



This document is scheduled to be published in the Federal Register on 09/30/2014 and available online at <http://federalregister.gov/a/2014-23135>, and on FDsys.gov

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Document Number AMS-NOP-13-0011; NOP-13-01FR]

RIN 0581-AD32

National Organic Program (NOP); Amendments to the National List of Allowed and Prohibited Substances (Crops and Processing).

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule amends the U.S. Department of Agriculture's (USDA's) National List of Allowed and Prohibited Substances (National List) to reflect a recommendation submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB) on October 18, 2012, and removes two previously expired substances. Consistent with the recommendation from the NOSB, this final rule adds biodegradable biobased mulch film to the National List with restrictive annotations. This action also adds a new definition for biodegradable biobased mulch film. This rule also removes two listings for nonorganic agricultural substances from the National List, hops (*Humulus lupulus*) and unmodified rice starch, as their use exemptions expired on January 1, 2013, and June 21, 2009, respectively. Two other substances that were recommended by the NOSB to the Secretary for addition to the National List, *Citrus hystrix*, leaves and fruit, and curry leaves (*Murraya koenigii*), have not been added to the National List based on comments received on the proposed rule.

DATES: Effective Date: This rule is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The incorporation by reference of certain

publications listed in this rule is approved by the Director of the Federal Register as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Melissa Bailey, Ph.D., Director, Standards Division, National Organic Program, Telephone: (202) 720-3252; Fax: (202) 205-7808.

SUPPLEMENTARY INFORMATION:

I. Background.

On December 21, 2000, the Secretary established within the National Organic Program (NOP) (7 CFR part 205) the National List regulations sections 205.600 through 205.607. The National List identifies the synthetic substances that may be used and the nonsynthetic (natural) substances that may not be used in organic production. The National List also identifies nonagricultural synthetic, nonagricultural nonsynthetic, and nonorganic agricultural substances that may be used in organic handling. The Organic Foods Production Act of 1990 (OFPA), as amended (7 U.S.C. 6501-6522), and USDA organic regulations, in section 205.105, specifically prohibit the use of any synthetic substance in organic production and handling unless the synthetic substance is on the National List. Section 205.105 also requires that any nonorganic agricultural and any nonsynthetic nonagricultural substance used in organic handling must also be on the National List.

Under the authority of OFPA, the National List can be amended by the Secretary based on proposed amendments developed by the NOSB. Since established, the Agricultural Marketing Service (AMS) has published multiple amendments to the National List beginning on October 31, 2003 (68 FR 61987). AMS published the most recent amendment to the National List on October 3, 2013 (78 FR 61154).

This final rule amends the National List to enact one recommendation submitted to the Secretary by the NOSB on October 18, 2012. This rule also removes two previously expired substances from the National List. Two other recommendations that were submitted by the NOSB to the Secretary on May 25, 2012, have not been finalized based on comments received on AMS' August 22, 2013 proposed rule (78 FR 52100).

II. Overview of Amendments

The following provides an overview of the amendments made to designated sections of the National List regulations:

Section 205.2 Terms defined.

Section 205.3 Incorporation by reference.

Section 205.601 Synthetic substances allowed for use in organic crop production.

This final rule amends sections 205.2 and 205.601 of the National List by adding a new definition and new substance to the National List for organic crop production. In addition, section 205.3 has been added to comply with incorporation by reference requirements.

Biodegradable Biobased Mulch Film

This rule adds a new definition for biodegradable biobased mulch film that includes criteria and third-party standards for compostability, biodegradability, and biobased content. These third-party standards are incorporated by reference at new section 205.3. For the final rule, we have added new section 205.3 to specify the current versions of the cited third-party standards and include information on the availability of these standards to meet requirements for incorporation

by reference.¹ Additional text regarding the availability of these standards has also been added to new section 205.3.

This rule also adds the substance “biodegradable biobased mulch film,” with restrictions, to new subparagraph (b)(2)(iii) of section 205.601. The new listing reads as follows: “Biodegradable biobased mulch films as defined in § 205.2. Must be produced without organisms or feedstock derived from excluded methods.”

Section 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”

This final rule amends section 205.606 of the National List regulations by removing paragraphs (l) and (w)(2) to remove two previously expired substances, hops (Humulus lupulus) and unmodified rice starch, whose use expired on January 1, 2013, and June 21, 2009, respectively. Further, this final rule redesignates paragraph (w)(3) as (w)(2) and paragraphs (m) through (aa) as (l) through (z).

III. Related Documents.

Two notices were published regarding meetings of the NOSB and its deliberations on recommendations and substances petitioned for amending the National List. Substances and NOSB recommendations addressed in this final rule were announced for NOSB deliberation in the following Federal Register notices: (1) 77 FR 21067, April 9, 2012 (curry leaves and C. hystrix); and (2) 77 FR 52679, August 30, 2012 (biodegradable biobased mulch film).

The expiration date of January 1, 2013, for the listing for hops was added to the National List on June 27, 2012, by a final rule (77 FR 33290) published in the Federal Register notice on June 6, 2012.

¹ Federal Register Document Drafting Handbook, Chapter 6: What is Incorporation by Reference, and How do I do it? April 2014 Revision. <http://www.archives.gov/federal-register/write/handbook/chapter-6.pdf>.

