Accredited Certifiers Association, Inc.
Accredited certifying agents working together to ensure the integrity of organic certification in the United States

October 26, 2016

Dr. Paul Lewis, Standards Division
National Organic Program
USDA-AMS-NOP
1400 Independence Ave. SW
Room 2646-So., Ag Stop 0268
Washington, DC 20250-0268

Re: AMS–NOP–16–0069; NOP–16–08
NOP 3012 Interim Instruction on Material Review

Dear Dr. Lewis:

Thank you for the opportunity to provide comments to the National Organic Program regarding the Interim Instruction on Material Review. The Accredited Certifiers Association (ACA) is a non-profit educational organization and our membership includes 51 USDA Accredited Certification Agents. We convened a Working Group from our membership to develop our comments; additional comments were also solicited from all our members.

Overview
The ACA appreciates the work of the National Organic Program on 3012 Interim Instruction for Material Review. The ACA supports the NOSB 2011 & 2012 Recommendations on Evaluation of Materials Review Organizations and we believe that the long-term goal of the National Organic Program should be the development of a Materials Review Organization (MRO) accreditation scope. Accreditation would provide the necessary oversight and enforcement of MROs to ensure accuracy and transparency of material review decisions, thus encouraging confidence in their work. We encourage the NOP to continue the work of developing an accreditation scope for Material Review Organizations.

There are several specific issues we have identified where additional clarification is requested. These are noted below.

a) Definitions
The definition of Material Review Organization (MRO) does not contain the requirement for ISO 17065 accreditation. However, in #4 under Policy, in order for an ACA to consult with an MRO, the MRO must be accredited to ISO 17065. As there are many ACAs that would meet the definition of MRO, but which do not have ISO 17065 accreditation, additional clarity would be provided if the definition of MRO also contained the requirement for ISO 17065 accreditation.

b) Section 4, Policy

Section 4, Policy lacks the clarity necessary to utilize this document properly as there is no distinction between the requirements for an ACA conducting their own review of a material and an ACA that accepts the decision of another ACA, an MRO or EPA.

We believe that Section 4 Policy should be divided into the following topics:

4 a) Options for Material Review, beginning with "*Certifiers have several options*," retaining the current sections 1 -4.

4 b) Requirements for Certifiers (beginning at *in all cases, a certifier must;)* and that this be divided into two sections

1. ACA conducting their own review of the material for compliance
2. ACAs accepting the decision of another certifier, or MRO, or EPA

The division will permit more detailed information to be applied to the various options for materials review determinations. Our detailed recommendations for revision of Section 4, Policy is attached in Appendix A.

NOP Interim Instruction on Material Review	ACA General Comments
4. Policy Certifiers must review all materials used by organic producers and handlers for compliance with the USDA organic regulations. *See* 7 CFR § 205.201(a)(2). All certifiers must verify that materials used by certified operations comply with the regulations, including the National List of Allowed and Prohibited Substances, and any annotations provided therein (see 7 CFR §§ 205.601-606). Certifiers have several options available for determining whether materials may be used in organic production or handling under the USDA organic regulations:	
1. Certifiers can verify that the material complies with the regulations by evaluating the product, all of the ingredients within the product, and, if applicable, the manufacturing processes, source materials, and processing aids used to produce the ingredients or final product (e.g., contacting the supplier/ formulator/ manufacturer to obtain full disclosure of the ingredients in the product and manufacturing processes, including processing aids).	We believe this section clearly states the requirements to be addressed when an ACA is reviewing a material for compliance. We also believe this is an area where further guidance from the NOP is needed to ensure consistent and accurate technical review of materials.
2. Certifiers may consult with another certifier who has already evaluated the product and accept that certifier's determination of the product's compliance with the regulations. The Washington State Department of Agriculture, as an accredited certifying agent, has a publicly available list of approved products available at http://agr.wa.gov/FoodAnimal/Organic/MaterialsLists.aspx.	We are in support of this section.

