USDA Agricultural Marketing Service

1400 Independence Avenue, SW.
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Washington, DC 20250-0268

October 16, 2019

MEMORANDUM TO THE NATIONAL ORGANIC STANDARDS BOARD

FROM: Jennifer Tucker, Ph.D.
Deputy Administrator
National Organic Program

Digitally signed by JENNIFER TUCKER
Date: 2019.10.16 17:49:28 -04'00'

SUBJECT: Biodegradable Biobased Mulch Film

In response to a recommendation of the National Organic Standards Board (NOSB), biodegradable biobased mulch film was added to the National List, effective October 30, 2014 (79 FR 58655).

Subsequently, the National Organic Program (NOP) published Policy Memorandum 15-1 "Biodegradable Biobased Mulch Film" to clarify how certifying agents and material evaluation programs should review the **biobased requirement** for these products.

Today, the NOP is transmitting a study completed by Michigan State University (MSU), "Biodegradable Biobased Mulch Films in Organic Crop Production" (September 2019). This study was funded by the NOP to compare the criteria in the final rule to the criteria in the policy memorandum and to supplement the technical information on mulch films. The study is attached and also available on the NOP's Petitioned Substances website.

Following our analysis of all information, we determined that Policy Memorandum 15-1 (January 22, 2015) did not present new information or impose additional requirements compared to the 2014 final rule. The NOP is therefore **withdrawing Policy Memorandum 15-1** to simplify analysis of options and next steps. A copy of the withdrawn policy memorandum is attached for your reference.

The NOSB Crops Subcommittee should review the MSU study and consider next steps to advance or conclude work on this topic.

Attachments:

Policy Memorandum 15-1 (Withdrawn October 10, 2019)
MSU Study, "Biodegradable Biobased Mulch Films in Organic Crop Production"

United States Department of Agriculture
Agricultural Marketing Service
National Organic Program

1400 Independence Avenue S.W.
Room 2648-South Building
Washington, DC 20250

Policy Memorandum

To: Stakeholders and Interested Parties

From: Miles V. McEvoy, Deputy Administrator
National Organic Program

Subject: Biodegradable Biobased Mulch Film

Date: Approved on January 22, 2015

WITHDRAWN

This policy is directed at certifying agents and material evaluation programs that are reviewing biodegradable biobased mulch film products for compliance with the USDA organic regulations (7 CFR part 205).

On October 30, 2014, the USDA organic regulations were amended to allow the use of biodegradable biobased mulch film in organic crop production (79 FR 58655). The term "biodegradable biobased mulch film" was added to sections 205.2 and 205.601 of the USDA organic regulations. The National Organic Program (NOP) has received questions from certifiers and material evaluation programs regarding interpretation of the term "biobased" in evaluating products for compliance. This policy memorandum clarifies how certifying agents and material evaluation programs should review the biobased requirement for these products.

As explained in the final rule, and consistent with the National Organic Standards Board's (NOSB) recommendation for this material, certifiers and material review organizations should review these products to verify that all of the polymer feedstocks are biobased. Pigments and processing aids are not considered feedstocks. ASTM International defines biobased as organic material in which carbon is derived from a renewable resource via biological processes. Biobased materials include all plant and animal mass derived from carbon dioxide recently fixed via photosynthesis, per definition of a renewable resource. Biobased feedstocks are composed of biological products or renewable agricultural or forestry materials.

Biodegradable mulch film that contains non-biobased synthetic polymer feedstocks, such as petrochemical resins, does not comply with the USDA organic regulations.

References

Organic Foods Productions Act of 1990, as amended
7 U.S.C. § 6517 National List

USDA Organic Regulations (7 CFR Part 205)
7 CFR § 205.2 Terms Defined

Biodegradable biobased mulch film. A synthetic mulch film that meets the following criteria:

(1) Meets the compostability specifications of one of the following standards: ASTM D6400, ASTM D6868, EN 13432, EN 14995, or ISO 17088 (all incorporated by reference; see §205.3);
(2) Demonstrates at least 90% biodegradation absolute or relative to microcrystalline cellulose in less than two years, in soil, according to one of the following test methods: ISO 17556 or ASTM D5988 (both incorporated by reference; see §205.3); and
(3) Must be biobased with content determined using ASTM D6866 (incorporated by reference; see §205.3).

7 CFR § 205.601 Synthetic substances allowed for use in organic crop production.
(2) Mulches.
(iii) Biodegradable biobased mulch film as defined in §205.2. Must be produced without organisms or feedstock derived from excluded methods

NOSB Recommendations
NOSB Recommendation for Biodegradable Biobased Mulch Film.

Approved on January 22, 2015

If you have any questions regarding this memorandum, please contact Lisa M. Brines at (202) 720-3252 or lisa.brines@ams.usda.gov.

WITHDRAWN

Biodegradable Biobased Mulch Films in Organic Crop Production
September 2019

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This work was supported by the U.S. Department of Agriculture's Agricultural Marketing Service under Agreement No. 19-NOPXX-MI-0002. Any opinions, findings, conclusions or recommendations expressed in this presentation are those of the author(s) and do not necessarily reflect the view of the U.S. Department of Agriculture.

EXECUTIVE SUMMARY

Plastic mulch film provides significant benefits to farming by increasing crop yields, crop quality, enhanced weed control, reduced evaporative water loss, and control of soil temperature. Today's mulch films are carbon-carbon backbone polymers like polyethlene (PE), which is not biodegradable. USDA organic regulations permit the use of this "synthetic" PE mulch film if it is removed at the end of each growing or harvest season. However, PE mulch becomes brittle due to weathering and fragments. The fragments can accumulate in soil and decrease soil productivity by blocking water infiltration, impede soil gas exchange, constrains root growth, and alters soil microbial community structures. Removal of these heavily soiled mulch films at the end of harvest season for trucking to landfill or recycling centers is difficult, laborious, and costly. **A solution** to the problems created at the end-of-life of the PE mulch film is to use completely soil-biodegradable mulch films that retain the performance characteristics of PE films but at the end-of-life can be plowed into the soil or recovered for on-farm composting (Sections 1 & 2.0)

This report reviews and analyzes the use of biodegradable, biobased mulch films in organic cropping systems. It provides the science of biodegradability, the conditions and end-point requirements for a completely soil biodegradable mulch film (Section 2.0, 2.1). The report explains "biobased", its value proposition, and shows with examples that biobased (carbon) content, while valuable, does not impact or control biodegradability (Section 2.2 & 2.3). Examples of polymers that are biodegradable and biobased are discussed in section 2.4. Fully biodegradable polyester polymers are synthesized from fossil and/or biobased monomers and provide viable mulch films that contain biobased content. This is discussed in Section 2.5. Discussions around the specific class of polymers used in biodegradable mulch films is presented in Section 2.6. Experimental studies, including using isotopic lables, validate complete biodegradability in soil. Section 2.7 summarizes field studies of commercial fully biodegradable mulch films and concludes that there is no significant effect on soil health (over a two year period) and no impact on crop yield or quality.

The report provides discussion and analysis on specific questions asked by USDA Agricultural Marketing Services and summarized below:

1. *Based on the **regulatory language** in the current USDA organic regulations (7 CFR Part 205), what criteria should be used to assess compliance of formulated (brand name) products that are available on the market today or to be developed. In addition, what is the threshold for minimum biobased content in such formulated products?*

The USDA organic regulations provide the criteria to be met by mulch film polymer products. The regulatory language requires biobased content without specifying minimum biobased content. The minimum biobased content for these products can be set at 25% or higher similar to the USDA BioPreferred program requirements (see Section 4.1). The EU mulch film standard does not specify any biobased content requirement. Biobased content has no impact on the biodegradability – the ability of soil microorganisms to utilize the carbon mulch film as food/fuel for its life process. A 100% biobased mulch film could be totally not biodegradable. Refer to sections 2.0, 2.1 through 2.5 and schemes 6 through 10 for specific discussions.