The listing and expiration date of June 21, 2009 for unmodified rice starch was added to the National List on June 21, 2007, by an interim final rule (72 FR 35137) published in the Federal Register on June 27, 2007.

The proposal to allow the use of three new substances, along with the deletion of two expired substances, was published as a proposed rule on August 22, 2013 (78 FR 52100).

Additional information on substances, including petitions, technical reports, and NOSB recommendations, are available on the NOP Web site at <http://www.ams.usda.gov/NOPNationalList>.

IV. Statutory and Regulatory Authority

OFPA authorizes the Secretary to make amendments to the National List based on proposed amendments developed by the NOSB. Sections 6518(k)(2) and 6518(n) of OFPA authorize the NOSB to develop proposed amendments to the National List for submission to the Secretary and establish a petition process by which persons may petition the NOSB for the purpose of having substances evaluated for inclusion on or deletion from the National List. The National List petition process is implemented under section 205.607 of the USDA organic regulations. The current petition process (72 FR 2167, January 18, 2007) can be accessed through the NOP Web site at <http://www.ams.usda.gov/nop>.

A. Executive Order 12866

This action has been determined not significant for purposes of Executive Order 12866, and, therefore, has not been reviewed by the Office of Management and Budget (OMB).

B. Executive Order 12988

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. This final rule is not intended to have a retroactive effect.

States and local jurisdictions are preempted under OFPA from creating programs of accreditation for private persons or State officials who want to become certifying agents of organic farms or handling operations. A governing State official would have to apply to USDA to be accredited as a certifying agent, as described in section 6514(b) of OFPA. States are also preempted under sections 6503 through 6507 of OFPA from creating certification programs to certify organic farms or handling operations unless the State programs have been submitted to, and approved by, the Secretary as meeting the requirements of OFPA.

Pursuant to section 6507(b)(2) of OFPA, a State organic certification program may contain additional requirements for the production and handling of organically produced agricultural products that are produced in the State and for the certification of organic farm and handling operations located within the State under certain circumstances. Such additional requirements must: (a) Further the purposes of OFPA, (b) not be inconsistent with OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

Pursuant to section 6519(f) of OFPA, this final rule would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601-624), the Poultry Products Inspection Act (21 U.S.C. 451-471), or the Egg Products Inspection Act (21 U.S.C. 1031-1056), concerning meat, poultry, and egg products, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act

(21 U.S.C. 301-399), nor the authority of the Administrator of the Environmental Protection Agency under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136-136(y)).

Section 6520 of OFPA provides for the Secretary to establish an expedited administrative appeals procedure under which persons may appeal an action of the Secretary, the applicable governing State official, or a certifying agent under this title that adversely affects such person or is inconsistent with the organic certification program established under this title. OFPA also provides that the U.S. District Court for the district in which a person is located has jurisdiction to review the Secretary's decision.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose is to fit regulatory actions to the scale of businesses subject to the action. Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

The Small Business Administration (SBA) defines small agricultural producers and handlers as those having annual receipts of less than \$750,000 (13 CFR 121.201). SBA defines small agricultural service firms, which would include accredited certifying agents, as those having annual receipts of less than \$7,000,000 (13 CFR 121.201).

The NOP reported that there were 18,513 certified organic farms and processing facilities in the United States at the end of 2013.² According to the 2011 Certified Organic Production Survey, nearly 90% of certified organic farms reported annual organic product sales of less than \$500,000.³ AMS believes that most of these entities would be considered to be small entities under the criteria established by the SBA.

In addition, the USDA has 82 accredited certifying agents that provide certification services to producers and handlers; 49 of these are based in the United States. A complete list of names and addresses of accredited certifying agents may be found on the AMS NOP Web site, at <http://www.ams.usda.gov/nop>. AMS believes that most of these accredited certifying agents would be considered small entities under the criteria established by the SBA.

In accordance with RFA, AMS has considered the impact of this action on small entities. The effect of this final rule would be to allow the use of one additional substance, biodegradable biobased mulch film, in organic crop production and to remove two previously expired substances. The new allowance for biodegradable biobased mulch film will provide small entities with more tools to use in day-to-day farming operations. AMS concludes that the economic impact of this addition, if any, will be minimal and beneficial to small agricultural producers. Accordingly, AMS certifies that this rule would not have a significant impact on a substantial number of small entities.

D. Paperwork Reduction Act

² Information about the 2013 List of Certified Operations is available on the NOP Web site at: <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5097484&acct=nopgeninfo>.

³ U.S. Department of Agriculture, National Agricultural Statistics Service. 2011 Certified Organic Production Survey. October 2012. Available at: <http://bit.ly/2011OrganicSurvey>.

No additional collection or recordkeeping requirements are imposed on the public by this final rule. Accordingly, OMB clearance is not required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, Chapter 35.

E. Executive Order 13175

This final rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

F. Comments Received on Proposed Rule AMS-NOP-13-0011; NOP-13-01PR

AMS received 120 comments on the proposed rule. Comments were received from organic producers and handlers, nonprofit organizations, industry groups, trade associations, input suppliers, accredited certifying agents, and private citizens.

Most comments addressed the proposed allowance of biodegradable biobased mulch film and supported its use in organic crop production. Thirteen comments addressed the proposed allowance of two new nonorganic ingredients and did not support their addition to the National List. Comments received for each substance are described in more detail below.

Several comments opposed the allowance of any nonorganic material in organic crop production and handling, but did not provide specific comments on the proposed amendments.