NOP Interim Instruction on Material Review	ACA General Comments
3. Certifiers may accept pesticides that have been determined by the U.S. Environmental Protection Agency (EPA) to comply with the USDA organic regulations.	We are in support of this section.
4. Certifying agents may consult with material review organizations accredited to ISO Guide 17065 (formerly ISO Guide 65). These material review organizations must abide by USDA Agricultural Marketing Service (AMS) guidance and policies on materials. The California Department of Food and Agriculture (CDFA) Organic Input Material (OIM) program may be consulted for their review of organic crop materials. The Organic Materials Review Institute (OMRI) may be consulted for crop and livestock materials, as well as for materials used in organic handling.	If a new MRO obtains ISO 17065 accreditation, must that MRO also be officially recognized by NOP prior to ACAs consulting with them? This Guidance does not specifically state that an MRO, with ISO 17065 accreditation, must still be recognized by NOP prior to ACAs consulting with them. We ask that NOP include this recognition requirement. We ask the NOP to require that NOP recognized MROs include the scope of approval and use annotation for any published material approvals. We also believe there would be additional clarity if NOP stated that only OMRI and CDFA are currently recognized as MROs.

NOP Interim Instruction on Material Review	ACA General Comments
In all cases, a certifier must:	
1. Maintain documentation to support its determinations about the status of a product's compliance with the regulations, including those products that are approved based on prior determination by another certifier, MRO, or the EPA;	We request that NOP specify the type of documentation that is necessary for a certifier to maintain when accepting the decision of another certifier, MRO or EPA. This is a very gray area in the proposed Instruction. MROs and EPA each have different types of information available for certifiers to use for their documentation, and not all have certificates or published lists to reference. Certifiers also have widely differing methods of maintaining information on reviewed materials. If accepting the review of other certifiers, can the ACA simply maintain information on any restrictions and when a re-review is needed? Our members note that if the requirement to maintain documentation requires complete product documentation (e.g. full ingredient lists, labels), there is little incentive to accept other decisions, as the work requirement would be the same. We urge the NOP to identify specific types of information, keeping in mind the Sound and Sensible approach regarding duplicative work.
2. Make synthetic vs. nonsynthetic or agricultural vs. nonagricultural determinations in compliance with the USDA organic regulations and NOP guidance regarding the classification of materials;	The current statement: *In all cases a certifier must* seems to indicate that if a certifier accepts the decision of another certifier, MRO or EPA, the certifier must also make a synthetic or nonsynthetic and/or agricultural or nonagricultural determination. We request NOP clarify whether making these determinations is required when accepting the decisions of another certifier, MRO or EPA. These classification determinations are important during the technical review of individual ingredients within a material. However, when an ACA is accepting the determination of another body, certifier, MRO or EPA, complete ingredient information is often not available. If an ACA accepting the determination of an ACA, MRO, or EPA, is <u>not</u> required to make synthetic vs. nonsynthetic or agricultural vs. nonagricultural

NOP Interim Instruction on Material Review	ACA General Comments
	determinations of materials approved, we suggest this statement be moved & included in 4.1 on page 2. We also point out that the NOP Guidance regarding Classification of Materials is only in "draft" form. We urge NOP to complete the work to publish Final Guidance on Classification of Materials. This will result in more consistency in product review among certifiers.
3. Demonstrate appropriate education, training, and experience levels for personnel conducting material reviews; and	NOP does not provide criteria for what may be "appropriate education, training and experience levels for personnel conducting material reviews". We request that the NOP provide additional specific criteria on the education, training and experience requirements for staff.
4. Create clear written protocols and procedures outlining the expectations regarding the depth and frequency of the review, and providing clear direction for the evaluation of ingredients, sub-ingredients, processing aids, and manufacturing methodologies at all stages associated with the production of the formulated product.	This statement provides several indicators for a material review process, but without more detailed guidance there will continue to be a lack of consistency among MROs, ACAs, and EPA. NOP does not provide specific, detailed criteria on how to conduct material review. Our members were expecting this type of information to be included in this document. We request that the NOP provide additional specific criteria how to conduct material review. The May 2012 NOSB Recommendation on Evaluation of Materials Review Organizations identifies the types of guidance and information needed by certification agencies in the materials review process to ensure consistency. We urge the NOP to begin implementation of this Recommendation.

c) Products with multiple reviews

The ACA is supportive of ACAs working together to resolve differing materials determinations, and we encourage NOP to support this plan also, rather than simply notifying NOP of the discrepancy as stated in # 1 of this section. Our members have noted that in several instances where there were differing determinations, discussions between the ACAs identified new information that enabled a resolution.

