Response to Comments
Classification of Materials

This document summarizes comments received on the draft guidance document, "Classification of Materials (NOP 5033)," which was posted on the AMS website for public comment. The public was notified of the availability of the draft guidance in a Federal Register notice on April 2, 2013 (78 FR 19637).

- ***CHANGES MADE IN RESPONSE TO COMMENTS***

The following changes were made to the sections of NOP 5033, Classification of Materials, and the decision trees, NOP 5033-1 and 5033-2, in response to comments.

4.5 Materials Derived from Agricultural Products (NOP 5033)

One comment requested that the term "enzymolysis" replace the terms "enzymatic hydrolysis" and "enzymatic digestion" on the basis that enzymes have a variety of functions, in additional to hydrolysis. We agree with the commenter and have updated the final guidance with the term "use of enzymes." We have also included a definition for the term "enzyme" in NOP 5033-1 and 5033-2. We believe this addresses the comment while also further simplifying the text.

4.8 Burning or Combustion (NOP 5033)

In response to comments, we have clarified that pyrolysis may be treated as equivalent to burning or combustion for purposes of classification of materials. We do not agree with comments that stated pyrolysis is the same as combustion, since pyrolysis occurs in the absence of oxygen; however, we agree with the majority of commenters that the process should be treated as equivalent to the burning of materials. Although all of these processes result in chemical change, burning (e.g., combustion) and other forms of heating biological matter have traditionally been classified as nonsynthetic processes for purpose of classification of materials.

Extractants in Synthetic/Nonsynthetic Decision Tree (NOP 5033-1)

Several commenters indicated that a step on the decision tree NOP 5033-1 was needed to distinguish extraction steps, including whether synthetic extractants are removed. We have adopted the suggestion and added this information to the decision tree.

Agricultural / Nonagricultural Decision Tree (NOP 5033-2)

We have adopted a commenter's suggestion to rephrase one of the questions on the decision tree as "Is the substance derived from crops or livestock?" We have amended the text for the final guidance to include both crop and livestock products, as well as substances derived from crops or livestock.

Definition of Nonagricultural Substance (NOP 5033-2)

Several comments referred to the definition of "nonagricultural substance" as defined under section 205.2 of the USDA organic regulations, which includes various examples of nonagricultural substances. In response, we have added a step in the decision tree to clarify that substances listed as examples in this definition are classified as nonagricultural. If these examples are later determined to be incorrectly classified, a rule change would be needed to amend the definition of "nonagricultural substance" at section 205.2.

Microorganisms, bacteria, yeast, enzymes, and their products (NOP 5033-2)

Several commenters expressed concerns about the classification of microorganisms, bacteria, yeast, enzymes, and products of microorganisms and enzymes. The draft guidance appeared to classify these substances as agricultural; however, many of these substances have been previously classified as nonagricultural by the National Organic Standards Board (NOSB). In addition, one commenter cited the inclusion of "bacterial culture" as an example specifically provided under the definition of "nonagricultural substance" at section 205.2 of the USDA organic regulations.

One commenter noted the distinction between microorganisms and fermented agricultural products and supported the continued classification of microorganisms as nonagricultural. One commenter preferred the current decision tree where enzymes are considered agricultural.

One commenter expressed concerns about the possible classification of citric acid, propionic acid, lactic acid, DHA, yeast, enzymes and other microorganisms as agricultural.

Several commenters noted the potential impact of this classification on livestock feed ingredients. There were concerns that the classification may conflict with NOP Guidance 5030 on evaluating livestock feed additives, and that this interpretation would result in prohibition of currently allowed nonsynthetic livestock feed additives.

NOP has amended the decision tree to clarify that these substances are classified as nonagricultural. This change is consistent with the majority of commenters' suggestions and is also consistent with previous classification decisions made by the NOSB on these substances. The changes also align the guidance with the definition for nonagricultural substance at section 205.2 of the USDA organic regulations.

Enzymes (NOP 5033-2)

One commenter requested that the term "enzymes" be removed as a starting substance in the decision tree. The commenter indicated that the substance is not an organism. NOP agrees that enzymes are not organisms and made this distinction in the decision tree. We have also included a definition of the term "enzyme" for additional clarity.

One comment requested that the definition of nonagricultural substance in section 205.2 of the USDA organic regulations be incorporated as a question in the decision tree. We have adopted the commenter's suggestion on this topic.

Aquaculture Products (NOP 5033-2)

Several comments expressed concerns about the classification of algae and aquaculture products. Commenters noted that there has been inconsistency in their classification in the past.

One comment requested that NOP clarify that algae that are microorganisms or bacteria be classified as nonagricultural and nonsynthetic, unless specifically listed as agricultural on section 205.606 of the National List. The commenter indicated that large aquatic seaweeds should remain classified as agricultural as listed on section 205.606.