Comments on the proposed removal of expired listings for hops and unmodified rice starch were supportive of this action. Therefore, AMS is finalizing the amendments that remove these two previously expired substances from section 205.606 of the National List.

Biodegradable biobased mulch film

Over one hundred comments addressed the proposed definition and allowance for biodegradable biobased mulch film. The majority of comments received were supportive of the proposed action.

One comment claimed that the proposed listing would allow materials to be used in ways that were not intended by the NOSB recommendation. We disagree. The definition and listing ensure that mulch film is biobased and meets additional standards for biodegradability and compostability consistent with the NOSB recommendation. Additional information on these issues is discussed in more detail below.

Two comments requested that other materials, herbicidal soaps for food crops and synthetic fabric weed barrier cloth (non-plastic), be allowed for weed control in organic crop production. AMS did not propose any action with respect to these materials in the proposed rule and, therefore, is not addressing these materials in this final rule. Parties interested in the allowance of these materials in organic crop production may submit a petition to the NOSB. This process can be initiated in accordance with the Notice of Guidelines on Procedures for Submitting National List Petitions (72 FR 2167).

Many commenters supported mulch film as a more environmentally sustainable alternative to traditional plastic mulch. Commenters indicated that mulch film would reduce landfill waste, reduce air pollution from burning of traditional plastic mulch, and be more sustainable and ecological since it uses renewable biobased resources. Some commenters also cited farms that have voluntarily surrendered their organic certification in order to use mulch film instead of traditional plastic film since they felt the mulch film is better for the environment.

AMS received a number of comments from certified organic producers who supported the use of biobased mulch film. Organic producers cited many environmental and economic

benefits from the use of mulch film including reduced plastic landfill waste, reduced labor costs, and reduced removal and disposal costs. Several producers noted that labor costs associated with hand weeding are a major expense for their operation and that the use of mulch film would reduce these costs.

Producers also noted that mulch films may allow for more effective weed control and improved cultivation of living mulches and cover crops. Comments specifically noted that mulch film would be beneficial to organic farmers without compromising the integrity of organic farming. One producer provided limited information about a successful on-farm trial using mulch film. Another producer noted that they used mulch film prior to becoming certified organic and expressed support for the use of the substance. One grower who supported the allowance of mulch film indicated that organic straw mulch, an alternative natural material, is increasingly hard to find.

One producer who supported the use of mulch film stated that biodegradable mulch films should be required instead of plastic mulch, and that biodegradable mulch films should be required to be tilled into the soil. We have not adopted the commenter's suggestion for required tilling, as discussed further below. Another commenter also indicated that traditional plastic mulch should be prohibited in organic agriculture. Removing the allowance for traditional plastic mulch on the National List is outside of the scope of this rulemaking action and, therefore, no further action was taken on this comment. Parties interested in a prohibition for traditional plastic mulch may submit a petition to the NOSB. This process can be initiated in accordance with the Notice of Guidelines on Procedures for Submitting National List Petitions (72 FR 2167).

Two comments supporting the use of mulch film indicated that foreign operations certified to other organic standards can currently use mulch films and export their certified

organic products into the United States; which puts domestic growers at a competitive disadvantage. This rulemaking action to allow the use of mulch film would address this concern.

Many comments indicated their support of the proposed listing at section 205.601 that prohibits mulch films made from or with excluded methods (i.e., genetically modified organisms or GMOs) because GMOs are not allowed for use in organic production. Several comments supported the use of mulch only if it does not contain any genetically modified material. Another comment stated that the proposed rule was unclear about biodegradable film that may contain genetically modified organisms and requested that the final rule require the mulch to be GMO free. One comment requested additional clarification on how far back in the production process that the use of excluded methods must be verified. One comment supported the prohibition on excluded methods but did not feel that it was necessary to specify the exclusion at section 205.601 since excluded methods are generally prohibited in organic production and handling. The comment indicated that targeting a single material with this restriction may lead to inconsistent certification decisions.

AMS has considered these comments and has retained the text that was proposed at section 205.601 that requires that mulch film must be produced without organisms or feedstock derived from excluded methods. There may be questions about whether the use of mulch film derived from genetically modified organisms should be interpreted as the use of an excluded method as prohibited under section 205.105(e), particularly if the manufacturing process eliminates any genetically engineered traits that are only detectible in the raw agricultural feedstock. Our intention is to implement the NOSB recommendation to prohibit the use of genetically engineered feedstock or organisms in the production of mulch film, regardless of whether the genetically engineered trait is retained or detectible in the finished product. We also

note that the NOSB indicated in its recommendation some concerns about consistency in the review of soil inputs for excluded methods and noted that it did not intend for this annotation to be interpreted as applying to other soil inputs.

Consistent with the NOSB recommendation and with the listing finalized at section 205.601, certifying agents and material evaluation programs will need to verify that mulch films are produced without organisms or feedstock derived from excluded methods. This includes verification that feedstock, including plant materials, microorganisms, enzymes, or other additives, are not genetically engineered or derived from genetically modified organisms. We have retained the language of “derived from excluded methods,” rather than “produced using excluded methods,” as suggested by one commenter, as we feel the proposed regulatory text is adequate to describe the intent.

