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Assessment of Biological Soil Amendments of Animal Origin Use, Research Needs, and Extension Opportunities in Organic Production

***Thais Melo Ramos*[1], *Michele T. Jay-Russell*[2], *Patricia D. Millner*[3], *Jessica Shade*[4], *Tracy Misiewicz*[4†], *Ulrike S. Sorge*[5†], *Mark Hutchinson*[6], *Jason Lilley*[6] and *Alda F. A. Pires*[1*]**

[1] Department of Population Health and Reproduction, School of Veterinary Medicine, University of California, Davis, Davis, CA, United States, [2] Western Center for Food Safety, University of California, Davis, Davis, CA, United States, [3] Environmental Microbial & Food Safety Laboratory, U.S. Department of Agriculture, Agricultural Research Service, Beltsville, MD, United States, [4] The Organic Center, Washington, DC, United States, [5] Department of Veterinary Population Medicine, University of Minnesota, St. Paul, MN, United States, [6] University of Maine Cooperative Extension, Waldoboro, ME, United States

The use of biological soil amendments of animal origin (BSAAOs) to improve soil fertility and quality plays an important role in organic agriculture in the U.S. However, organic practices, such as untreated manure application, may introduce foodborne pathogens and consequently increase the risk of fresh produce contamination. Certified organic farms follow the USDA-National Organic Program (NOP) standards, which stipulate a 90- or 120-day waiting period between incorporating raw manure into the soil and crop harvest, depending on whether the edible portions of the crops come into indirect or direct contact, respectively, with the soil. To determine knowledge, attitudes, behaviors, and practices of organic farmers related to use of biological soil amendments, we employed three evaluation tools: a national workshop held at the University of California-Davis (UC-Davis); multiple in-person focus groups (listening sessions) conducted around the United States, and an online survey. Results reveal that untreated BSAAOs (untreated manure and immature composted manure) are critical tools in organic production for managing soil fertility and improving soil quality. Overall, organic producers surveyed in this study agreed that there is a need for more science-based data to evaluate and establish an appropriately protective time interval between untreated manure application and crop harvest to reduce the risk of surviving foodborne pathogens contaminating organic fresh produce. This study highlights the need for development of outreach and educational tools intended to help organic producers implement mitigation strategies to reduce food safety risks related to BSAAOs in organically grown produce covered by the Produce Safety Rule (PSR) of the U.S. Food and Drug Administration Food Safety Modernization Act (FSMA). This study informs and will aid prioritization of research (e.g., on a time interval protective of fresh produce food safety when soil is amended with animal-biological amendments in organic fresh produce systems) and outreach

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Karl Matthews, Rutgers University, The State University of New Jersey, United States

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Keith Warriner, University of Guelph, Canada
Lisa Gorski, Western Regional Research Center, United States Department of Agriculture, Agricultural Research Service, United States

***Correspondence:**
Alda F. A. Pires
apires@ucdavis.edu

†Present address:
Tracy Misiewicz, University of Oklahoma, Norman, OK, United States
Ulrike S. Sorge, Tiergesundheitsdienst Bayern e.V., Poing, Germany

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programs (e.g., GAPs, food safety programs, soil testing, pre-harvest food safety mitigation strategies, and organic rules and regulations) aimed at improving food safety for organic vegetable, fruit, and nut growers who use animal-based soil inputs, including amendments and rotational grazing.

Keywords: compost, manure, produce, food safety, management practices, education

INTRODUCTION

The consumption of organic food has grown exponentially worldwide in the past decade (Rana and Paul, 2017). The U.S., in particular, has seen a rapid spike in organic production, and has one of the three largest organic industries, with an estimated area of 2.2 million hectares of production, and $43.3 billion in sales (Haumann, 2017). Organic agriculture is based on ecological principles, and the use of synthetic fertilizer and pesticides is prohibited on organic farms (USDA-AMS, 2000; USDA-NOP, 2011a). Instead, USDA-National Organic Program (NOP)-certified farms rely on natural soil amendments (i.e., compost, green waste, biological soil amendments of animal origin [BSAAOs] such as animal manure) in combination with other ecological nutrient management techniques, such as the use of locally adapted plant varieties, intercropping with nitrogen-fixing trees, crop rotations, and/or cover crops (USDA-AMS, 2000; Rosen and Bierman, 2005; Rosen and Allan, 2007).

The use of BSAAOs (e.g., manure and compost) to improve soil fertility and quality is common on organic farms in the U.S. (USDA-NOP, 2011a; Sharma and Reynnells, 2016), playing an important role in conventional agriculture nutrient management. However, untreated manure from livestock may frequently contain enteric pathogenic bacteria (e.g., *E. coli* O157:H7, *Salmonella* spp., *Listeria* spp., and *Campylobacter* spp.) (Hutchison et al., 2005; Sharma and Reynnells, 2016) and land spreading of manure can lead to the entry of pathogens into the food chain (Islam et al., 2005).

Pathogens in manure can be inactivated by various treatments, particularly heat treatments such as achieved with proper thermophilic composting (Millner, 2014b; Gurtler et al., 2018). The use of improperly treated manure is an important risk factor for the microbial safety of fresh produce (Harris et al., 2013; Liu et al., 2013). Manure pathogen levels depend on manure type (e.g., solid, slurry, or liquid), animal source (e.g., cattle, swine, small ruminants, poultry), handling and treatment of manure, livestock diet, and exposure to environmental factors (e.g., season, ambient temperature, rainfall, sunlight) (Bicudo and Goyal, 2003; Hutchison et al., 2005; Sinton et al., 2007; Moriarty et al., 2011; Harris et al., 2013). Many factors play a role in the survival and persistence of foodborne pathogens in soil, such as intrinsic properties of the microorganism, soil microbial communities, types and conditions of the untreated soil amendments, manure management and application (e.g., broadcasting with or without incorporation, injection), soil and environmental conditions (e.g., season, rainfall, humidity, sunlight) and agroecological conditions (Hutchison et al., 2005; Moriarty et al., 2011; Harris et al., 2013; Sharma and Reynnells, 2016).