We recognize that some aquatic plants (e.g., Pacific kombu, wakame) have been classified as agricultural on the National List. We also understand that some types of algae may be considered microorganisms, and thus, non-agricultural according to the decision tree at NOP 5033-2.

We have also added an asterisk (*) to the decision tree to clarify that in the absence of standards for organic aquatic animal production, products derived from aquatic animals (e.g., fish and crab meal) may be considered non-agricultural when used as livestock feed additives.

A request for additional public comment on the use of algae as a livestock feed additive will be solicited in draft guidance on Materials for Organic Livestock Production, which is currently in development.

- ***CHANGES REQUESTED BUT NOT MADE***

Additional Comment Period

Two comments requested that NOP reissue a revision of the guidance for an additional comment period. NOP has not accepted this request. Instead, the Office of Management and Budget (OMB) Good Guidance Policy allows for commenters to submit comments on guidance at any time; therefore, we did not feel an additional period for consideration of draft guidance was warranted.

Process Considerations

One commenter requested that classification be returned to the NOSB for further work. NOP does not see the need to postpone this guidance; however, we look forward to further collaboration with the NOSB on additional areas that may need to be addressed in future updates.

4.4 Eligibility for Organic Certification (NOP 5033)

We received comments regarding the statement included at section 4.4 of NOP 5033 that this guidance does not determine the eligibility for organic certification. The commenter indicated that agricultural substances listed at 205.606 should be eligible for organic certification and that nonagricultural substances listed at 205.605 should not be eligible for organic certification.

Another commenter provided information on the certification of nonagricultural substances and indicated that this would cause harm to organic integrity. The commenter suggested that any allowance to certify a nonagricultural substance should be specifically granted by the NOSB.

Another commenter urged NOP to clarify that NOP 5033 is to be used as a tool for the NOSB, accredited certifying agents and material review organizations to clarify the status of a substance prior to a decision about either certification or use as an allowed crop, livestock, or processing input.

We understand that this is a complicated topic due to the diversity of organic production and processing practices. In addition, some substances listed at section 205.605 have been certified organic, including natural flavors, yeast, and glycerin. As such, we believe that the eligibility of a substance for organic certification should be determined by the certifying agent in the course of reviewing the organic system plan. Any alternative approach may hinder innovation of new organic products and impact products that are currently certified. We have therefore retained the language to clarify that the eligibility for organic certification is outside of the scope of this guidance.

4.5 Materials Derived from Agricultural Products (NOP 5033)

One comment requested that the parenthetical examples of “cooking, baking, etc.” be removed and replaced with a reference to section 205.270(a). We have not accepted the commenter’s suggestion. The purpose of this section is to describe various types of chemical reactions. Some of the mechanical methods included at section 205.270(a) do not necessarily involve chemical reactions, such as separating, cutting, mixing, packaging, etc.; therefore, adoption of this reference to section 205.270(a) could lead to confusion.

One commenter noted that the section on processing methods for certified organic foods be moved to section 4.3. We have not adopted the commenter’s suggestion on this topic, as other types of processed agricultural products may also be eligible for use as a crop or livestock input.

One comment also indicated that fermentation or use of enzymes is not automatically natural (nonsynthetic) if it occurs due to microorganisms or enzymes that are not found in nature. NOP notes that the use of microorganisms or enzymes derived from excluded methods (e.g., genetically modified organisms) is already prohibited under section 205.105(e) of the USDA organic regulations. Therefore, additional amendment to the text was not needed.

4.6 Extraction of Nonorganic Materials (NOP 5033)

One commenter requested that volatile synthetic solvents not allowed under section 205.605 be clearly and specifically excluded in the reference to "any synthetic material used to separate, isolate, or extract…" We have not adopted the commenter's suggestion. *Nonorganic* materials used in production and handling are not subject to restrictions on extraction materials that apply to organic ingredients unless specified by the regulations. For example, the allowance of colors derived from agricultural products specifically states this prohibition on synthetic solvents at section 205.606.

Some commenters requested additional clarification and/or removal of the term "technical or functional effect" under section 4.6. One commenter noted that this review cannot be accurately done before a material review has taken place. Some commenters also requested removal of these terms due to the absence of a regulatory definition. One commenter provided a definition for "removal" and "technical and functional effect." We have not adopted the suggested definition for removal, whereby "a residue of a substance is removed if it, its reaction products, and its metabolites, cannot be detected after the removal process." The ability to detect a substance is variable and dependent on the several factors, including the chemical, test method, and instrument sensitivity. As such, we do not agree with the inclusion of this definition. We believe the adopted text is more consistent with previous classification decisions made by the NOSB and current practices used by accredited certifying agents and material review organizations.