2. *Do the evaluation criteria for formulated products differ between the introductory ("**preamble**") text published in the final rule and the **regulatory language of** the final rule?*

The regulatory language does not specify minimum biobased content, but in the preamble, the use of synthetic polymer components is excluded, i.e requiring 100% biobased content. Sections 4.0, 4.1, and 4.2 discuss and analyze this issue and suggests alternate.

3. *Do the evaluation criteria in the AMS* ***policy memorandum*** *dated January 22, 2015, differ from the criteria in the* ***regulatory language or the preamble*** *to the final rule?*

Consistent with the preamble and regulatory language. Section 5.0 and section 4.2 discuss and analyze this issue.

4. *Evaluate currently available formulated products against the criteria delineated in the final rule regulatory text, the final rule preamble, and the policy memorandum. Does evaluation using these three sets of criteria lead to different outcomes in terms of the number and/or types of products that meet the criteria? If no currently available formulated products meet any of the three sets of criteria, what specific criteria are not met by currently available products?*

As discussed and analyzed in the report, currently available biodegradable, biobased mulch film can meet the requirements except for "no synthetic components"/100% biobased content. Section 4.2 explains that synthetic substances allowed for use in organic production are (*§205.601).*:

(i) Plastic mulch and covers (petroleum-based other than polyvinyl chloride (PVC),

(ii) Biodegradable, biobased mulch film as defined in *§*205.2. Must be produced without organisms or feedstock derived from excluded methods.

Provided, that the use of such substances **do not contribute to contamination of crops, soil, or water.**

Polymers described in sections 2.4 to 2.6; schemes 8 through 10 are completely biodegraded (utilized by the soil microorganisms) as per standards specified in the organic regulations. The biodegradation process is a "naturally occurring biological process" and the end-products of this process are carbon dioxide and microbial biomass. Therefore, **they will not contribute to contamination of crops, soil or water** and comply with *§205.601 for allowed synthetic substances.*

5. *In consideration of the three sets of criteria (i.e., regulatory text, preamble text, and policy memo) together, if no formulated products meet the current criteria, outline at least three different scenarios for modifying the criteria that would allow for use of some currently available mulch films. Describe the impact each scenario might have on the number and types of products available, and the tradeoffs between the various scenarios.*

As discussed above, the only criteria that needs to be modified and aligned is "biobased (carbon) content/no synthetic polymer components requirements. Synthetic substances are allowed as per *§205.601* provided it does not contribute to contamination of crops, soil, or water. The biodegradability requirements set by the regulatory text, preamble text, and policy memo will ensure that these biodegradable mulch film polymers will not contribute to contamination of crops, soil, or water.

An alternate scenario would be to permit use of biodegradable "synthetic" mulch film if they are removed from the field similar to current PE mulch films followed by composting. This would be more economical and environmentally responsible approach to using PE mulch film. The report documents the issues with non-biodegradable PE mulch film fragments accumulating in soil with negative impacts on soil health and productivity (section 2.0 and references cited there). The use of biodegradable mulch film (biodegradability requirements identified in the USDA organic regulations, section 4.0) will ensure no build up or accumulation in soil of mulch film fragments. Section 2.7 and the references cited there document the benefits and the data indicates that biodegradable mulch films show no adverse impacts on soil health and productivity.

6. *Provide a brief review of recent (i.e., post 2015) studies addressing: (1) the persistence of biodegradable mulch films (either biobased* ***or non-biobased)*** *following field application; (2) the effects of these materials (biobased or non-biobased) on the soil and agroecosystem; and*

(3) the broader environmental and/or economic impacts of using biodegradable films, as compared to nonbiodegradable films, in agricultural production.

Section 2.0, 2.6 and 2.7 and the references cited discuss this point.

7. *Are there USDA Biopreferred® products, produced without excluded methods as defined by § 205.2 of the USDA organic regulations,[1] that would meet the criteria for use of biodegradable biobased mulch in the USDA organic regulations*

There are polymer intermediates and formulations produced without excluded methods in the USDA BioPreferred program that could meet the criteria for use in biodegradable, biobased mulch films. However, these polymer candidates have synthetic polymer components and are not 100% biobased.

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1. Introduction

In September 2014, the U.S. Department of Agriculture (USDA) Agricultural Marketing Service (AMS) National Organic Program (NOP) revised the USDA organic regulations (7 CFR Part 205) to allow synthetic **biodegradable biobased mulch film** in organic crop production (79 FR 58655; September 30, 2014). Subsequently, NOP published a policy memorandum clarifying how certifying agents and material review organizations should review the biobased requirements for these products (Policy Memo 15-1; January 22, 2015).

NOP has received numerous questions about the criteria for biodegradable biobased mulch films under the USDA organic regulations. Questions have come from USDA-accredited certifying agents, material review organizations, manufacturers, organic crop producers, and others.

This report provides a review and analysis of biodegradable biobased mulch films. It discusses issues and information gaps in the USDA organic regulations related to the biodegradable biobased mulch films. This report suggests scenarios with scientific rationale for modifying the regulatory criteria to permit use of currently available biodegradable biobased mulch films in organic cropping systems.

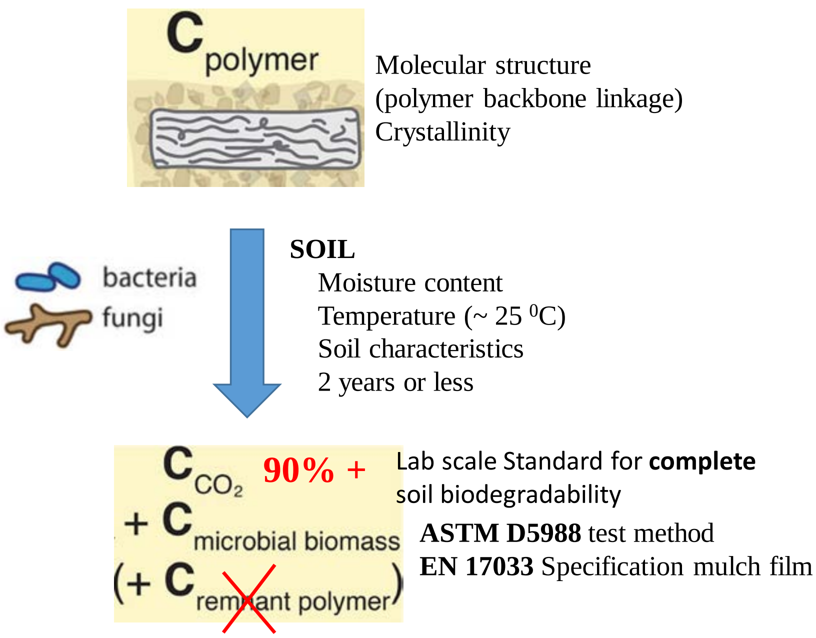
2.0 The plastic mulch film problem

U.S. farmers and farmers worldwide use plastic mulch film for growing vegetables and specialty crops because they provide significant benefits – increased crop yields, improved crop quality, enhanced weed control, reduced evaporative water loss, and control of soil temperature. The global agricultural film market is predicted to reach an annual volume of 7.5 million tons by 2021 with mulch films having a major share (1-2). Currently, China uses the most polyethylene (PE) mulch film, with an estimated 1.25−1.4 million tons of film applied annually (3, 4) covering approximately 20 million hectares or 12% of China's farmland (5, 6).

Today's mulch films are carbon-carbon backbone polymers like PE, which is not biodegradable. Removal of these mulch films at the end of harvest season for trucking to landfill or recycling centers is difficult, laborious, and costly. The mulch films are heavily soiled and are not easily recycled. PE mulch films, especially thin films, undergo embrittlement and fragmentation due to weathering (4, 6, 7). The fragments accumulate in agricultural soils. The Xinjiang region in northwest China practices intense mulch film application, and the PE concentrations in soils range from 120−350 kg residual film per ha and as high as 500 kg residual film per ha (7, 8).

