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July 19, 2016

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2016-N-0321 (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)

To Whom it May Concern:

The California Farm Bureau Federation (CFBF) is the state's largest general farm organization, representing over 53,000 family farmers and ranchers. We believe it is impossible for the Food and Drug Administration (FDA) to create a science-based standard to Biological Soil Amendments of Animal Origin (BSAAO) that encompasses the wide range of commodities in the many diverse regions of California. Our position is derived from California farmer and rancher input as well as through the attached analysis conducted by American Farm Bureau Federation (AFBF).

Sincerely,

Chelsea Molina
Federal Policy
California Farm Bureau Federation

Attachment: AFBF Comment to FDA-2016-N-0321

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July 5, 2016

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2016-N-0321 (Risk Assessment of Foodborne Illness Associated with Pathogens from Produce Grown in Fields Amended with Untreated Biological Soil Amendments of Animal Origin; Request for Comments, Scientific Data, and Information)

The American Farm Bureau Federation (Farm Bureau) is the nation's largest general farm organization, representing nearly six million member families and growers of virtually every commodity. The implementation of the Food Safety Modernization Act (FSMA) is a major challenge and we appreciate the Food and Drug Administration (FDA) recognizing that farmer and rancher input is integral in ensuring food safety goals are met. Farm Bureau also appreciates FDA seeking additional input on the use of Biological Soil Amendments of Animal Origin (BSAAO) in its "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" (FDA-2016-N-0321) published in the Federal Register on March 3, 2016. This docket sets in motion the next several years of FDA's work to assess, research, and ultimately propose standards that regulate how farmers use BSAAO, like raw manure.

Farm Bureau believes it is important to minimize the risk of foodborne illness throughout the food chain. However, this protection cannot come at the expense of options for farm inputs if science does not identify a present danger. BSAAO are valuable fertilizer options that have been used for centuries by farmers across the nation. In discussing the safety of BSAAO use, the prevalence, survival and transfer of pathogens throughout the farm-to-table process must be considered.

Data on the Prevalence of and Levels of Pathogens

Pathogens like *E. coli* O157:H7 and *Salmonella* are frequently associated with animals; however, their presence in BSAAO is relatively low. A survey of Georgia poultry litter found no *E. coli* or *Salmonella* in any samples.[1] Another study found *E. coli* in less than half of a percent of dairy and beef cattle across the state of Washington.[2] Still another detected *E. coli* in zero chickens, less than half a percent of pigs, 2.2 percent of sheep and what it stated was an anomalous 15.7

[1] Martin, S. A., McCann, M. A., & Waltmann II, W. D. (1998). Microbiological Survey of Georgia Poultry Litter. *Journal of Applied Poultry Research*, 90-98. doi:10.1093/japr/7.1.90
[2] Hancock, D. D., Besser, T. E., Kinsel, M. L., Tarr, P. I., Rice, D. H., & Paros, M. G. (1994). The prevalence of Escherichia coli O157.H7 in dairy and beef cattle in Washington State. *Epidemiology & Infections*, 199-207.

percent of cattle over a one year period.[3] Two additional studies found *E. coli* in just 1.4 percent and 3.21 percent of cattle.[4] Several studies noted that pathogens may not be consistently shed in feces, maintaining low levels of pathogens in manure overall. Even considering the variety in type of BSAOO applied, there is consistently a relatively low concentration of pathogens in raw soil amendments.

Data on Survival of Pathogens

The survival of even these few pathogens is important to consider. Studies on the survival of pathogens have varying results, indicating the need for two to 35 days to kill 90 percent or more of the microorganisms present.[5] Research further indicated the need for 54 to 126 days for pathogen levels to return to zero.[6] Most studies also note a primary increase in pathogen levels for the first three to seven days before decreasing. The science consistently supports the application threshold set in place by the National Organic Program (NOP).

