National Sustainable Agriculture Coalition

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Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Docket No. FDA-2016-N-0321

Submitted electronically via http://www.regulations.gov

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

On behalf of the represented member organizations of the National Sustainable Agriculture Coalition (NSAC), I submit the following comments to the request for comments, scientific data, and information to develop a risk assessment of foodborne illness associated with pathogens from produce grown in fields amended with untreated biological soil amendments of animal origin. NSAC welcomes the opportunity to submit comments, and looks forward to working with the Food and Drug Administration as the agency undertakes the research and risk assessment necessary to develop science- and risk-based standards for the application of untreated manure.

Sincerely,

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I. INTRODUCTION

The National Sustainable Agriculture Coalition (NSAC) welcomes the opportunity to submit comments regarding FDA's risk assessment of foodborne illness associated with pathogens from produce grown in fields amended with untreated biological soil amendments of animal origin (Docket No. FDA-2016-N-0321).

NSAC is an alliance of grassroots and farmer based organizations that advocate for federal policies and programs that support small and mid-size family farms, protect natural resources, promote vibrant rural communities, and ensure healthy food access through local and regional food system development. Many of our member organizations work directly with sustainable farmers, including farmers using organic production practices. NSAC has actively engaged in the FSMA rulemaking process with an eye toward ensuring that FDA's new food safety rules can achieve public health goals while supporting sustainable farms and food systems.[1]

This docket sets in motion the next several years of FDA's work to assess, research, and ultimately propose new standards that regulate how farmers use biological soil amendments, like raw manure. NSAC is strongly supportive of FDA's approach to undertake a thorough risk assessment and support additional research to fill knowledge gaps in the risks associated with various manure types and production methods - while taking into consideration regional and ecological variations - and we are pleased to see FDA begin this process so soon after finalizing the Produce Rule.

The information sought through this docket will inform the development of FDA's risk assessment model, which will provide the foundation for FDA's work on this topic going forward. We therefore believe it essential that FDA have as much information as possible demonstrating the many ways in which produce farmers use manure on their fields, so that the risk assessment considers the full range of uses and scenarios among farmers, and that research is supported to address the significant gaps in data and scientific understanding necessary to ensure a robust risk assessment. In particular, and discussed in more details below, our assessment of the available literature leads us to the conclusion that there are significant gaps in the research that are necessary to account for variations in animal husbandry, feed content and manure application in a field or agricultural context, making it difficult to interpret the risk of pathogen presence. We therefore urge FDA to work with the sustainable agriculture research community to evaluate the differences in pathogen presence and persistence resulting from different management practices (such as pastured livestock versus confined livestock) and organic systems versus conventional systems.

We appreciated the extra time provided to undertake the research needed to comment. We used the extra time to develop a survey targeting farmers nationwide that use manure in the production of covered produce. This survey was disseminated by NSAC member organizations, and through NSAC's own network. Despite the busy time of year for farmers, over 400 responded to the survey. We integrate the findings of this survey into our comments below.

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[1] Attached as an appendix are our comments on the biological soil amendment standards submitted to the 2013 Proposed and 2014 Supplemental Produce Rule. These comments provide additional detail regarding on-farm practices, and also include a review of the scientific literature through 2013.

II. GENERAL COMMENTS

NSAC and our members have been deeply involved in the FSMA rulemaking process, and Produce Rule standards governing the use of biological soil amendments of animal origin (BSAAOs) have been a point of particular importance and concern to the sustainable agriculture community. Many farmers that NSAC and our members work with and represent choose to use raw and composted animal manures; such practices are widely used by farmers – especially sustainable farmers, including farmers that are certified organic – to manage soil, nutrients, fertility, and pests. Indeed, FDA notes in the Federal Register notice that "produce farms use untreated BSAAO for various reasons, including that they are inexpensive, readily available, and rich nutrient sources for growing crops."

Farmers need to use fertilizer to grow crops, and there are two main types of nitrogen fertilizers: chemical fertilizers and biologically based fertilizers (including most importantly on-farm resources, such as manure, compost, and legume cover crops). Sustainable and certified organic farmers choose to use – and in the case of certified organic production, must use – biologically based fertilizers as the major nutrient sources in crop production. As an example of the widespread use of these amendments, USDA's National Agricultural Statistics Service 2014 Organic Production Survey (OPS), which surveyed all types of organic growers and not just produce, found that 66 percent of certified organic farms use green or animal manures, and that 47 percent of certified organic farmers use organic mulch or compost.[2]

These practices are fundamental and foundational aspects of sustainable and organic production systems that cannot simply be replaced by the use of synthetic inputs. Indeed, consumer advocates and farming organizations alike agree that soil health is improved through the use of biological soil amendments, and that the use of animal manure recycles nutrient resources, helps ensure that soils contain sufficient nutrients and organic matter to promote high-yielding, healthy crops, and plays a particularly important role on sustainable and organic farms.[3] Biologically based fertilizers serve multiple functions in a production system, including, but not limited to providing fertility.

According to our survey respondents, the number one reason why they apply untreated manure to their crops is to "improve organic matter and soil health" (194 responses, or 56%). This is significant in relation to risk mitigation, given that improving soil health can also promote attenuation of pathogens in soil. Many farmers also said they do so to "fulfill crop nutrient needs" (70 responses; 20%). Some farms also use manure as part of their nutrient management plans (17; 5%), or as a waste management strategy (13; 4%).

Of our total survey respondents, 369 responded to questions regarding the average percentage of their nutrient needs that are met by using untreated or un-composted manure. The aggregate responses are as follows:

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[2] USDA National Agricultural Statistics Service, **2014** Organic Production Survey.

[3] See Appendix, Joint Letter.

Q: On average, what percentage of your crop nutrient needs are met through the use of untreated manure or un-composted manure?		
Answer Options	**Response Percent**	**Response Count**
0%	25.42%	76
1-10%	26.42%	79
15-25%	13.38%	40
30%	3.68%	11
50%	12.04%	36
75%	11.71%	35
100%	7.36%	22

These responses varied geographically, with 36 percent of North Central respondents indicating that between 50-100 percent of their crop nutrient needs were met with untreated/un-composted manure; 31 percent of Northeastern respondents; 24 percent of Western respondents; and 16 percent of Southern respondents.