In the United States, there are an estimated 48 million illnesses, 128,000 hospitalizations, and 3,000 deaths due to foodborne disease each year. Among those 9.4 million illnesses, 55,961 hospitalizations, and 1,351 deaths are due to 31 major pathogens (e.g., Norovirus, *Salmonella* nontyphoidal, *Clostridium perfringens*, *Campylobacter* spp.) (Scallan et al., 2011; CDC, 2018). Fresh fruits, nuts, and vegetables are increasingly linked to foodborne illnesses, outbreaks, and recalls (Lynch et al., 2009; Berger et al., 2010). Specifically, produce (fruit, nuts and five vegetable commodities) accounted for 46% of foodborne illness outbreaks during the period 1998–2008, a larger share than any other category (Painter et al., 2013). Eighteen outbreaks were caused by organic foods from 1992 to 2014 in the U.S., 54% of outbreaks occurred from 2010 to 2014, 44% were associated with produce (e.g., alfalfa sprouts, grape tomatoes), and *Salmonella* spp and *E. coli* O157:H7 were the most common pathogens (Harvey et al., 2016).The contamination of produce commodities can occur pre-harvest through the application of raw and/or untreated manure, contaminated agricultural water, direct or indirect (e.g., soil-splash events) contact with contaminated soil or deposition of fecal material from domesticated animals and/or wildlife (Ingham et al., 2004; Olaimat and Holley, 2012; Sharma and Reynnells, 2016). Moreover, fresh produce that is consumed raw or with a minimal processing step presents a unique food safety risk due to the absence of a kill step between harvest and consumption (Olaimat and Holley, 2012; Weller et al., 2016). Therefore, it is crucial that raw manure application, compost processing, and application practices be adequate to minimize the risk of potential crop contamination (Cieslak et al., 1993; Natvig et al., 2002).

The current standards to prevent microbial contamination of crops are based on time-interval criteria between the application of animal-based soil amendments (i.e., raw manure and untreated manure) and time of crop harvest (USDA-NOP, 2011a,b). However, there are currently no safety regulations governing wait times for use of raw manure in conventional agriculture. Moreover, guidelines and proposed rules by organizations and federal agencies in the United States often overlap or are based on inadequate scientific data to minimize the risk of microbial contamination and how agricultural practices may affect contamination and survival (Sharma and Reynnells, 2016; Pires et al., 2018; Sharma et al., 2019).

The U.S. Food and Drug Administration's (FDA) Food Safety Modernization Act (FSMA) Produce Safety Rule (PSR) focuses on setting federal regulatory standards for the production, harvest, and handling of fruits and vegetables in an effort to prevent microbial contamination and reduce the potential of foodborne illnesses associated with fresh produce (FDA, 2015). The rule establishes standards for agricultural water, animal-based soil amendments, domesticated and wild animal intrusion, employee health and hygiene, and building and equipment sanitation (FDA, 2015). The PSR, Subpart F, defines a BSAAO as "untreated" if it has not been processed to adequately reduce microorganisms of public health importance (FDA, 2015). Untreated BSAAOs must be handled, conveyed, and stored in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application (FDA, 2015). Presently, the FSMA-PSR does not object to the NOP regulation of a 90- or 120-day ("wait time") interval between applications of untreated BSAAOs and harvest of crops (FDA, 2015, 2018). Recently, the FDA issued a draft guidance document to assist industry in complying with the PSR, which was open for public comment until April 22, 2019 (FDA, 2018). However, the FDA is reserving a final decision on this "wait time" interval until more critical research and a risk assessment are completed to provide scientific support (FDA, 2016). The current regulatory climate and uncertainty about appropriate standards shows the urgent need to conduct science-based assessments of current organic practices related to raw manure use and to identify potential food safety risks, which will benefit organic growers and their consumers (Pires et al., 2018).

The overall goal of this study was to identify knowledge gaps and to research outreach and education needs related to potential food safety risks with current practices for use of BSAAOs in organic and sustainable agriculture, with a focus on fresh produce commodities (vegetables, nuts, and fruits) covered under the PSR. Specifically, this study characterized the current management practices related to use of BSAAOs and food safety risks, and investigated the knowledge, attitudes, and perceived solutions related to the use of BSAAOs.

MATERIALS AND METHODS

This study was carried out in a three-phase assessment using complementary data collection methods: in-person focus groups (a series of listening sessions conducted at multiple locations across the U.S.: MN, MD, CA, PA, VT, WI, and FL), a one-and-a-half-day national workshop at UC-Davis, and a questionnaire (online survey). The target audiences included a wide variety of stakeholders in organic agriculture and produce food safety, including organic farmers, growers, researchers, extension specialists, extension agents, policy-makers, subject-matter experts, and industry workers in organic agriculture and food safety. The study protocol, inclusive survey instrument, in-person focus groups and workshop and respective consent procedures, was reviewed by the Institutional Review Board (IRB) Administration, University of California, Davis (protocol numbers 804625-1 and 1425129-1), and considered exempt. The consent documents were provided for in-person focus groups, workshop (consent document and power-point presentation) and survey (as cover letter).

