

**Formal Recommendation**  
**From: National Organic Standards Board (NOSB)**  
**To: The National Organic Program (NOP)**

**Date:** November 2, 2017

**Subject:** Petition to amend §205.203(c) to include anaerobic digestion products

**NOSB Chair:** Tom Chapman

**The NOSB hereby recommends to the NOP the following:**

Rulemaking Action: None

**Statement of the Recommendation:**

The NOSB does not recommend the addition of anaerobic digestate the National List to be used in organic production exclusive of days-to-harvest restrictions following application.

**Rationale Supporting Recommendation:**

Because of the potential for negative effects on human health through food-borne pathogens, the unproven safety of digestate fiber, and the many alternative practices and materials already in use in organic production, the NOSB has determined that anaerobic digestate as petitioned, without pre-harvest application intervals, is not compatible with a system of sustainable agriculture.

**NOSB Vote:**

**Classification Motion:**

Motion to classify anaerobic digestate as nonsynthetic

Motion by: Emily Oakley

Seconded by: Harriet Behar

Yes: 15 No: 0 Abstain: 0 Absent: 0 Recuse: 0

**Outcome:** Motion passed

**Motion to amend section 205.203(c)** to add bolded and underlined language at 205.203(c)(1)  
Raw animal manure, which must be composted **or undergo an anaerobic digestion process**  
unless it is...**(4) Anaerobic digestion products that have been processed to reduce pathogens.**

Motion by: Emily Oakley

Seconded by: Steve Ela

Yes: 0 No: 15 Abstain: 0 Absent: 0 Recuse: 0

**Outcome:** Motion Failed

**National Organic Standards Board**  
**Crops Subcommittee Petitioned Material Proposal**  
**Anaerobic Digestate**  
**August 15, 2017**

**Summary of Anaerobic Digestate [Petition](#):**

Cenergy USA, Inc. submitted a petition “to establish a separate classification for anaerobic digestate on the National list of Allowed and Prohibited Substances”. The petition requests that anaerobic digestate fiber, or digestate, produced without synthetic materials, be allowed for use in organic production exclusive of days-to-harvest restrictions following application.

The petition states: “the section for inclusion of substance: §205.600 as plant or soil amendments”; however, the material does not include any synthetic materials and so would not fall under §205.601, Synthetic substances allowed for use in organic crop production. The petition requests that anaerobic digestate materials not be classified as raw manure and therefore not be subject to pre-harvest intervals. If approved, an inclusion of anaerobic digestate would likely involve an amendment to 205.203(c), with a new listing defining a standard for anaerobic digestate.

The petition is for anaerobic digestate derived from plant and animal products in a two stage mixed plug-flow digester. Anaerobic digestate fiber is currently used in horticultural products, crop production, and landscape applications as a soil amendment and fertilizer with the same restrictions required of raw manure, when used in organic production. The fiber is an ingredient in potting soils, is used in fertilizers, and serves as an alternative to peat moss in the commercial greenhouse industry.

In this petition, anaerobic digestate fiber is manufactured by collecting animal manure and/or food scraps in a receiving pit. The petition states: “the waste is collected throughout the day, chopped as needed, and pumped directly into the anaerobic digester vessel”. During the first stage of production, the raw waste is mixed and heated to 101 °F. Either reclaimed waste heat or a boiler is used to maintain the digester temperature for the growth of methanogenic bacteria. Waste materials from the first stage gravity flow into the second stage of the vessel. Here “the methanogenic bacteria convert volatile fatty acids and acetic acids produced in the first stage of the anaerobic digestate vessel into a biogas”. Heat mixes the material in a rotational motion, and it is held at 101 °F for 21 days. Next the waste flows into an effluent collection pit for additional processing. The liquid and solids are separated, and a fiber of 30-35% solid material is produced.