A common theme that has arisen during our analysis of survey responses, and is present throughout our comments here, is the great diversity of conditions and practices reported by farmers based on their location and the specifics of their farming operation, which makes it very difficult to generalize about practices or proposed mitigation strategies. Indeed, this diversity not only points to additional areas of research requiring further inquiry, but it makes the strong case for a robust and comprehensive risk assessment that considers a wide range of agricultural, environmental, regional, and other factors – and suggests that there ultimately may need to be more than one appropriate application interval based on these factors.

We therefore are pleased to see FDA's continued recognition that pathogens that can be found in BSAAOs "once introduced to the growing environment, may be inactivated **at a rate that is dependent upon a number of environmental, regional, and other agricultural and ecological factors."** (emphasis added). We also appreciate FDA's acknowledgement that any "required application intervals for certain uses of untreated BSAAO could influence the number of crop cycles a farm is able to undertake each year and/or the choices farms make regarding which type of amendment to apply (*e.g.,* raw manure, composted manure, or other nutrient sources)." This risk assessment must consider a wide range of climatic scenarios, ecological factors, and management decisions in order to inform the development of an appropriate application interval(s); where data or information does not exist to provide sufficient explanation of these factors in various combinations, FDA must work with USDA, sustainable agriculture researchers, and other stakeholders to obtain that information.

III. COMMENTS ON ON-FARM PRACTICES

NSAC and our members conducted an informal survey from April 15 – June 3, 2016. We circulated an online and print survey through our members and through social media, targeting farmers that grow covered produce and use untreated BSAAOs in doing so. We received over 400 responses.

This survey is not definitive, nor was it formally carried out using statistical sampling methods. Rather, a dozen national, state, and regional NSAC member organizations distributed the survey through their newsletters and farmer email lists, and NSAC did the same. In order to receive helpful responses, we had to translate the questions or areas of information FDA posed in the docket. While in general this appeared successful, one particular area that continues to be a source of confusion for farmers are FDA's definitions of "untreated" versus "treated" manure, which we expound upon in more detail in the following section.

A. Aged Manure

We raised the issue during the Produce Rule rulemaking that FDA's definitions of "untreated" and "treated" BSAAOs was confusing and unnecessarily limiting,[4] and we were disappointed that this issue was not addressed in the final rule. We continue to encourage the agency to clarify its classifications of manure, and to move beyond the binary approach set forth in the rule, and we believe this process provides that opportunity.

Currently, FDA considers manure either "treated" or "untreated," with untreated essentially including any amendment with animal-derived components that has not been treated according to FDA's specified biological, chemical, or physical processes. This means all "untreated" BSAAOs are lumped into the same risk category as raw manure. We do not believe there is sufficient science to support a black and white definition of untreated versus treated manure, particularly with regard to such methods as aged and field stacked manure, or other passive composting methods. We therefore believe there is a significant need to explore this topic further, in order to ascertain whether all "untreated" manure should be classified as if it posed the same risk.

One fact our survey made abundantly clear is that – regardless of FDA's definitions – many farmers do not consider aged manure – that is, manure that has been piled up or stacked and left alone to decompose for a period of time (without monitoring for temperature - except by touch - or turning) –the same as untreated manure. Similarly, farmers that compost manure in a manner not aligned with FDA's definition of compost do not necessarily consider themselves as using "untreated" or "raw" manure.

Q: What type of manure products do you use?		
Answer Options	**Response Percent**	**Response Count**
Untreated	24.8%	77
Composted (purchased; labeled or marketed as composted or treated)	4.5%	14
Composted (purchased; not labeled or marketed as composted)	0.3%	1

[4] See Appendix B, C.

Composted (on-farm; with records)	5.8%	18
Composted (on-farm; without records)	29.9%	93
Aged or Stacked	25.7%	80
Compost tea	9.0%	28
Total Responses	**100.0%**	**311**

When asked to provide detail on the aging processes for those farms that identified using aged manure, we received the following responses, with 47 percent of respondents that age their manure do so for at least a year before using it:

Duration of Aging Process (mos.)	**Occurrences**	**Percentage**
36	1	2%
24	10	16%
12	18	29%
9	2	3%
6	13	21%
4	10	16%
3	6	10%
0	2	3%
Total Responses	**62**	100%

Given the prevalence of this practice among farmers using BSAAOs and the lack of data on pathogen persistence, we strongly urge FDA to consider the use of manure in this risk assessment as a spectrum of pathogen-attenuating treatments, not a black and white issue of "untreated" or "treated" until additional research is done. If, as a result of additional research into this subject, a risk assessment demonstrates that aged manure *should* be characterized and regulated the same as raw manure, then it would be appropriate to do so. But, absent such data, we strongly recommend that the agency's risk assessment reflect the varying risks posed by manure that may not meet FDA's definition of "treated," but also may not require the same precautions as truly raw manure. This is an area where the gaps in scientific understanding can and should be filled during this research and risk assessment process. We urge FDA to add this issue to its research agenda and work with USDA, university researchers, and other sustainable agriculture stakeholders.

B. Regional Usage

FDA requested comments on the "extent to which untreated BSAAOs are used in different regions in the United States." As noted above, we received 400 responses to our survey. Twelve percent of respondents were from the Western region[5], 36 percent from the Southern, 14 percent from the North Central region, and 38 percent from the Northeast. Roughly 70 percent of all respondents

[5] We based these geographic groupings on the four SARE regions, see http://www.sare.org/About-SARE/SARE-s-Four-Regions.

farm less than 50 acres. Over one-quarter (26 percent) farm between 50 – 500 acres, and less than three percent farm over 500 acres. Of the farms with over 500 acres in production, nearly all were either Certified Organic or Transitioning to Organic, meaning they are required to follow the National Organic Program application intervals for the use of raw and composted manure. Moreover, all of the transitioning farms over 500 acres were either USDA, Harmonized, or Global GAP certified, as were some of the Certified Organic farms.

