Biodegradable Mulch Film Made from Bioplastics

Crops

Identification of Petitioned Substance

Chemical Names:
Polymers: Polyhydroxyalkanoates (PHA); polylactic acid (PLA); Aliphatic-Aromatic Copolymers (AAC);
Monomers: 3-hydroxybutyric acid; 3-hydroxyvaleric acid; adipic acid; azelaic acid; sebacic acid; terephthalic acid; 1,3-propylene glycol; 1,4-butanediol; 1,6-hexanediol
Additives: titanium dioxide; carbon black

Other Names:
PLA: Polylactide
AAC: Aliphatic copolyester
PHA: N/A

Trade Names (bioplastic films):
PLA: NatureWorks PLA INGEO™
PHA: Mirel™, BioTelo
AAC: Ecoflex™, Eastar Bio™, MaterBi®

CAS Numbers:
See Tables 2a and 2b

Other Codes:
N/A

Summary of Petitioned Use

The use of biodegradable mulch film made from bioplastic has been petitioned to section 205.601 of the National List, for use in organic crop production. Biodegradable mulch film made from bioplastics (bioplastic mulch) is used in crop production as an alternative to petroleum-based plastic mulches that do not completely biodegrade (Rangarajan and Ingall, 2006). Bioplastic mulch is applied to agricultural fields as a thin plastic layer, about 0.6 mils (0.015 mm) thick and wide enough to cover the crop rows (Rangarajan and Ingall, 2006).

Characterization of Petitioned Substance

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

Commercial bioplastic mulches are produced by multiple companies worldwide and in variable formulations depending on the company producing the mulch and the planned use of the mulch. Biodegradable mulches are made from biodegradable polymers, including the three types described in the petition: polylactic acid (PLA), polyhydroxyalkanoates (PHA), and aliphatic-aromatic copolymers (AAC).

PLA is a polymer derived from plant starch such as corn or wheat starch. PHA is a polymer derived from the fermentation of sugars or lipids. AAC are synthesized from various constituents depending on the product in question (Bastioli, 2005), and the most common monomer constituents are discussed in this report. The mulches may also contain titanium dioxide or carbon black, which is used to color the mulch either white or black, respectively (Ngouajio et al., 2008). Plasticizers, including glycerol, stearamide, and erucamide are used in the production of bioplastic mulches.

Lactic acid is the monomer (base material) that makes up PLA, a polymer (a chain of monomers) in bioplastics, and can include both L(+)-lactic and D(-)-lactic acid.[1] Bacteria from the genus *Lactobacillus* are

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[1] The terms L(+)- and D(-) are used to distinguish the two enantiomers, or configurations, with the same chemical formula. The "L" and "D" indicate how the chemicals are structurally related by their configuration to a reference chemical, glyceraldehyde. The (+) and (-) indicate how polarized light rotates (either clockwise or counter-clockwise) when it is passed through a sample of the chemical. Both of the notations are used to distinguish molecules containing the same atoms, but arranged in a similar, but meaningfully different, manner.

used to ferment carbohydrates (sugars and starches) into lactic acid. Various species in the *Lactobacillus* genus produce varying amounts of either the L(+)- or D(-)-isomers. In addition, the various species of *Lactobacillus* are used to ferment different sugars and/or starch feedstocks, as listed in Table 1, below. The bacteria also require nutrients during the fermentation process, such as B-vitamins, nucleotides, and amino acids. These nutrients may be sourced from yeast, cottonseed flour, corn steep liquor, or soy flour, and are dependent on the species used (Garlotta, 2001).

PHA polymers are produced in three main ways: chemical synthesis, bacterial fermentation, or through the use of transgenic plant cells. There are a number of bacteria used to produce PHAs, which are highlighted in Table 1, below. When some bacteria, including *R. eutropha*, are grown in environments with limited phosphorus, nitrogen, oxygen, or magnesium, they metabolize carbon sources such as starch into granules of PHAs that can be used for PHA polymers (Jacquel et al., 2008). *R. eutropha* has been the most popular wild type (not genetically modified) strain of bacteria for industrial production of PHAs. In order to reduce costs and increase efficiency, some companies have used genetic engineering to manipulate *R. eutropha* and *E. coli* to increase PHA yields and chemical purity (Chen, 2009).

Aliphatic-aromatic copolymers (AAC) are synthetically produced by reacting a diacid constituent (including adipic acid, azelaic acid, sebacic acid, and terephthalic acid) with a diol constituent (1,3-propylen glycol, 1,4-butanediol, or 1,6-hexanediol), which are then linked with an ester linkage. The amounts and combinations of the aliphatic and aromatic constituents of AAC plastics vary by manufacturer and may also vary by specific product used. Although the primary focus of this technical report is the three petitioned bioplastic materials, the constituent compounds are also discussed where appropriate. The linkages of these monomers can be broken by hydrolysis or degradation by specific microorganisms, depending on the material (Bastioli, 2005). The bioplastic types are further described in Table 1.

The bioplastic mulch films may be formulated with carbon black to color the plastic so that the film absorbs heat and increases soil temperatures, or with titanium dioxide to color the film white and help reflect sunlight and reduce soil temperatures (Ngouajio et al., 2008). Properties of titanium dioxide and carbon black are further described below.

Properties of the Substance:

The properties of the common constituents of bioplastic mulches, as identified by the petitioner, are described in Tables 2a and 2b. The properties of plasticizers used in the manufacture of bioplastic mulches, as identified by the petitioner, are described in Table 3.

Specific Uses of the Substance:

The petitioned substances have a specific use in agricultural production as mulch films to cover the soil, modify soil temperatures, retain soil moisture, help to control weeds, and to help control insect problems (Tachibana et al., 2009; Gordon et al., 2008). Other materials have been developed from bioplastics, but they are not the uses described in the petition, nor should they be considered evaluated by this technical report. The uses of bioplastics that are not covered may include: tunnel films, string, planting pots, controlled release applications for fertilizers and pesticides, and other containers for use in agricultural production (Bastioli, 2005).

Approved Legal Uses of the Substance:

Multiple standards exist which evaluate the biodegradability of various materials, including bioplastics. These standards are developed in the U.S. by the American Society for Testing and Materials (ASTM), and are described in the response to Evaluation Question #4. While the ASTM standards are not regulatory limits, the standards establish criteria for whether the plastics completely biodegrade, a factor which is considered in cases such as the review of this technical report.