The petitioner states that digestate is not raw manure or compost, is virtually pathogen free, and therefore should not be restricted. They suggest that the two stage mixed plug-flow anaerobic digester produces a material that is equivalent to OMRI’s classification of processed manure (based on NOP Guidance NOP 5006 Processed Animal Manures in Organic Crop Production). While this classification specifies a minimum temperature of 150 °F for at least one hour and maximum moisture content of 12%, the petitioner proposes that these temperature, duration, and drying criteria are unnecessary for pathogen kill when using their digestion process.

**Summary of Review:**

The NOP first sent the petition to the Materials Subcommittee before making an eligibility determination. In agreement with the NOP, the MS determined that the petition should be sent to the Crops Subcommittee for review.

The CS requested a comprehensive technical review (TR) for all anaerobic digestate system technologies and feedstocks and posed the following supplemental questions:

1. Define anaerobic digestion (AD) and its end products.
2. Describe commercially available AD technologies and how the different technologies affect the end products.
3. Discuss differences between anaerobic digestate products and compost.
4. Provide a summary of all the methods in use for creating this material, with feedstocks, ingredients, and end products. The TR should also describe any materials (e.g., acids, bases, microorganisms, etc.) typically added during the anaerobic digestion process, and discuss the fate of these additives (e.g., if they are used up, removed, or contribute to the nutrient profile for the end product).
5. Explain a typical nutrient cycle for the feedstocks into end products from these processes, focusing on nitrogen.
6. Describe available data concerning pathogen (e.g., E. coli, Salmonella) control using anaerobic digestion and describe documented microbiological risks from use of AD products.

The TR provides a broad review of anaerobic digestate, looking at Plug Flow, Complete Mix, the Chinese Dome Digester, and the Indian Gobar System in addition to the Two Stage Mixed-Plug Flow method. It examined only the digestate fiber, not the liquid that is also an end product. There is broad variability in the physical and chemical properties of digestate fiber depending upon the feedstocks and fermentation process. The three products of anaerobic digestion are biogas, digestate fiber, and liquid (also referred to as the liquor).

According to the TR, “anaerobic digestate is best characterized as friable, flocculated organic matter” (LINES 96). “Application of AD recycles nutrients in a way that is similar to the application of raw manure and compost. However, a review of the literature indicates that the nitrogen in AD will have higher levels of ammonium ( $\text{NH}_4^+\text{-N}$ ) nitrogen” (TR LINES 136-138). “Sulfur amino acid decomposition under reducing conditions—such as in the absence of oxygen—increases the production of hydrogen sulfide gas, which is usually vented with the biogas unless it is precipitated prior to release. More research would be needed to investigate how the soil sulfur cycle is changed by anaerobic digestion technologies, and whether the reduced forms of sulfur from AD have an impact on plant availability and soil microorganisms” (TR LINES 185-189).

“While the anaerobic digestion process can take place without chemical additives, various substances are used to pre-treat the feedstocks, adjust the substrate during the digestion process, and treat the finished AD. Various other ingredients may be blended with the feedstocks before or injected during the digestion process, which may include acids and bases to adjust the pH, surfactants to dissolve and separate fatty acids, and sequestrants and chelating agents to precipitate and remove toxic metals. The fate of these various additives would depend on how they are partitioned when the digestate is removed. At least some can be reasonably expected to remain in either the digestate or the liquor. While it is possible to make some predictions about the likely fate of the additives based on their structure, function and activity, these predictions would need to be empirically tested by third-party peer-reviewed studies to see if these predictions are scientifically valid. Such studies are not available in the literature” (TR LINES 412-421).

“Adsorbents and surfactants may also be added to remove the scum from the liquor, both during the wastewater pretreatment process as well as after the gas is vented and the effluent is released. Some surfactants, such as sodium lauryl sulfate, polyethylene sorbitan fatty acids (Tween), and polydimethyl siloxane polyethers (Tegoprens) may accelerate digestion and increase the methane yield (Madamwar, Patel, and Patel 1991; Madamwar et al. 1992). Others, such as the alkyl sulfonates, appear to inhibit some of the organisms responsible for the digestion process and lower the methane yield (Hobson and Wheatley

1993). Some commercial sources of AD will add nitrification inhibitors. Most of these are proprietary products, and the active substances are trade secrets” (TR LINES 199-208).

