Anaerobic Digestate

Crops

Identification of Petitioned Substance

Chemical Names:
Anaerobic digestate

Other Names:
Acidogenic digestate; Methanogenic digestate; Anaerobic compost; Anaerobic digestate – Food waste; Food waste anaerobic digestate; Anaerobically digested manure; Biogas Biofertiliser; Biogas Digestate; Sludge.

Trade Names: Accomplish-LM; Energro; Magic Dirt Organic Garden Soil; Magic Dirt Organic Premium Potting Mix; Milorganite.

CAS Numbers:
None

Other Codes:
None

Summary of Petitioned Use

Anaerobic digestate (AD) is used as a fertilizer and soil amendment for crops, horticultural products, turf and landscape applications. It is primarily used to cycle organic matter, and also provides primary, secondary, and micronutrients. A specific form of AD has been petitioned for review by the National Organic Standards Board (NOSB) (Joblin 2016). This technical report will support the NOSB's review of this petition. In addition, this report will address specific focus areas requested by the NOSB Crops Subcommittee:

- Define anaerobic digestion (AD) and its end products. (*see Origin of the Substance)*
- Describe commercially available AD technologies and how the different technologies affect the end products. *(see Evaluation Question 2)*
- Discuss differences between anaerobic digestate products and compost. *(see Evaluation Question 11)*
- 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). (*see Evaluation Question 2)*
- Explain a typical nutrient cycle for the feedstocks into end products from these processes, focusing on nitrogen. *(see Action of the Substance)*
- Describe available data concerning pathogen (e.g., E. coli, Salmonella) control using anaerobic digestion and describe documented microbiological risks from use of AD products. (*see Evaluation Question 10)*

Anaerobic digestate produced from sewage sludge is outside the scope of this report, because sewage sludge is prohibited in organic production [7 CFR 205.105(g)]. However, many of the processes used for the anaerobic digestion of food and agricultural feedstocks were originally developed for the handling of sewage sludge, and this report will make references to processes and results involving sewage sludge where specific information on anaerobic digestate made from animal manure, food waste, crop residues, and other permitted feedstocks is unavailable from sources within the scope of the review. The liquid fraction of the anaerobic digestion process—referred to as the liquor—is also beyond the scope of this report, as is the methane gas generated as the primary product in most cases. Some references will be made to the liquor for the purposes of describing the process, mass balance, and the environmental impacts of co-products.

Characterization of Petitioned Substance

<u>Composition of the Substance:</u>

Anaerobic digestate (AD) is the solid or semi-solid fraction of the effluent produced by anaerobic digestion of organic matter. AD is composed mostly of water and organic matter. The specific composition varies widely, depending on the feedstock, origin, pre-treatment and digestion processes. The various feedstocks, additives, and prevalent technologies used in the anaerobic digestion process are discussed in Evaluation Question #2, and the biochemical reactions that take place are described in Evaluation Question #3.

Source or Origin of the Substance:

Anaerobic digestion is a microbiological process that decomposes organic matter in the absence of atmospheric oxygen (O_2), which enables specific microorganisms known as 'methanogenic bacteria' to convert organic matter to methane. These organisms are inhibited by the presence of O_2. The anaerobic digestion process produces three products: (1) biogas, (2) digestate, and (3) liquor. In most cases, the main product is methane (CH_4) or natural gas contained in the biogas, which is vented to be stored or directly used for fuel. The solid or semi-solid fraction from the anaerobic digestion process is known as the "digestate," and the liquid fraction is known as the "liquor." The biochemical reactions take place in airtight vessels known as anaerobic digesters.

Most AD in the United States is the product of digestion in publicly owned waste treatment works and is considered sewage sludge. Manure collected in pit lagoons in concentrated animal feeding operations (CAFOs) is the second greatest source in the United States. Industrial effluent and various other privately owned and mixed sources account for the rest. In addition to food processing wastes, other industrial effluents treated by anaerobic digestion include pulp and paper mill black liquor evaporation condensate, coal conversion condensate, and deionized industrial process waste waters (Speece 1983). Feedstocks, fermentation organisms, and processes are further explained in Evaluation Question #2.

In contrast to anaerobic digestion, composting is a process wherein the bacteria that decompose organic matter require O_2 to carry out their metabolic activity. Composting is therefore an aerobic process, while digestion is an anaerobic process. Some references refer to anaerobic digestate as 'anaerobic compost,' but this is regarded by some to be a misnomer or oxymoron, because compost generally refers to the product of an aerobic decomposition process. However, the two products are often visually indistinguishable. Compared with aerobic compost, anaerobic digestate will have a lower dry matter content, a narrower carbon-to-nitrogen (C:N) ratio, and more ammonium nitrogen (NH_4-N) (Walker, Charles, and Cord-Ruwisch 2009; Tambone et al. 2010; Möller 2016). Other comparisons between AD and aerobic compost are made in Evaluation Question #11.

Properties of the Substance:

The physical and chemical properties of AD are summarized in Table 1. Most of the numeric values are reported as ranges.

Table 1: Physical and Chemical Properties of Anaerobic Digestate

Property (Units)	Characteristic / Value	Source(s)
Physical state at 25°C / 1 Atm.	Semi-solid to Solid	(Rowe and Abdel-Magid 1995)
Color	Light to Dark Brown	(Rowe and Abdel-Magid 1995)
Odor	Musty, sometimes with distinct ammonia and hydrogen sulfide (rotten egg) notes	(Rowe and Abdel-Magid 1995; Higgins et al. 2006; Drennan and DiStefano 2014)
Dry Matter (%)	1.5 – 45.8	(Gutser et al. 2005; Nkoa 2014; Möller 2016)
Organic Matter (%DM)	38.6 – 75.4	(Nkoa 2014)
C : N Ratio	2.0 – 24.8	(Nkoa 2014)
Total Nitrogen (%DM)	3.1 – 14.0	(Nkoa 2014)
Total Nitrogen (%FM)	0.12 – 1.5	(Nkoa 2014)
NH_4 Nitrogen (% Total N)	35 - 81	(Nkoa 2014)
Total Phosphorous (%FM)	0.04 – 0.26	(Nkoa 2014)
Potassium (%FM)	0.12 - 1.15	(Nkoa 2014)
Calcium (%FM)	0.01 – 0.02	(Nkoa 2014)
Magnesium (%FM)	0.03 – 0.07	(Nkoa 2014)
Sulfur (%FM)	0.02 - 0.04	(Nkoa 2014)
Cadmium (ppm DM)	0.03 – 1.60	(Silvia Bonetta et al. 2014; Möller 2016)
Copper (ppm DM)	7.5 – 561.0	(Silvia Bonetta et al. 2014; Möller 2016)
Lead (ppm DM)	1.9 – 126.0	(Silvia Bonetta et al. 2014; Möller 2016)
CEC (meq/100g)	20.3 – 53.4	(Nkoa 2014)
pH	7.3 - 9.0	(Nkoa 2014)

CEC=Cation Exchange Capacity; DM=Dry Matter; FM=Fresh Matter; meq=milliequivalents; ppm=Parts Per Million

The wide range in values for physical and chemical properties shows how variable the substance can be. Anaerobic digestate is best characterized as friable, flocculated organic matter. When manure is used as a feedstock, the resulting AD may be visually indistinguishable from agricultural compost. Other feedstocks may yield a lighter colored and less opaque surface area (Marcilhac et al. 2014). When dried and cured, the odor is musty and inoffensive. However, in many cases, fresh AD tends to be wet, malodorous, and high in volatile fatty acid concentrations (Walker, Charles, and Cord-Ruwisch 2009).