C. Types of BSAAOs and Relevant Biological, Physical, and Chemical Parameters

FDA requested comments on the "types of untreated BSAAO and the soil type, and associated physical and chemical parameters (including but not exclusive to nutrient content, moisture and pH); and the crops typically grown in each BSAAO-amended soil type."

Poultry litter is the most commonly used among our survey respondents that identified only using one type of manure. However, over 40 percent of respondents use a mix of manure types. This includes anything from using all four types of manure FDA identified, to some combination of the four, as well as various combinations that also include goat, sheep, and rabbit manure.

Q: What type of manure do you use?		
Answer Options	**Response Percent**	**Response Count**
Cattle/Steer manure	14.7%	47
Poultry litter	22.9%	73
Swine slurry	0.9%	3
Horse manure	18.8%	60
Mixed/Other (please specify)	42.6%	136
Total Responses		**319**

A majority of respondents (over 60 percent) source BSAOOs from their own farm.

Q: Where does your manure or manure product come from?		
Answer Options	**Response Percent**	**Response Count**
From on-farm sources	61.9%	198
From off-farm source	36.9%	118
Don't know	1.3%	4
Total Responses		**320**

And of the farms that use on-farm manure, a significant majority use manure from pastured animals.

Q: Where does your manure or manure product come from?			
Answer Options	**From on-farm sources**	**Response Percent**	**Response Count**
Pastured, at least part of the year	169	85.8%	169

Not pastured	7	3.6%	7
Mixed	18	9.1%	18
Don't know	3	1.5%	3
Total Responses			**197**

This response indicates the need for a risk assessment to look at the varying risks posed by manure from pastured animals versus animals kept in confinement.

For farms that used on-farm manure, 47 percent reported that they used manure that had been composted on-farm, but without records. Many others reported using untreated (39 percent) and aged manure (41 percent). The range of aging times were described above.

Q: If you indicated using on-farm manure, which type(s) of manure product do you use?		
Answer Options	**Response Percent**	**Response Count**
Untreated	39.1%	77
Composted (purchased; labeled or marketed as composted or treated)	7.1%	14
Composted (purchased; not labeled or marketed as composted)	0.5%	1
Composted (on-farm; with records)	9.1%	18
Composted (on-farm; without records)	47.2%	93
Aged or Stacked	40.6%	80
Compost tea	14.2%	28
Total Responses*		**311**

Thirty-two percent of respondents are USDA Organic Certified farmers and twenty percent indicated that they are in transition to USDA organic – therefore they are bound to follow National Organic Program requirements for raw and composted manure. Forty-seven percent of respondents were Certified Naturally Grown, which also follows the National Organic Program standards for raw and composted manure. However, for those farms that were not certified organic and that composted on-farm without records, the range of methods for composting manure varied significantly. Regarding time and temperature, there was also a range, including a number of responses ranging from:

- 125°F for 180 days
- 120 – 150°F for 90 days
- 140-160°F for 42 days
- 130-150°F for 15 days
- 140°F for 14 days

Both temperature and duration of the composting process affect the degree to which pathogen numbers are reduced or eliminated in the final product, so that a long, relatively cool composting cycle may be as effective as a brief, hot one. While many growers do not have the infrastructure (state-of-the-art compost turners, monitoring equipment) to ensure a composting process that meets

* Responses exceed 100% because respondents could select more than one option.

NOP or FDA criteria for finished compost, they can potentially reduce risk by implementing longer composting cycles. We believe these considerations, illustrated by the survey responses cited above, again point to the need for FDA to revisit the binary classification of "untreated" and "treated" manure, and to provide additional guidance on acceptable compost methods. If compost made on-farms in a method not identified by FDA and/or without records is considered the same as truly "raw" manure, we believe such a classification requires substantial scientific research and risk assessment to do so.

FDA also requested comments on soil types, and the "proportion of produce farms that have one or more soil types per geographical location."

Q: Which characteristics best describe the soil types on your farm?		
Answer Options	**Response Percent**	**Response Count**
Sand	5.5%	21
Sandy loam	31.7%	120
Loam	12.1%	46
Silt loam	18.5%	70
Clay loam	37.5%	142
Clay	20.8%	79
Total Responses*		**478**

Survey respondents grow produce on the full gamut of soil textures from sandy to clayey. Nearly 20 percent reported having multiple soil types on their farms. By region, those farms were located in the Northeast (28), Southern (25), Western (12), North Central (7).

We also compared responses of manure type by soil type, and found a wide range of responses:

What type of manure do you use?	**Which characteristics best describe the soil types on your farm?**					
Answer Options	**Sand**	**Sandy loam**	**Loam**	**Silt loam**	**Clay**	**Clay loam**
Cattle/Steer manure	4	10	6	14	7	15
Poultry litter	4	25	14	9	17	31
Swine slurry	0	0	1	2	1	0
Horse manure	4	17	6	13	16	21
Mixed/Other (please specify)	6	43	12	26	27	55

Respondents also provided a wide range of physical and chemical parameters of their soil where BSAAOs are used, including measurements of drainage, tilth, and soil organic matter content. Most (73%) characterized their soil as well-drained, though some were poorly drained (19%), or tiled (8.2%). A majority (64%) also characterized their soil tilth as "good"; others as "well-aerated" (25%) and others as "compacted/hardpan." (20%). Over half of respondents consider their soil organic matter content as medium, and over one-quarter identify their soil organic matter content as high.

* Responses exceed 100% because respondents could select multiple options.

We also asked about the percentage of soil organic matter content quantitatively:

Answer Options	Response Percent	Response Count
Less than 2%	10.3%	31
3-5%	31.3%	94
6-10%	15.0%	45
Greater than 10%	8.3%	25
Don't know	35.0%	105

In developing and refining regulations or guidance regarding BSAAO, FDA should consider the impacts of soil type, texture, drainage, and organic matter content on the fate of pathogens introduced via manure applications, and the resulting degree of risk. There have been a few studies on the impact of soil texture and soil organic matter levels on rates of pathogen attenuation, but more data is needed to properly evaluate the impacts of these soil characteristics. We provide additional recommendations on this matter in the "additional research" section below.