4.7 Products of Naturally Occurring Biological Processes (NOP 5033)

One commenter noted that microorganisms or enzymes grown on synthetic substrates should be classified as synthetic. We understand the commenter's position; however, we note that this interpretation is not consistent with previous NOSB reviews of microorganisms. We suggest that parties interested in the reclassification and/or annotation of nonsynthetic microorganisms (e.g., bacteria, fungi, yeast, dairy cultures, etc.) or nonsynthetic enzymes to exclude synthetic substrates in their manufacturing process submit a petition to the NOSB for further review according to the National List petition process.

One commenter suggested additional clarification of section 4.7 to include an evaluation of the substrates. The commenter indicated that the process can only be considered "naturally occurring" if all substrates in the fermentation process are natural materials themselves. As indicated above, this interpretation is inconsistent with previous NOSB classification of these materials and was not adopted in the final guidance.

One comment indicated that there are no standards for certification of products of fermentation or clear criteria for determining which products of fermentation are agricultural or nonagricultural and which are synthetic or non-synthetic. NOP is unclear on the need for

additional guidance on fermentation processes at this time. Where the classification of a substance is unclear, the substance can be petitioned to the NOSB for further review.

One commenter suggested that the interpretation of the term "naturally occurring biologically processes" should include natural soil processes and plant derived exudates. We believe the guidance does not prohibit this interpretation and have retained the text as written.

4.8 Burning or Combustion (NOP 5033)

One commenter noted that some clays that are heated to high temperature (e.g., vermiculite or perlite) continue to be classified as nonsynthetic. We agree with the comments and believe that the guidance is clear on this issue.

One commenter indicated that pyrolysis should not be included, since it can be used to produce substances that are not typically identified as natural products. This commenter suggested that affected products should be petitioned to the NOSB for such classification. We understand that accredited certifying agents and material review organizations have not adopted this interpretation when reviewing materials and that this interpretation may disrupt the use of materials which are currently allowed in organic production and handling. Parties wishing to prohibit the use of these materials are encouraged to submit a petition to the NOSB for further consideration.

One commenter requested feedback on whether it was NOP's intent with this decision tree to leave it up to the end user to determine at what heat level chemical change is caused for non-biological minerals. This is not NOP's intent. In cases where the classification of a substance is unclear from the guidance, and when the substance has not been previously classified by the NOSB, the substance can be petitioned for review by the NOSB.

Another commenter also noted that combustion is not a naturally occurring biological process, but it is allowed. We agree that not all forms of combustion are naturally occurring processes; however, we have retained the text to be consistent with prior NOSB decisions on this issue.

NOP does not intend for all forms of heating to change the classification of a material. For heated materials where the classification is unclear, interested parties are encouraged to submit a petition to the NOSB so that the issue can be further reviewed.

5.2 Inputs for Organic Livestock Production (NOP 5033)

Several commenters indicated that the decision tree for agricultural/nonagricultural substances seems to classify aquaculture products, such as fish oil, as agricultural. They indicated that this is problematic for organic livestock feed requirements, since the USDA organic regulations do not include aquaculture standards at this time. One commenter indicated that poultry producers are considering aquaculture products such as fish and crab meal as an alternative to synthetic

methionine. We understand that this is an issue for organic livestock producers that may be using these nonsynthetic materials as feed additives.

We have added an asterisk (*) to the decision tree to clarify that in the absence of standards for organic aquatic animal production, products derived from aquatic animals (e.g., fish and crab meal) may be considered non-agricultural when used as livestock feed additives.

Other comments on the use of inputs for organic livestock production will be solicited in draft guidance on Materials for Organic Livestock Production, which is currently in development.

Synthetic/Nonsynthetic Decision Tree (NOP 5033-1)

One comment requested that the decision trees should clarify the review of other ingredients added to, but not fully removed, from the final product. For purposes of classification of materials as synthetic or nonsynthetic, we believe that the guidance sufficiently addresses this issue.

One commenter indicated that chemical changes that result from mechanical processes or action of water would be considered non-synthetic but are not mentioned. We believe that the guidance is adequate to address mechanical processing (e.g., physical processes). In cases where the classification of the substance is unclear, interested parties are encouraged to submit a petition to the NOSB so that the material can be reviewed.

Agricultural/Nonagricultural Decision Tree (NOP 5033-2)

We have not adopted one commenter's suggestion to amend the term "animal" to "terrestrial animal" in NOP 5033-2 and believe that the changes described above regarding aquaculture products address this issue.

One commenter suggested inclusion of an asterisk next to the "Agricultural/Nonagricultural'' box to denote that any auxiliary (ancillary) ingredients or processing aids present in the final material should be evaluated to the NOP regulations and policy.

As the issue of ancillary substances in organic handling is currently under review by the NOSB, we have not amended this guidance to provide further information on this topic at this time. We may consider revisions in the future based on the outcome of the NOSB review on this topic.