Table 1: Bioplastic Types, Sources, and Production Processes

Bioplastic Type	Polymer Production Process	Feedstock/Monomer	References
Polylactic Acid, PLA	Feedstock fermented by bacteria: *Lactobacillus* species, including *L. bavaricus, L. casei, L. maltaromicus, L. salivarius, L. delbrueckii, L. jensenii, L. acidophilus*	**Feedstock:** carbohydrates including: glucose, maltose, and dextrose from corn, potato starch, or wheat; sucrose from cane or beet sugar; lactose from whey. **Monomer:** D-lactic and L-lactic acid	(Garlotta, 2001); (Sigma-Aldrich, 2005)
Polyhydroxyalkanoates, PHA	Fermentation of feedstocks by various bacteria, both genetically-modified organisms (GMO) and/or non-GMO (Chen, 2009), including *Ralstonia eutropha, Alcaligenes latus, Aeromonas hydrophila, Pseudomonas putida, Pseudomonas oleovorans*, and various *Bacillus* species.	**Feedstock:** Strain-specific, includes glucose, sucrose, glucose + propionate, fatty acids, glucose + 1,4-butanediol, and lauric acid **Monomer:** At least 150 monomers, most common 3-hydroxybutyric acid or 3-hydroxyvaleric acid.	(Chen, 2009); (Jacquel et al., 2008)
Aliphatic-aromatic copolymers, AAC	Monomers formed from reacting diacids (adipic acid, azelaic acid, sebacic acid, terephthalic acid) with diols (1,3-propane diol; 1,4-butanediol; 1,6-hexanediol) to create an ester linkage.	**Feedstock:** Various sources, includes fossil fuels. **Monomers:** Various combinations of the substances listed at left, proprietary mixtures in some cases.	(Bastioli, 2005)

Table 2a: Properties of Common Constituents in Bioplastic Mulch

Property	Lactic Acid (monomer of polylactic acid)	3-hydroxy-butyric acid	3-hydroxy-valeric acid	Titanium Dioxide	Carbon Black
CAS #	50-21-5 (NLM, 2011)	300-85-6 (Wishart et al., 2009)	10237-77-1 (Wishart et al., 2009)	13463-67-7(NLM, 2011)	1333-86-4(NLM, 2011)
Color	Yellow to colorless (NLM, 2011)	Colorless (Sigma-Aldrich, 2005)	Colorless to pale yellow (DuPont, 2005)	White(NLM, 2011)	Black (NLM, 2011)
Physical State	Crystals or syrupy liquid (NLM, 2011)	Liquid (Sigma-Aldrich, 2005)	Solid (Wishart et al., 2009)	Amorphous crystals or powder (NLM, 2011)	Fine powder (NLM, 2011)
Molecular Weight	90.09 (NLM, 2011)	104.1 (Wishart et al., 2009)	118.1 (Wishart et al., 2009)	79.90 (NLM, 2011)	12 (NLM, 2011)
Odor	Odorless; some forms may have a slightly acrid odor (NLM, 2011)	N/A	“slight” (DuPont, 2005)	Odorless (NLM, 2011)	Odorless (NLM, 2011)
Melting Point	62.24° F (16.8° C) (NLM, 2011)	114.8° F (46° C) (NLM, 2002)	109-112.1° F (43-44.5° C) (DuPont, 2005)	3,349.4° F (1,843° C) (NLM, 2011)	Sublimes (turns from solid to gas) at 6,605.6-6,686.6° F (3,652-3,697° C) (NLM, 2011)
Boiling Point	251.6° F (122° C) (NLM, 2011)	266° F (130 ° C) (Sigma-Aldrich, 2005)	275° F (135° C) (DuPont, 2005)	4,532-5,432° F (2,500-3,000° C) (NLM, 2011)	7,592° F (4,200° C) (NLM, 2011)
Solubility	Miscible (mixes in all proportions) in water; soluble in alcohol and furfural; slightly soluble in ether (NLM, 2011)	444 mg/mL (Wishart et al., 2009)	3710 mg/mL (Wishart et al., 2009)	Insoluble in water and organic solvents; soluble in acids (sulfuric, hydrofluoric, etc.); soluble in alkali (NLM, 2011)	Insoluble in all solvents and water (NLM, 2011)
Reactivity	Explosive reactivity in mixture with nitric acid, water, and hydrofluoric acid when stored. (NLM, 2011)	Hygroscopic (will absorb and hold water) (Wishart et al., 2009)	With strong oxidizers, alkalies, strong acids, strong bases, reducing agents (DuPont, 2005	Reactive with lithium and metals at high temperatures (NLM, 2011)	Dust may form explosive mixtures in air. Considered an explosion hazard if more than 8% volatile material (NLM, 2011)
Flammability	N/A	N/A (Sigma-Aldrich, 2005)	Combustible (DuPont, 2005)	Not combustible (NLM, 2011)	Can be ignited when exposed to flame, burns slowly (NLM, 2011)
Hazardous Combustion/ Decomposition	Emits acrid smoke and irritating fumes when heated to combustion(NLM, 2011)	Decomposition may release carbon monoxide and carbon dioxide (Sigma-Aldrich, 2005)	Decomposes with heat, may release hazardous gases or vapors (DuPont, 2005)	Not combustible (NLM, 2011)	When burned emits carbon monoxide (NLM, 2011)

N/A: Information not available for selected property

Table 2b: Properties of Common Constituents in Bioplastic Mulch

Property	Azelaic acid (NLM, 2011)	Sebacic acid (CAMEO, Undated)	Terephthalic acid (NLM, 2011)	1,4-Butanediol (NLM, 2011)	1,3-Propane diol (Sciencelab.com, 2010)	1,6-Hexanediol (NLM, 2011, unless otherwise noted)
CAS #	1223-99-9	111-20-6	100-21-0	110-63-4	504-63-2	629-11-8
Color	Yellow to white	White	White	Colorless	Colorless to light yellow	White (Sigma-Aldrich, 2011a)
Physical State	Crystalline powder	Granular Powder	Crystals or powder	Liquid	Liquid	Crystals
Molecular Weight	188.22	202.28	166.13	90.12	76.09	118.17
Odor	N/A	N/A	N/A	Almost odorless	odorless	N/A
Melting Point	160.5° C	274.1° F	427° C	20.4° C	-16.6° F (-27° C)	42.8° C
Boiling Point	357.1° C	563° F	N/A	235° C	370.8° F	208° C
Solubility	Slightly soluble in ethyl ether, benzene, soluble in ethanol; soluble in hot water.	<1 mg/mL @ 70° F	Insoluble in chloroform, ether, acetic acid; slightly soluble in alcohol; water solubility 15 mg/L at 20° C	Readily soluble in water (1,000g/L @ 20° C); soluble in alcohol, ketones, glycol ethers	Easily soluble in cold water.	In water (3.1 g/L @ 25° C), soluble in alcohol, sparingly soluble in hot ether
Reactivity	Reactive with oxidizing agents	Reacts to neutralize bases, may react rapidly with aqueous basic solutions, can react with active metals to form metal salt and hydrogen gas, some reactions may generate flammable and/or toxic gases.	Dust may form an explosive mixture with air	Incompatible with oxidizing materials	Stable,	Can react with oxidizing materials
Flammability	Slightly flammable in the presence of heat	Probably Combustible	Combustible	Combustible when exposed to heat or flame	Combustible; flash point between 100° F and 200° F	Moderate fire potential when exposed to heat or flame

Property	**Azelaic acid (NLM, 2011)**	**Sebacic acid (CAMEO, Undated)**	**Terephthalic acid (NLM, 2011)**	**1,4-Butanediol (NLM, 2011)**	**1,3-Propane diol (Sciencelab.com, 2010)**	**1,6-Hexanediol (NLM, 2011, unless otherwise noted)**
Hazardous Combustion/ Decomposition	N/A	Should be stored under refrigerated conditions and kept away from oxidizing materials.	Emits acrid smoke and irritating fumes when heated to decomposition	Emits acrid smoke and fumes when heated to decomposition	Products of degradation more toxic than the parent compound.	Emits acrid smoke and fumes when heated to decomposition