D. Application Methods and Patterns

FDA requested comments on the "amount of untreated BSAAO applied per unit surface (*e.g.,* per acre) or the ratio of untreated BSAAO/soil, including typical ratio and variability by commodity type, including, for example, row crops such as leafy greens." FDA also requested comments on the "time of year, number of applications, and amount of untreated BSAAO that are applied."

The data generated by this question in our survey was very difficult to capture, because the range of application amounts, the number of applications, and the time of year varies significantly across regions and individual farms.

The range of responses included:
- 1 ton over 1/3 acre once per year
- 1 ton over ½ acre twice per month in the fall and winter
- 1 ton/acre every two or three years
- 3 tons/acre about 3 times per year
- 3 tons over 3 acres, cattle annually and poultry quarterly
- 10 tons/acre once annually
- 10 tons/acre for cattle, but 2 tons/acre for poultry

However, many farmers noted that their application rates and quantities varies greatly based on their soil sampling results and their crop nutrient needs – particularly those that are using crop rotations – and also on the availability of BSAAOs.

Application might occur at planting, during tillage, as a side dressing, or in the fall after harvest. 75 percent of respondents apply BSAAOs every year; these responses were fairly consistent across regions, with a slightly higher percentage in the Northeast and Southern that apply annually (76 percent) as compared to Western (70 percent) and North Central regions (73 percent).

In all regions, the most common time of year to apply BSAAOs was the spring and fall. The variations by region in time of application varied more than number of applications:

Q: What time of year do you apply manure?				
Answer Options	**North Central**	**Northeast**	**Southern**	**Western**
Year-round	23.8%	14.0%	28.7%	31.6%
In summer	14.3%	15.8%	10.2%	7.9%
In winter	9.5%	10.5%	18.5%	13.2%
In spring	26.2%	58.8%	43.5%	44.7%
In fall	59.5%	51.8%	38.9%	28.9%

FDA also requested comments on the "method of application (*e.g.,* surface, incorporated), and whether or not the amended soil is covered (*e.g.,* with plastic mulch)."

The vast majority of survey respondents (96%) spread manure onto the surface of the soil – as opposed to spraying it (3%) or injecting it (1%), and then 75% of those respondents would incorporate it into the soil. Two-thirds those respondents would incorporate it immediately, while one-third would let it dry before incorporating. The advantage of letting the manure dry is that solar UV may attenuate pathogen content; however, the disadvantage is that a substantial amount of nitrogen and sulfur could be lost as ammonia and H_2S. Few respondents cover their soil after apply BSAAOs (12%, using plasticulture).

Respondents provided a wide range of average application intervals; however, 37 percent of all respondents identified adherence to the National Organic Program application intervals (90/120 days). Other responses cited by some respondents include:

- 6 months: 16%
- 2 months: 9%
- 9 months or more: 9%
- 5 months: 9%
- 7 months: 6%
- 8 months: 6%
- 1 month or less: 4%

We think it's important to note again that the vast majority of farms surveyed were using aged and composted manure, but composted on-farm and without records, which puts them into FDA's "untreated" category. Indeed, all of the farms that indicated average intervals of less than 90 days also responded that the manure they used was composted or aged, which again speaks more to the confusion caused by FDA's binary classification of untreated and treated manure than it necessarily does the risk posed by farmers using shorter intervals.

E. Climate Conditions and Irrigation Practices

FDA requests comments on the "climate conditions and irrigation practices after soil is amended, before and after planting."

Many of our survey respondents reported that they do not apply un-composted manure products less than 90/120 days prior to harvest (as per the National Organic Program rules); during harvest; or in the winter (winter spreading is prohibited by law in some areas, and in general applying raw manure to frozen ground is not a best practice). Others do not apply untreated or un-composted BSAAOs during heavy rainfall or when the soil is too wet, when soil tests indicate it isn't necessary, and more generally during the vegetable growing season. And, as noted above, none of our survey respondents indicating applying truly raw (e.g. unaged) manure during the produce growing season.

F. Commodity Type, Cropping Cycle, and Crop Density

FDA requested comments on produce commodity type and cropping cycles. Forty-two percent of our survey respondents grow annual crops only, while the majority (54 percent) grow annual and perennial crops in rotation.

Which category best describes the crops produced on your farm?		
Answer Options	**Response Percent**	**Response Count**
Annual crops only	42.3%	157
Annual and perennial crops in rotation	54.4%	202
Perennial crops only	3.2%	12
Total Responses		**371**

All of our survey respondents have diverse farming operations. A significant majority grow multiple produce and non-produce commodities, and nearly half are integrated crop-livestock operations. Sixty-seven percent grow leafy greens; forty percent grow berries. Many also grow tree fruits (35%).

IV. COMMENTS ON HARVESTING, HANDLING, AND STORAGE

FDA requested comments on "harvesting, handling, and storage conditions that may affect pathogen detection and levels, survival, growth, or inactivation between harvest and retail sale along the farm-to-fork continuum."

A. Harvesting Practices and Conditions

FDA requests comment on harvesting practices and the average conditions as well as the range of climactic conditions prior to harvesting (*e.g.,* time and temperature, rain events) under which produce is handled in the field and in packing operations.

Responses to this question also vary widely based on location and commodity type. But when asked whether there were certain climatic conditions under which they would not harvest, 74% indicated that they would not harvest during heavy rain events; 36% during extreme heat; and 10% after irrigation. Other common responses included snow; crop failure; flooding; and dangerous weather conditions (e.g. high winds, thunderstorms).

B. Use of Antimicrobials or Other Treatments

FDA requests data on the types and concentration of antimicrobial chemicals or other treatments, if any, applied to the water used for wash or transport of produce during farm or other distribution operations prior to retail, and the efficacy of these treatments in reducing pathogen levels, as well as the likelihood of cross-contamination during wash or transport.

The vast majority of survey respondents (90%) do not treat their produce with antimicrobial chemicals. However, some indicated that they use a sanitizer like hydrogen peroxide or Sanidate 5.0 during washing, particularly those that are packing leafy greens. Many also clean their handling and storage tools, areas, and containers with bleach solutions.