This accumulation of recalcitrant PE mulch film fragments in agricultural soils around the world is cause for alarm because it decreases soil productivity by blocking water infiltration, impedes soil gas exchange, constrains root growth, and alters soil microbial community structures (3, 9). Plastic pollution of soils is also a threat to soil ecosystem health and function (10-12). PE micro fragments dispersed in soil and water readily absorb and concentrate toxins present in the environment (much like a sponge). Microorganisms colonize these fragments, and the birds and fishes eat them because they think it is food. This results in toxins and PE micro fragments being transported up the food chain (13).

A solution to the problems created at the end-of-life of the PE mulch film is to use completely soil-biodegradable mulch films that retain the performance characteristics of PE films but at the end-of-life can be plowed into the soil or recovered for on-farm composting. Complete soil-biodegradability requires demonstrating 90% + utilization (mineralization) of the mulch film's carbon by the soil microorganisms in the prescribed time (2 years or less for soil biodegradability). Scheme 1 explains this process and defines the conditions and endpoint for completely biodegradable mulch film in soil.

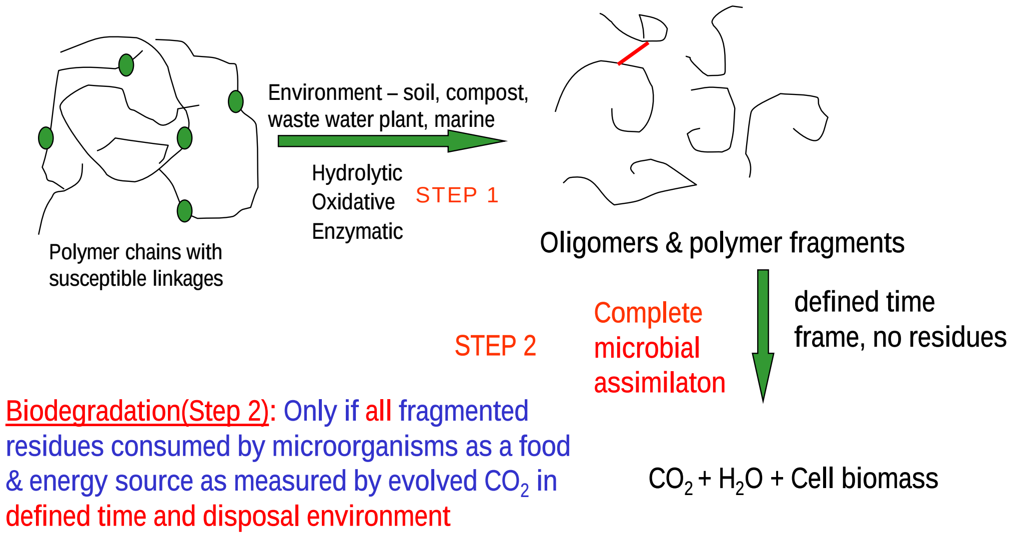


Scheme 1: Conditions and end-point for completely biodegradable mulch film in soil.

2.1. Understanding biodegradability

Biodegradability is an end-of-life process that harnesses soil microorganisms to assimilate/utilize the plastic film's carbon as food/fuel for its life processes in a safe and timely manner. Terms like "oxo", "hydro", "chemo", or "photo" degradable represent abiotic (non-biological process) mechanisms of degradation, and do not constitute "biodegradability". Biodegradability represents the biological process by which microorganisms present in the disposal environment assimilate/utilize carbon substrates as food for their life processes. Scheme 2 shows this process. Polymer chains with susceptible linkages designed into the polymer backbone degrade by hydrolytic, oxidative (abiotic), or enzymatic (biotic) reactions to smaller molecules or fragments. Microorganisms present in the disposal system (soil, compost) must **completely** utilize the fragments in a defined time as measured by the evolved carbon dioxide to make a soil biodegradable or compostable claim (14, 15).

Measuring the rate and extent of carbon dioxide evolved due to microbial metabolism forms the basis of ASTM, European, (EN) and International Organization for Standardization (ISO) standards.



Scheme 2: Biodegradation process schematic

Under aerobic conditions, microorganisms biologically oxidize the polymer carbon to CO_2 releasing energy as shown in the equation below. Microorganisms harness this energy for its life processes in a highly specialized cellular phenomenon that requires the participation of three metabolically interrelated processes: tricarboxylic acid cycle (TCA cycle); electron transport; and oxidative phosphorylation. All of the processes take place inside the cell. Under anaerobic conditions, CO_2+CH_4 (biogas) are produced (see scheme 3 below).

Thus, a measure of the rate and amount of CO_2 or (CO_2+CH_4) evolved, as a function of total carbon input to the process is a direct measure of the amount of carbon substrate utilized by the microorganism (i.e., the percent biodegradation).

Aerobic process

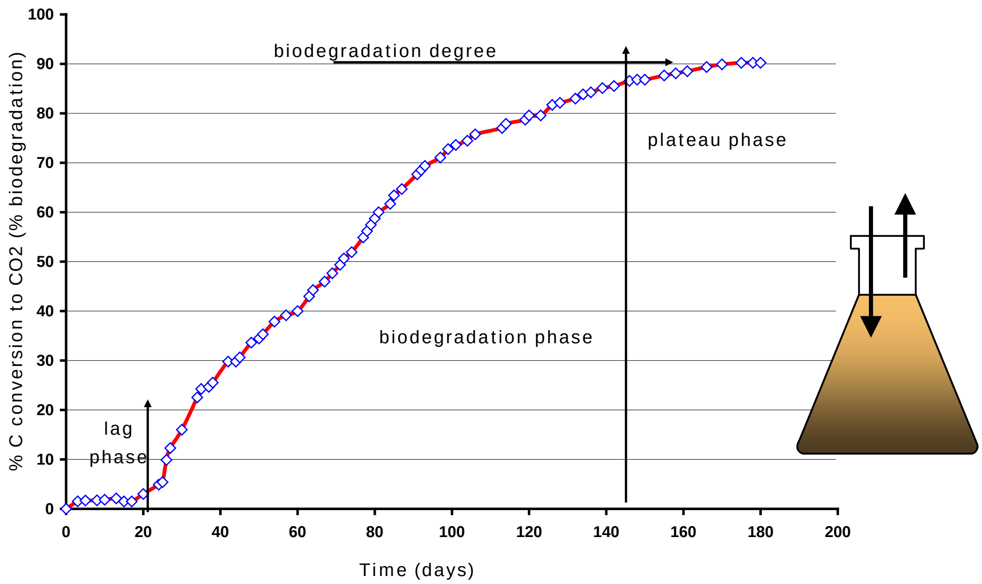
$$\text{Glucose/C-bioplastic} + 6O_2 \longrightarrow 6CO_2\uparrow + 6H_2O;\ \Delta G^{0'} = -686\ \text{kcal/mol}$$

Anaerobic process

$$\text{Glucose/C-bioplastic} \longrightarrow 2\ \text{lactate} \longrightarrow 3CO_2\uparrow + 3CH_4\uparrow\ \ \Delta G^{0'} = -47\ \text{kcal/mol}$$

Scheme 3: Basic equations describing the microbial utilization of carbon substrates.