However, time is not the only consideration relevant to this analysis. Soil type significantly affected bacteria survival, as did differences in temperature and aeration. Microorganisms can survive for several months in soil. However, Hutchison, et al. (2004) found population decline to be greater when spread BSAAO was left on the soil surface, rather than immediately incorporated into the soil.[7] Nicholson, Groves, & Chambers (2005) found that *E. coli* O157:H7, *Salmonella* and *Campylobacter* survived in solid manure heaps for less than one month and survived on two different soil types after spreading for up to one month.[8] Also, geographic diversity plays a major role in the survival of pathogens. The differences in survival rates due to soil types and temperature are significant and, along with unique growing seasons, again provide reason that the NOP 120 day standard continues to be the applied standard.

Data on Transfer to Produce

While the science demonstrates a minimal potential for pathogen survival, the next question addresses the transfer of said pathogens to produce and their survival there.

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[3] Chapman, P. A., Siddons, C. A., Cerdan Malo, A. T., & Harkin, M. A. (1997). A 1-year study of Escherichia coli O157 in cattle, sheep, pigs and poultry. *Epidemiology & Infections*, 245-250.

[4] Wells, J. G., Shipman, L. D., Greene, K. D., Sowers, E. G., Green, J. H., Cameron, D. N., . . . Wachsmuth, I. K. (1991). Isolation of Escherichia coli Serotype O157:H7 and Other Shiga-Like-Toxin-Producing E. coli from Dairy Cattle. *Journal of Clinical Microbiology*, 985-989.; Hancock, D. D., Rice, D. H., Thomas, L. A., Dargatz, D. A., & Besser, T. E. (1997). Epidemiology of Escherichia coli O157 in Feedlot Cattle. *Journal of Food Protection*, 462-465.

[5] Himathongkham, S., Bahari, S., Riemann, H., & Cliver, D. (1999). *Survival of Escherichia coli O157:H7 and Salmonella typhimurium in cow manure and cow manure slurry.* Elsevier Science B.V.

[6] Wang, G., Zhao, T., & Doyle, M. P. (1996). Fate of Enterohemorrhagic Escherichia coli O157:H7 in Bovine Feces. *Applied and Environmental Microbiology*, 2567-2570.; Fukushima, H., Hoshina, K., & Gomyoda, M. (1999). Long-Term Survival of Shiga Toxin-Producing Escherichia coli O26, O111, and O157 in Bovine Feces. *Applied and Environmental Microbiology*, 5177-5181.

[7] Hutchison, M. L., Walters, L. D., Moore, A., Crookes, K. M., & Avery, S. M. (2004). Effect of Length of Time before Incorporation on Survival of Pathogenic Bacteria Present in Livestock Wastes Applied to Agricultural Soil. *Applied and Environmental Microbiology*, 5111-5118.

[8] Nicholson, F. A., Groves, S. J., & Chambers, B. J. (2005). *Pathogen survival during livestock manure storage and following land application.* Elsevier.

Farm Bureau recognizes that pathogens can transfer to produce in the growing cycle. Experiments demonstrate that *E. coli* O157:H7 can enter the lettuce plant through the roots and migrate throughout the plant.[9] BSAAO may also come into direct contact or spread through soil-splash-mediated dispersal and internal colonization (landing on the leaves, entering damaged tissue areas, being pulled up by the roots and stem, attaching during germination, etc.).[10]

Yet, a Wisconsin study found low level contamination with *E. coli* to occur sporadically in washed carrots, lettuce and radishes regardless of whether manure had been applied[11]. Even so, the experiment commonly yielded enrichment-negative results for carrots and lettuce harvested less than 120 days after manure application. The researchers found carrots were more likely to be contaminated than lettuce. Results for radishes were more ambiguous; because of rapid rates of maturation, a 120-day interval could not be effectively evaluated. The study does draw the conclusion that reducing the National Organic Program standard to 100 days would only slightly increase the risk of contamination. Researchers note that such a decrease would give Wisconsin vegetable farmers greater flexibility in scheduling manure application and would lessen the likelihood of soil compaction caused by manure application too early in the spring.[12]

History does not demonstrate a problem with the NOP's 120 day interval; if it did, we would see a greater incidence of contamination in organic produce, which we do not. Given 15 years of following this standard without major problems, it is reasonable to assume, as numerous studies state, that this standard is suitable.