In-person Focus Groups

The first phase of the needs assessment was a series of in-person focus groups (i.e., needs assessment listening sessions) conducted at nine national agricultural and organic conferences frequently attended by farmers, growers, and industry members, including: 1) January 8–9, 2016 Minnesota Organic Farming Conference, St. Cloud, MN (23 participants); 2) January 14–16, 2016 Future Harvest, MD (25 participants); 3) January 20–23, 2016 EcoFarm, Pacific Grove, CA (35 participants); 4) February 4–6, 2016 Pennsylvania Association for Sustainable Agriculture (PASA), State College, PA (54 participants); 5) January 25, 2016 National Sustainable Agriculture Coalition (NSAC), Davis, CA (18 participants); 6) February 13, 2016 Northeast Organic Farming Association of Vermont (NOFA-VT), Burlington, VT (51 participants); 7) February 25–27, 2016 Midwest Organic and Sustainable Education Services (MOSES), Wisconsin, WI (6 participants); 8) January 25, 2016 US Composting Council (USCC), Jacksonville, FL (10 participants); 9) March 5–6, 2016 California Small Farm Conference, Sacramento, CA. These conferences represent four diverse U.S. geographic regions: the West, Midwest, Northeast, and Southeast. The listening sessions were announced in several media outlets, such as press releases, blogs, newsletters, and listservs of several organic producer organizations. Each moderator in the listening session followed a PowerPoint with an outline of specific themes (e.g., raw manure, compost, crop and fields practice, good agricultural practices, and sources of information) organized in 32 questions/statements to initiate the conversation among the participants. The questions were developed by the research team, including industry representatives, food safety scientists, soil researchers, extension specialists and educators. The number of statements, the areas covered, and sample questions are shown in **Table 1**.

National Workshop

The second phase involved a one-and-a-half-day workshop, which was held from January 25–26, 2016, at UC-Davis. The workshop included two components: (1) scientific presentations about the state of art on BSAAOs and food safety risks, and (2) active break-out groups with discussion/brainstorming to identify research priorities on use of BSAAOs and food safety risks. Thirty-two attendees from across the country participated in this workshop to characterize the use of biological soil amendments of animal origin and best microbial food safety practices in organic and sustainable agriculture. Participants included representatives of government agencies (FDA Division of Produce Safety and Division of Risk and Decision Analysis; USDA Agricultural Research Services; California Department of Food and Agriculture [CDFA]; California Department of Public Health [CDPH]; Washington State Department of Agriculture, Natural Resources and Conservation Services [NRCS]; CalRecycle), policy-makers (The Organic Center, Organic Trade Association), grower associations and industry representatives (California Certified Organic Farmers, Community Alliance of Family Farmers [CAFF], Association of Compost Producers, US Compost Council

TABLE 1 | Questions related to use of BSAAOs and food safety risks included in the in-person focus group session.

Topic	Questions/statements
Raw manure and untreated manure	• What are the animal sources for your manure? • Where do you acquire your manure? • How do you treat manure prior to application? • How do you store your raw manure prior to application? • What are some of your thoughts about use of manure and food safety risks? • How about food safety related to the treatment, storage, and application time?
Compost	• What are the animal sources for your compost? • Where do you acquire your compost? • What is your compost application method? • How do you store compost prior to application? • What are some of your thoughts about use of compost and food safety risks? • How about the treatment, storage, and application time? • How do you think these practices may affect food safety risks?
Crops and field practices	• Do you apply biological soil amendments directly to fresh produce? • If you implement rotational grazing, what types of animals, and crops do you raise? • What are some of your thoughts about BSAAOs/rotational grazing related to fresh produce food safety risks? • How important are these practices to your production system? • What is the typical interval between rotational grazing and crop harvest?
Testing and verification	• Do you purchase commercial compost or treated biological soil amendments? • If so, what type of verification system does your supplier use (third party evaluation, certified analysis, etc.)? • Do you test for microorganisms in your compost and raw manure? If so, explain.
Food safety concerns	• What specific pathogens are you most concerned about? • What concerns do you have about reducing or eliminating pathogens through: - Aging (time intervals for die-off) - Composting - Treatment
Good agricultural practices	• How do you implement GAPs on your farm? • What food safety risk mitigation actions do you take on? Do you have a food safety plan? • How do you assess the food safety risks on farm? What tools do you use? • Do you have a third-party food safety certification? If no, why not? • What are the challenges to meet the new food safety regulations?
Areas of improvement for extension/training	• What sources of information do you utilize in managing and applying biological soil amendments? • What topic areas would you like more training or information on? • What are additional trainings you need to be in compliance with GAPs and food safety? • How would you like to see the information and assistance delivered?

Research and Education Foundation [USCC], Washington Organic Recycling Council, Maine Organic Farmers and Gardeners Association [MOFGA], etc.), and representatives from research and extension institutions (University of California, Washington State University, Cornell University, University of Minnesota, University of Maine Cooperative Extension).