Thus, one can measure the rate and extent of biodegradation or microbial utilization (mineralization) of the test plastic material by using it as the sole carbon source in a test system containing soil or compost in the presence of air and under suitable temperature conditions (25 ^{0}C for soil and 58 ^{0}C for compost). Scheme 4 shows a typical graphical output of the percent carbon converted to CO_2 as a function of time in days. First is a lag phase during which the microbial population adapts to the available test C-substrate. Next is the biodegradation phase during which the adapted microbial population begins to utilize the carbon substrate for its cellular life processes as measured by the evolved CO_2. When all the substrate carbon is utilized, the CO_2 output reaches a plateau. Linear or any other form of data extrapolation is strictly prohibited because credible scientific substantiation for the extrapolation model does not exist for such complex biological systems.



Scheme 4: Measuring rate and extent of biodegradability using biodegradable polymer as the sole carbon source in compost (ASTM D5338, ISO 14855) or soil (ASTM D5988, ISO 17556).

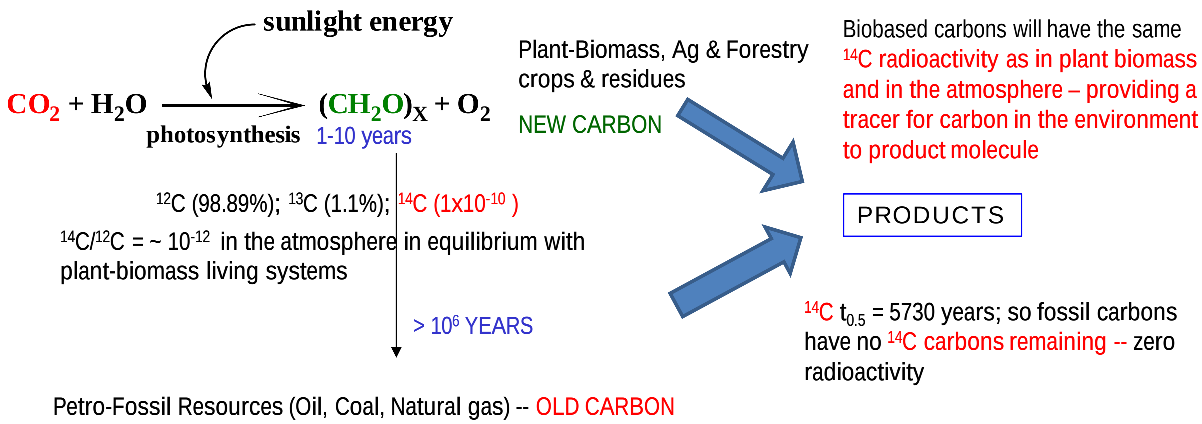
Claims of degradable, partially biodegradable, or eventually biodegradable are not acceptable, because the degraded fragments can have negative environmental and health impacts as previously discussed in section 2.0 (10-13). Biodegradable mulch films must demonstrate complete biodegradability in two years or less using ASTM D5988 or ISO 17556 test methods (14, 15).

2.2. Understanding Biobased (16, 17)

The term “biobased” refers to the origin of the carbon in the polymer molecule and indicates whether the carbon is derived from plant-biomass or fossil resources. Biobased plastics are “plastics in which the (organic) carbon (of the polymer molecule) in part or whole comes from plant-biomass like agricultural crops and residues, marine and forestry materials, algae, and fungi living in a natural environment in equilibrium with the atmosphere.”

Biobased offers the value proposition of carbon footprint reduction and supports rural agrarian economy. Biobased carbon content of a product is the amount of biobased carbon as a percent of the total organic carbon in the product. The biobased content is experimentally measured using radiocarbon analysis as codified in ASTM (D6866) & ISO (IS1660 pt2) standards. If inorganic carbon (talc, calcium carbonate) is part of the plastic, then one can report biogenic carbon content which is the amount of biobased carbon (organic + inorganic) as a percent of the total carbon (organic + inorganic) in the product. Scheme 5 provides an information capsule about biobased products and radiocarbon analysis for quantifying biobased (carbon) content.

biobased –containing organic carbon of renewable origin from agricultural, plant, animal, fungi, microorganisms, marine or forestry materials living in a natural environment in equilibrium with the atmosphere.



The amount of 14C is measured relative to a more abundant isotope (i.e., 13C or 12C) in the ion beam of an AMS (accelerator mass spectrometry) or by decay counting. Absolute quantification comes from comparing the sample's measured isotope ratio to that of pre 1950 biobased oxalic acid radiocarbon Standard Reference Material (NIST SRM) 4990c, (referred to as HOxII) after correcting for isotopic fractionation. Values must also be corrected for the C-14 pulse injected into the atmosphere (1950-63) from atmospheric testing of nuclear weapons

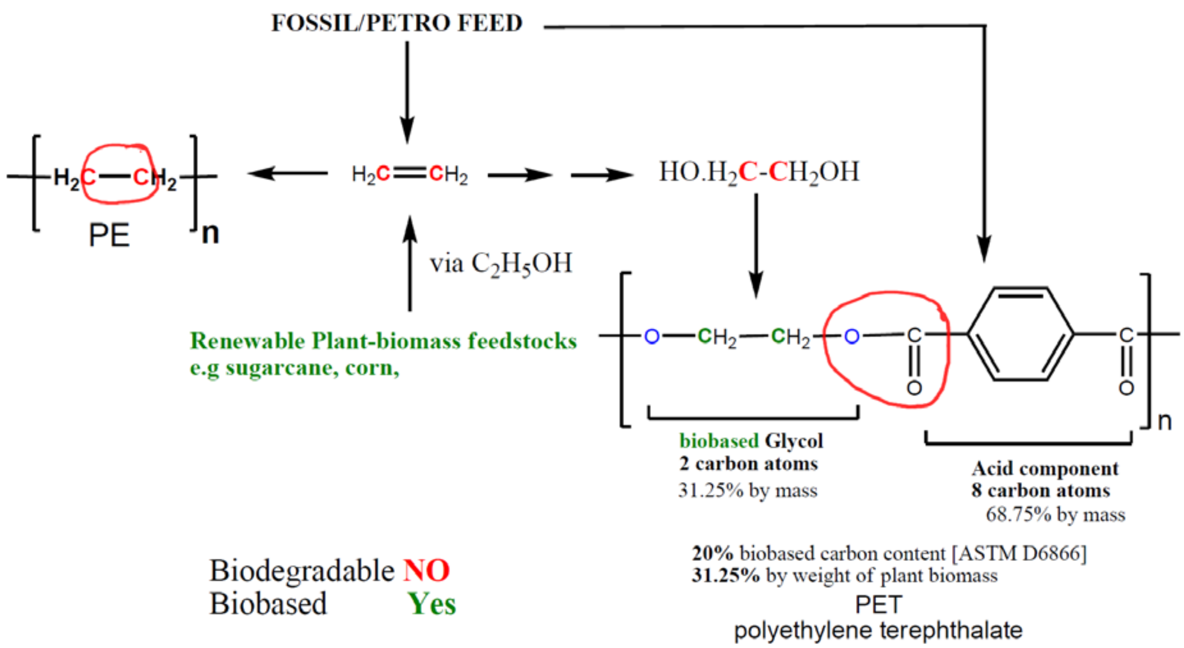
Scheme 5: Overview of biobased vs fossil-based product origins, and use of radiocarbon analysis to quantify biobased carbon content (ASTM D6866; ISO 16620)

Plant-biomass (biobased) resources are photoautotrophs. They **convert (remove) CO_2 in the environment** to carbohydrates, lipids, and proteins found in plant biomass using water and sunlight energy (photosynthesis). Petro/fossil resources (e.g., oil, coal, natural gas) are formed from plant biomass over millions of years. Therefore, plastics made from plant biomass resources can be credited with removal of CO_2 from the environment and incorporating the carbon into the polymer molecule in a short time (1-10 years). Plastics made from fossil resources cannot be credited with any CO_2 removal from the environment even if one considers a 100-year time scale (the time used in measuring global warming potential, GWP_{100}) because the fossil carbon has formed over millions of years (16, 17).