The majority of survey respondents (90%) have never tested their soils or BSAAOs for pathogens. However, of those who have tested for pathogens, none indicated that their tests ever came back positive for pathogens. However, one farmer noted that they did get a result back showing high generic *E.coli* levels in a manure pile, but within safe limits. Moreover, subsequent sampling of the manure pile after two additional months of aging showed that the coliform count dropped to almost zero.

Many of the respondents test their soil at least annually for nutrients and pH levels.

V. ADDITIONAL COMMENTS

FDA also requested comment on "the types of untreated BSAAO, produce commodities, relevant agricultural and ecological conditions, and appropriate mitigation strategies that the Agency should consider in the risk assessment."

We think it is imperative that FDA's risk assessment should consider not only the wide range of ecological and climactic conditions that may create regional variations in pathogen persistence, and the varying hazards posed by different manures types (e.g. their source, how long they've aged), but also the wide variety of agriculture practices, particularly those used by sustainable farmers, including certified organic farmers.

For example, practices like planting cover crops, using green manures, conservation tillage or no-till, crop rotations, and co-management of resource conservation and food safety are fundamental components of sustainable agriculture systems, and in some cases are required by USDA NOP for certified organic producers. Many farmers applying BSAAOs to their fields are also using these practices, and a comprehensive risk assessment should consider the possible impacts of these holistic systems on pathogen persistence.

VI. COMMENTS ON AVAILABLE AND RELEVANT SCIENTIFIC DATA AND INFORMATION

NSAC provided significant information to the docket during the 2013 proposed rulemaking process regarding the scientific literature available at that time regarding the proposed application intervals. We have reattached that data to this comment letter as an Appendix for inclusion in the risk assessment model, as it still relevant. For this docket, we performed another literature review for relevant studies since 2013, including studies focused on pathogen prevalence, mobility, and survival rates in untreated manure and fresh produce; mitigation strategies; and ecological conditions on farms (such as wildlife presence). We provide a reference list of those studies in Appendix A, and a discussion of some of the relevant findings here.

While each study offers valuable information on pathogen presence and mitigation strategies in animal manures, the literature collectively indicates that the variation in soils, climate, crop history, farming systems, and types of manures across the nation limit the valid inference that can be made from individual experiments in order to develop regulations. Studies that examine the environmental factors and agricultural practices contributing to food safety risks emphasize that pathogen reduction strategies must be tailored to individual farms due to the unique set of factors that influence the risk of contamination. (Strawn et al. 2013). **<u>It remains imperative that FDA – together with USDA, research institutions, and other stakeholders – develop a research strategy to assess this multi-dimensional variation in order to achieve the science-based rule-making FSMA requires.</u>**

This literature review first addresses "Pathogen Presence and Survival Rates in Untreated Animal Manures" accounting for different environmental conditions and agricultural practices. It then addresses "Pathogen Mitigation and Management Recommendations," and finally highlights "Areas for Further Research" including compost teas, cover crops, antimicrobial resistance risks, animal husbandry practices, soil health, and agricultural water contamination).

1. Pathogen Presence and Survival Rates in Untreated Animal Manures and Amended Soils Under Varying Agricultural, Climatic, and Ecological Conditions

The following studies address questions in the docket on pathogen prevalence and survival rate in animal manures used for biological soil amendments. Studies on pathogen presence in manure left from wild vertebrates and birds are also included, as they could be vectors of pathogens. These studies allow for a comparison of pathogen presence between domesticated animal manures and wild animal fecal matter, offering insight on which type of animal manure is a greater risk. The studies are grouped by agricultural, climatic, and environmental conditions; as described earlier, the multi-dimensional factors that affect food safety risks must be taken into account.

Tables 14-16 of the Conservation Handbook describe the prevalence of *E.coli*, *Salmonella* and *Campylobacter* in manure from dairy and beef cattle, swine, and poultry. (Baumgartner 2016). As of the Handbook's publication, just one study (in Switzerland) compares prevalence between organic and conventional farms. (Kuhnert, et al. 2005, as cited in Baumgartner 2016). Recent advances in antimicrobials for organic production indicate that prevalence rates may be changing, and additional research is required. (Donoghue et al. 2015).

a. <u>Precipitation Events</u>

A field trial in Salinas Valley, California simulated pathogen transfer from wildlife feces onto nearby lettuce during foliar irrigation by spiking five grams of rabbit scat with *E.coli* (1.29×10^8 CFU). The trial found that 0.00573% of the *E.coli* was transferred to the outer leaves of the positive heads of lettuce. 38% of the lettuce tested positive when tested immediately after irrigation. (Atwill et al. 2015)

In another field trial, researchers found that *E.coli* survived, with partial attenuation, on sweet onion bulbs after being overhead-watered by contaminated irrigation water during a 2-3 week field-curing period. (Moyne et al. 2015) In trials on *E.coli* persistence on spinach farms in Colorado and Texas assessing the correlation of environmental factors and agricultural management practices to *E.coli* concentration levels, precipitation emerged as a clear indicator of contamination probability. (Park et al. 2013) These studies indicate that irrigation practices play an important role in managing manure risks and that waterborne pathogens may be of greater concern than soil borne pathogens.

A 12-month study in California on soil amendments using different raw animal manures was used to validate minimum application intervals in field trials. Researchers used untreated horse, goat, cattle, and chicken litter amended soil under drought conditions and saw a 7.16 log reduction in *E.coli* after 120 days from manure application. *E.coli* populations survived longest in chicken litter, followed by horse, cattle and goat manure. Heavy rain events greatly increased the populations of *E.coli*. Thus, although *E.coli* seemed to be mitigating after 120 days, a period of heavy rainfall multiplied *E.coli* populations temporarily. (Jeamsripong et al. 2015). We note that, since this study was conducted during drought conditions in California, it's possible that the soil microbiota had gone dormant and therefore the heavy rain events resulted in anaerobic or hypoxic soil conditions that could favor microbial pathogens over beneficial soil microbes that can suppress pathogens in soil. It's also possible that the soil upon which the study was conducted had a history of conventional management, which could have resulted in a depleted stock of beneficial soil microbes that are less capable of suppressing pathogens. With FDA's commitment to assessing the full range of agricultural and ecological conditions present on a variety of farming operations and regions, this suggests the need to support additional research like this study that also considers varying agricultural management practices that may enhance soil aeration and microbiota, as well as regional variations in weather patterns and soil conditions.

