May 9, 2016

MEMORANDUM TO THE NATIONAL ORGANIC STANDARDS BOARD

FROM: Miles V. McEvoy
Deputy Administrator
National Organic Program (NOP)

SUBJECT: Guidance for Treated Manure Products

The Agricultural Marketing Service (AMS) published NOP 5006 Guidance, Processed Animal Manures in Organic Crop Production, on October 5, 2010, with minor revisions in July 2011. The National Organic Program Handbook document clarifies that manure, when treated (or “processed”) according to specific guidelines to reduce pathogenic microorganisms, is not the same as raw manure and, therefore, may be applied to organic crops and fields without an intervening period between application and harvest as is required for raw manure applications under USDA organic regulations.

Several manufacturers have contacted AMS seeking clarification about whether their manure treatment methods could be considered similarly, thereby eliminating the requirement for an intervening period between application and harvest (“application interval”) that is required under section 205.203(c)(1) of the USDA organic regulations. The manure treatment methods in the recent cases differ from the guidelines described in NOP 5006, and they are not eligible for consideration under the published National List Petition Guidelines because they do not use synthetic materials. Stakeholders have also asked AMS to clarify if anaerobic digestate made with manure as a feedstock requires an application interval, and for clarification regarding acceptable feedstocks and processes used for anaerobic digestate permitted in organic production. AMS is requesting that the National Organic Standards Board (NOSB) Crops Subcommittee add this topic to its work agenda, evaluate if the prescribed application intervals apply when these products are used, and determine if any additional action is needed by the NOSB.

AMS requests that the NOSB consider this topic in light of new Food and Drug Administration (FDA) rules under the Food Safety Modernization Act (FSMA) at 21 CFR Part 112. The FDA rules address the use of biological soil amendments of animal origin (21 CFR 112.51-112.60), including application restrictions (e.g., preventing contact with crops) and application intervals. The FDA rules include criteria for classifying soil amendments, including manure, as either “treated” or “untreated” according to how they are processed and microbial standards. One of the two microbial standards (§ 112.55(b)) described in the FDA regulations mirrors the microbial...
standard included in NOP 5006. AMS requests that the NOSB review the FDA rules when considering any recommendation to AMS regarding treated manure products in organic production.

On March 3, 2016, FDA published a Federal Register notice regarding their plan to conduct a risk assessment to evaluate the risk of human illness associated with the consumption of produce grown with untreated biological soil amendments of animal origin (see References). AMS plans to consult with the FDA on their risk assessment, and will keep NOSB informed of new developments in FDA policy.

NOP 5006 requires 1) heating and 2) drying. Specifically, manure must reach a minimum temperature of either 150° F for at least one hour or 165° F, and be dried to a maximum moisture level of 12%. NOP 5006 also allows for equivalent heating and drying processes. In determining the acceptability of an equivalent process, NOP 5006 requires the final product not contain more than $1 \times 10^3$ (1,000) MPN (Most Probable Number) fecal coliform per gram of processed manure sampled and not contain more than 3 MPN *Salmonella* spp. per 4 gram sample of processed manure.

In the recent inquiries received by AMS about treated manure, the treatment processes achieve microbial pathogen reduction that corresponds to NOP 5006 but without both a heating and drying step. In one case, the treatment process does not utilize a drying step. The final product is liquid, but the heat used in the treatment process accomplishes the reduction of microbes to levels in accordance with NOP 5006. Anaerobic digestate that includes manure as a feedstock shares similarities with this process. In a second case, the treatment reduces moisture and achieves pathogen reduction in accordance with NOP 5006 but does not employ heat. Moisture is reduced by subjecting raw manure to high speeds (over 700 mph) in a rotating “dryer” (no heat applied). AMS encourages the NOSB to solicit public comments on whether additional manure treatment technologies should be reviewed.

Based on review of this information and consultation with stakeholders, NOSB may propose further guidance or regulations on this topic or revision of existing guidance, including NOP 5006. If the NOSB requires assistance in evaluating treated manure, including manure treated via anaerobic digestion, AMS can facilitate the acquisition of technical review materials.

**References**

- **Organic Foods Production Act of 1990, as amended**

- **USDA Organic Regulations (7 CFR Part 205)**
  7 CFR 205.203 Soil fertility and crop nutrient management practice standard.
NOP Program Handbook: Guidance and Instructions for Accredited Certifying Agents and Certified Operations

NOP 5006  Processed Animal Manure in Organic Crop Production.
NOP 5021  Compost and Vermicompost in Organic Crop Production.

NOSB Recommendations


U.S. Food and Drug Administration—Regulations and Risk Assessment

- Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (7 CFR Part 112)
- 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 (81 FR 11572, March 3, 2016)