process has been demonstrated to satisfy the microbial standard in § 112.55(b).

(d) A scientifically validated composting process in accordance with the requirements of § 112.54(c) that has been demonstrated to satisfy the microbial standard in § 112.55(a) for *Listeria monocytogenes* (*L. monocytogenes*), *Salmonella* species, and *E. coli* O157:H7.

§ 112.55 What microbial standards apply to the treatment processes in § 112.54?

The following microbial standards apply to the treatment processes in § 112.54 as set forth in that section. (a) For *L. monocytogenes*, *Salmonella* species, and *E. coli* O157:H7, the relevant standards in the table in this paragraph or;

(a) For *L. monocytogenes*, *Salmonella* species, and *E. coli* O157:H7, the relevant standards in the table in this paragraph or;

For the microorganism—	The microbial standard is—
(1) <i>L. monocytogenes</i>	Not detected using a method that can detect one colony forming unit (CFU) per 5 gram analytical portion.
(2) <i>Salmonella</i> species	Negative or less than detectible limit (<1/30 grams). Less than three most probable numbers (MPN) per 4 grams of total solids (dry weight basis).
(3) <i>E. coli</i> O157:H7	Negative or less than detectible limit (<1/30 grams). Less than 0.3 MPN per 1 gram analytical portion.

(b) Less than three MPN *Salmonella* species per four grams of total solids (dry weight basis); and less than 1,000 MPN fecal coliforms per gram of total solids (dry weight basis).

§ 112.56 What application requirements and minimum application intervals apply to biological soil amendments of animal origin?

(a) Except as provided in paragraph (b) of this section, you must apply the biological soil amendments of animal origin specified in the first column of the table in this paragraph in accordance with the application requirements specified in the second column of the table in this paragraph and the minimum application intervals specified in the third column of the table in this paragraph.

If the biological soil amendment of animal origin is—	Then the biological soil amendment of animal origin must be— applied	And then the minimum application interval is—
(1)(i) Untreated	For covered produce whose edible portion has direct contact with the soil surface or soil particles, applied in a manner that does not contact the harvestable or harvested part of the crop covered produce during application and minimizes the potential for contact with covered produce after application.	9 months 120 days.
(ii) Untreated	For covered produce whose harvestable portion does not have direct contact with the soil surface or soil particles, applied in a manner that does not contact covered produce during prevents potential contact with the harvestable or harvested part of the crop during or after application.	0 days 90 days.

<p>(2) Treated by a scientifically valid controlled physical or chemical process, or combination of scientifically valid controlled physical and chemical processes, in accordance with the requirements of § 112.54(a) to meet the microbial standard in § 112.55(a).</p>	<p>In any manner (<i>i.e.</i>, no restrictions)</p>	<p>0 days.</p>
<p>(3) Treated by a scientifically valid controlled physical or chemical process, or combination of scientifically valid controlled physical and chemical processes, in accordance with the requirements of § 112.54(b) to meet the microbial standard in § 112.55(b).</p>	<p>In a manner that minimizes the potential for contact with covered produce with the harvestable or harvested part of the crop during and after application.</p>	<p>0 days.</p>
<p>(4)(i) Treated by a composting process in accordance with the requirements of § 112.54(c) to meet the microbial standard in § 112.55(b).</p>	<p>For covered produce whose edible portion has direct contact with the soil surface or soil particles, applied in a manner that minimizes the potential for contact with covered produce with the harvestable or harvested part of the crop during and after application.</p>	<p>45 days.</p>
<p>(ii) Treated by a composting process in accordance with the requirements of § 112.54(c) to meet the microbial standards in § 112.55(b).</p>	<p>For covered produce whose edible portion does not have direct contact with the soil surface or soil particles, applied in a manner that prevents contact does not contact covered produce with the harvestable or harvested part of the crop during and after application.</p>	<p>0 days.</p>
<p>(iii) Treated by a scientifically validated composting process in accordance with the requirements of § 112.54(c) to meet the microbial standard in § 112.55(a)</p>	<p>Applied in a manner that minimizes the potential for contact with the harvestable or harvested part of the crop during or after application.</p>	<p>0 days.</p>

(b) You may establish and use alternatives to the minimum application intervals established in paragraphs (a)(1)(i) and (a)(4)(i) of this section, provided you satisfy the requirements of § 112.12.