Survey

The third part of the needs assessment, which occurred from January 2016 to June 2016, was an online survey (Pires et al., 2018) that consisted of multiple-choice and open-ended questions. Organic farmers belonging to national and state organic farming organizations were invited (by email and mail) to participate in a survey to acquire information regarding the current practices for animal-based soil amendments, including animal rotational grazing, and food safety risks in organic and sustainable agriculture, with a focus on covered produce commodities in the PSR (Pires et al., 2018). Details regarding survey development, instrument, questions, sampling framing, targeted participants, and data recording have been described (Pires et al., 2018). Briefly, the survey included a total of 65 questions, which were grouped in 7 sections to collect information on: (1) demographics, (2) use of BSAAOs, (3) use of raw and untreated manure, (4) use of compost, (5) crop and field practices, (6) good agricultural practices, and (7) test and verification of BSAAOs.

RESULTS

In-person Focus Groups

Raw and Untreated Manure

The participant growers indicated that the types of raw manure used as BSA were: poultry (chickens, ducks, and turkeys), cattle (dairy and beef), small ruminants (goats and sheep), swine, horses and llamas. Some participants indicated that they used several manure sources. Some participants purchased their manure (off-farm), while others used on-farm sources (e.g., livestock and working horses). However, some farmers mentioned lack of access to neighbor farms' manure. A wide range of management and application practices were described, such as mixing manure with vegetation (e.g., residue crops and cover crops), composting, scrapings from the field, mixing with hay bales or bedding, spreading on cover crops, and incorporation into the soil with the residue crops. Midwest growers reported that bedding manure is applied in produce crop fields, while liquid manure was used for livestock forage crops or other crops (e.g., peas and cabbage). Application of raw manure often was used in farming crops (e.g., wheat and oats) among grower participants from the Southeastern region. The manure application frequency varied by region because of weather conditions, manure availability, and specific state regulations. The majority of the respondents reported manure application once or twice a year, most commonly in spring and fall. When asked about raw manure storage prior to application, piles (stacked outside or inside) were the most common storage type reported. In addition, the respondents reported storing manure from on-farm animals as part of deep bedding, or leaving it on cement pads for a few weeks until they could arrange to compost it. Locations for storage of manure locations were selected based on distance to produce fields, water sources and terrain conditions (e.g., slope).

The perception of food safety risks was also discussed in relation to raw manure use. In general, there was a consensus that using raw manure could be more risky for food safety than using composted manure. Nevertheless, some producers still used raw manure without composting it, whereas others preferred to compost it before application. Producers were unlikely to eliminate manure use in favor of compost due to cost, transportation, and labor barriers (e.g., lack of equipment). Many participants revealed that they did not have the capacity or dedicated space for full composting on their operation, but would use the raw manure mostly for non-soil-contact crops such as orchards. The participants expressed a distrust of commercial compost or manure from off-farm sources. However, many produce growers believed that purchased compost was safe from pathogens, persistent de-worming drugs, and pesticide standards. Some farmers expressed their belief that large-scale conventional livestock operations were responsible for high pathogen levels, and they were especially concerned about antibiotic-resistant bacteria in raw manure. The participants were not aware that aging manure and/or animal sources could have an impact on pathogen presence and survival. They expressed interest in knowing more about methods for minimizing pathogen contamination (e.g., washing farm equipment).

Compost

Commercial, on-site, and local compost were the main sources reported. Various animal sources (cattle, poultry, small ruminants) and compost types (animal origin, green waste and vermicompost) were reported across regions. On-site composting processes included windrow turned composting and aerated static pile. The majority of those who used compost indicated that compost was applied once to twice per year through incorporation into the soil, on surface or spread, and side-dressed. Similar to manure, spring and fall were the seasons in which compost was most frequently applied. The most common type of compost storage reported was outdoors (with or without any covering), and participants indicated that the raw manure and unfinished compost were stored in separate locations from the finished compost. Farmers reported different safety strategies for ensuring pathogen reduction: some monitored compost temperatures, whereas others used a set amount of aging time. Some mentioned that their compost was "cured," but many farmers expressed confusion about what "adequate curing" actually means. While organic growers understood the importance of composting and the general practices involved in composting, a large proportion of farmers indicated that they were unfamiliar with the foundational principles of composting practices. Specifically, they noted that there was a need for increased extension on the details of effective composting such as oxygen, temperature, moisture, and carbon/nitrogen ratio requirements. Participants mentioned the need for more detailed information on different composting systems and frequently mentioned "aged manure" as a type of compost. Most farmers followed the FDA-FSMA and USDA-NOP regulations for composting and manure application, but were unsure if there was any science supporting the regulations. Participant growers from Midwest listening sessions mentioned that composting of poultry carcasses could be challenging, while growers from the Southeast listening session reported no major problems with carcass composting, as long there was a good ratio between carbon (e.g., wood chips) source and chicken layers.

Most growers did not have a trusting relationship with external sources of commercial compost or treated soil amendments, and expressed interest in reports on quality and test results from purchased compost. Some of the growers who requested documentation from suppliers reported that suppliers did not always meet the compliance requirements for microbial reduction. The US Composting Council's Seal of Testing Assurance Program (STA) requires regular compost testing, including *Salmonella* and fecal coliforms (USCC, 2019). Whereas, the FSMA-PSR describes time-temperatures and practices for thermophilic composting process, that has been scientifically validated to meet the microbial standards of *Salmonella* species (not detected) and fecal coliforms (less than 1,000 MPN/gram of total solids) (FDA, 2015). Additionally, the records given to the farmers often did not reflect the accurate compost batch, but rather previous compost batches up to a year prior to the request date. Farmers also noted that purchased compost was often poor nutritional quality and too expensive. For example, a farmer shared his experience of receiving poor physical appearance of compost that was delivered hot and obviously inadequately decomposed, unfinished feedstock. In addition, there were concerns expressed about pesticide contamination in purchased manure and/or compost, because compost companies did not have knowledge about pesticide residues. Pesticide residues in purchased compost were reported as problematic, especially among growers from Washington State and Vermont. For example, one farmer had problems with his organic certification because testing picked up herbicides on his crop fields, which originated from horse manure he was using from off-farm suppliers. Several farmers mentioned that they wanted to test their compost and raw manure for pathogens, but they were not aware of any accessible tools or laboratories. Some respondents indicated that they only tested purchased compost, while most did not test at all.