In particular, fresh anaerobic material high in volatile organic sulfur compounds may produce a 'rotten egg' smell characteristic of hydrogen sulfide gas, and AD high in volatile ammonia will have a distinct ammonia smell. Hydrogen sulfide gas is generated by volatile organic sulfur compounds produced by the decomposition and putrefaction of sulfur-bearing amino acids—methionine, cysteine, and cystine—under anaerobic conditions. Blending feedstocks to reduce sulfur content, increasing the surface area of the feedstock by equipment that will reduce particle size, and hydrogen sulfide removal prior to the methanogenic step can all help reduce hydrogen sulfide in the AD (Higgins et al. 2006). Curing AD once the process is complete also reduces nuisance odors (Drennan and DiStefano 2010).

<u>Specific Uses of the Substance:</u>

Anaerobic digestate is used as a fertilizer and soil amendment for horticultural products, agricultural crop production, and landscape applications (Joblin 2016).

<u>Approved Legal Uses of the Substance:</u>

Anaerobic digestate from sewage sludge is subject to regulation by the United States Environmental Protection Agency (EPA) [40 CFR 503]. Concentrated animal feeding operations (CAFOs) are regulated as point sources of pollution by the EPA [40 CFR 412]. Most, but not all states, are authorized to issue permits to CAFOs. Exceptions are Idaho, Massachusetts, New Hampshire, New Mexico, the District of Columbia, tribal lands, and United States territories, all of which fall under the EPA's jurisdiction (US EPA 2016a). Anaerobic digesters on CAFOs are required to meet all federal, state and local regulations. These include the Best Management Practices for the application of manure [40 CFR 412.4].

Action of the Substance:

When used as a fertilizer and soil conditioner, AD acts primarily a source of organic matter. The nitrogen, phosphate and potash (NPK) values are relatively low, but may be comparable to compost. Value as a fertilizer varies according to the quality of the finished product (Ward et al. 2008; Alburquerque et al. 2012; Alfa et al. 2014; Nkoa 2014; Möller 2016).

Nutrient Cycling

Most studies conducted on nutrient cycling and anaerobic digestion involve sewage sludge, mixed municipal solid waste (MSW), or other feedstocks and ingredients which are prohibited for organic production. Less information is available on anaerobic digestion of livestock manure and the nitrogen cycle, but there are several key studies where the results are comparable to AD made with sewage sludge and municipal solid waste feedstocks. 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 (NH_4^+-N) nitrogen (Mata-Alvarez, Macé, and Llabrés 2000; Massé, Croteau, and Masse 2007; Sakar, Yetilmezsoy, and Kocak 2009; Nkoa 2014; Svoboda et al. 2015). It is believed that nitrogen is mineralized—decomposed to ionic form—and denitrified—reduced from the nitrate (NO_3^-) to ammonium (NH_4^+) by the anaerobic fermentation conditions (Akunna, Bizeau, and Moletta 1993). The partition of the ammonia into volatile losses to the atmosphere, solution with the liquid effluent, and remainder that is precipitated in the solid or semi-solid portion of the AD appears to vary according to feedstock, additives, and conditions such as pH, temperature and technology used. More research is needed to fully understand and compare different systems and conditions for manure management with anaerobic digestion. A few results offer some suggestions.

One study (Möller et al. 2008) compared five treatments: solid farmyard manure; undigested liquid slurry; digested liquid slurry; digested liquid slurry and field residues (crop residues and cover crops); and digested liquid slurry and field residues (crop residues and cover crops), and fermentation substrates composed of clover, grass and corn silage. The treatments were applied to soils used to grow spring wheat, winter wheat, rye and spelt. All the treatments increased yields and nutrient uptake compared with the no treatment control. The yields were the highest with the digested slurry with crop residues and added substrate. The other treatments were not significantly different from each other, but were significantly higher than the no treatment control. Another study (Loria et al. 2007) compared AD from swine manure with swine raw manure from the same source applied to corn fields in Iowa. The researchers concluded that there was no difference in plant-available nitrogen from the two sources.

The organic matter and carbon-to-nitrogen (C:N) ratio will be lower with AD than with dry manure or aerobic compost, partly because of the lower initial C:N ratio, and partly because of carbon loss via the generation of methane. Some hypothesize that the lower C:N ratio, combined with the toxic effect of ammonium nitrogen may have a depressing effect on soil microorganisms, particularly those responsible for fixing atmospheric nitrogen (N_2). However, these hypothetical adverse effects have not been empirically shown, and if anything AD usually has a beneficial effect—or at worst no adverse effects—on soil biological activity (Abubaker 2012). In particular, some of the facultative anaerobic bacteria found in AD are free-living, nitrogen-fixing organisms (Alfa et al. 2014).

Anaerobic digestion does not reduce the phosphorous content when poultry litter is used as a feedstock (Sakar, Yetilmezsoy, and Kocak 2009). Phosphorous content in anaerobically digested swine manure was also comparable to that of the raw manure (Loria and Sawyer 2005). Anaerobic digestion of swine manure increased the nitrogen-to-phosphorous (N:P) ratio (Massé, Croteau, and Masse 2007).

Less is known about how the anaerobic digestion process changes potassium content and availability. However, there is nothing to indicate that potassium losses are a factor. With swine manure, potassium levels may even be slightly concentrated in the AD given the carbon losses from methane generation and a little lost in solution in the liquid fraction of the effluent (Massé, Croteau, and Masse 2007).

Calcium, magnesium and the trace elements, specifically copper (Cu) and zinc (Zn), are mostly precipitated in the solid portion of the AD, but some may be removed in the liquid fraction of the effluent (Massé, Croteau, and Masse 2007; Sakar, Yetilmezsoy, and Kocak 2009). While Cu and Zn are considered essential micronutrients for plants, some sources of AD may have high levels that can lead to accumulation and toxic excess. Contamination by Cu and Zn are discussed further in Evaluation Question #5.

Anaerobic digestion appears to change the sulfur cycle, as discussed above with the properties of the substance, as well as under Evaluation Question #2. 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.

Combinations of the Substance:

Anaerobic digestate may be used as an ingredient in potting mix along with peat, coir, vermiculite and perlite. Various fertilizers may also be combined with AD, such as soybean meal, soybean flour, cottonseed meal, cottonseed flour, amino acids such as lysine, ammonium salts such as ammonium sulfate and ammonium nitrate, urea, potassium salts such as potassium sulfate, and micronutrients (Callendrello, Getman, and Nicholson 2015). Synthetic sources of these fertilizer ingredients are prohibited in organic production if they do not appear on the National List [7 CFR 205.105(a)].

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 sorbatan 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. Some substances known to inhibit autotrophic NH_3 oxidation and proposed for commercial application include 1,1,1-trichloroethylene (TCE); 3-methylpyrazole-1-carboxamide (MPC); 3,4-dimethylpyrazole phosphate (DMPP); and dicyandiamide (DCD) (G. McCarty 1999; Weiske et al. 2001).

Various additives manufactured using nanotechnology are being used on an experimental basis in anaerobic digestion. These include metal oxides, zero-valent metals, and nano-ash and carbon-based materials (Ganzoury and Allam 2015).

Status

Historic Use:

There is archeological evidence that humans used biogas produced by anaerobic digestion in Asia as early as the 10th Century BCE (He 2010; Bond and Templeton 2011). The first modern anaerobic digestion plant to produce biogas from organic waste was built in a leper colony in Bombay, India in 1859 (Kangmin and Ho 2006). New Zealand also had anaerobic digesters producing biogas from manure in the mid-19th century (Bond and Templeton 2011). The technology became widespread in south China by the late 19th century (Gregory 2010). In the 1920s and 1930s, again in the late 1950s and early 1960s, and during the 1970s energy crisis, innovation in anaerobic digestion technology and built capacity increased at a rapid rate in China (He 2010).