On-Farm Practices to the Use of Untreated BSAAO

There is much variability in the farming methods, type of farms, location of farms and type of BSAAO used across the country. BSAAO is a cost effective substitute for commercial fertilizers and on organic farms pursuant to the requirements of the National Organic Program and it needs to remain available to farmers. According to the USDA Economic Research Service ARMS survey, farmers reported using BSAAO on nearly 16 million acres of cropland as a fertilizer. This acreage is spread across the country; however, there is a direct correlation to the access and application of BSAAO. For example, the commodities that use the most BSAAO are typically on farms that raise livestock or in areas that have access to large amounts of manure. There are also multiple, different methods of application that impact pathogen levels and foodborne illness risks. For instance, it may be applied as slurry or pellets, and it may be spread on top of the soil, spread and tilled into the soil, or sprayed through an irrigation system.

[9] Monaghan, J. M., & Hutchison, M. L. (2012). Distribution and decline of human pathogenic bacteria in soil after application in irrigation water and the potential for soil-splash-mediated dispersal onto fresh produce. *Journal of Applied Microbiology*, 1007-1019.
[10] Buck, J. W., Walcott, R. R., & Beuchat, L. R. (2003). Recent Trends in Microbiological Safety of Fruits and Vegetables. *Plant Management Network*.
[11] Ingham, S. C., Losinski, J. A., Andrews, M. P., Breuer, J. E., Breuer, J. R., Wood, T. M., & Wright, T. H. (2004). Escherichia coli Contamination of Vegetables Grown in Soils Fertilized with Noncomposted Bovine Manure: Garden Scale Studies. *Applied and Environmental Microbiology*, 6420-6427.
[12] Ibid.

Farm Bureau believes that these factors, along with the variances in soil and region, make it impossible to set a science-based approach to BSAAO application that could have a direct correlation to food safety.

Harvesting, Handling and Storage Conditions Affecting Pathogen Levels

Farm Bureau recognizes that during harvest and post-harvest handling, there are a number of potential sources of food safety risk. These risks have been articulated in Farm Bureau FSMA comments previously filed with FDA and Farm Bureau continues to educate our members and assist FDA as FSMA is implemented to ensure minimal risk in the growing, harvesting and packing of produce.

However, there are many processes that minimize risk. Many fruits and vegetables undergo a washing and sterilization process prior to moving to the consumer. This cleaning can decrease the presence of pathogens on fresh produce. Also, storage conditions such as cleanliness, temperature and length of time stored also play a major role in decreasing the survival of pathogens. Methods of controlled ripening and packaging may also influence and limit the survival rates of pathogens.

Storage Conditions Affecting Pathogen Levels During Transportation and Consumer Storage

Storage conditions affecting pathogen levels during transportation and consumer storage raise many of the same concerns as the harvesting, handling and storage conditions by producers, harvesters, processors and packagers. Temperatures, timelines and cleanliness must always be considered. Farm Bureau encourages the education of all food handlers on the proper preparation, cooking and serving of all food products and on sanitary practices as part of state licensing procedures. This education is important for everyone to ensure the washing of fresh produce, separation of products to avoid cross-contamination and cooling/storing of fresh produce at proper temperatures.

Conclusion

Farm Bureau is committed to improving produce safety in a targeted, scientific and risk-based manner. We look forward to continuing our working partnership with FDA to implement FSMA and to promote farm practices ensuring food safety and respecting agricultural techniques and inputs.

Sincerely,

Dale W. Moore

Dale Moore
Executive Director
Public Policy