Two comments that did not support the allowance of mulch film requested that, if approved, that the regulations should explicitly state that engineered nanomaterials are prohibited in this material. We have not adopted by the commenters’ suggestion on this issue. AMS acknowledges that the NOSB considers engineered nanomaterials to be synthetic and prohibited under the organic regulations, and that the NOSB issued a separate recommendation on this topic in 2010.⁴ On December 17, 2010, NOP responded to this NOSB recommendation that 1) it would be difficult to identify and verify the absence of nanomaterials in organic products; and 2) NOP needed more information about how nanomaterials are defined, regulated and used in

⁴ NOSB Recommendation. Guidance Document – Engineered Nanomaterials in Organic Production, Processing and Packaging. October 28, 2010. Available on the NOP Web site at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5087795&acct=nosb>.

agricultural products.⁵ Since this time, AMS continues to analyze information received from various sources on this issue to determine next steps. We also noted that the NOSB recommendation for mulch film specifically indicates that a proposed clause prohibiting nanomaterials was omitted from the final recommendation due to the lack of a legal definition. For these reasons, AMS has not accepted the commenters' suggestion to amend the annotation for mulch film to specifically prohibit nanomaterials.

One comment from an accredited certifying agent requested clarification on the allowance of mulch film as a compost feedstock. The certifying agent indicated that they have received requests from producers about compostable cutlery and plates and encouraged further consideration by AMS of whether these materials may be used as a compost feedstock. The NOSB did not consider the use of mulch film or compostable cutlery and plates as a compost feedstock in its recommendation on mulch film and is outside the scope of this rulemaking action. Parties interested in a broader allowance for compostable bioplastic materials, such as compostable cutlery, may submit a petition to the NOSB. This process can be initiated in accordance with the Notice of Guidelines on Procedures for Submitting National List Petitions (72 FR 2167).

Several comments raised concerns about the potential adverse environmental impacts from use of this material. Comments cited concerns about accumulation of polymer fragments and mulch additives, such as dyes, fillers, and other synthetic film additives that may not completely biodegrade. Comments stated that inadequate data are available regarding potential long-term accumulation of additives that remain in the soil and provided details or references in

⁵ Memorandum for the Chairperson of the National Organic Standards Board, National Organic Program, December 17, 2010. Available on the NOP Web site at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5088266&acct=nosb>.

support of these claims. One comment opposed the allowance of mulch films because potential adverse impacts on wildlife and soil microbial communities. One comment claimed that AMS should not approve the use of mulch film in organics because the environmental impacts are largely unknown and due to a lack of ecotoxicological studies to test for potential residues or harmful compounds. Another comment asked a question about microbiological risk, but did not provide additional details about their concerns. One comment expressed concerns about the potential for inadvertent spread of mulch pieces from farms to adjacent ecosystems and indicated a need for further research in this area to assess risks to wildlife, aquatic life, and adjacent ecosystems. Another comment indicated that the question of residue left by the mulch film should be weighed against the tiny scraps of broken and stretched plastic that remain in the field after removal of traditional plastic mulch, despite efforts for complete removal.

AMS has considered the comments about the potential adverse environmental impacts from the use of mulch film and considered this issue in comparison to the current use of traditional plastic mulches. In addition, the NOSB evaluated this substance against the criteria in OFPA, which includes consideration of the potential for detrimental chemical interaction with materials used in organic farming systems; the persistence and areas of concentration in the environment of the substance and its breakdown products or other contaminants; the probability of environmental contamination during manufacture, use, misuse or disposal of the substance; the effects of the substance on biological and chemical interactions in the agroecosystem; and available alternatives.⁶ We understand that additional studies may be helpful on these topics and that the NOSB Materials Subcommittee has proposed that this topic be added to the NOSB's list

⁶ OFPA, 7 U.S.C. 6518(m).

of research priorities.⁷ At this time, however, we believe that the environmental benefits gained by the use of mulch film that were raised by the majority of commenters outweigh the potential benefits from delaying a decision until more studies are completed. In consideration of the comment on ecotoxicological effects, we have retained the criteria for compostability in the definition of biodegradable biobased mulch film since it provides a screen for ecotoxic effects via plant growth and seedling germination tests in soil, as further discussed below.

In addition, we believe that the potential inadvertent spread of mulch film can be adequately addressed by certifiers under the existing regulations at section 205.200, which require that the operation implement production practices that maintain or improve the natural resources of the operation, including soil and water quality. If an operation allows materials to negatively impact soil or water quality, certifying agents must address this issue as a noncompliance under section 205.200.

Several comments raised questions about the biodegradability of mulch films. One comment claimed that complete degradation is required to ensure that mulch meets the requirement under OFPA that synthetic mulches be “removed” at the end of the growing season and did not believe that this requirement was met by the proposed listing.

Section 6508(c)(2) of OFPA prohibits the use of plastic mulches, unless such mulches are removed at the end of each growing or harvest season. This provision is implemented under the USDA organic regulations at sections 205.206(c)(6) and 205.601(b)(2)(ii). As supported by comments, AMS considers biodegradation of biofilm mulch as a form of removal at the end of the growing or harvest season. If an operation uses practices that does not allow mulch to

⁷ NOSB Materials Subcommittee Proposal: Research Priorities for 2013. December 10, 2013. Available on the NOP Web site at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5106662>.

biodegrade, and, therefore, it accumulates over time, certifying agents must address this issue as noncompliance under sections 205.200, 205.206(c)(6), and 205.601(b)(2)(iii).