The first U.S. invention to employ anaerobic digestion is generally recognized to be the Cameron Septic Tank, patented in 1899 (Cameron, Commin, and Martin 1899). However, the untreated solids removed from these early anaerobic septic tanks were seen as having little value as fertilizer (Talbot 1900). On the other hand, aerobically treated sewage sludge was already seen as suitable for use as a fertilizer by the late 1800s (Goodhue 1897). The first anaerobically digested sewage sludge that was commercially produced on a large scale—Milorganite—was introduced in 1926 (Kadish 1928; Milorganite 2016). The Milwaukee Metropolitan Sewerage District used a two-step activated process: wastewater is first anaerobically digested (MMSD 2016), and is then aerated and dried before it is applied to agricultural land (Milorganite 2004).

Investigations into the anaerobic treatment of industrial wastewater—including food processing waste—began in the 1920s, but adoption was limited until the 1950s (P. McCarty 2001). Most food waste was fed to livestock, primarily pigs (Vaughn 2009). The balance of household food waste not fed to pigs was landfilled. When food industry waste was anaerobically digested, it was most often from facilities that were commingled with municipal sewage. With the passage of the Clean Water Act and the energy crisis of the 1970s, food processors, pulp and paper manufacturers, and other industries that had biomass by-products found it economically feasible to install anaerobic digesters to handle their waste streams and produce methane (Speece 1983; Coombs 1990).

Similar economic conditions led to the adoption of anaerobic digestion technology on U.S. farms, particularly large-scale animal operations with unprecedented amounts of manure. Historically, manure was either directly applied to land or aerobically composted and land spread. The adaptation of anaerobic digestion for the treatment of manure and food waste is a relatively recent development. The first anaerobic digester installed on a farm in the U.S. was located in Iowa in 1970 (Davis 2006).

With the development of technologies to produce methane from organic matter waste products, such as sewage sludge, animal manure, and food waste, there developed a growing volume of AD as a by-product of the methanogenic process. The practice of greenhouse production using AD as a soil media and substrate has been coined ‘digeponics’ (Stoknes et al. 2016).

Organic Foods Production Act, USDA Final Rule:

The Organic Foods Production Act mandates that an organic crop may not be harvested until after a “reasonable period of time determined by the certifying agent to ensure the safety of such crop, after the most recent application of raw manure, but in no event shall such period be less than 60 days after such application” [7 USC 6513(b)(2)(B)(iv)].

Anaerobic digestate made of manure feedstocks and digested by a non-chemical process does not appear on the National List as a prohibited nonsynthetic substance at §205.602. If manure-based AD does not meet processing requirements of §205.203(c)(2), it would be subject to the raw manure restriction at §205.203(c), which means it may only be (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. Products of anaerobic digestion processes made from non-manure feedstock materials would not be subject to this restriction.

Feedstocks containing synthetic substances not on the National List, and treatments with sulfuric acid or other synthetic substances that are not on the National List for use in anaerobic digestion are prohibited under §205.105(a). The NOSB did not recommend that sulfuric acid be added to the National List for this petitioned purpose (NOSB 2012). Sewage sludge is also prohibited as a feedstock under §205.105(g) and §205.203(e)(2).

International

Canadian General Standards Board Permitted Substances List (CAN/CGSB-32.311-2015)
"Digestate, anaerobic" appears in Table 4.2 of the Canadian General Standards Board's Permitted Substances List —Soil amendments and crop nutrition, with the following annotation: "Permitted to be used for soil amendment, provided that the following conditions are met:
a) the materials added to the digester shall be listed in Table 4.2. If feedstocks are obtained from off-farm sources, the digestate shall comply with the heavy metal restrictions in Table 4.2 Compost from off-farm sources;
b) the criteria for raw manure land application specified in 5.5.2.3 of CAN/CGSB-32.310 shall be met;
c) anaerobic digestate may be used as a compost feedstock if it is added to other substances which are then composted. See Table 4.2 Compost feedstocks"(CAN/CGSB 2015).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Anaerobic digestate is not explicitly mentioned in the Codex Guidelines. Microbial fermentation is mentioned as an acceptable process for fertilization and soil conditioning substances [§5.1(a)]. Farmyard and poultry manure are permitted with the annotation "Need recognized by certification body or authority if not sourced from organic production systems. 'Factory' farming sources not permitted." Slurry and urine are also permitted with the annotation "If not from organic sources, need recognized by inspection body. Preferably after controlled fermentation and/or appropriate dilution. 'Factory' farming sources not permitted." Sorted, composted or fermented home refuse is permitted with the annotation "Need recognized by certification body or authority." Human excrements are permitted with the following annotation: "Need recognized by the certification body or authority. The source is separated from household and industrial wastes that pose a risk of chemical contamination. It is treated sufficiently to eliminate risks from pests, parasites, pathogenic microorganisms, and is not applied to crops intended for human consumption or to the edible parts of plants" (FAO/WHO Joint Standards Programme 1999).

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
The original European Economic Community Commission (EC) organic food regulation permitted household food wastes that had been anaerobically fermented for biogas production. Liquid animal excrements were also permitted for use after controlled fermentation when not originating from factory farms [EC 2092/91]. *Liquid animal excrements* were included in the 2008 revised regulation.

A	Liquid animal excrements	Use after controlled fermentation and/or appropriate dilution Factory farm origin forbidden

Composted or fermented household waste was amended to in 2014 to include anaerobic digestate [EC 354/2014]. The amendment reads as follows:

B	Composted or fermented mixture of household waste	Product obtained from source separated household waste, which has been submitted to composting or to anaerobic fermentation for biogas production Only vegetable and animal household waste Only when produced in a closed and monitored collection system, accepted by the Member State. Maximum concentrations in mg/kg of dry matter: cadmium: 0,7; copper: 70; nickel: 25; lead: 45; zinc: 200; mercury: 0,4; chromium (total): 70; chromium (VI): not detectable

The regulation was also amended to create a new entry for *Composted or fermented mixture of vegetable matter,* with the following text:

B	Biogas digestate containing animal by-products co-digested with material of plant or animal origin as listed in this Annex	Animal by-products (including by-products of wild animals) of category 3 and digestive tract content of category 2 (categories 2 and 3 as defined in Regulation (EC) No 1069/2009 of the European Parliament and of the Council)* must not be from factory farming origin. Not to be applied to edible parts of the crop

* "Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1)" (EU Commission 2008).

Japan Agricultural Standard (JAS) for Organic Production

Anaerobic digestate is not explicitly mentioned in the Japanese Agricultural Standard. Appendix 1, Materials for Fertilizer and Soil Improvement includes a listing for "Other fertilizer and soil improvement materials" with the annotation, "Those (including the living things) applying to the soil for providing the plants with nutrition or changing the soil property so as to contribute to the cultivation of the plants, and those (including living things) for applying to the plant to provide it with the nutrition; and the natural substance or those derived from natural substances (those produced by burning, calcining, melting, dry distillating, and saponifying the natural substances and those produced of the natural substances without using any chemical method) and addition of no chemosynthetic substance"(Japan MAFF 2000).

IFOAM - Organics International

The IFOAM Standards permit "Biodegradable processing by-products, plant or animal origin, e.g. by-products of food, feed, oilseed, brewery, distillery or textile processing — Free of significant contaminants; or composted before bringing onto organic land and confirmed free of significant contaminants" (IFOAM 2014).

Evaluation Questions for Substances to be used in Organic Crop or Livestock Production

Evaluation Question #1: Indicate which category in OFPA that the substance falls under: (A) Does the substance contain an active ingredient in any of the following categories: 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? (B) Is the substance a synthetic inert ingredient that is not classified by the EPA as inerts of toxicological concern (i.e., EPA List 4 inerts) (7 U.S.C. § 6517(c)(1)(B)(ii))? Is the synthetic substance an inert ingredient which is not on EPA List 4, but is exempt from a requirement of a tolerance, per 40 CFR part 180?