Because this petition is for manure that does not meet the compost practice standard in 205.203(c)(2) and is requesting an exemption to the raw manure application practice standard in 205.203(c)(1), it is helpful to review some history for these two standards. The Preamble to the Final Rule published in 2000 (65 FR 80547) addresses the issues surrounding applications of manure that were discussed during the rulemaking process. The 120-day interval for crops in contact with the soil and the 90-day interval for other food crops were both supported by the NOSB. It explains on page 80567 that “commenters stated that the lengthy intervals between application and harvest would not impose an unreasonable or unfeasible burden on organic producers”. Additionally, “other commenters stated that the provisions were consistent with the requirements in existing organic standards and added that the restrictions were justifiable because they reflected responsible management practices”.

In 2010, the NOP published Guidance 5006 Processed Animal Manures in Organic Crop Production. It specifies guidelines for manure treatment to reduce pathogens that allow for such products to be applied without a pre-harvest interval.

Some manufacturers subsequently inquired if their manure treatment methods not specified in NOP 5006 could be viewed similarly. On May 9, 2016, the NOP sent a Memorandum to the NOSB on Guidance for Treated Manure Products. The memo notes, “Stakeholders have ... asked AMS to clarify if anaerobic digestate made with manure as a feedstock requires an application interval”. The memo goes on to request that the NOSB “evaluate if the prescribed application intervals apply when these products are used”. This proposal seeks to provide clarification on this request.

In addition to anaerobic digestate, other manufacturers employ heat without drying or a moisture reduction process without heating to treat manure. NOP 5006 requests that the CS also evaluate these treatment processes to determine if they should be allowed without a preharvest interval. Following the adoption of the Food Modernization Safety Act, the Food and Drug Administration (FDA) undertook a risk assessment of produce grown with manure. The CS is awaiting the outcome of the FDA’s assessment and will then determine how to evaluate these other manure treatment methods as a separate work agenda item.

### **Category 1: Classification**

1. For CROP use: Is the substance   **Non-synthetic** or   **Synthetic**?

Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [OFPA §6502(21)] If so, describe, using NOP 5033-1 as a guide.

No; the TR is not asking for a digestate listing using any synthetic materials.

2. Reference to appropriate OFPA category:

Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i)]; copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern?

No. The substance is not being petitioned as a synthetic, and these categories only apply to synthetic substances.

## Category 2: Adverse Impacts

1. What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]

None.

2. What is the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment? [§6518(m)(2)]

Heavy metals and other chemical contaminants may be present in digestate fiber. According to the TR, “the metal contaminants of greater concern in livestock systems are copper and zinc” (LINES 616-617), as would also be the case when such manure is used raw in field applications or as an ingredient in compost. Other chemical contaminants may include phthalates from degraded plastics and pesticides (TR lines 622-623).

3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]

Digestate is often made using manure from concentrated animal feeding operations (CAFOs), and as noted above, it is also sometimes used in raw manure field applications or as an ingredient in compost. “CAFOs are a significant source of environmental pollution and pose risks related to water contamination, greenhouse gas emissions, aerosol pollutants, heavy metal contamination, and farm chemicals such as pesticides, antibiotics, and growth hormones. Manure is also a vector for human and animal pathogens” (TR LINE 667-670).

4. Discuss the effect of the substance on human health. [§6517(c)(1)(A)(i); §6517(c)(2)(A)(i); §6518(m)(4)].

“The principal human health concern from AD is food-borne pathogens” (TR LINE 791). “Several peer-reviewed papers document that foodborne pathogens commonly survive the anaerobic digestion process, as summarized in Table 2. In particular, spore-forming pathogens are the most likely to remain viable after the anaerobic digestion process (Franke-Whittle and Insam 2013; Nkoa 2014)” (TR LINES 797-799).