One comment indicated that more investigation is needed on the different types of biodegradable mulches and claimed that not all are biodegradable. Another comment cited a study that showed that none of the biodegradable plastic mulches tested fully biodegraded in the soil after a two year period of soil incorporation following a cropping season.

One comment indicated that the NOSB recommendation is inadequate to ensure that biofilm mulches have completely biodegraded at the end of the growing or harvest season. Two comments indicated that complete degradation is necessary to qualify as “removal” at the end of the growing or harvest season, as required by OFPA under section 6508(c)(2). Another commenter posed questions on what the mulch film may degrade to.

Two comments did not support the rule and indicated that more research is needed to ensure adequate breakdown of mulch films. One comment indicated that it is not yet possible to establish adequate criteria that can be implemented by material review organizations, certifiers, and growers, while another commenter stated that no products currently exist in the marketplace that have been proven to fully degrade. Comments also cited a forthcoming ASTM standard that addresses aerobically biodegradable plastics in the soil environment. One comment suggested that AMS withdraw the proposed rule and postpone approval until an applicable standard is identified and products are developed that meet biodegradability requirements.

AMS has considered these comments. As explained in the proposed rule, we agree that growers will need to take appropriate actions to ensure complete degradation. These actions may be site-specific and be impacted by a number of factors, including climate, soil type, pH, soil microbial activity, irrigation, and other production practices. Section 205.200 requires that

production practices maintain or improve the natural resources of the operation, including soil and water quality. In addition, section 205.203 requires that the producer select and implement practices that maintain or improve the physical, chemical, and biological condition of soil. Thus, the use of a mulch film in a manner that causes it to accumulate in the field and not biodegrade over time would not be compliant with the existing requirements at sections 205.200 and 205.203. We believe the definition and criteria for biodegradable biobased mulch film as finalized at section 205.2 provide an adequate baseline for biodegradability. Additionally, the existing requirements at sections 205.200 and 205.203 provide adequate safeguards against misuse. If misuse is identified, certifying agents may reference these standards when issuing notices of noncompliance to operations as required under section 205.662.

Another comment raised questions about possible changes to product formulations and indicated that manufacturers change formulations frequently based on costs of available feedstock. Supplier and ingredient substitution is not unique to mulch film manufacturing and occurs with other formulated inputs products, such as blended fertilizers and soil amendments that are marketed for organic production. As part of the review process for input products, certifying agents and material evaluation programs must continue to ensure that any alternate formulations of approved mulch film products comply with any annotations provided on the National List.

Definition at Section 205.2

This rule adds a new definition for biodegradable biobased mulch film that includes criteria and third-party standards for compostability, biodegradability, and biobased content.

One comment indicated that certifying agents may not have the resources to perform the testing methods referenced in the proposed definition and recommended that AMS require

separate third-party verification to these standards and allow certifying agents to accept their verification. They also requested that AMS identify which third-party verifications can be accepted. AMS does not expect that certifying agents have equipment or resources to perform the tests referenced at section 205.2. Instead, as with review of any input used in organic production or handling, certifying agents and material evaluation programs that review these materials must have sufficient expertise to determine whether the appropriate tests have been conducted by the manufacturer or party seeking review. Alternatively, certifying agents may accept reviews (i.e., third-party verifications) conducted by other certifying agents or other approved third parties as explained under NOP Policy Memo 11-4.⁸

One commenter suggested that AMS use the word “plastic” in the definition to clarify that the rule is intended to regulate biodegradable bioplastic mulch film. We have not adopted the commenter’s suggestion, as the term “biodegradable biobased mulch film” is adequate to describe the intended material. In addition, the term used is consistent with the name used in the petition and the NOSB recommendation.

Compostability

In the proposed rule, AMS specifically requested comments on the applicability of the proposed compostability standards for biodegradable biobased mulch film.

Many comments supported the definition proposed at section 205.2 and indicated that all three testing standards – compostability, biodegradation, and biobased – that define biodegradable biobased mulch film are necessary because they ensure that the material is compatible with good soil management and principles. One comment supported the inclusion of

⁸ NOP Policy Memo 11-4 on Evaluation of Materials is available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5088949>

this standard since it provides additional evidence that approved mulch films will break down through biological processes.

Several comments indicated that both the compostability standards and biodegradability testing requirements serve an important screening purpose. The comments noted that the compostability standard provides an initial rejection point earlier in the timeline of reviewing mulch film and confirms the absence of any ecotoxic effects via plant growth and seedling germination tests in soil.

Three comments did not support the reference to the compostability testing, stating that it is designed for commercial composting and does not correlate between conditions found in the field or environmental conditions present on farms, which have lower achievable temperatures.

We have considered these comments and have retained the standards for compostability. We agree with the comments that compostability testing is important as an initial screen for ecotoxicity which is not otherwise addressed by the other criteria for biodegradability and biobased content; therefore, we have retained the compostability standards recommended by the NOSB and included in the proposed rule. The text was updated to cite the current version of this standard to meet incorporation by reference requirements.

Biodegradation

Some commenters noted that a new ASTM work item, ASTM WK29802, is under development with the working title, “New Specification for Aerobically Biodegradable Plastics in Soil Environment in the Temperate Zone.” This work item was initiated by ASTM on July 29, 2010.⁹ According to several commenters, this new specification is expected to be a better fit for testing the biodegradability of mulch film in a soil environment when compared to ASTM

⁹ This work item, ASTM WK29802, has since been renamed as “New Specification for plastics that are innately biodegradable in soil under aerobic conditions,” <http://www.astm.org>. Accessed August 4, 2014.