These OFPA categories apply only to synthetic substances, and are not applicable to AD products comprised of only nonsynthetic substances. It is not apparent in which OFPA category synthetic chemically treated anaerobic digestate falls. Previous petitioners have implied that food waste and manure are comparable to 'fish emulsions' (Torello 2012; A Callendrello 2015). However, there does not appear to be any explicit statutory authority in OFPA to allow for the synthetic chemical treatment of food waste or manure the way there is for fish emulsions.

Evaluation Question #2: Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)).

Summary of Anaerobic Digestion Process

Anaerobic digestate is a product of organic matter that is fermented in the absence of atmospheric oxygen. The prevalent use of anaerobic digestion in the United States is in the treatment of sewage sludge. The EPA classifies operations that use anaerobic digestion to treat waste by whether they are municipal, agricultural or industrial. As of August 2015, there were 1,270 sewage treatment plants, 247 commercial livestock operations, and 98 other facilities that produced biogas in the United States (US EPA 2015). The last category included municipal food digesters, single source industrial digesters, and co-digesters on farms and waste-water treatment plants. A system flow diagram that shows the basic steps of the process is contained in Figure 1.

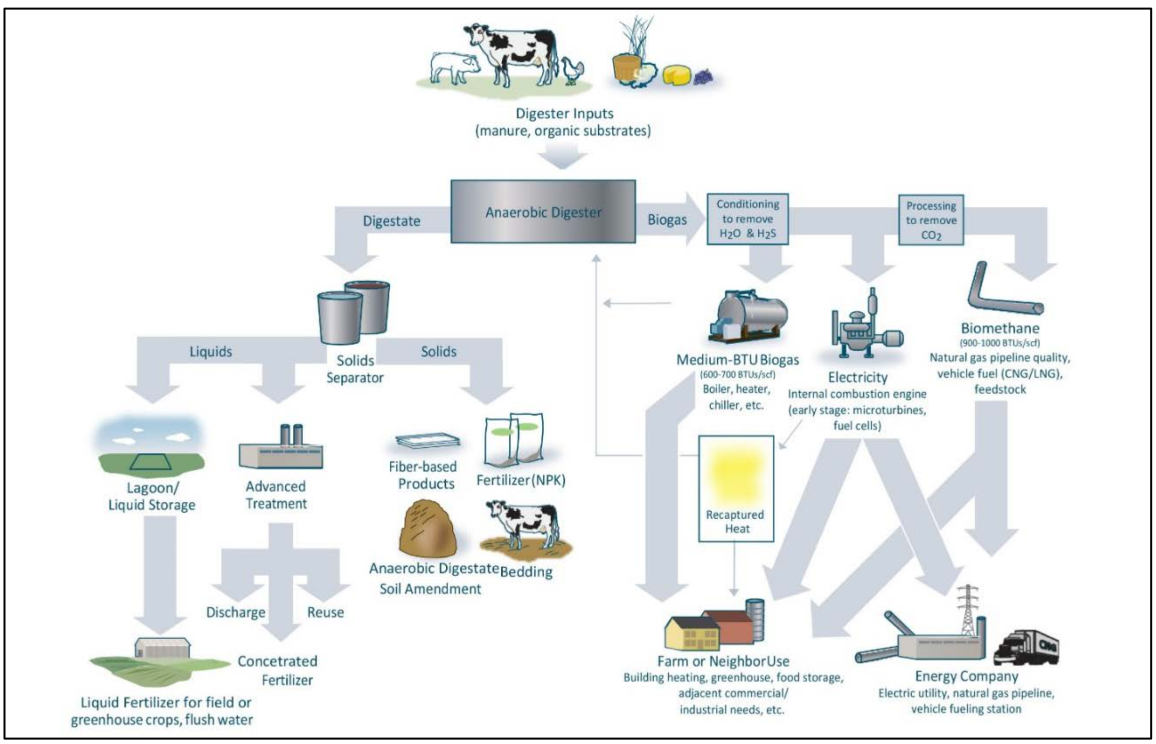

Figure 1: System flow diagram of basic AD process (Adapted from US EPA 2011)

Feedstocks

Virtually any form of organic matter can be used as a feedstock for AD. The ingestate—the mix of raw feedstocks fed into the digester—can be highly variable. Sewage sludge and livestock manure from CAFOs accounts for most of the feedstocks used to produce anaerobic digestate. Household food waste—the post-consumer organic matter discarded in the preparation of meals—and green waste —lawn and yard debris

—are potential sources from the municipal solid waste (MSW) stream. These sources may be blended with sewage sludge and/or CAFO manure.

Industrial effluent from a variety of sources may also be used. Industrial waste sources that are potential feedstocks for the anaerobic production of methane include food processing wastes, spent mash from ethanol and other biofuel production, paper mill sludge, coal conversion condensates, and deionized industrial process wastewaters (Speece 1983). Fish wastes may also be anaerobically digested with a liquid fertilizer (Ferguson 1990).

Blending a variety of agricultural, household, municipal, and industrial feedstocks enables the carbon-to-nitrogen (C:N) ratio and pH of the ingestate to be adjusted to optimal ranges for the production of methane (Ward et al. 2008). Outside the U.S., particularly in China and India, it is a common practice for there to be 'rural digesters' that combine animal manures, human wastes, and crop residues to produce biogas and fertilizer (Coombs 1990).

Methane digestion reactor vessels work best at a continuously and sustainably high throughput of ingestate. Manure is considered a relatively poor feedstock for methane production, but is the preferred feedstock for digestate fertilizer use. Industrial wastes are more productive feedstocks for methane production, but the resulting digestate is relatively poor as a fertilizer. Combining animal manure and industrial wastes on a large scale dramatically improves the economic return on investment of a methane digestion plant (Tafdrup 1995). Methane yields are higher than for animal manure alone, and the digestate's fertilizer value is greater than for industrial waste alone. Source separation of feedstocks increases handling costs and decreases plant efficiency.

Additives and other ingredients

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.

The most common chemical pre-treatment is the use of an alkali—usually sodium hydroxide (NaOH)—which increases the digestibility and increases methane yield (Hobson and Wheatley 1993). The treatment also neutralizes the pH of an acidic feedstock. Such treatment may increase the sodium content, depending on how much sodium in solution is leached out of the wastewater. Calcium oxide, calcium hydroxide and potassium hydroxide may also be added to acidic feedstocks to raise the pH as needed. Calcium oxide and calcium hydroxide could be expected to precipitate and remain in the solid portion of the digestate, where they would increase the calcium content as well as raise the pH. Potassium hydroxide would also be likely to precipitate and increase the K_2O value of the digestate. Urea is sometimes added during the process to adjust pH as well as to increase the nitrogen content of the digestate (Boncz et al. 2012). Pre-treatment may also involve ion exchange media.

For feedstocks that have a C:N ratio that is higher than optimal, ammonia is sometimes added (Hobson and Wheatley 1993; Shah et al. 2015). More often, the C:N ratio is too narrow and NH_3 needs to be stripped, otherwise it is at levels toxic to the methanogenic organisms, particularly thermophilic ones (Hobson 1990). Usually this is done by aeration prior to the anaerobic digestion. The ammonia gas is released into the atmosphere, decreasing the nitrogen content of the anaerobic digestion. The other method is to chemically precipitate the ammonia in the substrate by ion exchange. This may be done with various ion exchange media or adsorbents like zeolite, activated carbon or clay (Chen, Cheng, and Creamer 2008).

Other chemical treatments reported in the literature include hydrochloric, sulfuric and acetic acids; sulfur dioxide; chlorite salts, hypochlorite salts, and zinc chloride (Hobson and Wheatley 1993). Hydrogen sulfide (H_2S) gas can be toxic, and ferric chloride ($FeCl_3$) is sometimes used to remove it (Hobson and Wheatley 1993; AM Callendrello, Getman, and Nicholson 2015). Residual sulfide can also be removed from wastewater prior to digestion by aluminum sulfate and ferric chloride (Song, Williams, and Edyvean 2001). The aluminum and iron compounds would likely precipitate in the digestate, but some might remain in solution. Empirical studies are needed to determine the actual fate, but are not available in the literature. Sulfuric acid is sometimes used to lower the pH and prevent volatilization of ammonia (Torello 2012). Other additives may be used, some of which are proprietary. The fates of proprietary additives are unknown.

