

Raw Manure under the FSMA Final Rule on Produce Safety

When we talk about untreated biological soil amendments of animal origin (BSAAOs), we're essentially talking about raw manure. There are other substances that fall into this category, such as bone and fish meal, but in the main, the subject at hand is manure from cattle, chickens, horses and other farm animals.

The FDA is planning to conduct a risk assessment to determine how much consumer health is put at risk by the use of raw manure as fertilizer in growing crops covered by the Produce Safety rule, and what can be done to help prevent people from getting sick. Before starting, the agency wants the help of stakeholders in the produce industry, the animal agriculture industry, academia and members of the public in developing the framework of this assessment. A notice published in the *Federal Register* requests public comments and scientific data and information.

Why FDA Wants Public Input on Assessing the Risk of Raw Manure as Fertilizer: A Q&A with Samir Assar

Samir Assar, Ph.D., director of FDA's Division of Produce Safety, explains how the FDA is reaching out to the produce community and other stakeholders as the agency prepares to evaluate the agricultural use of raw manure.



1. What are FDA's concerns about the use of raw manure as fertilizer in crop production?

This is a food safety issue. Raw manure has the potential to contain foodborne pathogens (microorganisms that cause human disease). Pathogens that live in the intestines of animals can be transmitted from their manure to produce in a number of ways and from there to people under certain conditions. For example, *E. coli* O157:H7 (a particularly dangerous pathogen) lives in the intestines of some cattle and *Salmonella* (consistently one of the top causes of foodborne illness worldwide) lives in the intestines of some poultry.

A 2015 FDA report on the assessment of the risk to public health from on-farm contamination of produce identifies BSAs of animal origin as a potentially significant source of pathogens.

2. People clearly have strong feelings about this issue. What is the benefit that farmers see in using raw manure as fertilizer?

There are a number of reasons why growers may use raw manure. They see it as an effective way to provide nitrogen and other nutrients to the soil, and maintain soil quality and health.

There's a cost factor, too, since it's readily available at a lower cost. A produce grower, for example, may use manure provided by a neighboring dairy farm. Some small farms may lack the infrastructure to compost properly, leading them to use applications of raw manure.

As a practical matter, farms that raise livestock need to dispose of manure in a safe and environmentally sound way, and using it as fertilizer or sharing it with a neighbor may be viewed as one way to do that.

When the FDA first proposed the Produce Safety rule mandated by the FDA Food Safety Modernization Act (FSMA) in 2013, the proposed criteria included a nine-month interval between the application of raw manure (and other untreated BSAAOs) and the crop harvest when certain application methods are used.

Many growers and other stakeholders in the produce industry objected, focusing on the limitations of the data on practices across the U.S. and internationally. Organic growers specifically expressed concern about the differences between the proposed application interval and the USDA National Organic Program standards for raw manure application intervals.

In response, the FDA decided to reserve a decision on the minimum application interval and to conduct additional research and a risk assessment, which can evaluate the impact of interventions that include the use of application intervals. This change was included in the September 2014 supplemental notice for the produce rule and carried forward into the final version, which was issued in November 2015.

3. How will FDA engage the farm community and produce industry in developing criteria for the risk assessment?

The *Federal Register* Notice is the first step in a process throughout which we hope to work with the farming community, including the produce and animal agriculture sectors. We want their help in developing a risk assessment that will provide a strong scientific foundation for future agency positions on this issue. At every step in this process, we will do our best to be open through communications and outreach events.

4. What kind of input is the FDA seeking?

The information and comments that we're looking for are detailed in the *Federal Register* notice. They include:

- Data on the prevalence and levels of pathogens in both raw manure from different animal sources and soil amended (fertilized) with raw manure.
- Data on the survival of pathogens and their transfer to produce from soil amended with raw manure under various manure management systems and farming practices. Information could include the type of raw manure, the type of crops, and the application method.
- Data and information regarding on-farm practices and conditions associated with the growth and production of produce using raw manure, and harvesting practices. These include the type of raw manure, timing of and amounts of raw manure applied, application methods, kind of produce, climate conditions, irrigation practices, and crop density.
- Information on harvesting, handling and storage of such produce and their effects on the survival, growth or inactivation of pathogens.
- Appropriate mitigation strategies to consider in the risk assessment that reduce the public health risk associated with use of raw manure in the production of fruits and vegetables.

5. In the meantime, what protections do consumers have from raw manure if it's contaminated?

We have placed restrictions on how raw manure is applied. The final Produce Safety rule requires that covered farms not apply raw manure in a manner that contacts produce covered by the rule during application. And these farms are required to minimize the potential for contact after application.

To minimize the chance of contamination, we also stated that we believe it would be prudent for farmers to comply with the USDA's National Organic Program standards related to raw manure use while the research and risk assessment is ongoing. These call for a 120-day interval between the application of raw manure for crops in contact with the soil and 90 days for crops not in contact with the soil.

6. What is the role and responsibility of an FDA risk assessment?

FDA risk assessments are developed to inform decision making. The goal is to use the best science and risk modeling to integrate data and information in an objective and transparent way that increases understanding of the interactions between foods, hazards and consumers.

This particular risk assessment will evaluate and, if feasible, quantify the risk of human illness associated with consumption of produce grown in fields or other growing areas amended with raw manure. It will evaluate the impact on risk of certain interventions, such as use of a time interval between application and harvest.

It can also help us identify where we have the most uncertainty and can help direct further research and data collection efforts.

7. What happens next? Will the risk assessment proceed from there? When will the public have another opportunity for input?

After the *Federal Register* notice is published, stakeholders should submit their data, information and comments to the docket. The next step is that FDA scientists, in consultation with scientists at the U.S. Department of Agriculture (USDA), will use these and other available data to develop the risk assessment. We will provide updates and opportunities for stakeholders to provide input throughout the development process, and are developing a plan to provide this outreach.

One such venue will be a summit meeting that the Produce Safety Alliance (PSA)—a partnership between Cornell University, USDA and FDA—is planning.

When the risk assessment is developed and has undergone an external peer review, it will be made available for public comment.

8. What research has FDA already done into the survival of pathogens, such as *E. coli* O157:H7, in soil amended with raw manure?

The FDA has facilitated several research projects on the extent to which raw manures may contain pathogens, and how those pathogens may survive in soils amended with this manure. The agency has funded research with USDA's Agricultural Research Service (ARS), as well as other research. This includes work with one of our Center for Excellence Partnerships – the Western Center for Food Safety at the University of California, Davis – to investigate how soil type, geographical location, manure type and seasonal conditions that may affect the persistence and survival of pathogens in the produce-growing environment.

9. Where does composted manure fit into the picture?

There is a distinction and we respect it, related to the difference between raw manure and composted manure. Specifically, the focus of the risk assessment is on raw manure. We describe the parameters for determining the status of a “treated” or “untreated” BSAO in the Produce Safety final rule. Our concern for the purposes of this risk assessment is any manure that has not been processed to completion to adequately reduce pathogens. This clearly includes raw manure but could also include aged piles and incompletely processed manure, among other types.

10. Hasn't FDA already made up its mind that raw manure should not be used?

No. We have already provided for certain ways that raw manure can be used as a soil amendment in compliance with the produce rule, such as if it is applied in a manner that prevents contact with the crop before and after application. We will seek public comment on any eventual proposal to establish a time interval(s) for other untreated BSAO application methods allowed under the rule.

There are important public health concerns that we have a responsibility to address, but at the same time we recognize that the use of raw manure is an extremely complex and important issue. There are differing views and strong beliefs. We take those seriously.

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm482426.htm>