“While the anaerobic digestion process is documented to reduce certain pathogens, anaerobic conditions pose a different set of foodborne pathogen risks than would be found under aerobic conditions. Field validation of treatment processes is needed to verify that pathogens are not able to survive the anaerobic digestion process and migrate onto harvestable plant parts (Gerba and Smith 2005). That is because several pathogens are able to survive or at least remain viable after the anaerobic digestion process, but would be unlikely to survive aerobic composting. The indicator species used for aerobic compost, *E. coli* and *Salmonella* spp. may not be appropriate for anaerobic conditions. The indicator pathogens used for quality assurance of digested residues in Denmark are *Salmonellae*, *Listeria*, *Campylobacter* and *Yersinia* (Sahlström 2003)” (TR LINES 804-813).

Digestate fiber made from agricultural feedstock may be contaminated with *Listeria monocytogenes* as well as other common foodborne pathogens mentioned above (TR LINES 820-821, 824-831). *Clostridium perfringens* was not reduced in anaerobic digestion in several cases (TR LINE 830).

“Another foodborne pathogen of concern with AD is *Campylobacter jejuni*. While *Campylobacter* is a microaerophile, meaning that it requires some oxygen, it also thrives in oxygen-poor conditions. Anaerobic digestion was found to have little effect on *Campylobacter jejuni* populations after 112 days of digestion (Kearney, Larkin, and Levett 1993)” (TR LINES 833-836).

“*Bacillus anthracis*, the vector responsible for anthrax, was observed to survive anaerobic digestion of slaughterhouse wastes (Franke-Whittle and Insam 2013). The organism can be grown in either aerobic or anaerobic conditions, and also forms spores that can remain viable after thermophilic temperatures (J. E. Olsen and Larsen 1987). Prions, the vectors that transmit bovine spongiform encephalopathy (BSE), are not considered to be adequately digested in the fermentation process (Franke-Whittle and Insam 2013)” (TR LINES 844-850).

“The petition claims that the pathogen reduction in plant and animal materials properly processed in a two stage mixed plug-flow anaerobic digester produced an equivalent heating process to aerobic composting as specified in the NOP regulations at §205.203(c)(2) (Joblin 2016). The petition requests that such AD not be subject to a days-to-harvest interval after application. Laboratory analyses were included in the petition, but the sampling methodology was not described. The results were not peer-reviewed. While AD is not raw manure, it is not aerobically composted. The temperature reported in the petition is 38°C (101°F) (Joblin 2016). This is in the mesophilic range and below the temperature of 131°F specified in the NOP regulations for composting manure at §205.203(c)(2)” (TR LINES 854-861). In the production of anaerobic digestate from sewage sludge, the EPA requires that the material go through aerobic composting under the same conditions stipulated in §205.203(c)(2), a process to further reduce pathogens (PFRP). Aerobic composting of the digestate is a process to significantly reduce pathogens (PSRP) (TR LINES 918-924).

“The carbon-to-nitrogen ratio for the system is not specified. The patent does not make a pathogen reduction claim or provide any evidence that the system reduces foodborne pathogens equivalent to aerobic composting (Dvorak 2012) (TR LINES 861-863). The petition does not address risks/fates of anaerobic pathogens that may be present following the anaerobic digestion process that may not be relevant to those normally studied in aerobic composting. “No peer-reviewed studies were found to support that the petitioned PFRP was effective to a degree equivalent to the aerobic composting requirements for livestock manure specified in the NOP regulations at §205.203(c)(2). Independent research to determine whether the process is equivalent would require original research and third party review of the findings and is beyond the scope of this report” (TR LINES 863-867).

5. Discuss any effects the substance may have on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock. [§6518(m)(5)]

As a source of organic matter, digestate fiber is generally beneficial to soil health; however, the salt content may be higher than in compost (TR LINES 729-730).