Resulting fertilizers may be blended with synthetic substances to boost nutrient content as well as to stabilize the product. Commercial products may include calcium nitrate, phosphoric acid, potassium nitrate and urea.

Outputs

The main output of the anaerobic digestion process is biogas, which is purified into methane or natural gas. Methane (CH_4) is the primary commercial product in virtually all cases. Other emitted gases include carbon dioxide (CO_2), volatile ammonia (NH_3), and hydrogen sulfide (H_2S). What is left over from the venting of the gas can be further divided into solid and liquid through centrifugal force and thermal dehydration. The liquid portion is known as the liquor and the solid portion is known as the anaerobic digestate. The liquor may be further subdivided into the scum, primarily lipids that float on the surface, and the supernatant, the liquid between the precipitated sludge and the scum. The supernatant is mostly water, but depending on the feedstock and process used, it may be high in dissolved ammonium and phosphate, having a fertilizer value itself. The AD is the dewatered sludge separated from the supernatant.

Anaerobic Digestion Technologies

Two basic types of systems dominate the handling of agricultural wastes in the U.S.: The “Plug Flow” system and the “Complete Mix” system. These two technologies account for over 70% of all anaerobic digestion systems in operation (US EPA 2011). Other systems in the U.S. include “Covered Lagoon,” “Up-flow Anaerobic Sludge Blanket / Induced Blanket Reactor,” “Fixed Film / Attached Media Digester / Anaerobic Filters,” “Anaerobic Sequencing Batch Reactors,” and “High-Solids Fermentation.” Another relatively new technology is the “Two-Stage Mixed Plug Flow.” Many more systems are in place throughout the world. China and India have been the source of many significant innovations in anaerobic digestion technology. Anaerobic digestion systems are commonly used in rural areas in those countries. Two widely-adopted technologies are the “Chinese Dome Digester” and the “India Gobar System.”

Plug Flow

A plug flow digester consists of a long, narrow tank, typically heated and below ground, with an impermeable cover to collect the biogas. The contents move through the digester as fresh biomass is added. The biomass moves through the system as a ‘plug’ and is not mixed. Retention time is usually 15 to 20 days (Hamilton 2010).

Complete Mix

A complete mix digester is comprised of an above- or below-ground tank with an impermeable gas-collecting cover (US EPA 2011). The contents are mixed by a motor or a pump. Incoming liquids displace an equal amount of liquid in the effluent. The methanogenic bacteria flow out with the displaced liquid (Hamilton 2010).

Two Stage Mixed Plug Flow

A process referred to as a "two stage mixed plug flow anaerobic digester system" is the subject of the petition (Joblin 2016). This is a relatively new patented technology where the ingestate is received in a closed mixing chamber, and travels down a heated hairpin turn (Hamilton 2010). The gas generated is used to heat the fermenting biomass at a constant temperature (Dvorak 2012). During the second stage, methanogenic bacteria generate methane by the process described in Evaluation Question #3. The system is described in greater detail in the petition and the patent (Dvorak 2012; Joblin 2016).

Chinese Dome Digester

China has the largest biogas production capacity in the world, with millions of rural small-scale anaerobic digesters that are an integral part of their organic matter recycling, energy production, and water pollution prevention programs. The number of systems installed in China was estimated to be 26.5 million in 2007 (Bond and Templeton 2011). Most of these are small scale, in the range of 6-10 m^3. The most common design in China is the "China Dome Digester," a spherical concrete pit that is used to store animal manure—mainly from pigs and chickens—along with chopped straw (Kangmin and Ho 2006; He 2010). Human waste (nightsoil), crop residues, food processing waste, and organic household waste are also commonly commingled as feedstocks (Kangmin and Ho 2006). The gas is stored at the top of a rigid dome with a valve to maintain constant pressure. The biogas is piped throughout the village and used for cooking, heating, and other gas appliances (Hobson and Wheatley 1993). In the Northern provinces, the biogas is used for heating greenhouses used for year-round vegetable production. Both the liquid sludge and sediment of the AD are applied as fertilizers (Gregory 2010).

Indian Gobar System

There were over 3 million biogas plants in India as of 1999, and the number is estimated to be over 4 million at present (Bond and Templeton 2011). Most anaerobic digesters in India follow a design that is referred to as the 'gobar' system, after the Hindi word for 'cow dung'. Prior to the introduction of these systems, cow dung was dried and burned as a cooking fuel, leading to organic matter loss and inefficient heat exchange compared with biogas. The primary feedstock is dairy manure, but gobar anaerobic digesters may also use human waste, crop residues, and organic household wastes (Hobson 1990). These have a cylindrical metal tank that floats inside the digester and rises and falls with the feedstock and biogas content.

Effect of technologies on end product

All of the systems are designed primarily for their efficiency in biogas generation and yield (Tafdrup 1995; Ward et al. 2008). Fertilizer is considered a by-product. In a search of the literature, no study was found that directly compared the other end products—the digestate and the liquor—for their fertilizer value and toxicity. The quality of the digestate is more a function of the feedstocks than of the technology used to process it (Al Seadi et al. 2013; Möller 2016). Plug flow systems can be expected to have greater variability in fertilizer quality than complete mix systems, particularly when different feedstocks are introduced during the process. Original third-party peer-reviewed research would be needed to make scientifically valid comparisons of the nutrient content, physical quality, and contaminant levels of the four predominant technologies used to generate biogas with the petitioned system.

<u>Evaluation Question #3:</u> Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)).

Anaerobic digestion of organic matter is a natural bacterial fermentation process. Anaerobic digestate made from agricultural feedstocks or source-separated household food wastes, lawn clippings, and other plant material, and digested by a microbial process without chemical treatments is considered nonsynthetic and is not prohibited by §205.105 or §205.602.

The series of reactions that takes place during anaerobic digestion is complex and variable, but essentially involves a series of oxidation-reduction reactions to form hydrogen, carbon dioxide and acetic acid, and finally the carbon dioxide reacts with hydrogen to form methane (Abbasi, Tauseef, and Abbasi 2012). The process can be simplified to involve three distinct phases: (1) hydrolysis and acidogenesis, (2) acetogenesis and dehydrogenation, and finally (3) methanogenesis (Miyamoto 1997). Each stage relies on a different consortium of microorganisms.

During the first phase, a number of organisms decompose the long carbon chain polymers into soluble sugars by hydrolysis. These organisms excrete various enzymes, such as cellulase and lignase. In the process, these organisms also hydrolyze proteins into soluble amino acids and form fatty acids (acidogenesis). These catabolic reactions are described in reactions (1) and (2) (Gerardi 2003).

(1) $\text{cellulose} + H_2O \xrightarrow{\text{hydrolysis}} \text{soluble sugars}$

(2) $\text{proteins} + H_2O \xrightarrow{\text{hydrolysis}} \text{soluble amino acids}$

Various alcohols, esters and conjugate bases are also formed in the fermentation process. Among the most common acidogenic bacteria found in digesters are species of *Acetivibrio, Bacteroides, Bifidobacterium, Butyrivibrio, Clostridium, Enterobacteriaceae, Eubacterium, Lactobacillus, Peptostreptococcus, Propionibacterium, Ruminococcus, Selanomas* and *Streptococcus* (Archer and Kirsop 1990). This is not an exhaustive list.