N/A: Information not available for selected property

Table 3: Properties of Plasticizers used in Production of Bioplastic Mulch

Property	**Glycerin/glycerol (NLM, 2011)**	**Stearic acid amide (NLM, 2011; Sigma-Aldrich, 2010)**	**Erucamide (NLM, 2011) (Sigma-Aldrich, 2011b)**
CAS #	56-81-5	124-26-5	112-84-5
Color	Clear, colorless	Colorless	N/A
Physical State	Syrupy liquid	Powder	Solid
Molecular Weight	92.09	283.5	337.37
Odor	Mild odor	N/A	N/A
Melting Point	64.6° F (18.1° C)	228.2 (109° C)	167-176° F (75-80° C)
Boiling Point	554° F (290° C)	482° F (250-251° C)	676.4° F (358° C)
Solubility	5.3×10^6 mg/L in water; 6.7 g/L in acetone	Insoluble in water, soluble in ether, chloroform, and hot ethanol	Soluble in isopropanol, slightly soluble in alcohol and acetone
Reactivity	Incompatible with strong oxidizers; hygroscopic (absorbs moisture from the air)	Stable under recommended storage conditions	Avoid strong oxidizing agents; stable under normal storage conditions.
Flammability	Flash point 350.6° F (177° C)	N/A	N/A
Hazardous Combustion/ Decomposition	Decomposes on heating and produces acrolein	Fire creates carbon oxides and nitrogen oxides	Fire creates carbon oxides and nitrogen oxides

N/A: Information not available for selected property

U.S. Environmental Protection Agency (EPA):
EPA has issued multiple research grants to develop degradable plastics from starch and PLA. The general purpose of the grants has been to develop affordable, durable, and degradable bioplastics, with a focus on developing plasticizers and determining the degradability of the bioplastics. No specific federal regulations are in place which govern the use of bioplastics under the authority of the U.S. EPA.

U.S. Food and Drug Administration (FDA):
On April 12, 2010, FDA issued a Finding of No Significant Impact (FONSI) for PHA used in articles that may contain food. The specific substance is butanoic acid, 3-hydroxy-, (3R)-, polymer with 4-hydroxybutanoic acid at 4-10% by weight and butanoic acid, 3-hydroxy, homopolymer at 90-96% by weight. The FONSI states that the extent of any environmental impact from the production of dextrose from corn and fermentation of the feedstock is acceptable and will not significantly affect the quality of the human environment (FDA, 2010).

On August 11, 2009, FDA issued a FONSI for AAC used for coatings or single-use films in articles that may contain food. The specific substances were 1,4-benzenedicarboxylic acid polymer with 1,4-butanediol, sebacic acid, hexamethylene diisocyanate and not more than one percent by weight of polyhydric alcohol. The FONSI states that the extent of any environmental impact from the production of the material is acceptable and will not significantly affect the quality of the human environment (FDA, 2009).

On November 29, 2004, FDA issued a FONSI for PLA used in the manufacture of food contact articles. The specific substance is PLA comprised of up to 16% D-lactic acid polymer units. The FONSI states that the extent of any environmental impact from the production of PLA is acceptable and will not significantly affect the quality of the human environment (FDA, 2004).

Action of the Substance:
Bioplastic mulches are used in agricultural production to improve soil water retention, increase or decrease the temperature of the soil, control weeds, and mitigate insect damage (Tachibana et al., 2009; Gordon et al., 2008). White mulches are used to reflect light and heat, but may also increase growth or the quality of the crop (Tachibana et al., 2009; Gordon et al., 2008). Black mulches increase soil temperatures and allow for growth of crops in relatively cool areas or areas with shorter growing seasons (Gordon et al., 2008). The mulches are used as a physical barrier and do not interact or change chemically while they are intact. Once the bioplastic mulches break down, they may interact with the soil and microorganisms in the release of carbon dioxide, water, and carbon-based biomass (Bastioli, 2005).

Combinations of the Substance:
Lactic acid is included on the National List of Allowed and Prohibited Substances (hereafter referred to as the National List) in section 205.605 (a), "Nonsynthetics allowed in or on processed products labeled as 'organic' or 'made with organic (specified ingredients or food group(s))." Lactic acid is a precursor monomer that makes up PLA. None of the other substances are specifically listed in the National List.

Glycerol is also on the National List as 'glycerine' in section 205.603(a)(12) for use in organic livestock production as a "livestock teat dip, must be produced through the hydrolysis of fats or oils." Glycerol is also listed as 'glycerin' in section 205.605(b) for use in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))". According to 205.605(b), the glycerin must be produced by the hydrolysis of fats or oils.

Status

Historic Use:
Synthetic plastic mulches have been used in conventional agricultural production to suppress weeds, control moisture, and regulate soil temperature since the 1950s (Miles et al., 2007). In organic agriculture,

synthetic plastic mulches are included in the National List for the same purposes, but are required to be removed from the field at the end of the growing or harvest season by Section 205.206(c)(6). Bioplastic mulches were introduced in the 1980's, but their affordability and biodegradability have been barriers to their more extensive use. In addition, they are difficult to remove from the field at the end of the season due to the fact that they are not as durable as synthetic polyethylene (PE) mulches. Bioplastic mulches are not currently allowed for use in organic agriculture under the NOP.

OFPA, USDA Final Rule:

According to the NOP Final Rule (7 CFR 205.2), mulch is defined as "Any nonsynthetic material, such as wood chips, leaves, or straw, or any synthetic material included on the National List for such use, such as newspaper or plastic that serves to suppress weed growth, moderate soil temperature, or conserve soil moisture." The bioplastic mulches are produced in a manner which makes them synthetic materials (Bastioli, 2005).

Section 205.206(c)(6) of the NOP Final Rule states that weed problems may be controlled through "Plastic or other synthetic mulches: *Provided*, That, they are removed from the field at the end of the growing or harvest season." AACs are petroleum-based plastic, which are allowed synthetic inputs under section 205.601(b): "As herbicides, weed barriers, as applicable," under sub-section (2)(ii): "Plastic mulch and covers (petroleum-based other than polyvinyl chloride (PVC))." Given that these plastic mulches are required to be removed at the end of the season, the use pattern is different than the proposed use, and hinges on the extent that the mulch is degraded after the season ends.

In the Organic Foods Production Act, Title 7, Section 6508 of the U.S. Code, "Prohibited crop production practices and materials," plastic mulches are listed in subsection (c)(2). The section states that, "For a farm to be certified under this chapter, producers on such farm shall not –" "(2) use plastic mulches, unless such mulches are removed at the end of each growing or harvest season;"

International

Canada - Canadian General Standards Board –

The Canadian General Standards Board allows for "plastic mulch" as a permitted substance, classified as a crop production aid. Fully biodegradable films are permitted as mulches if they do not contain any substances prohibited by paragraph 1.4.1 of CAN/CGSB-32.310. Paragraph 1.4.1 of CAN/CGSB-32.310 states that the following substances may not be allowed when producing or handling organic products (partial list, limited to substances applicable to bioplastic mulches):

- Materials or products produced from genetic engineering
- Synthetic processing substances, aids and ingredients
- Intentionally manufactured nano-technology products

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

Evaluation Question #1: What category in OFPA does this substance fall 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?