“The majority of trials with agronomic and vegetable crops show that AD is beneficial for plant growth, at least compared with mineral (chemical) fertilizer and with no fertilizer; there were some contrary results in a review of the literature (Möller and Müller 2012). In situations where yields were reduced and quality degraded by the AD treatment, there was evidence that the amendment was phytotoxic. Germination has been negatively correlated with ammonia nitrogen, fatty acids, and volatile organic acids, suggesting these constituents in AD may be harmful to crops when applied in excess (Poggi-Varaldo et al. 1999; Walker, Charles, and Cord-Ruwisch 2009; Prays and Kaupenjohann 2016)” (TR LINES 738-744).

6. Are there any adverse impacts on biodiversity? (§205.200)

Depending on the source of the materials for the feedstock, there may be a detrimental impact on overall biodiversity. For example, “with systems that produce biofuel co-products, the continuous production of corn (maize) has led to a loss of biodiversity. In these cases, the solid biomass left after the fermentation of corn to make bioethanol is anaerobically digested to produce biogas, frequently co-digested with pig slurry collected from CAFOs. The anaerobic digestate is returned to the corn fields. The ecological efficiency of such a system has been questioned (Svoboda et al. 2015). Efforts to find alternative biofuel crops that increase biodiversity and reduce dependence on fossil fuel inputs have had limited success (Mast et al. 2014)” (TR LINES 746-751).

### Category 3: Alternatives/Compatibility

1. Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials. [§6518(m)(6)]

Organic producers employ a wide range of practices to foster soil health and fertility, including cover cropping, incorporating crop residue, crop rotation, and conservation and no-tillage techniques. There are numerous alternative materials to digestate fiber, including “compost, vermicompost, raw manure, heat-treated and processed manure, mulches, and organic fertilizers such as blood meal, bone meal, fish meal, soybean meal, alfalfa meal and cottonseed meal” (TR lines 876-878). In addition, anaerobic digestate may currently be used in organic production as an ingredient in compost or as a manure subject to the required preharvest intervals required of raw manure inputs in §205.203.

2. In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]

Because of the potential for negative effects on human health through food-borne pathogen, the unproven safety of digestate fiber, and the many alternative practices and materials already in use in organic production, this substance as petitioned without preharvest application intervals is not compatible with a system of sustainable agriculture.

### Classification Motion:

Motion to classify anaerobic digestate produced from nonsynthetic feedstocks as nonsynthetic

Motion by: Emily Oakley

Seconded by: Harriet Behar

Yes: 8 No: 0 Abstain: 0 Absent: 1 Recuse: 0

**Motion to amend section 205.203(c) as follows:**

§205.203 Soil fertility and crop nutrient management practice standard.

\* \* \* \* \*

(c) The producer must manage plant and animal materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances. Animal and plant materials include:

(1) Raw animal manure, which must be composted **or undergo an anaerobic digestion process** unless it is:

(i) Applied to land used for a crop not intended for human consumption;

(ii) Incorporated into the soil not less than 120 days prior to the harvest of a product whose edible portion has direct contact with the soil surface or soil particles; or

(iii) Incorporated into the soil not less than 90 days prior to the harvest of a product whose edible portion does not have direct contact with the soil surface or soil particles;

(2) Composted plant and animal materials produced through a process that:

(i) Established an initial C:N ratio of between 25:1 and 40:1; and

(ii) Maintained a temperature of between 131 °F and 170 °F for 3 days using an in-vessel or static aerated pile system; or

(iii) Maintained a temperature of between 131 °F and 170 °F for 15 days using a windrow composting system, during which period, the materials must be turned a minimum of five times.

(3) Uncomposted plant materials.

**(4) Anaerobic digestion products that have been processed to reduce pathogens.**

Motion by: Emily Oakley

Seconded by: Steve Ela

Yes: 0 No: 8 Abstain: 0 Absent: 1 Recuse: 0

**Approved by Francis Thicke, Subcommittee Chair, to transmit to NOSB, August 29, 2017**