Classification of Flavors

One comment supported the current classification of flavors as nonagricultural on section 205.605 on the National List. Since publication of the draft guidance, the NOSB also issued a recommendation on flavors, which recognizes the availability of nonsynthetic and organic

flavors. We believe the current guidance and text included at section 4.4 adequately addresses this comment.

One comment requested inclusion of a Natural Flavor Questionnaire in the Program Handbook to assist in verifying material compliance with the National Organic Program. As this is outside the scope of this guidance, we have not adopted the commenter's suggestion.

- ***OTHER***

Reclassification of Materials on the National List

Some commenters noted that some materials may need to be reclassified by the NOSB. Other comments noted that NOP may not reclassify a material as nonsynthetic that has already been classified by the NOSB as synthetic.

One commenter noted that a substantial phase-in time should be provided for producers and certifiers to come into compliance with the reclassification.

As previously noted, NOP has made edits to the draft decision tree to reflect the classification of microorganisms, bacteria, yeast, etc. as nonsynthetic and nonagricultural, rather than agricultural. We believe that adoption of this suggestion from commenters will minimize impacts on organic operations and is consistent with previous recommendations of the NOSB. This guidance is not intended to modify existing NOSB classifications. Further, any reclassification of substances that are on the National List (e.g., moving substances from section 205.605 to 205.606) must be recommended by the NOSB and would be subject to notice and comment rulemaking.

We encourage parties interested in the reclassification of any materials to submit a petition to the NOSB according to the National List petition guidelines.

Ancillary Substances, Processing Aids, and Other Ingredients

Commenters had varied opinions on the need to include additional information on other ingredients used to formulate or manufacture materials for organic production and handling. Some commenters suggested that this issue be considered separate from the classification of materials.

One commenter indicated that the decision trees were adequate to address single-substance generic materials but they do not address situations where additional ingredients are added to the material and may affect the classification of the substance as synthetic or nonsynthetic. One commenter indicated that when synthetic ingredients are added to a nonsynthetic material the entire substance should be classified as synthetic.

One commenter suggested inclusion of an asterisk next to the 'Nonsynthetic (Natural)' box to denote that any auxiliary (ancillary) ingredients or processing aids present in the final material should be evaluated to the NOP regulations and policy.

As the issue of ancillary substances in organic handling is currently under review by the NOSB, we have not provided further information in this guidance on this topic at this time. In addition, we have removed the previous entry for "enzymes" in Table 1 of NOP 5033-1 in order to reduce confusion. We may consider revisions in the future based on the outcome of the NOSB review on this topic.

- ***DEFINITIONS***

The following changes to definitions were not made to sections of NOP 5033, 5033-1, or 5033-2 in response to comments for the reasons provided.

Chemical Change

One commenter noted that the definition of "chemical change" may not align with the definition of "substance," i.e., that "chemical change" has been linked to "substance change." We have considered the comment, along with the examples provided, and have retained the definition as originally proposed.

Extract

One comment noted that the NOP definition of "extract" included acid-base extraction, which was not included in the NOSB recommendation, and proposed additional edits. We have not adopted the commenter's suggestions, as the current text is consistent with past classification decisions made by the NOSB, accredited certifying agents, and material evaluation programs.

Natural Source

Some commenters noted that the new term "natural source" was not defined by the NOSB and that the NOP's definition is circular. The alternative definition of "natural source" as "non-anthropogenic organic or inorganic matter" was suggested. The comment also noted that mineral is generally used to mean an inorganic solid material and would not include gaseous materials. The comment also noted that genetically engineered organisms should be explicitly excluded. We believe that the amendments to the decision tree above are adequate to address these issues. In addition, genetically engineered organisms are already prohibited under other sections of the USDA organic regulations.

Naturally Occurring Biological Processes

One commenter requested that the definition should indicate that a naturally occurring biological process does not involve synthetic materials in any way. Examples included adding synthetic chemicals to adjust pH or to provide nutrients for fermentation. We have not adopted the commenter's suggestion, as we believe this interpretation is inconsistent with the intent of the NOSB recommendation on this topic.

Nonsynthetic

One commenter requested an amendment to the definition of nonsynthetic to clarify that nonsynthetic should include substances that are chemically identical to those produced by plants and are used identically by the plant. NOP has not accepted this change, as the definition of nonsynthetic is previously defined under the USDA organic regulations at section 205.2. In addition, the classification guidance is consistent with previous recommendations by the NOSB that classify substances based on their production method, rather than by comparison with naturally occurring forms of the substances.

Substance

One commenter noted that the definition for substance was broader than the definition that was recommended by the NOSB. The commenter noted that they supported the definition in the draft guidance, but that it causes problems relative to the definition of chemical change. We have noted the comments on both definitions and retained the definitions of "substance" and "chemical change" as originally published.