Bioplastic mulch is used as a production aid, but is not technically considered a row cover. The substances are used as mulches (a category not listed above), which function as production aids because they increase soil temperature, reduce weed pressure, maintain soil moisture levels, and may help extend the growing season (Gordon et al., 2008). Bioplastic mulches are not named on the EPA List 4 inert ingredients.

<u>Evaluation Question #2:</u> 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)).

PHA and PLA polymers are produced in similar ways: fermentation of sugars or starches by specific bacterial strains which produce either PHAs or D(+)- or L(-)-lactic acid. The sugars and starches used to produce PLA include the following carbohydrates: glucose, maltose, and dextrose from corn, potato starch, or wheat; sucrose from cane or beet sugar; or lactose from whey (Garlotta, 2001). The source of the sugars and starches for PLA were not described in research in detail, but based on the adoption and production practices of bioplastics using genetically-modified organisms, the sugars, starches, and microorganisms used to manufacture PLA may be genetically-modified, or from genetically-modified sources (Chen, 2009; Corbin et al., 2012; Mooney, 2009). Fermentation of feedstocks for PLA production is carried out by various species of bacteria, including: *Lactobacillus* species, including *L. bavaricus*, *L. casei*, *L. maltaromicus*, *L. salivarius*, *L. delbrueckii*, *L. jensenii*, *L. acidophilus* (Garlotta, 2001). Information on genetically-modified organisms used in PLA production is not available, but it is possible that bacteria have been engineered for improved efficiency to produce PLA.

Once lactic acid is obtained, the monomers are converted to polymers in a two-step process. First, lactic acid is oligomerized (conversion of monomers to polymers of a specific length) into a linear chain by the removal of water (Bastioli, 2005). This process may be carried out either with or without a solvent; the solvents may vary, but include 2-butene-1,4-diol; glycerol; and 1,4-butanediol (Lunt, 2000; Garlotta, 2001). Then, the oligomer is converted to lactide, a cyclic (ring-like) dimer (combination of two similar monomers) which is then purified, opened and polymerized to form PLA (Bastioli, 2005). A catalyst may be required for ring opening, and those catalysts may include acids containing metal salts such as aluminum, tin, titanium, zinc, and rare earth metals; alkali metal complexes and other acids. Tin-containing catalysts have been shown to be effective and can be used for large scale production of PLA (Bastioli, 2005).

PHA polymers are produced through fermentation directly, so no additional processing of the raw material may be necessary before the polymers are processed into bioplastic films. Feedstocks for the production of PHAs are strain-specific, but may include: glucose, sucrose, glucose + propionate, fatty acids, glucose + 1,4-butanediol, and lauric acid (Chen, 2009; Jacquel et al., 2008). Fermentation of feedstocks for PHA production is carried out by various species of bacteria, both genetically-modified and/or non-GMO, including: *Ralstonia eutropha, Alcaligenes latus, Aeromonas hydrophila, Pseudomonas putida, Pseudomonas oleovorans*, and various *Bacillus* species (Chen, 2009; Jacquel et al., 2008).

AAC are produced from reacting diacids with diols to create ester linkages, as presented in Table 1. The sources of feedstocks for the various AAC are summarized in Table 4.

The design and manufacture of AACs has been manipulated to produce a polymer that is more readily biodegraded and therefore has a lower impact on the environment (Bastioli, 2005). However, many of the feedstocks for AAC polymers are derived from petroleum or its derivatives, or require a catalyst or some other external inputs for conversion.

Corn starch is added to many of the bioplastics, or may be used as a feedstock. Starch is extracted from corn or other sources by wet milling, which involves steeping the corn in an acid solution then splitting the kernel with a mill to eventually extract the dense starch. The starch is further processed or modified by enzymes or chemical treatments, depending on the grade and purpose of the starch (Bastioli, 2005).

Table 4: Feedstocks Used in the Production of AAC

Feedstock	Source
Adipic acid	Oxidation of cyclohexane. Cyclohexane is obtained from petroleum (NLM, 2011)
Azelaic acid	Oxidation of oleic acid (or other naturally-occurring fatty acids) by ozone (NLM, 2011)
Sebacic acid	Obtained from castor oil (from castor beans) by pyrolysis in the presence of alkali (Vasishtha et al., 1990)
Terephthalic acid	p-Xylene is the feedstock for all terephthalic acid production. p-Xylene is obtained from petroleum (NLM, 2011)
1,3-propanediol	Fermentation of corn syrup by genetically-engineered *Clostridium* or *Enterobacteriaceae* species (Biebl et al., 1999)
1,4-butanediol	Most popular process for production is reacting acetylene and formaldehyde (NLM, 2011)
1,6-hexanediol	Hydrogenation of adipic acid using a catalyst, copper chromite (NLM, 2011)

Plasticizers, including glycerol, stearic acid amide, and erucamide, are added to the polymers to increase malleability, tensile strength, and flexibility (Domenek, 2004). Glycerol is used in many commercial products and produced in one of two ways. (NLM, 2011). Glycerol may be produced as a byproduct from the conversion of naturally occurring oils and fats to fatty acids or fatty acid methyl esters. Glycerol can be obtained from treating fats with lye during the production of soap (NLM, 2011). Synthetic glycerol is also produced from propene, a petroleum hydrocarbon (NLM, 2011). Glycerin (glycerol) is currently included as a synthetic substance on the National List at sections 205.603 and 205.605(b). Its allowance on the National List is limited to the form produced by hydrolysis of fats and oils.

Stearic acid amide is produced by reacting stearic acid with ammonia (NLM, 2011). Stearic acid is obtained from fats such as tallow (beef fat) by boiling with soda lye, removing the glycerol, and decomposing the soap with hydrochloric acid or sulfuric acid (NLM, 2011). Erucamide is produced from the reaction of ammonia with erucic acid, which is the major fatty acid component of rapeseed oil (Stefansson, 1961). Erucic acid is obtained from the hydrolysis of rapeseed oil using alkali (NLM, 2011).

Evaluation Question #3: Is the substance synthetic? 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)).

As described in the Characterization of the Petitioned Substance section, bioplastic mulches are manufactured with the addition of synthetic plasticizers and colorants (titanium dioxide and carbon black), which are added using a synthetic process. For these reasons, the bioplastic mulches may be considered synthetic substances for the purposes of this report. Bioplastic mulches made from PLA are polymers of the monomers D(+)- and L(-)-lactic acid. Lactic acid is produced by fermentation of food products containing carbohydrates by various microorganisms including: *Lactobacillus* species, including *L. bavaricus*, *L. casei*, *L. maltaromicus*, *L. salivarius*, *L. delbrueckii*, *L. jensenii*, and *L. acidophilus* (Garlotta, 2001; Sigma-Aldrich, 2005). To develop PLA the lactic acid monomers must be polymerized. This is accomplished through the use of a chemical catalyst which may include metal salts (Bastioli, 2005). Fermentation is a naturally occurring process, but under laboratory conditions, the feedstocks and environmental conditions are manipulated in order to provide an environment that is most conducive to production of PLA, a process which would be unlikely to occur in nature (Bastioli, 2005). Thus, production of PLA is a synthetic process.