The term "BioPlastics" is used many times in literature and print/e-media to describe "Biobased" and "Biodegradable-Compostable" plastics without clearly differentiating between them. This has resulted in much confusion in the marketplace and amongst stakeholders and the public. Biobased refers only to the origins of the carbon in the molecule – the "beginning of life", whether the carbon originated from plant biomass or fossil resources. Biodegradable or compostable refers to the end-of-life – whether soil or compost microorganisms completely utilize (metabolize) the carbons as their food/energy source. **Biobased plastics are not necessarily biodegradable or compostable and biodegradable-compostable plastics are not necessarily biobased.** Sections 2.3 – 2.6 provide details with polymer examples. Biobased carbon content in a polymer molecule has **no connection** with its end-of-life behavior. The molecular structure of the polymer, particularly its backbone linkage and physical characteristics (like crystallinity and morphology), dictate the extent and rate of microbial assimilation (biodegradation) in disposal environments – see Scheme 1.

2.3. Examples of polymers that are biobased but not biodegradable in soil or compost.

Scheme 6 shows polyethylene (PE) manufacture from plant biomass via ethanol fermentation and from Naptha/natural gas (fossil feedstock). There is a 220-kton plant manufacturing 100% biobased PE from sugarcane in Brazil. As can be seen from scheme 6, the chemical-molecular structure of PE and its starting monomer ethylene is the same (identical) irrespective of whether the carbon originated from plant-biomass or petro-fossil feedstocks. The biobased or fossil-based PE molecule has a strong carbon-carbon backbone linkage (bond circled in red) and is crystalline. It is the linkage and the crystallinity that renders the PE molecule recalcitrant to biodegradation in soil or compost. The biodegradability is not dependent on the origins/source of the carbons. The end-of-life option for PE is recycling and not biodegradability or compostability.



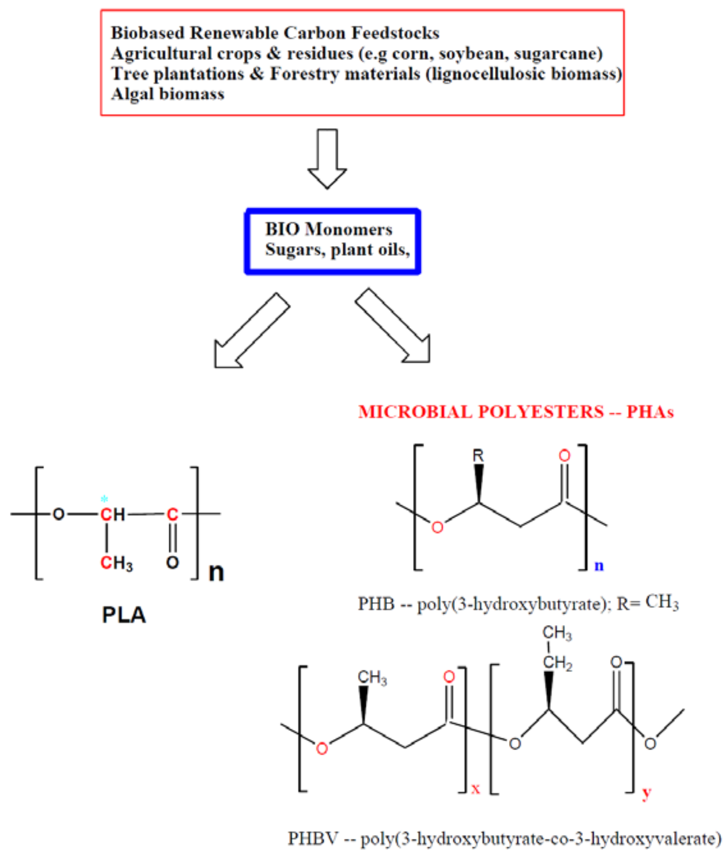
Scheme 6: Scheme showing route to biobased and fossil based PE and PET molecules – biobased but not biodegradable in soil or compost.

Biobased PET containing 20% biobased carbon content is manufactured by condensing biobased ethylene glycol with fossil-based terephthalic acid as shown in scheme 6. Coca-Cola, Danone, and several brand owners use biobased PET resin for their packaging. R&D efforts to manufacture terephthalic acid monomer from plant-biomass is being actively pursued but is not yet a commercial reality. The chemical-molecular structure, physical and chemical characteristics of 20% biobased PET or 100% biobased PET or 100% fossil PET is identical. The PET molecule has an ester backbone linkage (circled in red in scheme 6), but the hydrophobic aromatic ring (50 mol percent), crystallinity, and morphology renders this molecule not biodegradable in soil or compost.

The above two polymer molecules are classic examples of biobased but not biodegradable products – the biodegradability being evaluated as per ASTM/ISO standards discussed earlier in section 2.1, Scheme 3 & 4.

2.4. Examples of polymers that are both biobased and biodegradable in soil/compost.

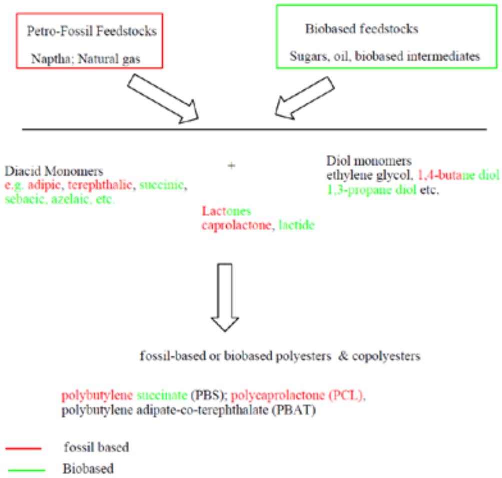
PLA (polylactide) is 100% biobased and fully biodegradable polymer in compost. It is an aliphatic polyester with ester group in the polymer backbone similar to PET. Soil biodegradability depends on the percent crystallinity and morphology of the polymer molecule. Microbial polyesters, the PHAs (polyhydroxy alkanoates) is another class of 100% biobased and completely biodegradable in soil, and compost environments. Scheme 7 shows the chemical structures and the origins of the carbon in this class of polymers. PLA and PHA polymers by itself are not readily usable in manufacture of agricultural mulch films because of processability, performance and cost issues. However, blends of these polymers with biodegradable synthetic polyesters are usable for manufacture of mulch films (see sections 5 & 6 for more discussions).



Scheme 7: Structures of 100% biobased polymers with complete biodegradability in compost and soil.

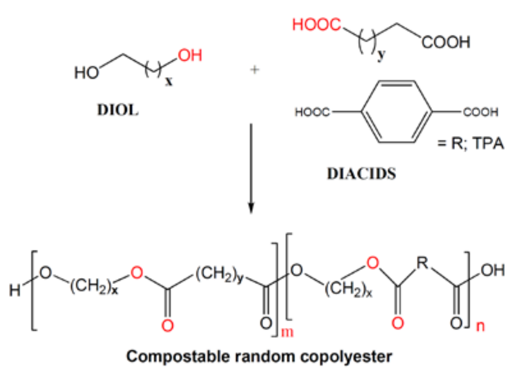
2.5. Examples of fossil based polyesters and copolyesters containing biobased content that are fully biodegradable in compost and soil

Condensation polymerization of diacids with diols gives polyesters whose properties including "biodegradability" is dictated by the molecular structure, crystallinity, morphology and other physio-chemical characteristics. As shown in Scheme 8 the diacids and diols can be obtained from both fossil and plant-biomass feedstocks. Polybutylene succinate (PBS) is obtained from the condensation of succinic acid and 1,4-butane diol monomers. It can be 100% fossil-based (so called "synthetic") or 100% biobased or partial biobased depending on the amount of biobased monomers used in place of the fossil based monomers. PBS is fully biodegradable in compost and soil as per the ASTM/ISO standards discussed earlier.