§ 112.60 Under this subpart, what requirements apply regarding records?

(a) You must establish and keep records required under this subpart F in accordance with the requirements of subpart O of this part.

(b) For any biological soil amendment of animal origin you use, you must establish and keep the following records:

(1) Documentation of the date of application of any untreated biological soil amendment of animal origin (including raw manure) or any biological soil amendment of animal origin treated by composting to a growing area and the date of harvest of covered produce from that growing area, except when covered produce does not contact the soil after application of the soil amendment;

(2) For a treated biological soil amendment of animal origin you receive from a third party, documentation (such as a Certificate of Conformance) that:

(i) The process used to treat the biological soil amendment of animal origin is a scientifically valid process that has been carried out with appropriate process monitoring;

(ii) The applicable treatment process is ~~periodically~~ **routinely** verified through testing using a scientifically valid analytical method on an adequately representative sample to demonstrate that the process satisfies the applicable microbial standard in § 112.55, including the results of such periodic testing; and (iii) The biological soil amendment of animal origin has been handled, conveyed and stored in a manner and location to minimize the risk of contamination by an untreated or in process biological soil amendment of animal origin;

(3) For a treated biological soil amendment of animal origin you produce for your own covered farm(s), documentation that process controls (for example, time, temperature and turnings) were achieved.

(4) For a treated biological soil amendment of animal origin you produce for your own covered farm(s) that is treated in accordance with 112.56(a)(4)(iii), documentation that:

(i) The process used to treat the biological soil amendment of animal origin is a scientifically validated process that has been carried out with appropriate process monitoring;

(ii) The applicable treatment process is routinely verified through testing using a scientifically validated analytical method on an adequately representative sample to demonstrate that the process satisfies the microbial standard in § 112.55(a), including the results of such periodic testing; and (iii) The biological soil amendment of animal origin has been handled, conveyed and stored in a manner and location to minimize the risk of contamination by an untreated or in process biological soil amendment of animal origin;

~~(4)~~ (5) Scientific data or information you rely on to support any alternative composting process used to treat a biological soil amendment of animal origin in accordance with the requirements of § 112.54(c)(3); and

~~(5)~~ (6) Scientific data or information you rely on to support any alternative minimum application interval in accordance with the

requirements of § 112.56(b).

OTA comments on 0-day application interval option

Solutions for Safe Organic Produce

- The proposed 45-day waiting period following compost applications should only be applied to crops in contact with the soil, and alignment with USDA organic regulations (no waiting period) should be applied to crops not in contact with the soil.
- We believe that FDA intends to imply that treated or untreated biological soil amendments of animal origin should be applied in such a way to minimize or not contact the edible portion of a crop covered under the regulations. The phrase “minimizes the potential for contact” is also very problematic because the interpretations may vary significantly. OTA proposes that FDA adopt the language used in the NOP regulations. For compost, the application intervals would read as follows:
 - **45-days:** The biological soil amendment of animal origin must be, for covered produce whose edible portion has direct contact with the soil surface or soil particles, applied in a manner that minimizes the potential for contact with the harvestable or harvested part of the crop during and after application.
 - **0-days:** The biological soil amendment of animal origin must be, for covered produce whose edible portion does not have direct contact with the soil surface or soil particles, applied in a manner that prevents contact with the harvestable or harvested part of the crop during and after application.
- We also request that FDA include an additional option and allow a 0-day application interval for compost that meets the composting process described in §112.54(c) AND meets the following testing, curing, handling and record keeping criteria:
 - Testing of the finished compost, at the point of sale, to demonstrate the validity of the treatment process using established sampling protocol and testing procedures. The microbial standards in 112.55(a) is the most appropriate standard to use;
 - Applied in such a way that minimizes the potential for contact with covered produce during and after application (as per 112.52);
 - Storage and handling requirements (as per § 112.52);
 - *Curing (FDA Guidance to be developed on a measurement for stability/maturity)
 - Records to support the testing, established protocols, monitoring and training (as per §112.60(b)(4)).

The combination of meeting time and temperature, stability (curing), and microbial standards assures the risk of transmitting viable pathogenic organism is sufficiently minimized.