PHAs are created during fermentation of starches, glucose, or other feedstocks by *Ralstonia eutropha*, *Alcaligenes latus*, *Aeromonas hydrophila*, *Pseudomonas putida*, *Pseudomonas oleovorans*, and various *Bacillus* species. Recently, researchers have developed genetically-engineered bacterial strains that produce PHA more efficiently and in differing polymer amounts. In non-genetically-modified bacterial production of PHA, the rate of PHA production can be increased by changing the ratio of carbon and nitrogen in the fermentation food source (Chen, 2009; Bastioli, 2005). To produce one kilogram of PHA, researchers calculated that 2.5 kilogram of glucose must be used in fermentation (Bastioli, 2005). PHA production by fermentation is a natural process, but the conditions used in laboratories to maximize yields and polymer amounts are not naturally occurring. In addition, genetically-modified organisms do not occur naturally.

Some feedstocks used to produce AAC (Table 3) are naturally occurring, but the chemical processes used to refine them for use do not occur in nature, nor do the synthesis processes that are used to create the ester linkages. The production of AAC is a synthetic process.

Erucamide, stearic acid amide, and glycerol may all be produced from naturally-occurring sources. However, the production of the plasticizers is dependent on processes involving heat, or a combination of strong acids and/or bases to convert the source material to the desired chemical form (NLM, 2011). These production methods are not naturally-occurring and the production of the plasticizers is therefore synthetic.

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

The petitioner states that biodegradable mulch film is defined in two ways. First, by complying with a number of different American and international standards including: ASTM D6400 and D6868; EN 13432 and EN 14995; and ISO 17088. Second, by "show[ing] at least 90% biodegradation absolute or relative to microcrystalline cellulose in less than two years, in soil, tested according to ISO 17556 or ASTM 5988." The American Society for Testing and Materials (ASTM) standards D6400 and D6868 cover biodegradable plastics (ASTM, 2012; ASTM, 2011). Standard D6400 covers plastics or products made from plastics that are designed to be composted in municipal and industrial composting facilities under aerobic conditions. Standard D6868 covers products with a biodegradable plastic film or coating that may be attached to compostable substrates, which are designed to be composted in a municipal or industrial aerobic composting facility.

The harmonized European standard EN 13432 describes the testing requirements for packaging recoverable through composting and biodegradation. Standard EN 14995 evaluates the compostability of plastics and is similar to EN 13432, but applicable to a broader scope of plastics that may be used in applications other than packaging. These standards define compostability in an industrial composting environment.

ASTM standard D5988 describes the standard test method for determining aerobic biodegradation of plastic materials in soil, and is equivalent to the International Organization for Standardization (ISO) standard 17556. This standard is most applicable to the proposed use of the bioplastic mulch because the mulches will be left in the field at the end of the season to biodegrade according to their petitioned use.

ASTM Standard D5988 is designed to be applicable to bioplastic materials that are "not inhibitory to the bacteria and fungi present in the soil." Thus, if a product complies with D5988, it could be assumed that the bioplastic does not inhibit soil bacteria or fungi by its breakdown processes. These standards measure the biodegradability of a substance in comparison to microcrystalline cellulose, the reference material, over the course of two years. Biodegradability is quantified by measuring the amount of carbon dioxide released from the soil over time. In fact, many bacteria and fungi in the soil can use bioplastics derived from starch as a carbon source (Shah et al., 2008). In the review by Shah et al. (2008), the various microorganisms that break down bioplastics are identified. PLA is broken down by *Fusarium solani*, *Fusarium moniliforme*, *Penicillium roquefort*, *Amycolatopsis sp.*, *Bacillus brevis*, and *Rhizopus delemer*.

In a research report by Rangarajan and Ingall (2006) from Cornell University, the investigators concluded that bioplastic mulch should be chiseled or tilled into the soil as soon as possible during times of warm temperatures and moisture. The researchers note that if the bioplastic mulch is tilled late in the season, it will remain in the soil until spring, but will begin to degrade once soil temperatures increase. Rototilling to create smaller pieces of mulch was shown to shorten degradation time, as did tilling into soils high in organic matter. In addition, soils that have high levels of moisture and are warm have increased decomposition rates for bioplastic mulches. According to research reports and the requirements of ASTM D5988, the breakdown time for bioplastics ranges from approximately six months (from late summer to spring) up to two years (the maximum amount of time noted in the ASTM standard).

PLA is fully biodegradable when composted in large-scale composting systems at temperatures greater than or equal to 140 °F (60 °C) (Shah et al., 2008). PLA degradation begins with a two week period where hydrolysis breaks the PLA into lactic acid and water-soluble compounds. Once this breakdown occurs, PLA is completely mineralized to CO2, water, and biomass within a total of 4-6 weeks in compost at 140 °F (60° C) (Shah et al., 2008). Reports have been published on the degradation of PLA in soil. Burial tests in soil show that PLA degradation is slow and takes a long time to start (Tokiwa and Calabia, 2006). No degradation was observed in one study of PLA sheets buried in the soil for 6 weeks (Ohkita and Lee, 2006). Another study showed that up to 75% of a PLA/corn starch biocomposite film was degraded in soil over 20 months, based on the remaining molecular weight of the films (Urayama et al., 2002). Once the PLA polymer is degraded into smaller molecules, it is further broken down to carbon dioxide and water by microorganisms (Tokiwa and Calabia, 2006).

Degradation of PHA occurs by enzymatic hydrolysis at the surface of the film, which is carried out by soil microbial populations (Bastioli, 2005). Hydrolysis breaks the PHA polymers into oligomers and monomers, which are subsequently consumed and assimilated by microbes in the soil as nutrients. Due to the fact that there is a variety of ways that PHA compounds can be manufactured, decomposition rates may vary depending on the type of PHA (crystallinity, additives, and surface area) and the soil microbial populations (Bastioli, 2005). In a soil degradation study with the PHAs poly(3-hydroxybutyrate) and poly(3-hydroxybutyrate-co-3-hydroxyvalerate), Mergaert and colleagues (1993) found that PHAs broke down most quickly at 40° C, with a rate of weight loss of 0.64% per day. Breakdown was slower at lower temperatures (28° C and 15° C) and in different soils, and ranged from 0.03% to about 0.25% for those temperatures (Mergaert et al., 1993).

All of the commercially available AAC polymer materials contain terephthalic acid, which is most responsible for determining the degradation rates in AAC plastics. As the fraction of terephthalic acid increases, the degradation rate decreases. No significant biological degradation was found when the molar fraction of AAC was increased to more than 60%, which is thought to be due to the relatively low melting point of terephthalic acid (Bastioli, 2005). Few data are available on the degradation of AAC in soil, but results of one study showed that an AAC containing 1,4-butanediol, adipic acid, and terephthalic acid (at 40%) showed a 50% weight loss in the soil after 3 months. The film completely degraded when it was in compost for 3 months. When the terephthalic acid was increased to 50%, no weight loss was detected within 3 months (Bastioli, 2005).

