



BEYOND PESTICIDES

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March 29, 2017

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Ave., SW
Room 2648-S, Mail Stop 0268
Washington, DC 20250-0268

Re. MS: Materials Classification Guidance and Next Steps

These comments to the National Organic Standards Board (NOSB) on its Spring 2017 agenda are submitted on behalf of Beyond Pesticides. Founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers and farmworkers, Beyond Pesticides advances improved protections from pesticides and alternative pest management strategies that reduce or eliminate a reliance on pesticides. Our membership and network span the 50 states and the world.

The final NOP guidance on materials classification fails to provide the solution we were anticipating. The guidance is still incomplete –lacking a clear criterion for the removal of extractants, a non-circular definition of “natural source,” and policies on products of fermentation, pyrolysis, and the addition of synthetics to nonsynthetics. In addition, policies are needed on how the NOSB should deal with materials that may be either synthetic or nonsynthetic and the preference for nonsynthetics over synthetics. Some specific materials have been highlighted for NOSB attention.

NOP’s Final Guidance on Materials Classification

What’s new?

In most respects, the final guidance document (NOP 5033) is substantially the same as the draft, but there are some changes:

- Extraction has been added to the synthetic/nonsynthetic decision tree.
- Microorganisms or enzymes would have been agricultural if produced on an agricultural substrate under draft; under final, will be nonagricultural.
- Products of pyrolysis of nonsynthetic materials are now nonsynthetic. This includes biochar as well as liquid or gaseous synfuels.

- The response to comments adds a new interpretation that products of fermentation that are grown on synthetic substrates can be classified as nonsynthetic.

The guidance is incomplete.

The guidance does not provide a clear criterion for the removal of synthetic extractants.

The guidance says,

For purposes of classification of a material as synthetic or nonsynthetic, a material may be classified as nonsynthetic (natural) if the extraction or separation technique results in a material that meets all of the following criteria:

- At the end of the extraction process, the material has not been transformed into a different substance via chemical change;
- The material has not been altered into a form that does not occur in nature; and
- Any synthetic materials used to separate, isolate, or extract the substance have been removed from the final substance (e.g., via evaporation, distillation, precipitation, or other means) such that they have no technical or functional effect in the final product.

The guidance does not define “technical or functional effect.” NOP argued against an alternative definition of removal proposed by a commenter, “a residue of a substance is removed if it, its reaction products, and its metabolites, cannot be detected after the removal process.” NOP said, “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.”

Although detection methods may vary, the ability to detect a residue is a clearly defined criterion, unlike the dependence on an undefined term.

The Fall 2015 debate over laminarin demonstrates a need for a definition.

The laminarin proposal from the Crops Subcommittee stated:

The reaction and filtration steps result in a purified laminarin in which the sodium and sulfate ions do not have a technical or functional effect. This is quite different than the listing for aquatic plant extracts that are classified as synthetic for crop production at 205.601(j)(1). In those the extracting agents such as potassium hydroxide does leave behind enough potassium to have a functional effect as a fertilizer. In laminarin, neither the sodium (at 0.001%) nor the sulfate ions (at 0.0034%) have a functional effect for disease suppression.

At the time, Beyond Pesticides maintained:

The fact that sodium and sulfate ions do not affect disease suppression does not mean that they have no technical or functional effect. We do not know what other technical or functional effects the sulfate and sodium/potassium might have on laminarin. Are they preservatives? Sodium sulfate is used as a viscosity modifying agent in cosmetics. The scientific literature review *Safety Assessment of Inorganic Sulfates as Used in Cosmetics* performed by Cosmetic Ingredient Review¹ (CIR) states that sodium sulfate is used as a viscosity-control agent. Does the concentration found in laminarin perform this effect? Table 3 of the CIR report (attached) indicates that the answer is “yes.”

A definition of “removal” that does not depend on undefined terms could give a rational basis for the resolution of such disagreements.