Scheme 8: Overall process for producing biodegradable polyesters and copolyesters using both fossil and 100% biobased monomers.

Scheme 8 & 9 show the general process for producing completely biodegradable polyesters and copolyesters with biobased (carbon) content.

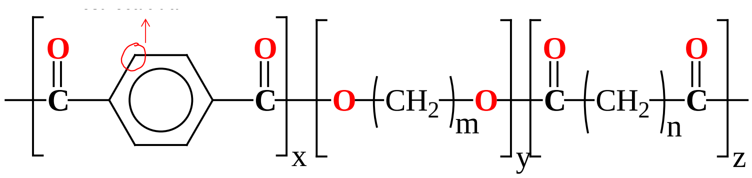


Scheme 9: General synthesis of biodegradable copolyesters.

In the above synthesis (Scheme 9), when x and y is 4, the commercial polymer Polybutylene adipate-co-terephthalate (PBAT) structure is formed (scheme 10, section 2.7). It is comprised of adipic acid, terephthalic acid and 1,4-butanediol monomer units. Replacing these fossil based monomers with biobased monomers in part or full will result in a **biobased and fully biodegradable PBAT**.

2.6. Biodegradable, biobased polymers used in agricultural mulch films

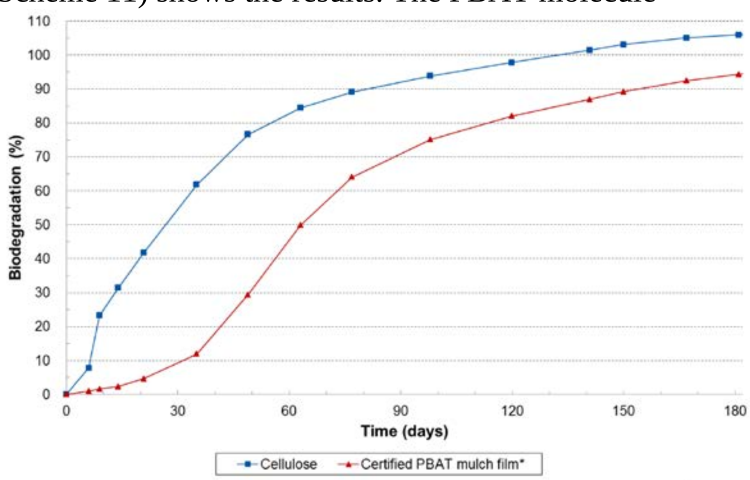
Aliphatic and aliphatic-aromatic copolyesters of the general structure shown in schemes 8 & 9 find application as biodegradable agricultural mulch film. There are several manufacturers of this class of polymer resins.



Scheme 10: General structure of biodegradable PBAT copolyesters.

As discussed earlier, using monomers derived from plant-biomass feedstocks like succinic or adipic acids or butanediol or other diols in the synthesis of these copolyesters (schemes 8 &9) creates **biobased content** in the co-polyester molecule. Blending with other biobased polyesters like PLA or PHAs (Scheme 7) is another approach to incorporating biobased content. Blends of PBAT-PLA are commercially available and used in agricultural mulch film applications.

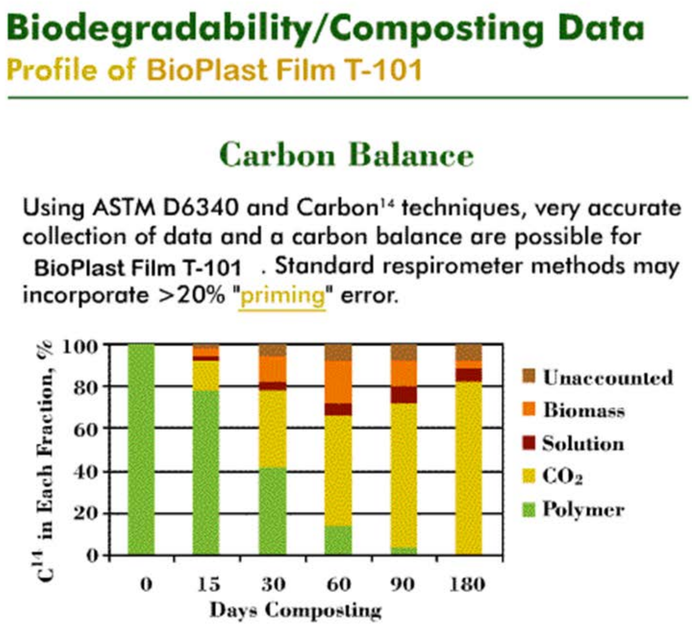
PBAT and PBAT-PLA blend formulations used in agricultural mulch films show complete biodegradability using ASTM/ISO standards referenced in the USDA organic regulations and discussed earlier (section 2.1). OWS, an approved, internationally recognized biodegradability and compostability testing laboratory reported on the soil biodegradability of an EU certified PBAT based mulch film (18). Soil biodegradability study was conducted under ISO 17556/ASTM D5988, which are specified in USDA organic regulations. Attached graph (Scheme 11) shows the results. The PBAT molecule



Scheme 11: Soil biodegradability of PBAT with biobased content – www.ows.be

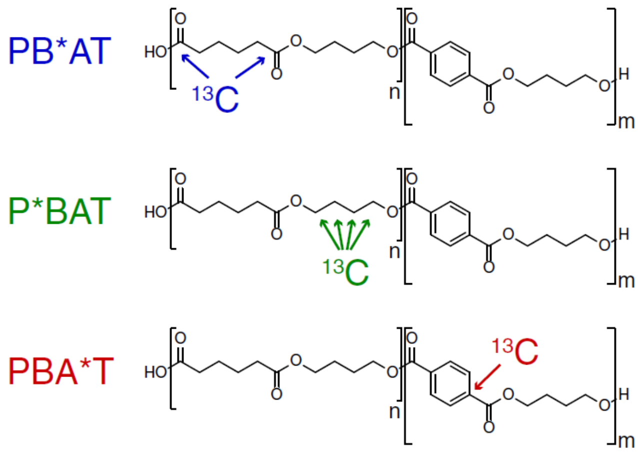
shows 94.4% ± 1.7% absolute biodegradation in 180 days. On average, cellulose shows 90.5% ± 9.6% soil biodegradability based on 79 experiments that ran for 95 to 1,811 days. The minimum biodegradability obtained was 73.0% as a minimum and 112.8% as a maximum (18). In longer running experiments, the biodegradation percentage sometimes reaches over100% due to the "priming effect" – microorganisms cannibalize dead microorganisms in a carbon-starved environment.

Carbon isotopic labelling studies provide unequivocal experimental evidence that soil microorganisms mineralize even the most recalcitrant aromatic carbon of the polymer molecule. PBAT has been synthesized with a C-14 radiolabel on the most recalcitrant aromatic carbon (circled in red in scheme 10). Biodegradability using ASTM D5338 was studied and the results are shown in scheme 12. The data shows that 90% of the radiolabel carbon appears as CO_2, a few percent in biomass, and some in solution – providing a total (closed) carbon balance and validating the complete microbial utilization (biodegradation) of the aromatic component of PBAT.