Carbon black, a coloring component used in some bioplastics, is elemental carbon in the form of a particulate that is manufactured from burning or partial combustion of hydrocarbons (NLM, 2011). Carbon black has been used to increase organic carbon content in soils due to its recalcitrant nature, meaning it is resistant to breakdown in the soil environment (Cheng, 2008). The half-life of carbon black in the soil has been reported as 59 years in one study (Cheng, 2008). Biochar, a method of generating carbon black for soil amendment, may help promote nutrient use efficiency in treated soils (Chan, 2008; Hunt, 2010).

Titanium dioxide, a white coloring component used insome bioplastics, is found naturally as the minerals rutile, octahedrite, brookite, ilmenite, and perovskite (NLM, 2011) . Titanium dioxide is not bioavailable to humans or animals based on laboratory testing. The U.S. EPA has stated that there are no concerns for nontarget terrestrial organisms resulting from the use of titanium dioxide as an inert ingredient in pesticide products (U.S. EPA, 2005). However, titanium dioxide may persist in soil as the by-product of titanium tetrachloride hydrolysis (ATSDR, 1997), so it may persist from use in bioplastic mulch as well. Titanium dioxide may settle out into sediments and persist for long periods of time (ATSDR, 1997). The compound is characterized by ATSDR as "a very inert compound" (ATSDR, 1997).

Erucamide, a plasticizer used in some bioplastics, is released to the environment through multiple manufacturing processes. The material binds strongly to soil and sediments in water and is likely to bioconcentrate in aquatic organisms, meaning it will occur at higher levels further up the food chain (NLM, 2011). The physical properties of erucamide suggest that the material will persist in the environment, and would be found in the water, soil and air if released (NLM, 2011).

Glycerol, a plasticizer used in some bioplastics, released to the environment will be present as both a vapor and a particle in the atmosphere, but will be degraded within hours (NLM, 2011). The material is very mobile in soils, but will not likely volatilize from dry soil, and will not likely volatilize from water nor adsorb to sediment in water (NLM, 2011). The potential for bioconcentration in aquatic organisms is low for glycerol in aquatic environments (NLM, 2011).

Limited environmental data were found on stearic acid amide, a plasticizer used in some bioplastics. Stearic acid is naturally occurring in many plant and animal oils. Stearic acid will be degraded if it is released to air, with an atmospheric half-life of 17 hours (NLM, 2011). The material is expected to be immobile in soil and is not expected to volatilize from soil. The half-life for biodegradation of stearic acid in soil ranges from 1.9 to 13 days, so long-term bioconcentration is unlikely (NLM, 2011).

Evaluation Question #5: 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)).

Ecotoxicology studies on biodegradable polymers following partial or complete decomposition in the soil are not common (Bastioli, 2005). Time-dependent inhibition of higher plants has been observed when organic material in the soil is in the process of degradation (Bastioli, 2005). Studies were not found that specifically assessed the ecotoxicity of bioplastics following degradation in the soil, and a better understanding of bioplastic degradation and soil environmental effects is needed (Corbin et al., 2012).

As discussed in the response to Evaluation Question #4, bioplastic mulch as petitioned complies with ASTM standards that limit the time of decomposition to 2 years (ASTM, 2012). However, research reports have shown that bioplastic mulch may break down during the period between late summer and spring (Rangarajan and Ingall, 2006). Generally speaking, breakdown rates of mulches may be inconsistent and can vary depending on climatic factors such as temperature, sunlight and moisture; soil type; crop cover and weed pressure (Rangarajan and Ingall, 2006). Rainfall, warm temperatures, sunlight, and soils high in organic matter help increase microbial activity in soils and thereby increase breakdown rates of bioplastic mulch (Rangarajan and Ingall, 2006). In addition, the type of mulch used may affect the breakdown rate, as different companies produce mulches of different composition. A report by Miles et al. (2007) found that cornstarch-based black film mulches (Garden Biofilm) that were tilled into the soil at the end of the growing season had broken down to the point that they were not visible to the naked eye by the following spring.

Given the application and purpose of bioplastic mulch described here, it seems unlikely that the source material (the bioplastic film) would interact with other organisms and cause toxicity. The material is manufactured to remain intact and inert during its intended use, then (ideally) break down at the end of the season. Bioplastic mulches differ from PE mulches in that they break down more readily in the soil, eventually mineralizing under ideal conditions. PE mulches, which are allowed in organic agriculture only if removed at the end of the growing or harvest season, degrade to a much lesser degree and are less likely to break down over time. PE mulches may tear into larger pieces and be difficult to remove from the soil. The PE mulches may persist in the soil and the long-term impacts of are in need of further study (Kasirajan and Ngouajio, 2012).

Bioplastic mulch serves as a physical barrier in crop production, and suppresses weeds by blocking out light and suppressing growth, so these effects could be considered adverse to the weeds, though these are intended effects. The physical barrier of the mulch also helps the soil retain moisture and helps prevent insect problems by blocking access of insects to the soil from above, and preventing grubs from moving from the soil to the foliage (Rangarajan and Ingall, 2006). Again, this could be considered an adverse effect, but it is one of the purposes of the product.

It is possible that the use of the bioplastic mulches could kill some soil organisms due to the increased temperature of the soil. This would also be expected with PE mulches, which are allowed for use in organic agriculture if removed at the end of the growing or harvest season. Bioplastic mulches and PE mulches would be expected to have a similar effect on soil microorganisms. In fact, a practice called solarization has been suggested as an alternative to using soil fumigants. This process involves covering moist soil with plastic film and exposing the area to sunlight during warm months. The increase in temperature may prevent the emergence of annual weeds and may kill both beneficial and pathogenic soil microorganisms (Pokharel, 2011).

Studies have shown that PLA is broken down to carbon dioxide, water and biomass when composted, and is "fully biodegradable" (Shah et al., 2008). PHA mulches are degraded first by exogenous enzymes from soil bacteria. Next, water-soluble monomers are taken in by the bacteria and metabolized to carbon dioxide and water under aerobic conditions. Methane is produced if the PHA are degraded under anaerobic conditions (Shah et al., 2008). In general, composting of bioplastic mulches raises the temperature to levels that are not found in soil and decreases the time to complete mineralization.

A study was conducted on AAC treated in a composting plant, and the compost was later used in agriculture. Toxicity testing was carried out on *Photobacterium phosphoreum* and *Daphnia magna*, and no adverse effects were found from exposure to the composted material (Bastioli, 2005). It is possible that aromatic constituents of AAC could remain in soils prior to complete mineralization, however one review states that AAC fully biodegrade to carbon dioxide, water, and biomass (Shah et al., 2008). A detailed study was not found that quantified the distribution and speciation of aromatic hydrocarbons in the soil following AAC breakdown.

Carbon black, a coloring agent used in some bioplastic mulches, is a particulate form of elemental carbon, meaning that it is not possible for carbon black to break down in the environment any further. In occupational settings, exposure to carbon black dusts may occur through inhalation, which is the most common exposure route, especially during manufacturing of products containing carbon black (NLM, 2011). The highest exposure rates are found following spills of carbon black pellets. Adverse health effects from exposure to carbon black include cough, phlegm, headache, fatigue, and irritation of the airways (NLM, 2011). Chronic exposures may lead to pneumoconiosis, a lung disease caused by breathing in dust from coal, graphite, or other man-made carbon (NLM, 2011). The carbon black dusts in these exposure scenarios would be unlikely to be present in the outdoor environment following normal use due to its incorporation into the bioplastic film, but could be present in the manufacture of bioplastic films containing carbon black.