The lack of clarity extends to other extraction criteria for nonsynthetic materials. One is “The material has not been altered into a form that does not occur in nature.” Since NOP rejected the request that the decision trees clarify the review of other ingredients added to, but not fully removed from, the final product, this criterion is also vague.

Decision tree

Finally, the definition of “natural source” (naturally occurring mineral or biological matter), which begins the synthetic-nonsynthetic decision tree is circular.

NOP punts to the NOSB.

Materials classification guidance had been a project of the Materials Subcommittee (MS) of the NOSB until NOP took it off the MS work agenda in 2012. NOP issued draft guidance in 2013, and ever since, the NOSB has awaited final guidance, postponing addressing some classification questions because the final guidance was imminent. Now the final guidance may leave questions for the NOSB to resolve. Among the issues postponed are classification of some forms of tocopherols based on extraction method, and of carrageenan and xanthan gum based on manufacturing process. Although the NOSB voted to sunset carrageenan, a reclassification as synthetic could ensure that the NOSB decision is binding on NOP.

In addition to the incompleteness due to missing or inadequate definitions, NOP has suggested in its response to comments that those who find the guidance incomplete or otherwise unsatisfactory should petition the NOSB for a resolution:

- “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

¹ Cosmetic Ingredient Review, 2013. *Safety Assessment of Inorganic Sulfates as Used in Cosmetics*, <http://www.cir-safety.org/sites/default/files/inorgs032014slr.pdf> (The 2013 Cosmetic Ingredient Review Expert Panel members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; Curtis D. Klaassen, Ph.D.; Daniel C. Liebler, Ph.D.; Ronald A Hill, Ph.D. James G. Marks, Jr., M.D.; Ronald C. Shank, Ph.D.; Thomas J. Slaga, Ph.D.; and Paul W. Snyder, D.V.M., Ph.D. The CIR Director is Lillian J. Gill, D.P.A. This report was prepared by Wilbur Johnson, Jr., M.S., Senior Scientific Analyst and Bart Heldreth, Ph.D., Chemist.)

submit a petition to the NOSB for further review according to the National List petition process.”

- “Where the classification of a substance is unclear, the substance can be petitioned to the NOSB for further review.” [products of fermentation]
- “Parties wishing to prohibit the use of these materials are encouraged to submit a petition to the NOSB for further consideration.” [Pyrolysis]
- “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.” [heating nonagricultural substances]
- “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.”
- “We encourage parties interested in the reclassification of any materials to submit a petition to the NOSB according to the National List petition guidelines.” “This guidance is not intended to modify existing NOSB classifications.”
- “One commenter indicated that when synthetic ingredients are added to a nonsynthetic material the entire substance should be classified as synthetic.” “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.” [Is this a response? It appears to be intended as such.]
- “We have also replaced the term “feedstocks” with “sources,” and included “animal material” as an allowed source, as requested by commenters. We have considered that the inclusion of “animal material” may raise questions about the allowance of manure as a feedstock for biochar, since the use of ash from manure burning is prohibited under section 205.602(a) of the USDA organic regulations. Although the pyrolysis process for biochar production is different than burning, we clarified in NOP 5033, Classification of Materials, that, for purposes of classification, pyrolysis may be treated as equivalent to burning or combustion. As the issue of biochar has not been considered by the NOSB, we are not providing clarification at this time on whether the use of biochar derived from manure is appropriate for organic production.” [5034-3]
- “Parties interested in further consideration of corn gluten are encouraged to submit a petition to the NOSB according to the National List petition guidelines.” [5034-3]

Moving Forward

Issues left unresolved.

As noted above, the NOP guidance is incomplete. Here we suggest some policies that the NOSB should adopt to provide more complete guidance.

Provide a clear criterion for the removal of synthetic extractants.

The criterion in the NOP guidance depends on undefined terms –technical and functional effects. In addition to lacking clarity, this criterion does not make sense in the

context of materials classification. A material is synthetic or nonsynthetic based on its characteristics and the process by which it is manufactured. The effects of synthetic contaminants are not relevant to classification –although the effects may point out the importance of the classification.