Crop and Field Practices

The participants that implemented rotational grazing used a wide variety of animal species, such as sheep, cattle, and chickens. Rotational grazing is an integrated crop/livestock system where livestock and crops are raised with the goal of utilizing the products of one for the growth of the other (Hilimire, 2011). Many participants adopted the grazing practices just for orchards, while others separated grazing from harvest timing of crops. Farmers from West listening sessions reported the use rotational grazing depended on type of crop (tree nuts/fruits vs. fresh produce) as well as requirements from third-party certification organizations. Farmers using grazing practices in fields for fresh produce followed the NOP standards for raw manure (90 and 120 days interval between the grazing and crop harvest). Benefits of rotational grazing included nutrient recycling, soil fertility and pest control (e.g., chickens). The farmers noted challenges such as not having enough land for effective field rotation, struggling to meet tight application-to-harvest intervals, and a lack of guidance within the FSMA requirements about rotational grazing. For example, one California farmer asked how contamination occurs when animal grazing is used on-farm and if the risks of using rotational grazing were the same as those with raw manure application. Most producers did not know that rotational grazing is not addressed in Subpart F related to application of BSAAOs in the PSR, but is mentioned in Subpart I "Domesticated and Wild Animals" (FDA, 2015).

Good Agricultural Practices and Food Safety

To get a sense of how important food safety was to producers, participants were asked about their concerns regarding pathogen reduction and what mitigation strategies could be used to reduce the risk. Participants reported that they had good agricultural practices (GAPs) in place and several actions were taken to reduce food safety risks on their farms. However, many producers reported that food safety plans are intimidating and time-consuming for small farmers, and other participants commented that they avoid creating food safety plans. On the other hand, many participants had developed written food safety plans and reported having written standard operating procedures (SOPs). They mentioned that there is a need for more research to guide the development of food safety plans. The microorganisms that the farmers were concerned with included *E. coli*, *Listeria*, *Salmonella*, toxoplasmosis (in case of cats having access to the farm fields), and plant pathogens. Regarding GAPs annual training, some farmers offered an annual training to their employees. Several farmers commented that they did not think there were tools available for them to improve on-farm food safety without going through a third-party audit certification.

Most producers who used raw manure reported that having separate equipment for raw manure is helpful, but others noted that dedicated equipment for manure handling and composting is prohibitively expensive. Farmers reported that cleaning equipment between handling raw manure and finished compost to avoid cross-contamination could be a more affordable alternative to having dedicated equipment, but they recognized that many operations do not follow this practice. Most farmers indicated they had questions about available information regarding FSMA requirements for different types of operations, and suggested that training would be an effective tool for improving their knowledge. In addition, participants discussed barriers that impede compliance, such as lack of funding for grants to help farms implement a food safety plan. Record keeping, pathogen and water testing were mentioned as challenges for FSMA compliance across all the regions.

Areas of Improvement for Extension/Training

Participants indicated their sources of information were conferences, local cooperative extension offices, books, trade-journal articles, peer-reviewed papers, industry magazines, and sustainable agriculture online resources. They indicated that they would like more training or information on GAPs, food safety programs, soil testing, pre-harvest food safety mitigation strategies, handling and application of raw manure (including sanitation of tools and equipment), contamination sources through the supply and processing chain, production methods, and organic rules and regulations. Producers reported that extension programs are not always accessible or relevant to organic producers. Regarding food safety plans, farmers noted that plans could be improved by the development of farmer-friendly educational materials with clear models and examples. Several respondents suggested that the guidelines would have been more helpful if they were developed with farmer input and written in a way that farmers can understand and implement them. Another suggestion focused on providing more consumer information about the meaning of food safety, because the term "organic" to some consumers means it is safe enough that they do not need to wash the food before they consume it. In general, participants had negative perceptions of regulations, food safety, and use of soil amendments of animal origin. The communication gap between farmers and other entities, such as governmental agencies or scientists, was a top concern, as was the need for translational science and increase of communication between the different sectors.

Survey

The multi-regional survey focused on the use of animal-based soil amendments and food safety risks in organic farms. A complete description of the findings of this survey can be found in Pires et al. (2018). Briefly, 81.8% (486/594) of the participant producers were USDA-NOP certified organic, 1.7% (10/594) were in USDA transition certification, and 2.2% (13/594) were conventional. With regard to crop types, 89.2% (594/666) of the participants produced fresh produce. Seventy-four percent (440/594) of producer participants were familiar with FSMA regulations and the use of animal manure. Of those, 69.8% (307/440) were familiar with FSMA regulations and the use of animal manure as a soil amendment. The question about the impact of the FSMA-PSR as related to use of soil amendments containing raw manure was answered by 70.5% (419/594) of the participants: 27.0% (113/419) of respondents reported that it will have an impact, 39.3% (165/419) said it will have no impact and 33.7 % (141/419) said the impact was unknown (Pires et al., 2018). The basis for this even spread between responses is likely a combination of differential focus on specific FSMA-PSR provisions among growers and confusion about how the aspects detailed in the FSMA-PSR would translate into realties on their fields.