Titanium is abundant in nature and usually found in the form of stable minerals, including rutile, ilmenite, anatase, brookite, octahedrite, and perovskite (NLM, 2011). Titanium compounds, including titanium dioxide, a coloring agent used in some bioplastic mulches, are not expected to bioaccumulate in aquatic organisms (NLM, 2011). Titanium compounds are expected to be immobile in soils and are not expected to volatilize from soil surfaces (NLM, 2011). Industrial exposures are mainly from dust and fumes created in furnace operations (NLM, 2011).

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

The production of PLA and PHA involves fermentation processes and feedstocks derived from natural sources (with the exception of genetically-modified organisms). The potential for environmental contamination from these products is limited, with the exception of the metal salt catalysts used to polymerize PLA (Bastioli, 2005). Tin compounds are one of the metal salts used, and they are found in the environment from anthropogenic sources such as coal combustion, oil combustion, copper-nickel production, municipal waste incineration, and the incineration of sewage sludge (NLM, 2011). No reports of tin contamination from production of bioplastics were found.

Many of the feedstocks used in the production of AAC could be hazardous if they were spilled or discharged into the environment during manufacture and processing. As feedstocks or intermediates, these compounds are not present in the AAC plastics. No specific reports of environmental contamination from these compounds as a result of manufacturing bioplastics were found. Systematic reviews of the environmental impact from manufacturing of bioplastic mulches were not found.

A review of life-cycle analyses of biodegradable polymers was conducted by (Bastioli, 2005) and it was concluded that starch polymers (including PLA and PHA) do not perform better than fossil fuel-based polymers in all environmental categories. However, a net environmental benefit was found from using starch-based biodegradable polymers that was not found with fossil fuel-based polymers (Bastioli, 2005). The authors reported that they could not generally conclude that biodegradable polymers were more environmentally beneficial than petrochemical polymers, and they recommended additional comparative life cycle assessments.

As discussed in the response to Evaluation Question #4, erucamide, glycerol, and searic acid amide could be released to the environment through multiple manufacturing processes, including bioplastics production. No research reports were found that described environmental releases of these chemicals from bioplastics manufacturing. Erucamide material binds strongly to soil and sediments in water and is likely to bioconcentrate in aquatic organisms, may persist in the environment, and would be found in the water, soil and air if released (NLM, 2011). Glycerol could be released to the environment following manufacturing and will be degraded in air within hours (NLM, 2011). Glycerol is very mobile in soils, will not likely volatilize from water nor adsorb to sediment in water, and has a low potential to bioconcentrate (NLM, 2011). Limited environmental data were found on stearic acid amide. Stearic acid is naturally occurring in many plant and animal oils, and will degrade in air, with an atmospheric half-life of 17 hours (NLM, 2011). Stearic acid is immobile in soil and has a biodegradation half-life of 1.9 to 13 days, so long-term bioconcentration of stearic acid is unlikely (NLM, 2011).

Evaluation Question #7: 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)).

In the manner that bioplastic mulches are used in organic production, it is unlikely that they would have any interactions with other substances used in organic crop or livestock production or handling. The plastics are inert in the soil when they are intact, and are biodegraded by soil microorganisms. Reports of chemical interactions between bioplastic mulches and other substances used in organic production were not found.

Evaluation Question #8: 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)).

Bioplastic mulch may adversely affect some soil microorganisms living under the mulch, as increased soil temperatures may cause solarization of the soil (Pokharel, 2011). This effect would likely occur with PE mulch as well, which is allowed for use in organic agriculture only if removed at the end of the growing or harvest season. Solarization can also lead to the death of dormant plants or seeds in the soil. If these effects are intended, then the mulch is seen as a pest control device, but due to the nonspecific nature of the effects, beneficial organisms may be killed in the process (Pokharel, 2011).

If the applicable standards for biodegradation are applied to bioplastic mulches, the environmental persistence of bioplastic mulches would be less than 2 years in the soil (ASTM, 2012). Given the complete aerobic biodegradation of bioplastic mulches, the by-products are carbon dioxide, water, and soil biomass. Soil biomass refers to the total amount of microorganisms in the soil, excluding plant roots and macrofauna (larger insects and worms) (NRCS, 2012). The increase in biomass may cause a concomitant increase in the populations of microorganisms that degrade the mulches on a local basis. This could lead to changes in the population dynamics of microorganisms in the soil. It is imperative that complete degradation be observed with the test substance in order to ensure that the mulches are completely degraded after their use. Some trials have shown complete degradation of starch-based mulches based on visual assessment (Miles et al., 2007), but it is possible that some residues of aromatic polymers remain (Bastioli, 2005).

Researchers have argued for more extensive research into the biodegradation pathways of the various bioplastics for a more complete understanding of the potential impacts (Shah et al., 2008). Complete degradation of the bioplastics depends on blending the polymers to maximize degradability and depends on the composition of soil microorganisms. Due to the diversity of bioplastics currently being developed, testing is necessary to determine which polymer mixtures are degraded completely and what effects incomplete degradation may have on the agro-ecosystem (Shah et al., 2008).

Evaluation Question #9: Discuss and summarize findings on whether 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)).

Bioplastic mulch behaves in a similar manner to PE mulch with regard to its permeability while the mulch is intact, and it is reasonable to assume that water and related pesticide residues would run off of the mulch in a manner similar to PE mulch. An evaluation of the runoff loss of water and pesticide residues in soil resulting from the use of polyethylene (PE) mulch was conducted by Rice and colleagues (Rice et al., 2001) in 2001. The researchers compared runoff amounts following rain events for plots where tomatoes were grown with PE plastic mulch and vegetative mulch (hairy vetch). In the plots where PE mulch was used, 50 to 75% of the field was covered with the PE mulch, which is an impervious surface. In one season, the loss of water was 2-4 times higher and the loss of soil sediment was three times higher in plots where PE mulch was used compared to those where hairy vetch residues were used. Mean pesticide loads following runoff events for PE mulch were 6-9 times higher for endosulfan (an insecticide) and 19 times higher for chlorothalonil (a fungicide) compared to runoff loads for hairy vetch. These pesticide active ingredients are not allowed for use in organic agriculture, so the toxicological impact from pesticide runoff in organic agriculture may be different. However, pesticide residue runoff is higher with plastic film than with other mulching practices due to the impervious nature of the film, so increased pesticide and fertilizer runoff will be an issue whenever plastic mulches are used in agricultural production, regardless of whether they are used in an organic or conventional system. The researchers concluded that using PE mulch may have a harmful effect on the environment due to increased runoff and is less sustainable than vegetative mulch (Rice et al., 2001). Based on their similarities in construction and intended use, bioplastic mulches would likely have similar environmental impacts to PE mulch, though their greater tendency to degrade sooner than PE mulch may decrease some of the adverse environmental impacts.