Per FDA proposed rule: **Curing means the maturation stage of composting, which is conducted after much of the readily metabolized biological material has been decomposed, at cooler temperatures than those in the thermophilic phase of composting, to further reduce pathogens, promote further decomposition of cellulose and lignin, and stabilize composition.*

Appendix C – USDA NOP Organic Regulations - 7 CFR 205.203 - 205

§ 205.203 Soil fertility and crop nutrient management practice standard.

(b) The producer must manage crop nutrients and soil fertility through rotations, cover crops, and the application of plant and animal materials.

(c) The producer must manage plant and animal materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances. Animal and plant materials include:

(1) Raw manure, which must be composted unless it is:

(i) Applied to land used for a crop not intended for human consumption;

(ii) Incorporated into the soil not less than 120 days (4 months) prior to the harvest of a product whose edible portion has direct contact with the soil surface or soil particles; or

(iii) Incorporated into the soil not less than 90 days (3 months) prior to the harvest of a product whose edible portion does not have direct contact with the soil surface or soil particles.

(2) Composted plant and animal materials produced through a process that (i) established an initial Carbon:Nitrogen ratio of between 25:1 and 40:1; and

(ii) Maintained a temperature of between 131 deg. F and 170 deg. F for 3 days using an in-vessel or static aerated pile system; or (iii) Maintained a temperature between 131 deg. F and 170 deg. F for 15 days using a windrow composting system, during which period the materials must be turned a minimum of five times.

§ 205.205 Crop rotation practice standard.

The producer must implement a crop rotation including but not limited to sod, cover crops, green manure crops, and catch crops that provide the following functions that are applicable to the operation:

(a) Maintain or improve soil organic matter content;

(b) Provide for pest management in annual and perennial crops;

(c) Manage deficient or excess plant nutrients; and

(d) Provide erosion control.

§ 205.206 Crop pest, weed, and disease management practice standard.

(a) The producer must use management practices to prevent crop pests, weeds, and diseases including but not limited to:

(1) Crop rotation and soil and crop nutrient management practices, as provided for in §§ 205.203 and 205.205.

(b), (c), (d).....

(e) When the practices provided for in paragraphs (a) through (d) of this section are insufficient to prevent or control crop pests, weeds, and diseases, a biological or botanical substance or a substance included on the National List of synthetic substances allowed for use in organic crop product may be applied to prevent, suppress, or control pests, weeds, or diseases: Provided, That, the conditions for using the substance are documented in the organic system plan.

ABSTRACT

This survey addresses the scientific basis of proposed hygiene rule changes potentially affecting organic growers due to the FDA Food Safety Modernization Act. Approximately 40 published scientific studies were examined which deal with pathogen survival after application of manure to soil and pathogen reduction during the composting process. The survey chose original studies that reported time frames for pathogen reduction and tabulated the average and standard deviation of best/worst case results (in days). The data were divided according to a focus on manure application or manure composting. The results 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 has proposed to significantly extend. Scientific data for compost studies also reveal wide variances in findings and although the reduction times for pathogens in composting are shorter than manure application ranges they are on average considerably longer than the 3/15-day limits taken from early EPA 40 CFR Part 503 material and which are presently used as NOP guidance. Therefore, the present challenge is to focus attention to upgrading existing composting rules and guidelines in order that they more clearly reflect current scientific findings.

INTRODUCTION

In order to assess what scientific studies say regarding pathogen survival in soil and manure environments it is very important to select from a wide variety of published reports. Current research increasingly reveals 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, such as lab scale versus field scale. However, the chief weight of the variability is likely 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 very 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)¹ 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

¹ Numbered references may be found in the Appendix “Pathogen Reduction Times (PRD) from Scientific Papers”

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, 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 contaminated manure application may be 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 also be interpreted as providing proof for strong ecosystem barriers or competitive factors operating in any 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 is produced each year and ultimately soil applied. An early, excellent and extensive review of the complexity of environmental factors influencing the fate of introduced microorganisms is by van Veen (1997) and a summary of the broad range of treatment options that reduce pathogens in manure is by Martens and Böhm (2009).

DISCUSSION

The pathogen reductions times reported by Mukherjee et al. (2006) are convenient as they closely corroborate existing NOP standards. In examining a larger range of published scientific reports it is possible to obtain a nearer estimate of what are likely to be reasonable, scientifically-derived standards. As indicated in the Appendix, 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 50 to 94 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. Other recent studies in what appear to be normal environments also show fairly long survival times of 217 and 231 days respectively for E. coli O157:H7 (Islam et al. 2005) and Salmonella (Islam et al. 2004) in soil with inoculated composts. These data were however produced on coastal plains soils of marginal fertility and using the same compost plus inoculum for each several published papers. This underscores the need to examine varying environments and materials.