In the present study, the survey included two open-ended questions regarding the new FSMA-PSR related to the use of animal-based soil amendments.

Research Question 1: Will the requirement in the FSMA Produce Safety Rule related to use of soil amendments containing raw manure have an impact on your farm? If yes, why?

According to our respondents, several growers indicated that the previous requirement of a 9-month interval time from application to harvest in the rule proposed by FSMA-PSR could preclude the use of raw manure and compost on small- or medium-sized farms. Growers shared that they intend to comply with the new FSMA regulations, but the regulations often conflict with convenience, affordability, production cycle, space requirements, and paperwork load. There were strong feelings expressed about this issue by many participants. Direct quotes from participants can be viewed in **Supplementary Material 1**.

Most responses indicated that little, if any, information is available to aid producers in their decision-making process, and that there is a critical need for more available information regarding food-safety tools focusing on the use of BSAAOs and establishment of farm policies. They also noted that there is a lack of science-based information to support the new proposed rule from a food-safety standpoint (**Supplementary Material 1**).

A few respondents provided interesting perspectives about the advantages of the new guidelines proposed by the FDA, noting that because they were already familiar with NOP guidelines for application and harvest, they would be comfortable using the current FSMA 90- and 120-day intervals. They emphasized their interest in regulations that supported food safety and some already comply with the NOP standards for raw manure and compost. Some mentioned that the new guidelines would greatly affect the soil health and the soil microbiome, and some adopted the record-keeping on their farms.

Research Question 2: Do you have anything else you would like to add on the topics BSAAOs?

While respondents included a wide diversity of additional topics on biological soil amendments, some themes emerged that may be helpful for focusing future research efforts. Many of the farmers surveyed were interested in alternatives to current farm management practices, and suggested that research and education efforts related to food safety training is a priority area for these farmers. Some participants reported that raw manure applied at the proper time is not harmful, while others will keep making their own compost on-site. On the other hand, others mentioned that raw manure or compost from their own farms could pose food safety risks. When it comes to compost processing standards and testing, respondents noted that while good practices are important, third-party audits and laboratory testing are too expensive for small-scale operations. A few growers stated that the regulatory burden is overwhelming, distracting, discouraging, and frustrating, and they need help maintaining better practices through outreach, education, and realistic expectations.

National Workshop

The needs assessment workshop to characterize the use of BSAAOs and microbial food safety best practices in organic and sustainable agriculture held at UC-Davis examined the most current research on the safety of BSAAOs, the FDA plans for a risk assessment examining "wait times" for manure application, and an overview of the state of knowledge and need for research from the perspective of the organic sector. Representatives from the FDA discussed their risk assessment analysis framework around investigating "wait time" intervals of untreated manure, and encouraged the group to work with the knowledge gaps that will be identified in their Federal Register Notice.

To set the groundwork for identifying research gaps that should be tackled in the organic field, USDA-ARS scientists presented a summary of the most current research findings about raw manure "wait times" for food safety, addressing concerns such as the potential for pathogen regrowth in manure-amended soils, compost stability and quality, the wait period between application or incorporation of untreated manure and crop harvest, pathogen transfer rates to edible portions of fresh produce, and the effect of soil health on pathogen survival. Speakers also addressed compost and soil health, the industry's perspective on compost, and preliminary findings from the farmer surveys and listening sessions detailing the current use practices and attitudes of farmers around manure use and food safety. The presentations were followed by discussion sections focused on raw manure, compost, extension, farmer trainings to identify gaps in knowledge about the science supporting food safety, and laying the groundwork for developing a research plan to provide information about the complex issue of food safety.

Some of the top issues that came out of the workshop included the need to get more scientific information into the hands of farmers; interest in the interaction between soil health and plant and foodborne pathogen suppression; the effect of manure source, farm environment, and seasonality on pathogen survival and persistence in the manure amended soils; and the fact that many organic growers maintain an extremely cautious food safety protocol, including implementing the same "wait times" for composted manure as they do for raw manure, which is unnecessary due to the pathogen reduction in manure that is composted with adherence to time-temperature exposures and handling practices and processes that are documented to inactivate and decrease pathogen populations to acceptable levels. For fecal coliforms, acceptable is 1,000 Most Probable Number per gram total solids (dry weight basis) and for *Salmonella* it is <4 Most Probable Number per gram total solids (dry weight basis) (FDA, 2015).

DISCUSSION

This study investigated how growers, policy-makers, academic researchers, and extension staff perceive on-farm food safety strategies to minimize microbial contamination and the factors associated with their food safety perceptions in organic agriculture. Through our outreach, we were able to identify several major themes highlighting the importance of these issues to farmers and the gaps in farmer knowledge and tool availability. Additionally, this study highlighted several important issues regarding the use of BSAAOs in the production of fresh produce and the impact that food safety requirements might have on organic growers. There was general agreement on the need for a multi-disciplinary, transdisciplinary, and integrative approach to providing information about the complex issue of food safety and BSAAOs use. All the participants were unanimous regarding the need for more science-based data on time-intervals for the survival of foodborne pathogens in soil amended with animal-biological amendments in organic fresh produce systems. This viewpoint reflects both a dearth of published scientific material on time-intervals in organic systems, as well as a scarcity of communication regarding the limited number of studies that have been published, and/or how studies on foodborne pathogen survival times in conventional systems translates to organic systems. The ultimate goal of these needs assessments was to inform and prioritize research and outreach programs to improve food safety in organic vegetable, fruit, and nut production due to microbial contamination from animal-based soil inputs including amendments and rotational grazing.

