
**FDA Proposed Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption
Subpart F – Standards Directed to Biological Soil Amendments of Animal Origin and Human Waste
OTA Talking Points**

Background

- The organic industry generates close to \$31 billion in sales and continues to be the fastest-growing sector in agriculture. Organic production relies on compost and manure as part of the foundation for soil health and fertility.
- Current USDA organic regulations require either a 90- or 120-day waiting period between untreated manure application and crop harvest depending on whether the edible portion of the crop comes in contact with soil. Compost is not subject to any waiting period following application regardless of crop.
- Proposed FDA regulations would require a 9-month waiting period following untreated manure applications and a 45-day waiting period following compost application for all crops covered by the produce safety rule.
- The Food Safety Modernization Act (FSMA) mandates that FDA develop rules that do not duplicate or conflict with existing organic regulations.

Regulatory Conflict and Ramifications

- A recent survey conducted by the Washington State Department of Agriculture (WSDA) and the Organic Trade Association (OTA) received responses from over 300 of the approximately 8,100 certified organic producers in the U.S. This level of response equals a confidence level of 95% and a confidence interval of 5.51%.
- Results indicate that FDA's proposed waiting periods between application and harvest for compost and untreated manure will restrict organic producers' ability to rotate crops as part of preventive pest and disease control and to comply with the established USDA Organic Regulations at 7 CFR 205.205 (Crop rotation practice standard).
- Failure to implement crop rotation as part of a preventive pest management program will force organic producers out of compliance with current USDA organic regulations and prompt organic certifiers to pursue adverse action.

Scientific Evidence

- The scientific justification for a 9-month application interval for untreated manure is based on one or two papers that present the worst-case scenario. Numerous other studies on pathogen persistence in soil align more with the current USDA organic regulations (90/120 days depending on soil contact).
- The cited literature doesn't clearly indicate how FDA decided upon a 45-day waiting period as necessary to mitigate the risk of pathogen exposure from compost.
- The use of selective science from worst-case scenarios for assessing pathogen risk from manure and the establishment of seemingly arbitrary waiting periods for compost are inconsistent with FDA's mandate that it develop science-based produce safety rules.

Solutions for Safe Organic Produce

- The proposed 9-month waiting period following untreated manure applications for all produce should be brought into alignment with USDA organic regulations by implementing a waiting period of 120 days for crops in contact with the soil (i.e. potatoes) and 90 days for crops not in contact with the soil (i.e. apples).
- The proposed 45-day waiting period following compost applications should only be applied to crops in contact with the soil, and alignment with USDA organic regulations (no waiting period) should be applied to crops not in contact with the soil.
- Additionally, the 45-day waiting period following compost applications should be removed entirely from compost that has been managed in accordance with time and temperature requirements **AND** tests free of the specific disease causing pathogens outlined in 21 CFR 112.55(a).

Summary

- Survey results establish a conflict between current USDA organic regulations and proposed FDA produce safety regulations.
- Scientific literature cited in the proposed produce safety rule support concerns that manure and compost pose a food safety risk, but do not support the waiting periods proposed by FDA. Aligning with USDA organic regulations for the use of manure and expanding options for compost use patterns and quality testing will eliminate regulatory conflict without a reduction in food safety.