Indeed, a comprehensive examination of risk factors including climate events, farm ecology and agricultural practices to minimize *Salmonella* presence in pre-harvest environments found that *Salmonella* presence was higher in areas with poor drainage. (Strawn et al. 2013).

b. <u>Comparisons Among and Between Wild and Domestic Animal Feces</u>

One study compares pathogen presence in wild animal manures as well as in raw cattle manure, commonly used as a biological soil amendment. This study confirmed previous research that cattle and feral swine fecal material continue to be more likely to contain shiga toxin-producing *E.coli* than fecal material from small mammals and birds. For mitigation, the study recommends conducting hazard analyses on produce fields with a specific focus on animal presence and access to sources of nearby human pathogens. (Jay-Russell et al. 2014). Another study found that rodents near CAFOs are a minimal pathogen risk to nearby produce fields, while birds present a greater risk. The study recommends research on cost-effective co-management practices. (Kahn- Rivadeneria et al. 2015).

One laboratory study compared *Salmonella* and *E.coli* concentrations on domestic cattle, deer, wild pig, raccoon, and waterfowl feces. The study found that *E.coli* survives the longest in cattle feces (12 months), and *Salmonella* survived longest in raccoon (12 months) and pig feces (5 months). (Wang et al. 2015). Another study on *E.coli* survival in soils amended with raw manure found that survival rates ranged from 47 to 266 days, and found no relation between survival time and the presence of virulence genes. (Franz et al. 2011)

A later study on *Salmonella* and *E.coli* survival in soil amended with swine and dairy cattle manure was conducted under field conditions and offers slightly more applicable data. Pathogen die-off occurred in three phases, with an initial rapid decline that then slowed over a period followed by extended persistence at low levels. *E.coli* declined more quickly in soil amended with swine manure compared to dairy manure; this trend was reversed for *Salmonella* decline. The study also found that while seasonal variation did not hold measurable significance, moisture and temperature both significantly affected the decline of pathogens. In most cases, die-off occurred within 120 days, although low levels of persistent cells were recovered beyond this time and should be studied further. (Wang et al. 2016)

Since these studies do not account for variation in animal husbandry, feed content and manure application in a field or agricultural context, it is difficult to interpret the risk of pathogen presence. <u>We urge FDA to work with the sustainable agriculture research community to evaluate the differences in pathogen presence and persistence resulting from different management practices (such as pastured livestock versus confined livestock) and organic systems versus conventional systems.</u>

c. <u>Seasonal Variability</u>

One study, which collected 300 manure samples from cattle raised in confinement in the Southwestern United States found that there was a peak in *Salmonella* and *E.coli* in manure during the fall compared to the spring and summer. (Kahn-Rivadeneira et al. 2015)

A study of eight beef cattle ranches near leafy produce farms in the Central California coast found that five of the ranches tested positive for *E.coli* O157 at least once during the study, conducted over 2.5 years. The prevalence of *E.coli* O157 was greatest in fecal samples, followed by water, and was least prevalent in sediment samples. The study concluded that *E.coli* O157 prevalence was relatively low in this region, spatially constrained, but increased with higher maximum soil temperature, humidity, and herd size. The study also pointed to variations in weather, such as wind speed, affecting pathogen presence. (Benjamin et al. 2015)

d. <u>Buffer Zones and Vegetation</u>

A study on *E.coli* and *Salmonella* prevalence among sheep grazed on alfalfa fields in California found twice the prevalence of *Salmonella* in fecal samples compared to soil samples. The prevalence of *E.coli* in fecal samples was more than three times that of soil samples. However, prevalence rates of pathogens overall were low in feces, and rare in soils from fields with grazing sheep. The study found a 30-ft. buffer distance between grazing lands and the edge of a crop to be adequate. (Hoar et al. 2013). Another study found suggests that windbreaks that intercept pathogen would be better than bare ground buffers. (Burley, 2011, as cited in Baumgartner, 2016).

Another study on *E.coli* and *Salmonella* presence in produce, irrigation water, and rodents to determine whether vegetation near farmland is associated with foodborne pathogens in the California Central Coast region found *E.coli* prevalence in fresh produce increased over six years despite (or perhaps because of) extensive vegetation clearing. Furthermore, the study found evidence that *E.coli* presence was highest in farms near livestock grazing areas, and no evidence of increased prevalence of *E.coli* or *Salmonella* near non-grazed, natural vegetation areas. In fact, pathogen prevalence increased the most on farms where non-crop vegetation was removed. (Karp et al. 2015)

In another study on California walnut orchards, hedgerows did not present a food safety risk from the *E.coli* pathogens carried by rodents. Rodents were observed equally in fields with managed edges (mowed or sprayed) and hedgerows of California native shrubs and grasses. (Sellers, 2015)

2. Pathogen Mitigation and Management Recommendations

Food safety hazards require mitigation strategies that can be captured through co-management practices. Since 2013, research has found the use of integrated pest management, improved sanitation, and additional practices to reduce the risk due to wild animals.

a. Drainage

In a study on the influence of controlled tile drainage in mitigating antibiotic contamination of surface and ground water following liquid swine manure application on clay loam soil, researchers discovered that controlled tiled drainage eliminated contaminant transport at manure application. Campylobacter antibiotic resistant genes were present in groundwater and soil prior to manure application, and increased thereafter. Campylobacter genes were reduced by controlled tile drainage as opposed to free tile drainage. (Frey et al. 2015). We believe this study is important within the context of soil type and texture. The permeability of soil types and the resulting drainage characteristics can be important factors to consider when assessing pathogen persistence in soil. Indeed, FDA requested information on soil types, and while our survey provided some insights into this issue (as discussed above) it also suggests the need for FDA to support additional research into the topic of drainage and pathogen persistence.