The second phase involves the conversion of the various fatty acids, alcohols, sugars and cellulose into acetic acid and its acetate conjugates, as well as hydrogen. The acetogenic organisms most frequently found in anaerobic digestion are of the genera *Acetobacterium*, *Acetoanaerobium, Acetogenium, Butyribacterium, Clostridium, Eubacterium* and *Pelobacter* (Archer and Kirsop 1990). Their activity results in the chemical reaction in (3) (Gerardi 2003).

(3) $CH_3COOH \rightarrow CH_4 + CO_2$

In the third and final phase, the methane generating (methanogenic) organisms use the acetates and hydrogen as substrates to produce methane. Methanogenic organisms include members of the genuses *Methanobaterium, Methanobrevibacter, Methanosarcina, Methanococcus, Methanogenium, Methanomicrobium* and *Methanospirillum*. While some of the organisms in the first two phases are oxygen-tolerant, all the methanogenic organisms are strictly anaerobic and cannot survive in the presence of atmospheric oxygen (O_2) (Gerardi 2003). The production of methane is summarized in reaction (4) (Gerardi 2003).

(4) $CO_2 + 4H_2 \rightarrow CH_4 + 2H_2O$

The process may be mesophilic, with temperatures in the range of 15-45°C (60-113°F), or thermophilic at temperatures in the narrower range of 50-65°C (122-149°F) (Hobson 1990). However, thermophilic anaerobes are very sensitive to temperature changes and the methanogenic process generally will falter in the 40-45°C range (Gerardi 2003). For that reason, the prevalent anaerobic digestion technologies are mesophilic at present.

Once the anaerobic digestion process is complete, the digestate can be applied directly to the land, or it may be further treated for pathogens. Mesophilic AD is more likely to require further pathogen reduction than thermophilic AD. Processes recognized by the EPA to significantly reduce pathogens (PSRP) include aerobic composting; acidification with sulfuric acid, followed by ozone treatment and addition of sodium nitrite; and addition of cement kiln dust or lime kiln dust (US EPA 2016b). Processes to further reduce pathogens (PFRP) include aerobic composting; treatment with chlorine dioxide followed by addition of sodium nitrite; microwave treatment; calcium oxide (quicklime); ozonation followed by nitrate treatment; sulfuric acid followed by lime; steam heat; thermal biooxidation and agitation (US EPA 2016b).

<u>Evaluation Question #4:</u> Describe the persistence or concentration of the petitioned substance and/or its by-products in the environment (7 U.S.C. § 6518 (m) (2)).

Anaerobic digestate is readily biodegradable. However, non-biodegradable contaminants such as plastics, glass, and heavy metals may persist, accumulate and concentrate in the environment over time (Alburquerque et al. 2012; Nkoa 2014). These issues are further discussed in Evaluation Questions #5 and #6.

<u>Evaluation Question #5:</u> Describe the toxicity and mode of action of the substance and of its breakdown products and any contaminants. Describe the persistence and areas of concentration in the environment of the substance and its breakdown products (7 U.S.C. § 6518 (m) (2)).

The main contaminants of toxicological / health concern are (1) pathogens, (2) heavy metals, and (3) other chemical contaminants. Human pathogens are addressed in Evaluation Question #10.

Heavy metals

Compost from agricultural wastes is less likely to have cadmium and lead than industrial effluent or sewage sludge, but these metals may be introduced in mixed waste streams (Nkoa 2014). The metal contaminants of greater concern in livestock systems are copper and zinc (Massé, Croteau, and Masse 2007). There is evidence that these metal contaminants in animal manure result from excessive supplementation (Brugger and Windisch 2015).

Other chemical contaminants

The most likely chemical contaminants of AD are considered to be phthalates from degraded plastics and pesticides (Zemba et al. 2010). Plastics and glass are common contaminants in source separated household food waste. Pesticides are found both in livestock manure from conventional operations and as residual contaminants of non-organic food.

Manure from conventional farming operations may contain antibiotics, anthelmintics, other animal drugs and pesticides, as well as various other chemicals used as production aids. Feedstocks from conventional agriculture—including food waste from crops grown with pesticides—can be contaminated with pesticide residues. While the digestion process may decompose some of these substances, some are more persistent than others. Crop residues from conventional farms may also have the potential to be contaminated with pesticides prohibited in organic production (Battersby and Wilson 1989; Chen, Cheng, and Creamer 2008; Govasmark et al. 2011).

One study (Battersby and Wilson 1989) looked at the degradation and persistence of 77 potential chemical contaminants of AD feedstocks. These included agricultural chemicals, such as pesticides that would be residues found in conventional agricultural by-products, and various chemicals that would likely be found in industrial wastewater and municipal sewage sludge. Some were degraded completely, some were partially degraded to some degree, and some were persistent, being concentrated by the volume reduction of the digestion process. Synthetic pyrethroids were readily biodegradable in anaerobic conditions. Among the pesticides that were persistent were the chlorinated hydrocarbons lindane and dieldrin. The slimicide pentachlorophenol (PCP) inhibited digestion microorganisms, and was considered not to have a biodegradation potential. The herbicides 2,4-dichlorophenoxyacetic acid (2,4-D) and 2,4,5-trichlorophyoxyacetic acid (2,4,5-T) were degraded relatively quickly. However, PCP, 2,4-D, and 2,4,5-T have been shown, under the reductive conditions of anaerobic digestion, to be dechlorinated into 3,4-dichlorphenol and 4-chlorophenol (Mikesell and Boyd 1985). The substance 4-Chlorophenol was the most persistent of the chlorophenols in methanogenic river sediments (NLM 2016). Some of the non-biodegradable substances inhibited the digestion processes because of their toxicity to the fermentation organisms. Among the families of compounds that are potential inhibitory contaminants of anaerobic digestion are alkyl benzenes, halogenated benzenes, nitrobenzenes, phenols and alkyl phenols, nitrophenols, alkanes, halogenated aliphatics, alcohols, halogenated alcohols, ethers, ketones, acrylates, carboxylic acids, amines, nitriles, amides, and pyridine and its derivatives (Chen, Cheng, and Creamer 2008). The severity of inhibition is primarily a function of toxicant concentration and exposure time; recovery is a function of biomass concentration, retention time and temperature (Yang and Speece 1985).

With the increased use of nanomaterials in conventional agriculture and food processing, these are expected to become a potential source of contamination. Under experimental conditions, various nanoparticles have been shown to dramatically inhibit the anaerobic digestion process and methane generation because of their toxicity to digester microorganisms (Ganzoury and Allam 2015).

<u>Evaluation Question #6:</u> Describe any environmental contamination that could result from the petitioned substance's manufacture, use, misuse, or disposal (7 U.S.C. § 6518 (m) (3)).

Concentrated animal feeding operations (CAFOs) are a primary source of feedstocks for commercially produced AD (US EPA 2004). The large-scale confinement of animals produces a great volume of manure that poses a risk of environmental contamination. 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.

The EPA conducted a risk assessment of CAFOs and considered anaerobic digestion to be a potential risk management strategy for CAFOs, but acknowledged that the strategy requires additional research (US EPA 2004). The complexity and capital investment required for anaerobic digestion are barriers to adoption by producers. At the time of the risk assessment, the EPA estimated the failure rate of complete-mix aerobic digesters to be 70% and the failure rate of plug-flow mixers to be 63% (US EPA 2004). The causes of anaerobic digester failures are poor design, improper installation for the site, poor equipment specification, inability to maintain temperatures sufficient for digestion, insufficient insulation, inadequate screening and separation, high maintenance, and equipment malfunctions. Aerobic digester system failures result in spills, water pollution, excessive nutrient runoff, and nuisance odors.

Livestock wastes collected from CAFOs may have detectable levels of antibiotics and growth hormones (US EPA 2004). Environmental contamination from the antibiotics depends on the persistence of the specific antibiotics used and the levels found in the slurry. If sufficiently diluted, the residual antibiotics in the slurry can be biodegraded (Hobson and Wheatley 1993). However, at higher concentrations, such as when every animal in the operation is receiving therapeutic doses, the antibiotics have been observed to severely interfere with the microbial decomposition process (Fischer, Iannotti, and Sievers 1981).