Anaerobic degradation of bioplastics may produce methane in addition to carbon dioxide and water (Gu et al., 2000). Methane is a greenhouse gas, and large-scale anaerobic degradation of bioplastics may increase total methane emissions (NLM, 2011). Research was not found that quantified methane emissions from bioplastic mulch use. Ensuring that degradation of bioplastic mulches takes place in an aerobic environment in the soil would be necessary to prevent methane emissions from this use.

Adverse environmental impacts from the use of bioplastic mulches are only likely to occur if the material does not completely biodegrade in soil. The applicable ASTM and other international standards require that products completely biodegrade within a prescribed period of time. A study cited in the petition (Minuto et al., 2008) from the International Federation of Organic Agriculture Movements (IFOAM) World Congress evaluated soil degradation of bioplastic mulches in Italy. Researchers evaluated Mater-Bi (AAC bioplastic) at thicknesses of 12, 15, and 18 µm (listed in the table as NF803) for biodegradation at the end of the growing season, 14 days after rototilling the planting rows. Degradation was measured by the weight of residues per square meter of sieved soil. All three materials had begun to break down during the crop cycle and they degraded further once tilled into the soil (see table 5, below).

Table 5: Biodegradation of AAC Mulch at the End of the Crop Cycle (from Minuto et al., 2008)

Mulching film –	**New film**	**Tomato**				**Brussels sprouts**				**Lettuce**			
thickness (µm)	(g/m²)	residues of film at the end of the crop cycle (g/m²)											
		upon soil°		in the soil^		upon soil°		in the soil^		upon soil°		in the soil^	
NF803 – 18	25.0	8.3	b*	0.6	b	4.0	b	2.2	b	7.8	a	0.9	b
NF803 – 15	22.9	7.4	a	0.4	a	2.2	a	1.2	b	7.0	a	0.7	b
NF803 – 12	15.3	7.2	a	0.2	a	1.3	a	0.1	a	7.0	a	0.2	a
PE black – 50	n.a.**	n.a.	-	n.a.	-	n.a.	-	n.a.	-	n.a.	-	n.a.	-
Bare soil		-	-	-	-	-	-	-	-	-	-	-	-

° g/m² of film residues upon soil before rototilling; ^ g/m² of film residues in the soil (evaluated sieving the soil up to 20 cm depth) 14 days after rototilling; * see table 1; ** because of technical and environmental reasons PE was not incorporated in the soil.

A product development research report from Metabolix, (Krishnaswamy et al., 2008), included by the petitioner describes the degradation of poly(hydroxybutanoic acid) (PHB), a type of PHA plastic. Small pieces of the plastic were buried in the soil and evaluated weekly starting on the fourth week, and continuing for 12 weeks. The authors note that both enzymatic and hydrolytic breakdown processes are responsible for the breakdown of the bioplastic film. The molecular weight of the films influenced breakdown times, with the lowest molecular weight film breaking down within 4 weeks, while the highest molecular weight film did not fully break down after more than 16 weeks.

Comprehensive studies were not found that described the environmental impacts of the use of bioplastic mulch, as most researchers concluded that the mulches would degrade to carbon dioxide, water, and soluble biomass (Shah et al., 2008; Bastioli, 2005). Due to the wide variety of potential chemicals released from the incomplete degradation of bioplastics, this is a data gap. Some reports have shown that bioplastics containing terephthalic acid at concentrations over 50% do not completely biodegrade in soil (Bastioli, 2005). Terephthalic acid was found to be non-toxic to species involved in its breakdown in a staged anaerobic reactor system (Kleerebezem et al., 1997). No additional data were found that described the environmental impact of terephthalic acid. It is possible that additional steps would be necessary to degrade bioplastic residues containing terephthalic acid.

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)).

As described in the response to Evaluation Question #9, pesticide runoff may be increased if plastic mulches are used in agricultural production due to the creation of impervious surfaces (Rice et al., 2001). These surfaces allow water to runoff of fields much more rapidly than if vegetative mulches are used, and the runoff water carries with it more soil and increased pesticide loads compared to vegetative mulches. The increase in pesticide loads may lead to an overall increase in the pesticide load in waterways which could potentially impact human health by causing increases in pesticide loads in downstream drinking water sources. As discussed in the response to Evaluation Question #9, the resulting toxicity of the runoff is dependent on the type of pesticide used and the environmental fate of the active ingredients, which may vary widely depending on whether the crops are in conventional or organic production, the types of crops raised, and the pest pressures in specific areas. No other reports of impacts on human health from the use of bioplastic mulches were found in the published literature.

Evaluation Question #11: **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)).**

The petitioned substance would be an alternative to synthetic, non-degradable substance, polyethylene plastic mulch. Bioplastic mulch is produced through synthetic processes as previously described, but is created to be biodegradable, a reason for its petitioned use in organic agricultural production. However, there are some natural substances are available for the petitioned use.

Mulches made from biomass include bark, cocoa-bean hulls, corncobs, grass clippings, leaves, pine needles, sawdust, straw, wood chips, and others, depending on the types of organic matter available to farmers (Williams, 1997). These mulches can be used to conserve moisture, help to control weeds, moderate (usually decrease) soil temperatures, and reduce water runoff (Williams, 1997). Biomass mulch availability may depend on what types of plants or crops are available in the area and the type of crop they are used in. The types of biomass produced will vary depending on the region, and the producers and availability of biomass mulch will also likely vary.

A cultural option for mulching is living mulch, which involves planting low-growing cover crops that is effective at competing with weed species. The drawback of living mulch is that living mulches compete for nutrients and water and reduce yields. Living mulches can be chosen from a wide variety of cover crops and would depend on availability and the needs of the farmer. Living mulches are discussed further in the response to Evaluation Question #12 (Corbin et al., 2012; Miles et al., 2007).

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

A 2006 trial with watermelon in Kentucky evaluated alternatives suitable for organic watermelon production (Silvernail et al., 2006). Three alternatives to plastic mulching were evaluated: roll-down of a cover crop of winter rye and hairy vetch; roll-down of the cover crop followed by mulching with hay; and cover crop incorporation (mixing into the soil) followed by mulching with newsprint and hay. The plastic mulching system resulted in the longest vine length, largest yield, and lowest weed pressure, but yields from the newspaper and hay system were 33% lower than the conventional plastic system. However, the investigators concluded that the system that used newspaper and hay mulch provided the best compromise between economic return and environmental impact (Silvernail et al., 2006).

Miles et al. (2007) found that yields from crops produced with paper mulch were lower than yields produced with other mulch products, and the differences were significant for some crops. The researchers found that paper mulches were more suitable for cool season crops than warm season crops. Cornstarch and paper mulches both were found to be degraded completely, based on visibility, by the spring following summer harvesting. The plastic/bioplastic mixed mulches used in the study were not found to biodegrade when incorporated into the soil or when composted (Miles et al., 2007).

Another option for mulching is so-called living mulch, which involves planting a low-growing cover crop that is effective at competing with weed species. The drawback is that living mulches compete for nutrients and water and reduce yields. Reports discuss the need to strike a balance between environmental impact, cost, ease of use, and crop yields to determine which alternative is most beneficial for individual farms and crops (Corbin et al., 2012; Miles et al., 2007).

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