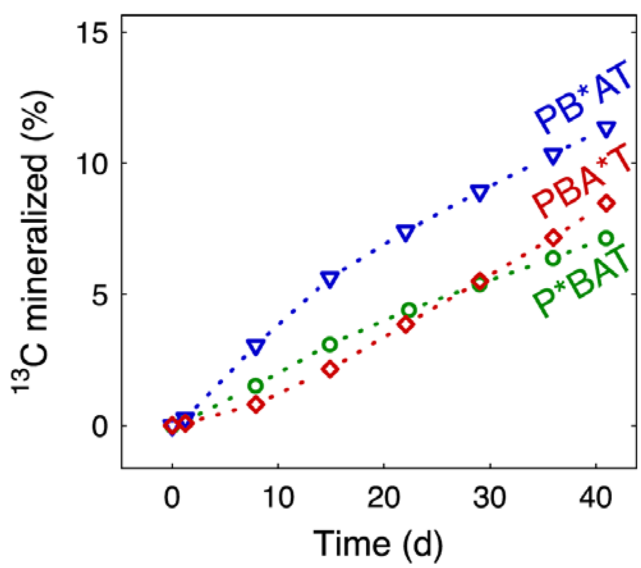


Scheme 12: Radiocarbon composting studies showing complete biodegradation of aromatic component of PBAT.

More recently, Zumestein et al, (19) labelled the carbon of each monomer unit in the PBAT molecule as shown below:



They found that soil microorganisms, including filamentous fungi, used carbon from each monomer unit of PBAT. to gain energy and to form biomass. Biomass refers to cellular biomass, and the PBAT carbons incorporated into lipid molecules. Mineralization (biodegradation from each of the monomer units constituting PBAT) was also observed as shown in scheme 13 below.



Scheme 13: Carbon-13 isotopic labelling experiments showing soil biodegradation of all components of PBAT

Both these experiments unequivocally establish that soil microorganisms completely assimilate PBAT in acceptable periods of 2 years or less – a requirement of the USDA regulations.

2.7. Field Studies of Biodegradable Mulch Films (BDMs).

In the field, the biodegradable mulch films like PBAT, PBAT-PLA, and PHA-PLA blends are just as effective as PE mulch in improving the production of specialized crops compared to bare soil for several different cropping systems and different environmental conditions. Environmental studies have not shown any adverse impacts associated with the incorporation of biodegradable mulch films (BDMs) into the soil to date. More research is needed to monitor any potential formation of terrestrial micro and nanoplastics from biodegradable mulch films and ensure that there is no residual soil ecotoxicity. There is need for tuning the physicochemical properties of the biodegradable mulch films with the needs of specific cropping systems and climates. The biodegradable mulch films could provide additional environmental benefits by formulating them to deliver macro and micronutrients to the crop as they biodegrade in soil, or deliver pesticides directly into the soil (20).

Sintim et al. (21) showed that there was no significant effect on soil health over two years of monitoring and that the soil microbial communities did not differ much either. They found significant enrichment in bacterial and fungal gene copies under BDM treatments over 2 years, but no significant change under PE and no mulch. Another important observation was that repeated tillage of BDMs into the soil across 4 years did not impact crop yield significantly and had no major effect on crop quality.

2.8. Additive (oxo or organic) based PE biodegradables.

Oxo, organic, or enzyme additives added to conventional plastics like PE, do not make these plastics biodegradable in soil or compost in any meaningful time. They can break down into very small particles, potentially contributing to environmental contamination by microplastics. The potential impact of microplastics on the (aquatic) environment and human health have generated serious concerns worldwide. The U.S. Federal Trade Commission, the European Union, and major NGOs have reviewed the data and the biodegradable claims have not been substantiated (20, 21).

3.0. European Union activities on biodegradable mulch films

Biodegradable mulch films have been available on the EU market for many years, meeting a high level of acceptance among European farmers. The use of mulch films increase yield, improve the quality of crops, enhance weed control, and reduce use of irrigation and pesticides. **Biodegradable** mulch films offers all of the performance characteristics of the standard conventional mulch films, but provides the added advantage of being plowed into soil at the end of the growing season. Soil microorganism completely utilize these **biodegradable** mulch films as their carbon food and remove it from the soil in 2 years or less.

EN 17033:2018 (24) is the new European product standard developed by the European Committee for Standardization (or "CEN") Technical Committee 249 on Plastics, titled "Biodegradable mulch films for use in agriculture and horticulture – Requirements and test methods" (available via https://standards.cen.eu/). It specifies the necessary requirements for complete biodegradability and appropriate test methods for measurement. The standard is expected to be the reference document for farmers, distributors, and stakeholders, and form the basis for certification and according labels for biodegradable mulch films. EN 17033 is likely to replace other pre-existing national standards in Europe.

EN 13655, the applicable standard for conventional mulch films, was split into two standards to include end-of-life options: a) for mulch films that have to be recovered after use (revised EN 13655), and b) for mulch films that can be incorporated into the soil due to their property of biodegradation (new EN 17033).

Specifically:

1. The European Parliament in October **2017** voted to include biodegradable mulch film in the EU Fertilizer Regulation. After deliberations by the three EU institutions (European

Parliament, European Council and European Commission) the final text language states that the EU will assess the inclusion of biodegradable mulch film in the EU fertilizer regulation.

2. Article 50 on biodegradability review states that by July 16, 2024, the EU Commission will carry out a review in order to assess the possibility of determining the biodegradability criteria for mulch films. This will include a consideration of incorporating them into component material as part of the regulation annex II in 2024.
3. The voluntary consensus European standard EN 17033 assesses and specifies the biodegradability and the ecotoxicology parameters together with mechanical and optical characteristics of mulch film.
4. Biobased content is **not** a requirement of the EN 17033.
5. The EU Fertilizer Regulation does not include any provision for organic vs conventional farming.
6. Countries such as France, Italy, Spain, and Portugal can use biodegradable mulch films. The Italian association for organic farming has signed a protocol with the Italian association for bioplastics on the use of biodegradable mulch film that meet EN 17033 requirements.
7. In general, European agricultural stakeholders have reacted positively to EN 17033 and they see this document as an important step in defining truly biodegradable mulch films.

4.0. Analysis & Comments on USDA Organic Regulations for use of biodegradable, biobased mulch film

The USDA organic regulations define "biodegradable biobased mulch film" at 7 CFR 205.2 as **synthetic** mulch film that meets the following criteria:

(1) Meets the compostability specifications of one of the following standards: ASTM D6400, ASTM D6868, EN 13432, EN 14995, or ISO 17088 (all incorporated by reference; see §205.3);

Composting represents the most aggressive biological environment, and if the biodegradable mulch film cannot meet the specification requirements set for compostable products as prescribed in the ASTM/EN/ISO standards, then it will not completely biodegrade in soil at room temperature conditions. Furthermore, this mandatory requirement ensures that the biodegradable mulch film after breakdown in soil will satisfy safety requirements of ecological toxicity. It also ensures that minor constituents present at 1 to 10% levels are completely biodegradable – see requirement (2) below.

(2) Demonstrates at least 90% biodegradation absolute or relative to microcrystalline cellulose in less than two years, in soil, according to one of the following test methods: ISO 17556 or ASTM D5988 (both incorporated by reference; see §205.3); and

ASTM D5988 and ISO 17556 are test methods that provide specific guidance on conducting a test to measure biodegradability of mulch films under soil conditions. **Section 2.1; and schemes 1 through 4 describe and illustrate the scientific fundamentals and basis for measuring biodegradability**. Test method standards do not provide pass/fail criteria. Therefore, the USDA organic regulations set the pass/fail criteria (specifications) for biodegradable mulch film at

90%+ biodegradability using D5988 or ISO 17556 test methods.

Note: 90% + biodegradability represents the experimental threshold that must be met to claim **complete biodegradability or full microbial utilization –** the 90% experimental threshold accounts for experimental error, few percent carbon remaining tied up in microbial biomass, and the statistical requirements of setting an absolute threshold value. The 90%+ biodegradability requirement **does not** imply that 10% of non-biodegradable material can be used in the formulations. This is a major misperception. Indeed, compostability specification standards ASTM D6499 & D6868 strictly mandate that any other material/s present at levels between 1-10% must be tested **separately** for complete biodegradability. This ensures that all of the organic components in a mulch film formulation are completely utilized (biodegraded) by the soil microorganisms.