The use of untreated BSSAOs (i.e., untreated manure and immature composted manure) was reported as being important or very important at in-person focus groups sessions. USDA-NOP certified organic producers use animal-based soil amendments to improve soil fertility and health. Applications of biological soil amendments, including uncomposted and untreated animal manure, benefit several soil characteristics including nutrients, water retention, permeability, water infiltration, drainage, aeration, and structure (Rosen and Bierman, 2005; Rosen and Allan, 2007). The sources of manure reported by participants were diverse (e.g., poultry, horses, small ruminants, and cattle). The growers may choose to use raw manure because it is widely available, locally produced, and low-cost. Some participants reported the application of untreated manure on produce crops; others used raw manure primarily for non-soil contact crops, such as orchards. Manure management and application practices were not uniform; varied from region to region depending on season, weather patterns, and state-specific regulations for application. In contrast to our study, Adalja and Lichtenberg (2018a) reported that 75% of the surveyed participants treated soil amendments, and a very small number of the growers—those considered small-scale farmers—would be affected by FSMA regarding application of untreated manure.

However, the use of untreated BSAAOs can be a potential source of microbial contamination of fresh produce and increase the risk of foodborne illnesses when best agricultural practices are not followed (Olaimat and Holley, 2012; Sharma and Reynnells, 2016). The current practices of untreated manure or immature composted manure applications is based on time-intervals (USDA-NOP, 2011a; LGMA, 2016). Initial FSMA produce safety regulations required a 9-month window between applying raw animal manure and harvest (FDA, 2015). Due to widespread comments from the agriculture industry and limited information available, the FDA removed the 9-month waiting period and instead postponed a final decision of adequate waiting periods until more research and risk assessment were conducted (FDA, 2015). The FDA is conducting a risk assessment and, in collaboration with the U.S. Department of Agriculture and other stakeholders, is undertaking critical research to provide scientific support for appropriate time interval(s) between applications of raw manure and harvest of fresh produce (FDA, 2016). Meanwhile, until more data is collected, the FDA does not object to the NOP standard, which requires that untreated animal manure be applied at least 90 days or 120 days prior to crop harvest, depending on whether the edible portions come into direct or indirect contact with the amended manure (USDA-NOP, 2011a; FDA, 2015). Participants at in-person focus group sessions reported the concern that the current time-interval standards may not be adequate for risk reduction for organic producers; as such, there was concern about risk despite the fact that they follow waiting period standards established by USDA-NOP that address raw manure into the soil and crop harvest.

Regarding composting, on the one hand, some participant growers found that on-farm composting was a challenge due to limited space, costs, state-specific regulation, and a lack of information or communication on the best practices to guarantee consistent nutrient quality and a microbially safe final product. On the other hand, commercial composting sources were sometimes reported as unreliable in terms of nutrient value, microbial reduction, testing, and traceability. The PSR establishes applications restrictions (e.g., application methods and application intervals) for BSAAOs based on whether they are untreated or treated and based on the level of treatment and microbial standards (FDA, 2015). FSMA-PSR provides two examples of scientifically valid, controlled biological treatment (i.e., composting) but other treatment processes are acceptable that were validated scientifically to meet microbicidal standards (FDA, 2015, 2018). Achieving 131°F (55°C) at key test positions for 3 consecutive days in aerated static compost piles, or for 2 weeks with five turnings in windrow piles, followed by sufficient curing times for composted feedstocks, are essential to reduce pathogen and parasite populations (Millner, 2014a,b; Patel et al., 2015; Sharma and Reynnells, 2016; Gurtler et al., 2018). Although some farmers mentioned that their compost was "cured," many expressed confusion about what "adequate curing" actually means. Moreover, a large proportion of farmers considered aged manure as a composting process, demonstrating a misunderstanding of the principles of composting. These findings highlight the need for clear guidance on on-farm composting and curing, and the development of educational materials and outreach programs regarding best on-farm practices for manure management (including storage, transportation, composting, and application) across the country for organic growers using BSAAOs. Moreover, given the diversity in scale of US farms, food safety policy recommendations should take into account the wide diversity of farming practices and grower input. Because one size doesn't fit all, a grower-centered approach will enhance new policy, standards, and metrics (Parker et al., 2012). This is particularly important for the use of BSAAOs, as those practices vary greatly.

Several studies have described and characterized GAPs by highlighting food safety risks related to vegetables and fresh produce production (Hultberg et al., 2012; Tobin et al., 2013; Marine et al., 2016; Adalja and Lichtenberg, 2018a; Sinkel et al., 2018), but a few have focused on current food safety practices under the FSMA-PSR (Lichtenberg and Tselepidakis, 2016; Adalja and Lichtenberg, 2018a; Pires et al., 2018) or organic systems (NSAC, 2016). The present study differs by using several needs assessment tools (survey, in-person focus groups, and workshop) targeting mainly organic producers, stakeholders, researchers, and policy-makers across the U.S. Moreover, the emphasis was on BSAAO use and specific GAPs associated with food safety. The GAPs USDA program was developed as a food safety audit to assess farm management practices and guide small-scale farm process improvement (USDA-AMS, 2011), and lately USDA has incorporated the Produce GAPs Harmonized Safety Standard into the 2011 GAPs and GHP audit program (USDA-AMS, 2011, 2018). The growers in our study unanimously reported that they have GAPs in place and have SOPs to minimize the food safety risks. Despite the fact that most growers had adequate knowledge of food safety risks related to use of BSAAOs, implementation of GAPs and developing a food safety plan was often seen as cost- and time-prohibitive for many small-to-medium-scale farmers, and growers frequently sourced this out to third-party entities. Similarly, cost and lack of time were frequently reported as challenges among Kentucky fresh produce farmers (Sinkel et al., 2018) and as a deterrent to verify GAP compliance for Pennsylvania growers (Tobin et al., 2013). The PSR establishes on-farm standards for agricultural water, animal-based soil amendments, domesticated and wild animal intrusions, employee health and hygiene (FDA, 2015, 2018). A food safety plan is not required as part of FSMA per se, but is included in the standardized curriculum developed by the PSA (2017) and is frequently part of food safety protocols of different certification agencies (LGMA, 2016).