D5988.¹⁰ Since this new standard has not yet been published, we are unable to fully consider this alternative. Once the standard has been published, parties interested in further consideration of this alternative standard may submit a petition to the NOSB. This process can be initiated in accordance with the Notice of Guidelines on Procedures for Submitting National List Petitions (72 FR 2167).

One comment noted that a label of a commercial product which references ASTM D5988 only implies that the product was tested, but does not guarantee any level to which the product actually degraded. We believe this comment is addressed through the definition for biodegradable biobased mulch film which states that the substance “demonstrates at least 90% biodegradation absolute or relative to microcrystalline cellulose in less than two years, in soil.” This requirement provides a baseline for biodegradability which is consistent with the NOSB recommendation.

One commenter indicated that it was unclear whether the biodegradability specifications (i.e., ASTM D5988) apply to mulches received from the vendor, or mulches exposed to weathering, or both. AMS intends for the specifications provided under section 205.2 to apply to mulch films as received from the manufacturer or supplier by the producer.

One commenter indicated that the biodegradation standard ASTM D5988 was inappropriate because it is a laboratory test performed under a controlled environment and it does not address the wide variety of conditions found on organic farms. In addition, the comment indicated the standard ASTM D5988 is insufficient because it does not require complete degradation of mulch. Instead, the standard only requires demonstrating 90% biodegradation in testing, which does not address residual components of mulch that could build up in soils over

¹⁰ ASTM D5988-12, Standard Test Method for Determining Aerobic Biodegradation of Plastic Materials in Soil. ASTM International. <http://www.astm.org>.

time. The commenter also indicated that different rates may be observed in different climates and soil conditions.

Two additional comments cited research studies and ongoing field studies that found that several biodegradable mulches that comply with the ASTM biodegradation standards showed variable levels of decomposition during the growing season.

AMS understands that the complete degradation of mulch film may be impacted by a number of factors, including climate, soil type, pH, irrigation, and other production practices. The two referenced standards for biodegradability, ISO 17556 and ASTM D5988, are intended to provide a baseline that any mulch film must meet. These standards do not exempt the producer from other parts of the USDA organic regulations that require production practices that maintain or improve soil quality and other environmental conditions, as discussed earlier.

Biobased Content

One comment indicated that there is no correlation between the percentage of biobased content and rate of complete biodegradation. The commenter stated that biobased infers that materials are being used that have renewable content, but nothing more. We have not amended the regulatory text in response to this comment since the requirement for biobased content is intended to ensure that feedstock is derived from renewable materials, rather than fossil fuel sources, to be consistent with the NOSB recommendation. We understand that some minor additives, e.g., plasticizers, colorants, etc., may not be available in biobased form; however, we expect that the feedstock will be biobased and that content will be determined using ASTM D6866 testing methods. If there are questions about whether a particular formula is in compliance, AMS encourages certifying agents and material evaluation programs that review these materials to

contact NOP prior to making decisions on materials and products that are potentially problematic or controversial.

One comment suggested an amendment to the language for biobased content to read as follows (suggested text italicized): “Must be biobased with all carbon derived from a renewable resource via biological processes, with content determined using ASTM D6866 testing method.” The commenter claims that the NOSB recommendation stated that all the carbon must be “derived from a renewable resource via a biological process.” The comment further states that, by not explicitly including this component, AMS would be broadening the use allowance for mulch film beyond that which was recommended by NOSB.

We have reviewed the comment against the NOSB recommendation and noted that the NOSB recommended a definition for 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 (ASTM).” As previously explained in the proposed rule, we have not incorporated a separate definition for biobased and believe that the definition of “biodegradable biobased mulch film” incorporates the intent of the NOSB on this issue. Therefore, we have not adopted the commenter’s suggestion. The ASTM D6866 testing method is a standard test method to quantify the biobased content of samples. The test methods directly discriminate between product carbon resulting from contemporary carbon input and that derived from fossil-based input.¹¹ We have not included the term “all carbon,” as suggested by the comment, to account for trace amounts of carbon that may be present from additives (e.g., plasticizers, colorants including carbon black, etc.) used in the manufacturing process. The suggested text could also cause

¹¹ <http://www.astm.org/Standards/D6866.htm>

confusion in interpretation when a margin of error is reported as part of testing results. In addition, we have not included the term “carbon derived from a renewable resource via biological testing methods” since it is redundant with the term “biobased” and the testing criteria for biobased content. AMS believes that the proposed definition meets use the intended use that was recommended by the NOSB. As this use was recommended by the NOSB and was included in a proposed amendment to the National List published August 22, 2013 (78 FR 52100), the allowance for biodegradable biobased mulch film is consistent with the authority granted by AMS under OFPA.¹²

One comment indicated that the biobased definition provides inadequate information regarding what types of products will be allowed and what will be prohibited. The comment indicated that the “biobased” definition from the USDA BioPreferred® program only requires that a product have a minimum of 25% biobased content, allows GMO biobased feedstocks, and does not provide clear information on what is allowable for the remaining balance of the content. The comment requested that AMS provide names of specific polymers that can be synthesized from renewable sources and are proven to be biodegradable in the soil.