(3) Must be biobased with content determined using ASTM D6866 (incorporated by reference; see §205.3).

Section 2.3 explains the concept, the science, and the basis for using biobased (carbon) content (ASTM D6866). As explained in that section, biobased (carbon) content is the amount of biobased carbon as a percent of the total (biobased + fossil based) organic carbon in the product. It provides for a reduced carbon footprint based on the amount of biobased carbon content, and experimentally measured using radiocarbon analysis as per ASTM/ISO standards. It supports a rural agrarian economy. The USDA BioPreferred Program envisions increasing the purchase and use of biobased products. Most importantly, the USDA Biopreferred Program identifies products/product categories containing a range of biobased (carbon) content and does not require 100% biobased (carbon) content.

4.1. USDA BioPreferred Program

The BioPreferred Program was created by the Farm Security and Rural Investment Act of 2002 (the 2002 Farm Bill) and reauthorized and expanded as part of the Agricultural Act of 2014 (the 2014 Farm Bill). The program's purpose is to spur economic development, create new jobs and provide new markets for farm commodities. The increased development, purchase, and use of biobased products reduces our nation's reliance on petroleum, increases the use of renewable agricultural resources, and contributes to reducing adverse environmental and health impacts.

The two major parts of the program are:

- Mandatory purchasing requirements for federal agencies and their contractors

Purchase biobased products in categories identified by the Department of Agriculture (USDA). To date, USDA has identified 139 categories (e.g. cleaners, carpet, lubricants, paints) of biobased products for which agencies and their contractors have purchasing requirements. Each mandatory purchasing category **specifies the minimum biobased content** for products within the category

- Voluntary labeling initiative for biobased products.

USDA wants to make it easy for consumers to identify biobased products. The USDA Certified Biobased Product label provides useful information to consumers about the biobased content of the product. This label assures consumers that the product contains a verified amount of renewable biological ingredients (referred to as biobased content). Consumers can trust the label to mean what it says because manufacturer's claims concerning the biobased content are thirdparty certified and strictly monitored by USDA.

The USDA BioPreferred program defines Biobased Products as products derived from plants and other renewable agricultural, marine, and forestry materials and provide an alternative to conventional petroleum derived products. Biobased products include diverse categories such as lubricants, cleaning products, inks, fertilizers, and bioplastics. For the purposes of the BioPreferred Program, biobased products do not include food, animal feed, or fuel. Biobased (carbon) content is measured using ASTM D6866.

4.2 The "Synthetics" Issue.

Item 3 (see section 4.0 above) of the USDA Organic Regulations requires that the mulch film must be "biobased" with content determined using ASTM D6866. It does not specifically state that 100% biobased content is required. More importantly, biobased content does not impact or influence soil biodegradability – see Scheme 1 and section 2.1. However, the preamble to the final rule (section 6) indicates that *NOSB intended to define biobased so that this category would not allow products derived from petroleum – polymers derived from fossil based monomers like adipic acid, terephthalic acid, 1,4-butanediol partly or completely* – see section 2.6, scheme 8 and 9.

Synthetic substances allowed for use in organic production are (*§205.601)*:

(i) Plastic mulch and covers (petroleum-based other than polyvinyl chloride (PVC),

(ii) Biodegradable, biobased mulch film as defined in *§*205.2. Must be produced without organisms or feedstock derived from excluded methods.

Provided, that the use of such substances **do not contribute to contamination of crops, soil, or water.**

Biobased, soil biodegradable polymer formulations are available commercially with minimum biobased contents 25% for mulch film applications. Increasing biobased content reduces performance and processability, while increasing cost. These polymers are described in sections 2.4 to 2.6; schemes 7, 8, & 9. They are completely biodegraded (utilized by the soil microorganisms) as per standards specified in the organic regulations. It is a "naturally occurring biological process" and the end-products of this process are carbon dioxide and microbial biomass. Therefore, they will not contribute to contamination of crops, soil or water and comply with *§205.601 for allowed synthetic substances.*

The USDA BioPreferred products in the voluntary labelling program have biobased content 25% or higher. In the Federal mandatory purchasing program, biobased contents range from 10% to 90% as designated by the USDA based on commercial availability, cost, and performance.

5.0. Analysis and Comments on USDA Policy Memorandum on Biodegradable Biobased Mulch Film (PM 15-1, January 22, 2015; available in the NOP Program Handbook)

The policy memorandum is generally consistent with the regulatory language, as it relates to biobased content and biodegradability requirements at the end-of-life of the product. While the following sentence is consistent with the preamble of the final rule, it poses issues in terms of currently available mulch films:

"Biodegradable mulch films that contain non-biobased synthetic polymer feedstocks, such as petrochemical resins, do not comply with the USDA organic regulations".

Polymers described in section 2.4, scheme 7 are 100% biobased and fully biodegradable in soil. However, these polymers are not readily processable into mulch films with the required performance properties. Polymers described in section 2.5 and 2.6 (schemes 8 through 10) can be processed into mulch films with biobased content (but not 100%). The mulch film demonstrates complete soil biodegradability using specified ASTM/ISO standards, which is validated by isotope labelling studies.

The USDA BioPreferred program and the legislative language in the 2002 Farm Bill and the reauthorized and expanded 2014 Farm Bill defines biobased products as "derived in whole" or "**in part**" from renewable biomass feedstocks like plants and other renewable agricultural, marine, and forestry materials. The USDA BioPreferred program products in the voluntary labelling program have biobased content 25% or higher. In the Federal mandatory purchasing program, biobased contents range from 10% to 90% as designated by the USDA. There is no requirement for 100% biobased content. More importantly, biobased content does not influence or affect the soil biodegradability of the polymer molecule.

The process to manufacture PLA and PHAs (Figure 7), polymers used in biobased, biodegradable mulch film formulations does not, typically, use excluded methods and contain no GMOs. However, it is not clear if this extends to the growing of the crops – U.S. corn in particular which provides the starting "sugar" feedstock for manufacturing PLA. Almost all U.S. corn is GMO based, and is the feedstock used by the only U.S. manufacturer of PLA. Potato or tapioca starch or sugarcane, which may be non-GMO sources, can also provide the "sugar" feedstock. Several Chinese and one European company use this sugar feedstock for manufacture of PLA.

6.0. Analysis & Comments on the Preamble to the final rule (79 FR 58655, September 30, 2014)

The preamble is generally consistent with the regulatory language and AMS policy memorandum 15-1. The following paragraph/statements raises issues that may need resolution:

"We noted that the NOSB intended to define biobased so that this category would not allow products derived from petroleum. We understand this to mean that mulch films derived from aliphatic aromatic copolymers (AACs), e.g. synthesized from adipic acid, terephthalic acid, and 1,4-butanediol, would be prohibited. Further guidance in this area may be more appropriate for other organizations or agencies with specialized technical expertise in this area. We note that this list may need to be updated over time in response to advances in technology"

Currently, fully biodegradable commercial mulch films are not 100% biobased. The new ester backbone polymers (schemes7 through 10) are completely biodegradable in soil within two years and meet prescribed regulatory requirements except for 100% biobased content. Scheme 7 describes 100% biobased and fully soil biodegradable polymers. However, these polymers are not readily processable into films and do not meet performance and cost requirements. Schemes 8, 9, & 10 describe polymers that can be formulated to give biodegradable mulch films with biobased (carbon) content of 25% and higher. The value proposition (as pointed out in the beginning section) is its ability to deliver performance and at its end-of-life (end of growing season) plowed into the soil where soil microorganisms completely utilize (biodegrade) it as food for its life process. Sections 2.0 through 2.2 provides discussion on basics of biodegradability and section 2.6 schemes 12 & 13 present isotopic labelling studies that validate complete biodegradability in soil.

Specifying a minimum “biobased content” instead of 100% biobased content would be in harmony with the USDA BioPreferred program.

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