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 virtually all similar studies reported in the literature - use manure or cattle artificially inoculated with pathogens such as Salmonella or E. coli O157:H7. This is justified in order to obtain sufficiently high detection of pathogen so that the study will be successful. Levels of inoculation such as 10^7 cfu per gram solids especially with Salmonella and E. coli O157:H7 are extremely unrealistic, however. Most analysts observing naturally present E. coli O157 or Salmonella in manures report 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 other unnatural circumstances of many studies, it is clear that several of the reported results have been obtained on a worst/worst case premise.

COMPOSTING STUDIES

Composting manure 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. This assumption dates back to the 1950's. In an early review of pathogen reduction Wiley (1962) cautioned in a fashion that would still seem partly true today 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 significantly on the EPA 40-CFR Part 503 rule ("EPA 503") (USEPA 1989, 1993) 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 that substantiates these short pathogen reduction times. However, a considerable effort was made under EPA sponsorship to document the relationship of fecal coliform and fecal streptococci as a surrogate tests for presence of Salmonella, from which the modern EPA rule on testing *Salmonella* or fecal coliform in sludge is based (see Janko 1988, USEPA 1989). In applying the EPA 503 rule to compost 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 a C:N requirement), and therefore is a somewhat weaker guideline.

Recent scientific data 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 – Ref #7) of Clemson University emphasize that pathogen inactivation during composting is very complex. The authors point out that other factors in addition to time x temperature are also important. These include 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 newly emerging thinking about multiple factors being of importance for composting beyond simple time x temperature rules.

The apparent discrepancy of scientific data for compost pathogen reduction compared to the original EPA Chap 503 guidelines has been discussed in 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 [EPA] 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 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. All these composts were of significant age. 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. A recent paper by Elsas (2012) provides evidence that pathogen survival in soils is inversely related to soil microbial richness. Soils on organic farms are significantly more biologically alive than conventional farms (Reganold et al. 1993, Mäder 2002, Brinton et al. 1979).

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 that turned windrow-composting functions better than static-compost for pathogen reduction. Pathogen reduction of turned composts required generally a range of time from 28 to 56 days and in some instances there was measurable survival of *E. coli* O157 out to 84 days. This appears to be the only study aside from Brinton et al. 2009 which examines naturally occurring pathogens instead of preparing artificially contaminated materials. In a somewhat similar approach, Shepherd (2011) examined minimally managed compost heaps and found survival times mostly in the 7 to 35 day range with *E. coli* O157 survival to 60 days on edges (tails) of composts.

A clear impression is gained in examining the field “real-world” compost studies compared to lab-studies, the latter involving incubators, chambers and pouches inserted into artificially heated composts. Lab studies appear to report short reduction times (hours to days) and the field studies significantly longer (weeks into 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), selective heat-survival, and accumulation of pathogenic spore formers due to hot composting (Böhnelt and Lube, 2000). In other words, environmental factors tend to contribute to lengthened survival.

SUMMARY AND RECOMMENDATIONS

Based on this survey of scientific findings there appears to be 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 very consistent with if not slightly more lenient to requirements presently used within the NOP. Virtually all scientific studies examined herein employ unnatural scenarios such as placement of sachets of artificially contaminated manure in small lab vessels and heating constantly, or inoculation of manures with levels of pathogens several orders of magnitude higher than would be normally encountered. For example, in over 10 years pathogen testing Woods End Laboratories has only encountered about 6 positive samples of *Salmonella* in compost out of hundreds tested and the quantities observed for positive samples were close to the reporting MLD of < 3 cells in 4g. Similarly, in examining commercial compost from 94 facilities, while 6% tested positive for *E. coli* O157:H7, only one sample could be quantified at 10^5 MPN/g; all others were very close to the minimum detection of 4.0 - 6.8 MPN/g TS.