b. Biological Control

One study on the use of falconry in leafy green fields in California found that it is related to lower fecal contamination rates in lettuce. Falconry as a deterrent of nuisance birds can be a tool for farmers using integrated pest management techniques to mitigate the risks of food safety. (Jay-Russell and Suslow, 2015)

Studies on coprophagous insects have found them to be successful in suppressing *E.coli* on agricultural landscapes. A study on the scooped scarab (*Onthophagus Hecate)*, a generalist dung beetle common in Maine blueberry fields, examined its role both as a biological control and as a pathogen vector. The study found that beetles feeding on *E.coli* inoculated deer scat were not found to vector the pathogen to fruit. Beetles lowered the amount of pathogenic *E.coli* persisting in soils compared to soils without beetles. (Jones et al. 2015). Another study is looking at organic crop-livestock integrated farms for evidence that good biodiversity encourages decomposition of livestock manure and attenuation of *E.coli* through coprophagous insects as well as competing beneficial microbes. (Snyder 2014).

c. Buffer Zones

Research on buffer strips indicates "removing noncrop vegetation does not improve produce safety." To the contrary, one study found that pathogen prevalence increased the most on farms where non-crop vegetation was removed. (Karp et al. 2015)

Wild vertebrates and birds can be vectors of disease and pathogens, particularly in areas near CAFOs. One study from the Southwest recommends increasing the distance from leafy green fields to a CAFO beyond 400 feet to mitigate bird activity in produce fields. (Jay-Russell) Another study found that rodents do not appear to be significant sources of *E.coli*. The study recommends targeting bird control on produce fields. (Jay-Russell et al. 2014, Kahn-Rivadeneria et al. 2015). However, this study does not account for the fact that many produce growers – particularly in California – have removed trees and other vegetation from the landscape due to buyer pressure. Given FDA's commitment to supporting co-management, we believe that research into whether providing birds with habitat on the edges of the fields could reduce in-field crop contamination.

d. Solarization

Table 19 "Environmental Practices that Influence Pathogen Reduction in Soil." (Baumgartner) provides guidance for all types of growers to mitigate on farm pathogen risk through particular environmental and conservation practices. Table 19 addresses docket question 2 by describing environmental practices that reduce pathogen survival rates in soil. Research indicates that higher intensity UV radiation reduces survival of pathogens in soil. (Baumgartner). Ongoing research on remediation and recovery measures following soil contamination by *Salmonella* also identified solarization (through soil thermal heating, not UV intensification) as a beneficial practice. This topic requires additional research as it can be easily implemented and may already be widely practiced.

e. Conservation

In addition, Table 20 "Conservation Practices that Influence Pathogen Reduction in Soil" (Baumgartner) offers additional mitigation practices. The full handbook on co-management distills many years of data into tables that identify pathogen pathways in order to determine areas of focus for risk management.

3. Areas for Further Research

We appreciate FDA's intention to incorporate rainfall, season, soil type and climatic conditions in their risk assessment. However, we remain concerned by the significant gaps in the available data, particularly regarding the specificity and diversity of the scenarios that FDA is considering. We strongly urge the agency to work closely with USDA and other partners to support additional research in the following subjects, and we strongly recommend that FDA further refine its strategy to isolate high-risk practices by developing a process to address the following key areas.

a. Aged Manure

As discussed above and confirmed in our survey of 400 producers, many farmers passively age their manure in field stacks, often for 1-3 years. The risks posed by such manure likely is not the same as that posed by fresh, raw manure, but the scientific literature is scant on the issue. We therefore urge the agency to investigate the available data on this topic and support additional research where necessary to fill gaps in the understanding of the range of manure types that may be broader than the agency's current classifications of "untreated" and "treated." An evaluation of the risks posed by manure that has been passively aged for a period of months-to-years, to understand the proper classification for such passive practices within the FSMA scheme is critical.

Indeed, the degree of pathogen attenuation during aging may well depend on how well aerated the center of the pile is, and the balance of Carbon to Nitrogen in the pile. Moreover, storing manure in fairly dry aerobic stacks or windrows is very different than storing liquid or semiliquid manure in lagoons, as the latter can create an environment more tolerant of anaerobic conditions than beneficial microbes. Only through a robust and comprehensive assessment of the varying risks posed by manure aged under different conditions and lengths of time can we can we satisfy FSMA's mandate for science- and risk-based standards. We urge the agency to ensure this research is undertaken.

b. Soil Health, and Soil Type, Texture, and Drainage

Studies continue to suggest that soils with diverse and active microbial community would be more antagonistic towards externally introduced human pathogens. (Erickson et al. 2014). FDA should consider the relationship between practices that promote soil health and reduce pathogen persistence in developing a risk assessment model that can account for the mitigating effects of such practices. In particular, our survey indicated that improving soil health and soil organic matter is the #1 reason that produce farmers apply manure. FDA should conduct research to determine if the long term soil health benefits of manure applications include accelerated attenuation of any foodborne pathogens that enter the soil via manure application or other means.

We also strongly urge FDA to gather existing research data and conduct additional research into the impacts of soil type and soil texture, drainage, aeration, and organic matter content on the dynamics of pathogen attenuation following manure applications at realistic rates commonly used by producers (e.g., ~10 tons/ac annually – see survey results above). Our survey clearly illustrated that vegetable and fruit growers deal with all kinds of soil, from the most sandy to the most clayey, and often with two or more textural types within one farm. In order to develop science based regulations or guidelines regarding application intervals and other measures to minimize risk from BSAAOs, accurate research information on this complex web of soil-manure-pathogen interactions is essential.

c. Animal Husbandry Practices

While antibiotic-resistant pathogens emanating from animals treated with antimicrobials often find their way into soil and produce that is consumed raw, the same is not true for animals raised organically. Not only are organically-raised animals free of antimicrobials, but research on the use of plant-based antimicrobials has been successful in mitigating the presence of *E.coli* and other pathogens in livestock and poultry as well. (Donoghue et al. 2015; Upadhyay et al. 2014; Venkitanarayanan et al. 2013)

Further, we believe consideration must be made on animal husbandry practices, since they have a direct impact on the prevalence of pathogens in animal manures. FDA should conduct studies on pathogen persistence in soils amended with manure from organically-raised versus conventionally raised animals and birds, and also should compare those raised in pasture based systems versus raised in concentrated animal feeding operations, or CAFOs. Note that, in our survey, some 85 percent of respondents who apply manure from on-farm sources pasture their livestock and poultry at least part of the year. Research into the impact of pasturing and other animal husbandry practices on pathogen loads in manure is essential to a more accurate risk assessment and development of science-based application intervals and other risk mitigation practices for BSAAOs.