Provide a non-circular definition of “natural source.”

If “naturally occurring mineral or biological matter” needs no further definition, then “natural source” also needs no definition. Perhaps “natural source” could be defined as “mineral or biological matter derived from a non-anthropogenic source.”

Clarify products of fermentation.

Fermentation processes produce foods or food ingredients in several ways:

1. **Foods and ingredients that are organisms grown by fermentation—that is, the biomass produced by the fermentation process.** These include nutritional yeast and baking yeast. Yeast may be certified organic when produced in compliance with an approved organic systems plan.² Marroquin International petitioned to have yeast reclassified as agricultural and listed on §205.606. It made the argument that yeast, like mushrooms, should be considered livestock under OFPA. “Microorganisms” are listed on §205.605(a).
2. **Food processing changes raw agricultural ingredients into new products defined by the products of fermentation.** These include wine, beer, vinegar, lactic acid pickles, yogurt, and miso.
3. **Production of food additives through fermentation of specific strains of microorganisms.** These include nucleotides, various vitamins, etc. that are isolated from the products of fermentation. They may be either **primary metabolites** –substances produced by the fermenting organism that are essential to its growth, such as nucleotides, nucleic acids, amino acids, proteins, carbohydrates, lipids, etc.—or **secondary metabolites** –which have no obvious role in the metabolism of the cultured organisms, such as antibiotics and other drugs.

There are products of fermentation permitted in organic food in all of these categories.

Materials on §205.605(a) that are products of fermentation include:³

1. Food organisms: yeast.
2. Fermented foods do not need to be listed, but yeast, microorganisms, and dairy cultures, which are the agents that ferment the food, are listed.

² NOP, Certification of Organic Yeast. NOP 5014 issued March 2, 2010.

³ Materials on §205.605(a) that are up for sunset in 2016 are addressed in separate comments. Those up for sunset in 2017 are addressed below.

3. Metabolites: L-lactic acid, citric acid, L-malic acid, gellan gum, glucono delta-lactone, enzymes.

Materials on §205.605(b) that are products of fermentation include metabolites:⁴ glycerin, xanthan gum, various vitamins that may be produced by fermentation (B2, B12, C, D2, E, K2, biotin, and some combinations).

Finally, there are metabolites of fermentation listed on §205.606:⁵ fructooligosaccharides (FOS), Inulin –oligosaccharide enriched (IOE), whey protein concentrate.

Classification: agricultural vs. nonagricultural

The fact that products of fermentation are included on three different lists for processing is a sign that the classification of products of fermentation needs to be clarified. In particular, the Handling Subcommittee (HS) stated, “Glycerin, produced organically by fermentation is an agricultural product as defined in 7 CFR 205.2, since it is a processed product produced from an agricultural commodity, e.g. cornstarch.”⁶ This is also consistent with the NOP classification decision tree, which preserves the nonagricultural classification through fermentation. However, it is not consistent with the definition of a “nonagricultural substance” in the regulations.

The regulations define “agricultural products” (following the OFPA definition) and “nonagricultural” (without a definition in OFPA) in §205.2:

Agricultural Products. Any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock that is marketed in the United States for human or livestock consumption” (§2103(1)).

Nonagricultural substance. A substance that is not a product of agriculture, such as a mineral or a bacterial culture that is used as an ingredient in an agricultural product. For the purposes of this part, a nonagricultural ingredient also includes any substance, such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction. [Emphasis added.]

Perhaps some of the inconsistency in the classification of materials as agricultural or nonagricultural could be resolved by asking, “What makes a product of fermentation agricultural?” If the product of fermentation is agricultural, then it can be certified organic, and we need to define acceptable practices in organic fermentation processes.

⁴ These materials are all addressed in our comment on materials on §205.605(b) that have uses prohibited by §205.600(b)(4).