The presence of antibiotics in CAFO manure creates conditions for the selection of antibiotic-resistant microorganisms (US EPA 2004). Antibiotic-resistant bacteria are able to persist in the presence of antibiotics in ingestate and can become prevalent in anaerobic digesters (Resende et al. 2014). While these organisms help to degrade antibiotics, their persistence increases the occurrence of antibiotic resistant genes in the bacterial population (Aydin, Ince, and Ince 2016). The antibiotic resistant plasmids found in AD populations are transferable to non-resistant bacteria (Wolters et al. 2015).

<u>Evaluation Question #7:</u> Describe any known chemical interactions between the petitioned substance and other substances used in organic crop or livestock production or handling. Describe any environmental or human health effects from these chemical interactions (7 U.S.C. § 6518 (m) (1)).

Most of the interactions between AD and other substances used in organic production are biological and not strictly chemical in nature. AD can be reasonably expected to act like other organic soil amendments in increasing cation exchange capacity (CEC), increasing the ability of soil to retain moisture, and buffering soil from rapid changes in pH.

<u>Evaluation Question #8:</u> Describe any effects of the petitioned substance on biological or chemical interactions in the agro-ecosystem, including physiological effects on soil organisms (including the salt index and solubility of the soil), crops, and livestock (7 U.S.C. § 6518 (m) (5)).

In general, the addition of organic matter from AD has a beneficial effect on soil ecology and health (Walsh, Jones, et al. 2012; Nkoa 2014; Möller 2016). A review of the literature found that most studies showed AD increased overall soil biological activity compared with either non-organic (conventional) fertilizer application or a no-treatment control (Möller 2015). Compared with a no-treatment control and mineral (chemical) fertilizer, anaerobic digestate increased the population of organic matter decomposing bacteria and the soil became bacterially dominated in relation to soil fungi (Walsh, Rousk, et al. 2012).

Studies that compared AD with undigested / uncomposted feedstocks and with compost provided results that were less clear. The addition of AD from slaughterhouse waste, source-separated household food waste, pig slurry, and distillers waste to soils in Sweden significantly improved soil microbial nitrogen mineralization and the potential ammonia oxidation rate (Abubaker, Risberg, and Pell 2012).

There is no evidence that AD is toxic to earthworms. Barley fields in Denmark that had digestate from vegetative feedstocks showed no significant difference in earthworm populations (Frøseth et al. 2014). Anaerobic digestate can be composted with earthworms. Vermicompost made from AD with the earthworm species *Perionyx excavatus* and *Perionyx sansibaricus* concentrated nutrients, reduced fecal coliform levels to below detection, and increased stability (Rajpal et al. 2014).

The salinity of AD will vary according to the ingestate and process used. The salt content of AD is generally higher than the salt content for compost (Möller 2016). Feedstocks that lead to the greatest salinity in the AD include marine fish processing waste water (Omil, Méndez, and Lema 1995; Guerrero et al. 1997), marine microalgae (Mottet, Habouzit, and Steyer 2014; Shah et al. 2015), and pig slurry (Moral et al. 2008; Zhang, Lee, and Jahng 2011). Excessive salinity in the ingestate can inhibit methanogenesis (Shah et al. 2015). Pretreatment with water can leach sodium and chlorine in solution and reduce the electrical conductivity. However, pretreatment with sulfuric acid increases the salinity of the liquid (Tampio, Marttinen, and Rintala 2016).

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).

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).

With respect to livestock, the EU Expert Group for Technical Advice on Organic Production noted that animal by-products from factory farms should be excluded for all feedstocks used in biogas digestate applied to organic farms because of animal welfare concerns (EGTOP 2011).

Evaluation Question #9: Discuss and summarize findings on whether the use of the petitioned substance may be harmful to the environment (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).

Risks to the environment depend on the feedstocks and the quality of the finished AD. Heavy metal contamination and persistent chemical contamination are potentially harmful to the soil (Nkoa 2014). Long-term research on the effects of repeated application of AD from agricultural or source separated household wastes have not been conducted. The risks from CAFOs and industrial wastewater feedstock sources may be comparable to the environmental risks posed by sewage sludge.

Over-application and/or poorly timed application of AD can result in environmental damage similar to the misapplication of raw manure and compost. Application on frozen ground will result in poor incorporation into the soil and is likely to lead to runoff into surface water when the soil thaws if there is a snow melt or heavy rains. Loading rates higher than what can be incorporated into the soil may also cause nutrient leaching into groundwater and runoff into surface waters, particularly nitrogen and phosphorous (Holm-Nielsen, Al Seadi, and Oleskowicz-Popiel 2009; Nkoa 2014). While anaerobic digestion and biogas generation reduce greenhouse gas emissions, production of biogas in CAFOs and the application of unstable AD may lead to increased water pollution in sensitive watersheds, compared with a more systems-based approach to manure management (Svoboda et al. 2013).

While AD reduces greenhouse gas (GHG) emissions compared with liquid manure stored in slurry pits, it does release some greenhouse gases (Holm-Nielsen, Al Seadi, and Oleskowicz-Popiel 2009). For sorted municipal solid waste, anaerobic digestion had the lowest GHG emission factor compared with—in decreasing order—landfilling, incineration and composting (Mata-Alvarez, Macé, and Llabrés 2000). Contamination of even pre-sorted household food scraps and other organic matter collected by municipal solid waste is a possibility. Despite the risks, the EPA regards aerobic digestion to be a favorable alternative to landfilling and incineration of the organic fraction in municipal solid waste (US EPA 2015).

Evaluation Question #10: Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4)).

The principal human health concern from AD is food-borne pathogens. Microorganisms that produce various natural toxins, such as the verotoxins from *Escherichia coli* O157: H7, *Campylobacter spp., Cryptosporidium parvum, Listeria monocytogenes, Salmonella* spp., and *Clostridium* spp. are commonly found in manure and food waste. Various foodborne pathogens are a concern with animal manure and other animal by-products used as feedstocks for AD. Public health incidents, such as outbreaks of verotoxin producing *E. coli,* and *Salmonella* spp. have been linked to manure contamination of drinking water and food (US EPA 2004). 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).

Table 2: Pathogens Surviving in Anaerobic Digestate

Pathogen	Feedstock(s)	Source(s)
Bacillus anthracis	Slaughterhouse wastes	(Franke-Whittle and Insam 2013)
Campylobacter jejuni	Dairy slurry	(Kearney, Larkin, and Levett 1993)
Clostridium spp.	Animal slurry; Cow dung and Poultry litter; Slaughterhouse wastes	(P. Olsen and Thorup 1984; Alfa et al. 2014; Franke-Whittle and Insam 2013; Silvia Bonetta et al. 2014)
Escherichia spp.	Cow dung and Poultry litter; Food waste and animal manure	(Alfa et al. 2014; Murphy et al. 2016)
Klebsiella spp.	Cow dung and Poultry litter	(Alfa et al. 2014)
Listeria monocytogenes	Agricultural wastes; Household food wastes	(Kearney, Larkin, and Levett 1993; Silvia Bonetta et al. 2014; Maynaud et al. 2016; Murphy et al. 2016)
Salmonella spp.	Dairy slurry	(Kearney, Larkin, and Levett 1993; Murphy et al. 2016)
Shigella spp.	Cow dung and Poultry litter	(Alfa et al. 2014)
Yersinia enterocolitica	Dairy slurry	(Kearney, Larkin, and Levett 1993)

The microbial populations of aerobic and anaerobic conditions are different (Gerardi 2003). 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).

