

Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane
Room 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 Scientific Data, Information, and Comments; Extension of Comment Period

The undersigned associations appreciate the opportunity to provide input on FDA's request for data and information on its assessment of human health risks associated with the use of raw manure as fertilizer in crop production (*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*).

Our associations are the leading organizations for U.S. farmers and ranchers, and represent producers of livestock, poultry, eggs and dairy numbering in the hundreds of thousands across the nation.

With its current notice, FDA is embarking on a multiyear project that may require a full decade from the launch of its risk assessment to a final rule that regulates the use of manure. Our chief concern is that the agency's risk assessment and subsequent risk management decisions could adversely impact animal agriculture if not fully informed by current and emerging scientific research, or if well-established and widely used conservation and environmental practice standards are not properly considered in its model framework.

The agency recognized the complexity of the issue and the range of attendant variables associated with addressing human pathogens in soil when it advanced the Produce Safety rule under FSMA in 2013. 80 Fed. Reg. 74353 (Nov. 27, 2015). In light of concerns raised over key provisions in the rule, FDA proposed and later deferred until further notice its recommendation of a nine-month interval between raw manure application and crop harvest for certain application methods.

We appreciate the FDA's current acknowledgement that additional research and evaluation will be necessary to avoid potentially arbitrary decisions in any final future rule on interventions, including the use of application intervals for manure. In fact, the agency has noted specifically in its outreach announcements, news releases and in discussions with us that it "wants the help of stakeholders" – including the animal agriculture industry – "in developing a risk assessment that will provide a strong scientific foundation for future agency positions on this issue."

Because we share the agency's commitment to science-based decision making for minimizing food safety risks to the greatest extent possible, we reached out informally to FDA staff in recent months to begin a discussion and better understand the agency's approach in several areas, including: (1) what is the agency's objective for the current data call (e.g., what information does FDA realistically expect to receive); (2) what is the agency's plan to identify and address gaps in data and research; (3) how will the agency identify its priorities for near- and long-term research; and (4) how might the animal agriculture community best provide relevant information and perspective to FDA on the linkage between food safety decisions and conservation practices.

In our discussion, we noted that even as we appreciate the agency's interest in receiving input from animal agriculture and other stakeholders, the relatively brief window for receiving information and data does not provide an opportunity for a proper exchange between FDA and industry representatives on some important technical and practical issues, including the practical realities of animal husbandry and related conservation matters for which FDA has stated it seeks additional details.

The agency has informed us that given the current comment period represents a first step in FDA's effort to fill existing information gaps, additional technical and scientific data or information on management practices will be accepted going forward as the agency proceeds with its work on the risk assessment after the current comment deadline. We would look forward to providing additional input in response to the agency's outreach efforts.

We have also suggested that FDA consider including expert stakeholders from the animal agriculture community in its "summit" meeting planned for next year through the Produce Safety Alliance, a partnership between Cornell University, USDA and FDA. We believe that this venue and other opportunities for discussion could prove invaluable in providing a necessary perspective and informing the risk assessment. In the course of our review of the "Final Qualitative Assessment of Risk to Public Health from On-Farm Contamination of Produce" located in the docket, we have begun discussions on manure and pathogen issues with academic experts in the field.

With respect to the scientific literature on manure and pathogens as well as experience with the National Organic Program, we reference and support the brief comments to the FDA docket by the American Farm Bureau Federation, which highlight some general findings in the scientific literature that we summarize below:

- **Pathogen Prevalence Data** – While human pathogens like *E. coli* O157:H7 and *Salmonella* are associated with animals and a variety of Biological Soil Amendments of Animal Origin (BSAAO) are applied, they occur at a relatively low concentration levels in raw soil amendments.
- **Pathogen Survival Data** – The science consistently supports the application interval of 120 days set by the National Organic Program (NOP). In addition to time as a factor in bacteria survival, temperature, aeration, soil type, geography and related considerations point to the appropriateness of the NOP standard.
- **Produce Transfer Data** – The 15 years of experience with the NOP's 120 interval shows no problem with a higher incidence of organic produce contamination using this standard.
- **Untreated BSAAO and on-Farm Practices** – There is wide variability in the use of BSAAO across the country as a cost-effective substitute for commercial fertilizer and for use on organic farms. There are multiple application methods that may impact pathogen levels, making it difficult to set a science-based approach to applying BSAAO that directly correlates to food safety.
- **Pathogen Levels and Harvest, Handling and Storage Conditions** – There are a number of sources of food safety risk, but there are many processes and protocols for sanitation and cleaning produce prior to reaching the consumer that limit and influence the survival rates of pathogens.
- **Pathogen Levels During Transportation and Consumer Storage** – Pathogen levels associated with transportation and consumer storage and handling raise

many of the same issues as harvesting, handling and storage by producers, harvesters, processors and packagers.

We appreciate the opportunity to provide initial input in response to FDA's request for information, and we look forward to follow up discussions on several important topics for the animal agriculture community.

Sincerely,

American Farm Bureau Federation

National Cattlemen's Beef Association

National Chicken Council

National Council of Farmer Cooperatives

National Milk Producers Federation

National Pork Producers Council

National Turkey Federation

United Egg Producers

U.S. Poultry & Egg Association