⁵ Materials on §205.606 are addressed in comments on that section.

⁶ NOSB Handling Subcommittee proposal for glycerin, October 14, 2014.

NOP policy on organic yeast allows yeast to be a certified organic nonagricultural ingredient. Following that approach would allow other organic substances on 205.605(a). It is tempting to view yeast and other products of fermentation as agricultural. Issues surrounding the classification and listing of food additives produced by fermentation or extracted from fermentation products would be easier to resolve if fermentation processes were regarded as agricultural production systems. It may be argued that defining what organic production means in the context of vat fermentation is no more difficult than defining organic aquaculture.

However, the NOSB has been clear that soil-less systems are not organic.⁷ Organic agriculture is premised on a belief that the foundation of healthy plants and animals is healthy soil. This, indeed, is a problem in defining organic aquaculture.

Thus, the materials classification guidance, which treats fermentation as a processing method that does not change the classification of the substrate from agricultural to non-agricultural only works if both the substrate and the product of fermentation meet the definition of agricultural, and not nonagricultural substances. Thus pickles, wine, and cheese are all agricultural, but substances whose relationship to the substrate is unrecognizable – such as glycerin, as a product of fermenting cornstarch—are nonagricultural. Fructooligosaccharides (FOS), a product of fermenting glucose, and inulin enriched with oligosaccharides (which contains FOS) are also inappropriately listed on §205.606 because they are nonagricultural.

Classification: Synthetic vs. Nonsynthetic

The classification of some “nonsynthetic” substances needs to be revisited. For example, citric acid and L-lactic acid were originally added to the National List based on TAP reviews that gave a simplified version of their production using fermentation. Commercial production of these acids, however, involves synthetic chemical reactions that were not considered in the original classification decision.

Other issues

A number of products of fermentation that are on the National List may be made using genetically engineered organisms or genetically engineered substrate. Both of these issues should be addressed by annotation or in a general policy.

In some cases, fermentation may create undesirable byproducts. The TAP review for glucono delta-lactone, for example, recommended annotating to ensure that it is not produced by a strain that produces a toxin. (This was not included in the listing.)

Clarify pyrolysis and heating of non-agricultural substances.

NOP, while stating that pyrolysis is not the same as combustion, also says, “For purposes of classification of materials, pyrolysis (i.e., high temperature decomposition of substances in the absence of oxygen) may be treated as equivalent to burning or combustion.” Other forms

⁷ NOSB recommendation, Production Standards for Terrestrial Plants in Containers and Enclosures (Greenhouses), April 29, 2010.

of chemical change by heating –for example, production of quicklime by heating limestone to release carbon dioxide– are treated as synthetic processes. It is not at all clear why heating minerals should be treated as a synthetic process, while all forms of heating biological matter are treated as nonsynthetic processes. Since NOP encourages those who disagree to petition the NOSB, the NOSB needs clarity on the issue.

Does a nonsynthetic material become synthetic if a synthetic substance is added?

NOP has responded to this issue as if it were equivalent to ancillary substances. In fact, many processes for producing petitioned substances involve the addition of synthetic substances (with or without a “removal” step). This issue needs to be addressed directly.

Some specific substances have been highlighted.

The NOP guidance highlights the need to address the classification of corn gluten and biochar from manure.

Corn gluten

NOP mentions the issue of classification of corn gluten from wet corn milling, as raised by commenters, but does not give a specific response, saying only, “We have retained classification as nonsynthetic due to the historical consideration of corn gluten as nonsynthetic; however, further consideration of this issue may be warranted by the NOSB. Parties interested in further consideration of corn gluten are encouraged to submit a petition to the NOSB according to the National List petition guidelines.” This does not base the decision on the classification guidance.