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

A simple resolution would be to require the overall length of time for composting (plus curing) 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 newer 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. Pathogen regrowth has been a theme from the very beginning (Janko, 1988) but involves more complicated testing than routine pathogen counts and perhaps for this reason has not taken hold. 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 mentioned but vaguely 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 ÖNORM standards for compost (2005) require multi-phasic testing assuming detection thresholds of 1 cell in 50g fresh compost, the results to be compared to an end-use risk matrix (see Appendix I). ÖNORM considers commercial bagged compost and hobby-gardening with compost to be the highest risk group. The importance of considering end-use categories is reflected in a recent US study specifically examining pathogen transfer to plants under casual gardening practices (Erickson et al 2013).

To address composting curing issues, there is evidence that scientists have described a variety of Maturity Index standards for compost completeness (CalRecycle 2001), none of which has taken hold in the USA. An index by definition requires more than one indicator, a precautionary principle based on the concept of triangulation to avoid a single lab test being applied dogmatically and therefore very inaccurately. 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. <>

This paper is a contribution to the Organic Trade Association and organic farmers worldwide.

William Brinton M.D.

Director – Woods End Farm & Laboratories Inc.

Faculty Associate,
University of Maine

The author declares no conflict of interest.

Appendix I ONORM (Austrian) Compost HYGIENE MATRIX

APPENDIX II, tabulation of surveyed studies with numbered references #1-29

ADDITIONAL REFERENCES

1. Austrian Standards Institute (ONORM). 2005. Compost Hygiene Recommendations [Kompost—Hygieneanforderungen] —E. coli, Salmonella sp., Listeria sp., Campylobacter sp. [Probenahme, Untersuchungsmethoden, Ergebnisdarstellung]. S 2204. Ed. Österreichisches Normungsinstitut, Vienna. Available at: <http://www.on-norm.at/publish/home.htm>. (summary attached)
2. Brinton W, P. Storms and C Blewett (2009) Occurrence and Levels of Fecal Indicators and Pathogenic Bacteria in Market-Ready Recycled Organic Matter Composts. *Journal of Food Protection*, Vol. 72, No. 2, 2009, Pages 332–339
3. Brinton, W 2002. Compost Quality and Management Issues. *Resource Recycling* June 2002
4. Brinton, W 2010. Characterizing Compost Completeness. *Biocycle* Vol 2:30-34
5. Brinton et al. 1979. Effects of organic and inorganic fertilizers on soils and crops: results of a long term field experiment in Sweden. Research Report Nordisk Forskningsring, Järna, Sweden
6. Commission of the European Communities. 2002. Regulation (EC) no. 1774/2002 of the European Parliament and of the Council 3 October 2002 laying down health rules concerning animal byproducts not intended for human consumption. *Off. J. Eur. Communities* L273.
7. CalRecycle. 2001. Compost Maturity Index. Dr. Buchanan Chair. Available at: www.calrecycle.ca.gov/organics/products/quality/compmaturity.pdf
8. Droffner, M. L., and W. F. Brinton. 1995. Survival of E. coli and Salmonella populations in aerobic thermophilic composts as measured with DNA gene probes. *Zentralblatt Hygiene Umweltmed.* 197:387-397.
9. Droffner, M. W. Brinton and E Evans (1995) Evidence for the prominence of well characterized mesophilic bacteria in thermophilic (50–70°C) composting environments. *Biomass and Bioenergy* Volume 8, Issue 3:191–195
10. Elsas, J van D., M Chiurazzia, C. A. Mallona, D. Elhottova V. Krištufek, and J. Falcão Salles. 2013. Microbial diversity determines the invasion of soil by a bacterial pathogen. *PNAS* vol. 109: 4 1159–1164
11. Erickson, et al. (2013) Fate of Escherichia coli O157:H7 and Salmonella in soil and lettuce roots as affected by potential home gardening practices. *J Sci Food Agric* 93: 3841–3849