Salmonella is a likely pathogen in both aerobic and anaerobic conditions. It is the most common cause of foodborne enteritis in the U.S., and is responsible for the most food poisoning hospitalizations and deaths (Scallan et al. 2011). *Salmonella* species are able to survive in mesophilic digestion processes, but are more likely to be reduced in thermophilic conditions (J. E. Olsen and Larsen 1987; Sahlström 2003).

Another pathogen of particular concern for AD from agricultural wastes is the facultative anaerobic bacterium *Listeria monocytogenes* (Maynaud et al. 2016). *Listeria monocytogenes* is the organism responsible for listeriosis, and is fatal in almost 16% of all cases in the U.S. (Scallan et al. 2011).

Bacteria of the *Clostridium* genus are obligate anaerobes, which means that they are unable to carry out metabolic functions or reproduce in the presence of atmospheric oxygen. However, unlike other obligate anaerobes, *Clostridium* species produce endospores that enable them to remain viable under aerobic conditions. The human pathogen *Clostridium perfringens* is a common source of foodborne illnesses, and is responsible for Pig-bel Syndrome. *Clostridium tetani* is responsible for tetanus. *Clostridium botulinum* is relatively rare, but it is the organism responsible for producing the toxin that causes botulism, which is more serious. Anaerobic digestion did not reduce *C. perfringens* in several cases (Bagge, Sahlström, and Albihn 2005; Si Bonetta et al. 2011; Silvia Bonetta et al. 2014).

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).

Lettuce grown on peat with AD liquid inoculated with *E. coli* O157:H7, *Salmonella* and *Listeria monocytogenes* resulted in contamination of the leaves with all three pathogens. The *E. coli* O157:H7 and *Salmonella* both were internalized by the lettuce, while the *Listeria monocytogenes* was on the surface (Murphy et al. 2016). The study found that the pathogen levels were higher with AD liquid than with composted food waste. The AD process and the moisture content of the AD were not reported.

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). Anaerobic digestate in the EU is required to comply with the EU regulation that limits what animal by-products may be used as fertilizers [EC 142/2011].

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). 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). 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 is beyond the scope of this report. Other acceptable PFRPs are discussed further in Evaluation Question #11.

<u>Evaluation Question #11:</u> Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).

Nonsynthetic substances that could be used in place of AD to provide similar functions include aerobic compost, vermicompost, raw manure, various mulches such as straw and leaves, and various plant and animal by-products with fertilizer value, such as blood meal, bone meal, fish meal, soybean meal, alfalfa meal and cottonseed meal (Parnes 1990). There are a number of blended fertilizers made with various ingredients allowed for organic production (CDFA-FFLDRS 2016; OMRI 2016; WSDA 2016).

Uncomposted (raw) animal manure may be applied to certified organic land, but it may have higher levels of pathogens, and will also be subject to a minimum interval from application to harvest in accordance with §205.203(c). Manure may be heat treated to achieve pathogen reduction comparable to composting, but the product may be unstable, and thermal treatment beyond the thermophilic range will reduce populations of beneficial soil microorganisms.

Comparison of Anaerobic Digestate and Compost

The definition for compost at §205.2 reads, "The product of a managed process through which microorganisms break down plant and animal materials into more available forms suitable for application to the soil. Compost must be produced through a process that combines plant and animal materials with an initial C:N ratio of between 25:1 and 40:1. Producers using an in-vessel or static aerated pile system must maintain the composting materials at a temperature between 131 °F and 170 °F for 3 days. Producers using a windrow system must maintain the composting materials at a temperature between 131 °F and 170 °F for 15 days, during which time, the materials must be turned a minimum of five times."

The first key difference between AD and compost is in the C:N ratio. In most cases, AD has a larger C:N ratio for the ingestate as well as the digestate. The C:N ratios of the feedstocks used in anaerobic digestion are sometimes as low as 1:1 and seldom higher than 20:1 (Nkoa 2014). As pointed out in Table 1, the C:N ratio of AD is less than 25:1. The stability, maturity, and various other physical, chemical, and biological characteristics of AD can be improved by co-composting it with bulky organic material with a higher C:N ratio (Bustamante et al. 2012). Anaerobic digestate from winery wastes was shown to have a greater nitrogen mineralization capacity compared with aerobic compost under laboratory conditions (Canali et al. 2011). On the other hand, AD from MSW resulted in lower mineralization and greater immobilization rates than aerobically composted MSW (Larsen et al. 2007).

The second key difference is that aerobic composting always has a thermophilic step, while most anaerobic digestion processes remain in the mesophilic zone below 55°C (131°F). While thermophilic anaerobic digestion is technically feasible, it is not the prevalent technology for reasons explained above—mainly that most methanogenic anaerobic bacteria are mesophiles and that the thermophiles are relatively difficult to manage during the transition phase from the mesophilic to the thermophilic stage. As was shown in Evaluation Question #10, there is evidence that mesophilic human pathogens that are reduced by the thermophilic stage in compost are able to survive mesophilic anaerobic digestion.

Most of the research on the equivalence of pathogen reduction between aerobic compost and thermophilic anaerobic digestion has been conducted on sewage sludge, but some has been done on manure and the results consistently show that thermophilic processes are more effective than mesophilic processes in reducing pathogens (Gerba and Smith 2005). The EPA's process to further reduce pathogens (PFRP) in sewage sludge by aerobic composting has the same time and temperature requirements as the NOP definition for compost (US EPA 2003). Aerobic composting of AD is recognized as a process to significantly reduce pathogens (PSRP) and a PFRP by the EPA (US EPA 2016b). By contrast, the PFRP for thermophilic anaerobic digestion of sewage sludge that is equivalent to aerobic composting is "liquid sewage sludge is agitated with air or oxygen to maintain aerobic conditions and the mean cell residence time (i.e. the solids retention time) of the sewage sludge is 10 days at 55°C (131°F) to 60°C (140°F)" (US EPA 2003).

While vermicomposting is not recognized as a PSRP or PFRP by the EPA, it has been demonstrated as an effective way to reduce certain indicator pathogens in AD (Rajpal et al. 2014). However, that study did not look at *Clostridium* spp. or *Listeria monocytogenes.* The EPA also recognizes thermal processing with steam heat, heat drying, or pasteurization; microwave-, beta- or gamma-irradiation; and thermal oxidation and agitation as PFRPs for AD that are equivalent to aerobic composting (US EPA 2003; US EPA 2016b).

A comparison of AD and aerobic compost made from different blends of agricultural and source-separated household waste feedstocks found that the AD had significantly higher macronutrient (NPK) content (Tambone et al. 2010). The lower carbon content is a partial explanation. The same study found that the nitrogen mineralization rate for the aerobic compost was higher, in part due to the greater stability and maturity.

There are some environmental advantages that anaerobic digestion has over aerobic composting. One is that aerobic composting results in the release of uncontrolled emissions of volatile compounds, such as ketones, aldehydes, ammonia, and methane, while these substances are trapped or captured in the anaerobic digestion process (Mata-Alvarez, Macé, and Llabrés 2000). As noted in Evaluation Question #5, some pesticide contaminants can be degraded by anaerobic digestion. The composting process also has mixed results in the degradation of pesticide and antibiotic contamination. While aerobic composting and anaerobic digestion yielded comparable results in degrading certain biodegradable pesticides, there were some differences. In a direct comparison, anaerobic digestion was better able to biodegrade triazole fungicides than aerobic composting of food waste (Kupper et al. 2008).

Evaluation Question #12: Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m) (6)).

The NOP regulations require the use of soil fertility and crop nutrient management practices in accordance with §205.203. Organic growers rely on crop rotations that include cover crops grown as green manure to cycle nutrients, as well as organic soil amendments, particularly compost (Baker 2009; USDA / NRCS 2016). Nutrient cycling without the use of off-farm inputs can be done by growing cover crops and grazing livestock. Such systems are low-input, low-output, and may not be feasible under various environmental or production circumstances.

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