Biochar

In its response to comments on NOP 5034, NOP raises a number of issues relating to biochar. First, it is produced by pyrolysis, and as noted above, the NOSB needs to address pyrolysis as an issue. Second, although ash from manure burning is prohibited, NOP permits biochar produced by pyrolysis of manure. Although NOP states, “As the issue of biochar has not been considered by the NOSB, we are not providing clarification at this time on whether the use of biochar derived from manure is appropriate for organic production,” biochar from manure is not prohibited in NOP 5034. Thus, not only the classification of biochar, but also the question of whether it should be on §205.602 as a prohibited natural substance (if it is classified nonsynthetic) should be addressed by the NOSB.

MS Notes from December 13, 2016

The notes from the December 13, 2016 MS/GMO Subcommittee meeting say,

Classification of Materials guidance document (All). The guidance was recently published and the MS members discussed such things as how to classify a generic material that is produced in numerous ways, which can result in both a synthetic and nonsynthetic forms. For example, materials like xanthan gum and tocopherols, which may be produced both synthetically and non-synthetically, but that are listed on

205.605(b). The MS will discuss whether or not the NOSB should develop a policy about this. A member noted that annotations can complicate things and strongly encouraged members to simplify the list for certifiers, inspectors, and clients. Another member noted that NOSB members submitted comments on the draft Classification of Materials guidance document when it was first published, and it would be useful to review those comments and compare them to what was actually adopted. She suggested that the classification of materials guidance specify the policy regarding the use of non-synthetic versions of synthetic materials on the National List.

Classifying a generic material that is produced in numerous ways.

Given the confusion that is caused by the placement on the National List of a material that may be synthetic or nonsynthetic, the NOSB should develop policy to address such situations. In particular, NOSB subcommittees should not accept that all producers of a material will use the same manufacturing methods as the petitioner. Some manufacturing methods, even if they do not result in a change of classification, may be more acceptable than others. Technical reviews should investigate different manufacturing methods, and if some are more acceptable than others, then the listing should reflect that in an annotation. If some manufacturing methods result in a classification of synthetic, and some result in a classification of nonsynthetic, then the listing(s) should reflect that through annotation.

Annotations.

The notes quoted above say, “A member noted that annotations can complicate things and strongly encouraged members to simplify the list for certifiers, inspectors, and clients.” On the contrary, we believe that annotations clarify NOSB intentions. Such intentions may currently be documented only in the discussion section of a recommendation or in transcripts of NOSB meetings. It is important that material review organizations and certifiers have easy access to the full criteria that distinguish allowed from prohibited materials.

In the case of crop and livestock materials, classification may determine whether a material appears on the National List at all. If the NOSB decides not to list the synthetic form, the Petitioned Substances Database should reflect the decision in the status line, as in: “Synthetic unless made by X process. Not recommended for listing.”

NOP response to MS.

We hope that the review of the final guidance provided at the beginning of these comments will help the subcommittee in its assessment of NOP responses to the Materials Subcommittee comments.

Should the guidance specify the policy regarding a preference for nonsynthetic over synthetic versions of materials?

We agree that the guidance should include, in section 3.1 *The National List of Allowed and Prohibited Substances*, a statement of the preference for nonsynthetic over synthetic versions. Given the difficulty of changing the long-awaited classification of materials guidance,

the policy statement might also be included in the Policy and Procedures Manual, at the beginning of section 4.H *Substance/Material Review Process*. (It is also included in the *NOSB Principles of Organic Production and Handling* in Appendix 1.)

Conclusion

The final NOP guidance on materials classification fails to provide the solution we were all anticipating. The guidance is still incomplete –lacking a clear criterion for the removal of extractants, a non-circular definition of “natural source,” and policies on products of fermentation, pyrolysis, and the addition of synthetics to nonsynthetics. In addition, policies are needed on how the NOSB should deal with materials that may be either synthetic or nonsynthetic and the preference for nonsynthetics over synthetics. Some specific materials have been highlighted for NOSB attention. Beyond Pesticides urges the Materials/GMO Subcommittee to add these issues to its agenda.

Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Terry Shistar".

Terry Shistar, Ph.D.
Board of Directors