12. Franz et al. 2008. Manure-amended soil characteristics affecting the survival of *E. coli* O157:H7 in 36 Dutch soils. *Environmental Microbiology* (2008) 10(2), 313–327
13. Gong, C et al. 2005. Survival of pathogenic bacteria in compost with special reference to *E. coli*. *Jrnl of Environ. Sci* 17:770-774
14. Islam, M., M P. Doyle, S C. Phatak, P Millner, X Jiang. 2005. Survival of *Escherichia coli* O157:H7 in soil and on carrots and onions grown in fields treated with contaminated manure composts or irrigation water. *Food Microbiology* 22:1, 63-70.
15. Islam, M., M P. Doyle, S C. Phatak, P Millner, X Jiang. 2004. Persistence of *Salmonella enterica* Serovar Typhimurium on Lettuce and Parsley and in Soils on Which They Were Grown in Fields Treated with Contaminated Manure Composts or Irrigation Water. *Foodborne Pathogens And Disease* Vol 1:1-27-35
16. Janko, W.A. (1988) Occurrence of Pathogens in Distribution and Marketing Municipal Sludges. EPA -600/1/1-87/014. Sponsoring Agencies: HERL, ORD, USEPA. Available by NTIS Springfield VA
17. Kim, J F Luo, and X Jiang. (2009) Factors Impacting the Regrowth of *Escherichia coli* O157:H7 in Dairy Manure Compost *J. Food Prot.*, Vol. 72, No. 7
18. Martens W. and R. Böhm (2009) Overview of the ability of different treatment methods for liquid and solid manure to inactivate pathogens. *Bioresource Technology* Vol 100:22 5374–5378
19. Mäder, P., Fließbach, A., Dubois, D., Gunst, L., Fried, P., Niggli, U., 2002. Soil fertility and biodiversity in organic farming. *Science* 296, 1694–1697.
20. NOP Rule (2000) U.S.D.A. Agricultural Marketing Service. National Organic Program. 7 CFR Part 205. U.S. Department of Agriculture, Agricultural Marketing Service, Washington, DC.
21. Reganold, J., A. S. Palmer, J. C. Lockhart, A.N.I Macgregor. *Science* Vol 260 344-349.
22. Semenov, A. V., E. Franz, L. Van Overbeek, A. J. Termorshuizen, and A. H. C. Van Bruggen. 2008. Estimating the stability of *Escherichia coli* O157:H7 survival in manure-amended soils with different management histories. *Environ. Microbiol.* 10:1450–1459.
23. Shepherd, M. 2011 Developing Strategies to Control Human Pathogens in Minimally–Maintained Dairy Manure–Based Compost Heaps. Doctoral Dissertation. Clemson University
24. Singh, R. 2011. Thermal Inactivation Of Stress Adapted Pathogens In Compost. Doctoral Dissertation In Microbiology. Clemson University
25. USEPA. 1989. United States Environmental Protection Agency, CFR-40 Chap 503 Proposed Rule. Sludge Guidelines. Sept 1989 Federal Register; Revised and published as CFR-40 Chap 503. Final Rule. Feb 1993
26. Van Veen, van Overbeek, van Elsas. 1997. Fate and Activity of Microorganisms Introduced into Soil. *Microbiology and Molecular Biology Reviews*, 61:121–135
27. Wichuk and McCartney (2007) A review of the effectiveness of current time–temperature regulations on pathogen inactivation during composting. *J. Environ. Eng. Sci.* 6: 573–586

REQUIREMENTS AND INTERPRETATION OF ÖNORM COMPOST TEST RESULTS

Table 1 – Minimum Test Requirements and Compost Application and Handling Conditions in Dependence on Microbiological Test Results

COMPOST GROUP	Salmonella sp.	E. coli (EHEC Serovar 0157:H7)	Campylobacter sp.	Listeria sp.
Bagged Commercial	0 §	0	0	0
Recreation areas, school playgrounds, parks, sports arenas	0	0	0	0
Home Gardening	0	0	X ‡	X
Erosion control, surfaces with surface water potential, dikes, dams, embankments	0	0	X	X
Pasture and hay land (forage harvesting)	0	Curing and Re-testing or 6-weeks holding-time before use ¹⁾	X	X
Cultivated soils – Field forage production	0	Curing and Re-testing or 6-weeks holding-time before use ¹⁾	X	X
Cultivated soils – field veges near soil, small fruits, gardening, (exception of ornamentals)	0	Only for preceeding crops ¹⁾	X	X
Cultivated soils – other harvested field crops	0	Plowing under ¹⁾	X	X
Wine grapes, Fruit, Hops	0	Curing and Re-testing or 6-weeks holding-time before use ¹⁾	X	X
Horticulture – Ornamentals	0	No limitations on use	X	X
Christmas Trees	0	No limitations on use	X	X
General Landscaping	0	X	X	X
Reclamation and landfill cover	0	X	X	X
Bio-filter material	X	X	X	X
§ 0 ... may not contain any detectable bacteria at the method MLD (<1/50g as is compost) ‡ X ... Not required for testing ¹⁾ In case of a positive detection of E. coli the stated handling measures take effect.				