The ACA is concerned with how the NOP has been communicating decisions on products with multiple reviews that reach different conclusions. ACA members discussed this issue at

2016 ACA Training and agreed that NOP needed to improve how they communicate with all certifiers and MROs on all products when NOP makes a decision on a product where certifiers have previously disagreed.

In addition, the following have been identified as problematic with the process:

- Timeliness of the NOP decision process: The NOP's decision on ZumSil was communicated over 2 years after the certifier submitted the product to NOP for consideration. Other members have indicated they submitted products over a year ago and are still awaiting a determination.
- Whether the NOP's method of communicating decisions is consistent with the instructions (previously PM 11-4); examples include:
  - ❖ An ACA submitted a disputed material question following the PM 11-4 guidance, but the decision was relayed orally from NOP staff, not in writing, and other ACAs were not informed of the results of the decision.
  - ❖ A question was submitted to NOP regarding a compost product approved by 2 MROs, but only one had a restriction for raw manure. After discussion with one MRO, NOP relayed the information that certifiers would still need to review the proposed use to determine whether the product was in compliance with any restrictions/annotations in rule. Only the asking ACA was informed of this decision.
- In some cases, the NOP notification identified a branded product and did not include information on the generic material in the product. This practice is not in compliance with PM 11-4 or NOP 3012

We are also suggest the following revision in the last sentence of the Section:

> A decision made by certifying agents about the status of a branded (formulated) product ~~remains~~ may remain in effect until the NOP notifies all certifying agents about the status of a material under the regulations.

This sentence indicates that a wrong decision on the allowance of a product must remain in effect until NOP notifies all ACAs. The revision would allow an ACA the flexibility to revise its decision if additional information warrants a revision to the status.

We thank you for the opportunity to provide comments on this document.

Respectfully submitted,

Patricia Kane

Patricia Kane
ACA Coordinator

Appendix A.
ACA Suggested Revisions to Section 4. Policy

Certifiers must review all materials used by organic producers and handlers for compliance with the USDA organic regulations. *See* 7 CFR § 205.201(a)(2). All certifiers must verify that materials used by certified operations comply with the regulations, including the National List of Allowed and Prohibited Substances, and any annotations provided therein (see 7 CFR §§ 205.601-606).

a) Options for Material Review

Certifiers have several options available for determining whether materials may be used in organic production or handling under the USDA organic regulations:

1. Certifiers can verify that the material complies with the regulations by evaluating the product, all of the ingredients within the product, and, if applicable, the manufacturing processes, source materials, and processing aids used to produce the ingredients or final product (e.g., contacting the supplier/ formulator/ manufacturer to obtain full disclosure of the ingredients in the product and manufacturing processes, including processing aids).

2. Certifiers may consult with another certifier who has already evaluated the product and accept that certifier's determination of the product's compliance with the regulations. The Washington State Department of Agriculture, as an accredited certifying agent, has a publicly available list of approved products available at http://agr.wa.gov/FoodAnimal/Organic/MaterialsLists.aspx.

3. Certifiers may accept pesticides that have been determined by the U.S. Environmental Protection Agency (EPA) to comply with the USDA organic regulations.

4. Certifying agents may consult with material review organizations accredited to ISO Guide 17065 (formerly ISO Guide 65). These material review organizations must abide by USDA Agricultural Marketing Service (AMS) guidance and policies on materials. The California Department of Food and Agriculture (CDFA) Organic Input Material (OIM) program may be consulted for their review of organic crop materials. The Organic Materials Review Institute (OMRI) may be consulted for crop and livestock materials, as well as for materials used in organic handling.

b) Requirements for Certifiers

1. ACAs verifying material compliance must

a. Maintain documentation to support its determinations about the status of a product's compliance with the regulations,

b. Make synthetic vs. nonsynthetic or agricultural vs. nonagricultural determinations in compliance with the USDA organic regulations and NOP guidance regarding the classification of materials;

c. Demonstrate appropriate education, training, and experience levels for personnel conducting material reviews; and

d. Create clear written protocols and procedures outlining the expectations regarding the depth and frequency of the review, and providing clear direction for the evaluation of ingredients, sub-ingredients, processing aids, and manufacturing methodologies at all stages associated with the production of the formulated product.

2. ACAs accepting the decision of another certifier, or MRO, or EPA must:

a. Maintain the following documentation to support a determination about the status of a product's compliance with the regulations made by another certifier, MRO or the EPA:
Specific documentation should be identified by NOP and added to this section.