AMS expects that all feedstock for biobased mulch films will be biobased and that content will be determined using ASTM D6866 testing methods. We understand that the criteria included in the USDA organic regulations may exclude some products that are defined as “biobased” under the USDA BioPreferred® program, which allows a lower percentage of biobased content and may contain petroleum or fossil fuel derived feedstock, and allows genetically modified organisms. We understand that some minor additives, e.g., plasticizers,

¹² Section 6517(d)(2) states: No additions. – The Secretary may not include exemptions for the use of specific synthetic substances in the National List other than those exemptions contained in the Proposed National List or Proposed Amendments to the National List.

colorants, etc., used in mulch film allowed under this rule may not be available in biobased form; however, we expect that the feedstock for the mulch film will be derived from biobased sources. The use of feedstock derived from excluded methods is specifically excluded under the listing at section 205.601.

At this time, AMS is not prepared to issue a specific list of polymers that are available from renewable (e.g., biobased) resources. We noted that the NOSB intended to define biobased so that this category would not allow products derived from petroleum. Based on review of the petition and NOSB recommendation, 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. We believe that the criteria outlined under sections 205.2 and 205.601 provide adequate guidance to certifying agents and material evaluation programs that will review these types of products for compliance with the USDA organic regulations. Certifying agents would not review products to the USDA BioPreferred® program criteria, which are established for biobased products.

One comment stated that the proposed standard for measuring biobased content, ASTM D6866, is a poor measurement tool for measuring biobased content in reference to starch. The comment requested that AMS recognize this shortcoming and grant a special consideration for starch, since some mulch films are starch based. The comment indicated that special consideration has been granted in Europe, but did not provide additional information in support of this claim. We have considered this comment but have not amended the text in response. In the absence of an alternative third-party testing standard for biobased content, we have retained

the biobased testing method, ASTM D6866, cited in the original petition and recommended by the NOSB. We have amended the text for the final rule to specify the current version of this standard to comply with incorporation by reference requirements. Due to lack of additional information on this issue, parties interested in further consideration of this topic may submit a petition to the NOSB. This process can be initiated in accordance with the Notice of Guidelines on Procedures for Submitting National List Petitions (72 FR 2167).

Additional Guidance

In the proposed rule, AMS specifically requested comments on whether guidance on management practices is necessary to prevent mulch film from accumulating in fields.

Two comments indicated that additional guidance was unnecessary at this time if manufacturer's instructions are followed and with the knowledge that each organic farmer has about their soil and climate conditions.

One comment indicated that guidance could be useful since growers will be eager to use this new material, but did not provide additional details on the need or scope of the guidance. Another commenter supported the creation of a guidance document to ensure that the biodegradable mulch films are not accumulating in the soil and indicated that it would help to prevent accumulation issues from occurring due to a lack of experience.

One comment provided additional background on the rationale for NOSB recommending the development of guidance so that growers would understand what actions are needed to ensure complete degradation.

One comment indicated that regulations must be promulgated that detail best management practices for using and degrading mulch film. The commenter indicated that AMS should not wait until problems arise with respect to the use and incomplete degradation of mulch

film before mandating best management practices since this would compromise organic integrity.

AMS has considered the comments and determined not to move forward with additional guidance on this topic at this time. As explained above, we agree that growers may need to take appropriate actions to ensure complete degradation. These actions may be site-specific and be impacted by a number of factors, including climate, soil type, pH, soil microbial activity, irrigation, and other production practices. AMS encourages parties with specific technical expertise in this area, such as product manufacturers and university research programs, to continue to provide technical assistance to producers on this topic.

Substances not added to the National List

Citrus hystrix, leaves and fruit

Curry leaves (*Murraya koenigii*)

Thirteen comments addressed the proposed allowance of two nonorganic ingredients in organic processing: Citrus hystrix, leaves and fruit, and curry leaves (*Murraya koenigii*). These substances were proposed to be added to section 205.606 of the National List based on two NOSB recommendations. Several comments opposed the allowance of any nonorganic ingredients in organic processing, including nonorganic Citrus hystrix and curry leaves. Several comments opposed the specific allowance of Citrus hystrix and curry leaves due to concerns about pesticide residues, particularly on imported ingredients, since the majority of production occurs outside of the United States.¹³ One comment opposed the import of any food into the United States, which is outside of the scope of this action. One comment raised questions about whether these ingredients would be checked for pesticides, other substances, or evaluated for

¹³ One example cited: <http://english.doolnews.com/curry-leaf-laced-with-deadly-pesticides-kerala-news-10453-10453.html>

purity and another commenter raised questions on how the nonorganic ingredients were produced. One comment indicated that these plants are relatively easy to cultivate and that companies need to contact growers to see if they are willing to grow organic forms of these ingredients. One producer indicated that their farm produces organic curry leaves in Hawaii, but did not provide details on the amounts produced. Several comments raised questions about organic search requirements for commercial availability and claimed that allowing nonorganic ingredients would decrease the incentive for developing organic sources of these ingredients. Another comment supported the allowance of the nonorganic ingredients only under an alternative labeling program whereby the products would not be labeled as organic and only if the allowance of nonorganic ingredients met additional criteria. These additional criteria are beyond the scope of the USDA organic regulations.