Scientific Papers examining reduction of manure and compost pathogens (E. coli; E.coli O157:H7; Salmonella, Listeria spp)

Color Keys: compost study manure study

ITEM	Pub Date	Authors	Primary Institution	Focus - Abbreviated Title	Days to disappearance		FDA#
					best case	worst case	
1	May-02	Jiang, Morgan, Doyle	Center for Food Safety	Manure-E.coli-O157 loss in soils	42	193	191
<p><i>Fate of Escherichia coli O157:H7 in Manure-Amended Soil. APPLIED AND ENV. MICROBIOLOGY, May 2002, p. 2605–2609 Vol. 68, No. 5</i></p>							
2	Nov-04	Ingham et al	Univ. of Wisconsin	E. coli loss in manure fertilized soils	100	168	
<p><i>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</i></p>							
3	Oct-03	Jiang, Morgan, Doyle	Center Food Safety	Compost inactivation of E. coli O157	1	6	
<p><i>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</i></p>							
4	Jan-05	LeJeune and Kauffman	Ohio State Ag. R & D	O157 survival cattle bedding	13	22	
<p><i>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.</i></p>							
5	May-05	Johannessen et al	Natl Veterinar Inst (Oslo)	O157 in greenhouse soils and lettuce	56	84	
<p><i>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.</i></p>							
6	Jul-11	Rogers et al	Clarkson U, Pottsdam, NY	Pathogen decay in Manured Soils	55	120	
<p><i>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.</i></p>							

ITEM	Pub Date	Authors	Primary Institution	Focus - Abbreviated Title	best case	worst case	FDA#
7	Jun-11	Singh et al	Clemson U. Bio Dept		1	5	
<p><i>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.</i></p>							
8	Jul-96	Wang, Zhao and Doyle	Center for Food Safety	O157 fate in Bovine Feces	49	70	198
<p><i>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.</i></p>							
9	Sep-98	Kudva, Blanch and Hovde	U. Idaho, Moscow, ID	O157 Fate Manure/Slurry Var. Temp	47	120	177
<p><i>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.</i></p>							
10	Nov-99	Fukushima et al	PHI Shimane Prefecture	O157 Survival Bovine Feces	7	126	
<p><i>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.</i></p>							
11	Jul-01	LeJeune, Besser, Hancock	WSU Vet School	O157 survival cattle troughs	180	245	
<p><i>LeJeune, J.T., T.E. Besser, D.D. Hancock. Cattle Water Troughs as Reservoirs of Escherichia coli O157. Appl. Environ. Microbiol. Jul 2001.67.07.3053-3057</i></p>							
12	Sep-04	Hutchinson et al	Direct Labs. Ltd, UK	O157 decline livestock waste soil	15	60	
<p><i>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</i></p>							
13	Nov-05	Davis et al	U. Idaho, Moscow, ID	O157 Survival cattle bedding	35	60	
<p><i>Davis, M.A. et al. Escherichia coli O157:H7 in Environments of Culture-Positive Cattle. Nov 2005. Appl. Environ. Microbio. 71.11.6816-6822.</i></p>							
14	Feb-05	Hutchinson et al	Direct Labs. Ltd, UK	Pathogen Fate spread onto Fescue	2	63	
<p><i>Hutchinson et al. Fate of Pathogens Present in Livestock Wastes Spread onto Fescue Plots. Feb 2005. Appl. Environ. Microbiol. 71.02.691-696.</i></p>							