Participants often indicated the desire for outreach and educational programs on diverse topics (e.g., GAPs, food safety programs, soil testing, pre-harvest food safety mitigation strategies, sanitation, management of raw manure, and regulations) and programs that are organic-agriculture–specific, as they found extension programs were not always accessible or relevant to organic producers. They were particularly interested in training and assistance on development of food safety plans. In contrast, a recent study on the assessment of effectiveness of a GAPs course provided to Iowa growers conducted by Shaw et al. (2015) reported several areas in need of educational materials, such as cleaning surfaces, packaging, worker health, and training. There is the need to develop training and cost-effective programs for farmers without a traditional agriculture background and/or those who may be exempt under the FSMA-PSR (Harrison et al., 2013; Shaw et al., 2015). Moreover, information and educational tools should be easily available to help producers in their decision-making process on mitigation strategies to reduce food safety risks and BSAAOs in organic produce production.

In-person and surveyed growers expressed several concerns and challenges regarding compliance with FSMA-PSR regulations: in particular, those using soil amendments of animal origin, and small-to-medium-scale farmers. Participants shared that compliance with regulations may conflict with convenience, affordability, production cycle, space requirements, record keeping, and farm labor. Considering that organic farmers employed more workers per acre (2–12%) than conventional farmers (Finley et al., 2018), the new regulation may increase this difference. A recent study by Adalja and Lichtenberg (2018b) reported that food safety practices required by the PSR varied by farm size and sustainable farming practices. The expenditures per acre on most of the food safety practices decreased with farm size, suggesting that compliance with PSR will be more difficult for small-scale farms (Adalja and Lichtenberg, 2018b). Moreover, growers using sustainable farming practices, such as use of biological soil amendments and livestock grazing practices in integrated agricultural systems, spend more (13–60%) than conventional growers on many food safety practices for sampling and testing, field inspection, employee sanitation, soil amendment treatment, and third-party auditing (Adalja and Lichtenberg, 2018b). The authors concluded that the cost of compliance with PSR requirements will be more burdensome for small-scale farmers and sustainable producer growers compared to large growers and conventional farmers (Adalja and Lichtenberg, 2018b).

We found in our study that the top challenges perceived by the participants to meet demands for food safety and compliance with the regulatory requirements of the PSR include (1) lack of access to relevant information about the use of untreated manure and transitioning to compost, (2) no scientific consensus on the appropriate time periods between applications of manure and harvesting, and (3) a communication gap between farmers and governmental agencies. The communication gap between farmers and other entities, such as governmental agencies or scientists, was a top concern, as was the need for increased extension and flexibility for growers. Therefore, there is a need to provide science-based information accessible to the farmers to support in the development of educational materials and on-farm food safety outreach initiatives intended to encourage the implementation of food safety practices on fresh produce farms to reduce risks, to improve communication between growers, researchers, government agencies, and audit agencies.

CONCLUSION

This study found that there is a wide range of practices and food safety perceptions regarding the use of BSAAOs in the production of fresh produce and the impact that food safety requirements might have on organic growers. Untreated BSAAOs are very important regionally for certified organic producers, but manure management practices are not uniform. There is a need for more science-based data on time interval for the survival of foodborne pathogens in soil amended with animal-biological amendments in organic fresh produce systems. Future research should support the development of educational materials and on-farm food safety outreach initiatives intended to encourage the implementation of food safety practices on organic fresh produce farms. Moreover, progress in developing standards and practices for safe, beneficial use of BSAAOs in agriculture will continue to require dialogue and exchange of ideas between growers, researchers, government agencies, and audit agencies. Because each farm is a unique operation researchers and extension specialists will continue to benefit from farm and grower cooperation and input to foster translational research and communications, the results of which can address current and emerging concerns from these various groups, all of whom are dedicated to protecting food safety, public health and sustainable agriculture.

DATA AVAILABILITY

All datasets generated for this study are included in the manuscript and/or the **Supplementary Files**.

ETHICS STATEMENT

The study protocol, inclusive survey instrument, in-person focus groups and workshop and respective consent procedures, was reviewed by the Institutional Review Board (IRB) Administration, University of California, Davis (protocol numbers 804625-1 and 1425129-1), and considered exempt. The consent documents were provided for in-person focus groups, workshop (consent document and power-point presentation) and survey (as cover letter).

AUTHOR CONTRIBUTIONS

MJ-R, PM, JS, TM, US, MH, JL, and AP contributed conception, design, and completion of the needs assessment study. MJ-R, JS, TM, and AP summarized the results. TR and AP wrote the first draft of the manuscript. All authors contribute to manuscript revision, read, and approved the submitted version.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fsufs.2019.00073/full#supplementary-material

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