After consideration of the comments, AMS has not amended section 205.606 to include Citrus hystrix and curry leaves. We noted a lack of comments in support of the proposed rule to allow these ingredients in organic handling. While an organic handler originally submitted the petition for these ingredients for review by the NOSB, no handlers commented on the need for nonorganic Citrus hystrix and curry leaves. In the absence of comments in support of their allowance, we have not determined at this time that these substances are necessary to the production or handling of an agricultural product, as required by section 6517 of OFPA; therefore, we have not added these substances to the National List.

However, AMS believes that the majority of issues raised by commenters that opposed the inclusion of curry leaves and Citrus hystrix do not uniquely apply to these ingredients when compared to other ingredients that are eligible for inclusion on section 205.606 of the National List. For example, demonstrating that an organic form is not commercially available is required

prior to use of any nonorganic substance listed at section 205.606. In addition, the use of imported ingredients listed at section 205.606 is allowed, provided that the ingredients comply with any food safety requirements under the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301-399) or the authority of the Administrator of the Environmental Protection Agency under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136-136(y)) that apply to all food.

In addition, we specifically note that this action does not change the eligibility of processed products that are labeled “made with organic (specified ingredients or food group(s))” to contain nonorganic forms of Citrus hystrix or curry leaves, as allowed under section 205.304 of the USDA organic regulations. Handlers interested in using nonorganic forms of these ingredients continue to be eligible for the “made with organic (specified ingredients or food group(s))” label claim, provided that all other requirements under the USDA organic regulations are met.

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agriculture, Animals, Archives and records, Incorporation by reference, Imports, Labeling, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

For the reasons set forth in the preamble, 7 CFR part 205 is amended as follows:

PART 205 – NATIONAL ORGANIC PROGRAM

1. The authority citation for 7 CFR part 205 continues to read as follows:

Authority: 7 U.S.C. 6501 – 6522.

Subpart A—DEFINITIONS

2. Amend § 205.2 by adding a new definition for “Biodegradable biobased mulch film” in alphabetical order to read as follows:

§ 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).

* * * * *

3. Add § 205.3 to subpart A to read as follows:

§ 205.3 Incorporation by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, we must publish notice of change in the Federal Register and the material must be available to the public. All approved material is available for inspection at the USDA Agricultural Marketing Service, National Organic Program, 1400 Independence Avenue SW, Washington, DC 20250; (202) 720-3252, and is available from the

sources listed below. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741-6030 or go to

http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(b) ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428; phone 1-877-909-2786; <http://www.astm.org/>.

(1) ASTM D5988-12 (“ASTM D5988”), “Standard Test Method for Determining Aerobic Biodegradation of Plastic Materials in Soil,” approved May 1, 2012, IBR approved for § 205.2

(2) ASTM D6400-12 (“ASTM D6400”), “Standard Specification for Labeling of Plastics Designed to be Aerobically Composted in Municipal or Industrial Facilities,” approved May 15, 2012, IBR approved for § 205.2.

(3) ASTM D6866-12 (“ASTM D6866”), “Standard Test Methods for Determining the Biobased Content of Solid, Liquid, and Gaseous Samples Using Radiocarbon Analysis,” approved April 1, 2012, IBR approved for § 205.2.

(4) ASTM D6868-11 (“ASTM D6868”), “Standard Specification for Labeling of End Items that Incorporate Plastics and Polymers as Coatings or Additives with Paper and Other Substrates Designed to be Aerobically Composted in Municipal or Industrial Facilities,” approved February 1, 2011, IBR approved for § 205.2.

(c) European Committee for Standardization; Avenue Marnix, 17- B-1000 Brussels; phone 32 2 550 08 11; www.cen.eu.

(1) EN 13432:2000:E (“EN 13432”), September, 2000, “Requirements for packaging recoverable through composting and biodegradation – Test scheme and evaluation criteria for the

final acceptance of packaging,” IBR approved for § 205.2.

(2) EN 14995:2006:E (“EN 14995”), December, 2006, “Plastics – . Evaluation of compostability – Test scheme and specifications,” IBR approved for § 205.2.

(d) International Organization for Standardization, 1, ch. de la Voie-Creuse, CP 56, CH-1211 Geneva 20, Switzerland; phone 41 22 749 01 11; www.iso.org.

(1) ISO 17088:2012(E), (“ISO 17088”), “Specifications for compostable plastics,” June 1, 2012, IBR approved for § 205.2.

(2) ISO 17556:2012(E) (“ISO 17556”), “Plastics – Determination of the ultimate aerobic biodegradability of plastic materials in soil by measuring the oxygen demand in a respirometer or the amount of carbon dioxide evolved,” August 15, 2012, IBR approved for § 205.2.

Subpart G—ADMINISTRATIVE

4. Amend § 205.601 by adding paragraph (b)(2)(iii) to read as follows:

§ 205.601 Synthetic substances allowed for use in organic crop production.

* * * * *

(b) * * *

(2) * * *

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

* * * * *

5. Amend § 205.606 by:

A. Removing paragraph (l);

B. Redesignating paragraphs (m) through (aa) as (l) through (z) respectively;

C. Removing newly redesignated paragraph (v)(2); and

D. Further redesignating newly redesignated paragraph (v)(3) as (v)(2).

Rex A. Barnes
Associate Administrator
Agricultural Marketing Service

[FR Doc. 2014-23135 Filed 09/29/2014 at 8:45 am; Publication Date: 09/30/2014]