ITEM	Pub Date	Authors	Primary Institution	Focus - Abbreviated Title	best case	worst case	FDA#
15	May-04	Nicholson et al	ADAS Gleadthorp UK	Pathogen Survival land application	30	64	
<p><i>Nicholson, F. , S.J. Groves, B.J. Chamber. Pathogen Survival During Livestock Manure Storage and Following Land Application. May 2004. Elsevier Ltd. Online.</i></p>							
16	Jun-09	Erickson et al	Center Food Safety	Inactivation of Salmonella in manure	3	4	
<p><i>Inactivation of Salmonella spp. in cow manure composts formulated to different C:N ratios . Bioresource Technology 100 (2009) 5898–5903</i></p>							
17	Apr-07	Franz et al	Wageningen University	Manure from Organic vs Conv Farms E.coli	94	109	
<p><i>Prevalence of Shiga Toxin-Producing Escherichia coli in Manure from Organic and Low-Input Conventional Dairy Farms . APPLIED AND ENVIRONMENTAL MICROBIOLOGY, Apr. 2007, p. 2180–2190 Vol. 73, No. 7</i></p>							
18	Aug-05	Mukherjee et al	Food Sci., Univ. Minn	ECO157 transfer from soil appl. Manure	69	92	
<p><i>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</i></p>							
19	Jan-13	Berry et al	USDA Animal Research Ctr	Fate during Minimally Managed composting	28	84	
<p><i>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</i></p>							
20	Apr-10	Wei et al	Dept Food Sci Univ DE	Fate of Viruses during Manure Composting	1	9	
<p><i>Fate of Human Enteric Viruses during Dairy Manure–Based Composting . Journal of Food Protection, Vol. 73, No. 8, 2010, Pages 1543–1547</i></p>							
21	Dec-07	Shepherd et al	Center Food Safety		5	120	
<p><i>Fate of Escherichia coli O157:H7 during On-Farm Dairy Manure-Based Composting . Journal of Food Protection 70.12: 2708-2716</i></p>							
22	Apr-09	Erickson et al	Center Food Safety	Pathogen Inactivation in Composting	1	4	
<p><i>Pathogen Inactivation in Composting . Compost Sci Util Vol 17:229-236</i></p>							

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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	2009	Shepherd, W	Clemson Univ Doctorate	Compost Methods for Pathogen Reduction	7	60	
26	2005	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							
27	2004	Islam et al.	Center Food Safety	Persistence E.coli-O157 from Compost	154	217	104
Persistence of EHEC O157:H7 in Soil and On Leaf Lettuce and Parsley Grown in Fields Treated with Contaminated Manure Composts or Irrigation WaterJornal Food Prot. 67:7							
28	2004	Weil et al	Penn State University	Destruction Pathogens Mushroom Compost	1	6	183
DESTRUCTION OF SELECT HUMAN PATHOGENIC BACTERIA IN MUSHROOM COMPOST DURING PHASE II PASTEURIZATION, Poster presented at the 2004 ISMS/NAMC conference in Miami, Florida 2004							
29	2010	Shepherd et al.	Clemson Univ.	Heat Shock Reduction of Compost E. coli	5	60	168
Effect of heat-shock treatment on the survival of Escherichia coli O157:H7 and Salmonellaenterica Typhimurium in dairy manure co-composted with vegetable wastes under field conditions. Bioresource Technology 101 (2010) 5407–5413							
30	2003	Liao et al.	USDA MRCS Maine	Pathogens in potato soil from manure	40	70	
Occurrence of gastrointestinal pathogen in soil of potato field treated with liquid dairy manure. Food Agric. Environment Vol 1:2:224-228							

Note * FDA # refers to FDA cited literature from the Federal Register Vol 78 No 11 January 16 2013

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SUMMARY OF FINDINGS

MEAN OF PATHOGEN REDUCTION DAYS (PRD)**Manure based products**

number of examined studies
20

Manure Average PRD

standard deviation (SD) of mean, days

	BEST	WORST
	50.0	94.2
	49.8	68.7
1) Average case + one SD	100	163
2) Average of all Best/Worst Case Scenarios		72
3) Average margin of error estimating reduction		59
4) <i>Suggested safety set-back in days based on average plus SD margin of error (2) + (3)</i>	DAYS	131.3

For Manure Composting

soil applied and planted
number of examined studies
11

Compost Average PRD

standard deviation of mean, days

	BEST	WORST
	3.5	36.3
	7.5	38.3
1) Average worst case + one SD		75
2) Average of all Best/Worst Case Scenarios		20
3) Average margin error to estimate reduction		23
4) <i>Suggested safety set-back in days based on average plus SD margin of error (2) + (3)</i>	DAYS	42.8

Disclaimer: This survey does not purport to have examined ALL published scientific studies. Studies eligible for inclusion in this survey reported original observed data for days of reduction for manure and compost pathogens