Indeed, a recent pilot study looked at the persistence of generic *E.coli* and fecal coliforms as indicators of pathogen presence in fields where sheep where grazed in the spring and then were later planted with summer crops. The pilot study, while acknowledging that environmental conditions and farming practices can vary by season and region, indicates that *E.coli* in the soil post grazing is undetectable by the 120 day NOP standard. (Patterson et al. 2016).

Moreover, animals raised on pasture (not just those raised under organic standards) must also be evaluated differently from animals raised on feed rations in CAFOs. A 2009 study cited earlier data that found *E.coli* levels in animals fed grain to be higher compared to pastured animals. The study offers a review of how animal feed affects pathogen levels. (Callaway et al. 2009)

Another study found that pathogen presence increases with greater herd sizes. (Benjamin et al. 2015) Both *E.coli* concentrations and antibiotic resistance are also associated with proximity to CAFOs. (Li et al. 2015) Not only is the manure from a CAFO a direct risk, but contamination often occurs through ecological processes such as through leaching and groundwater contamination, as well as through wildlife vectors. (Kahn-Rivadeneria et al. 2015, Li et al. 2015) The risk posed by manure produced in CAFOs indicates a need for a comparative analysis on antimicrobial resistant bacteria and pathogens in manure from animals raised in CAFOs versus animals raised on pasture.

d. Antimicrobial Resistance Risks

The growing problem of antimicrobial resistance also affects the mobility of pathogenic bacteria, which can transfer from the feces of domesticated animals through environmental vectors such as soil, water, wildlife and animals, and pose a food safety hazard. One study on soils treated with cattle manure noted that while antimicrobial resistant bacteria could not be detected in the manure itself, it actually multiplied in manure-treated soil, indicating the spread of antimicrobial resistance through manure application. (Hu et al. 2015)

Several studies call for minimizing the level of antibiotics and antibiotic resistant bacteria in the environment through improved management of manure containing antibiotic residues. One study on the impact of raw manure on the prevalence of antibiotic resistant genes in soil and on vegetables at harvest detected the presence of bacteria that are not typically found on vegetables grown in manure-free soil. (Marti et al. 2013) A later study noted that in the "humid continental climate" of the United States, a 1-year period following the application of raw manure is sufficient to mitigate the presence of antibiotic resistant genes. (Marti et al. 2014) Therefore, until antibiotic use in animals declines, it is important to differentiate not only between the different animal-origins of manure, but also between manures of animals treated with antimicrobials and animals raised organically.

e. Cover Crops and Crop Rotation

Cover cropping is widely practiced by a variety of farmers, and may be useful in decontaminating soils. However, there is little research available on this practice; one ongoing study on low-residue cover cropping in California on fields contaminated with chicken manure known to harbor *Salmonella* did not see any microbial benefits. However, the study recommends that further studies on cover cropping would be helpful to determine whether this can be included in a set of integrated management techniques for producers to mitigate pathogen risks from animal manures. (McConchie and Suslow 2015)

Crop rotations that alternate produce crops with either cover, forage, or feed grain crops, or perennial sod (hay or pasture) may offer additional opportunities to co-manage soil conservation and food safety, and to enhance the food safety outcomes of crop-livestock integrated systems. Manure applications and manure deposits by grazing livestock during the forage / non-produce phase of the rotation, with no manure (or only manure composted to proposed FDA criteria) during the produce crop phase of the rotation may be a safer and more effective way to obtain the soil health and crop nutrient benefits of manure and other BSAAOs. Enhancing soil health through these conservation crop rotations and BSAAO inputs can speed the attenuation of any pathogens inadvertently introduced (e.g., by wildlife) in the produce cropping phase; and cover crops and perennial sod crops can also serve as buffers between areas receiving manure and areas under vegetable and fruit production. FDA should conduct research into the potential of strategic use of crop rotation and cover crops to minimize foodborne pathogen risks in produce production, especially in crop-livestock integrated systems.

f. Compost Teas

Compost teas are a valuable source of fertilizer and can be created using a variety of (composted) manure types and applied to fields in a variety of ways. One study on compost tea application on lettuce found that side dressing is a safer application route compared to foliar application for mitigating *E.coli* risks. (Ravishankar et al. 2014)

FDA's approach to regulating compost teas, truly raw manure, and aged manure must consider the manure origin, processing level, and application methods. Additional research on pathogens in manure products will help determine the level of risk these practices pose.

Appendix A - RECENT PUBLICATIONS / CURRENT RESEARCH

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Jay- Russell, Michele and Trevor Suslow. "Use of falconry as deterrent of nuisance birds in leafy greens fields in Northern California," Center for Produce Safety. University of California, Davis. 2015 (Abstract)

Jay- Russell, Michele, Anne Justice-Allen. "Reducing the Risk for Transfer of Zoonotic Foodborne Pathogens from Domestic and Wild Animal to Vegetable Crops in the Southwest Desert." Center for Produce Safety. University of California, Davis, 2014. (Abstract)

Jeamsripong, S, P. Millner, M. Sharma, A. Zwieniecka, J. Wong, P. Aminabadi, E. Atwill, and M. Jay-Russell*. 2015 "Field-validation of Minimum Application Intervals for Use of Raw Animal Manure as a Soil Amendment in the Central Valley, California" International Association for Food Protection July 2015. (Abstract)

Jones, Matthew S., Shravani Tadepalli, David F. Bridges, Vivian C. H. Wu, Frank Drummond "Suppression of *Escherichia coli* O157:H7 by Dung Beetles (Coleoptera: Scarabaeidae) Using the Lowbush Blueberry Agroecosystem as a Model System." PLOS, April 7, 2015

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