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Dr. Paul Lewis
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National Organic Program
USDA-AMS-NOP
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Room 2646-So, Ag Stop 0268
Washington, DC 20250-0268

October 31, 2016

Re: Interim Instruction - Materials Review - NOP 3012 - AMS-NOP-16-0069; NOP-16-08

Dear Mr. Lewis:

Thank you for the opportunity to comment on the Interim Instruction for Materials Review. MOSA is a nonprofit organic certification agency rooted in the Midwest, certifying approximately 2000 producers and handlers. Through making certification decisions, we have extensive experience with reviewing input materials; we maintain an internal materials review database which includes almost 6000 brand name products and generic materials. We appreciate the National Organic Program's intent to provide further guidance on requirements for review of materials by certifiers. While this document offers some useful additional clarifications, there are areas where additional guidance is necessary. Specific examples are provided below in our comments.

We encourage the NOP to fully take up the 2011 and 2012 NOSB materials review recommendations, which outlined areas where additional guidance and specificity were needed. The Accredited Certifiers Association comments on those recommendations emphasized the need for actual criteria for evaluation of materials, and the NOSB, ACAs, OMRI and the OTA all have asked for an accreditation scope for materials review. The long term goal should be the development of a Materials Review Organization (MRO) accreditation scope. Accreditation would provide oversight that is currently lacking. First and foremost, criteria is necessary to develop consistency in review processes. Without criteria for review, inconsistencies will continue to exist between agencies, MROs, and the EPA, and the policies proposed in this document will not resolve this issue. We also recognize that development of criteria and a scope of accreditation is a significant undertaking. We offer comments on *this* document and encourage further development of guidance in the area of materials review.

Definitions- We find the definition for Material Review Organization helpful. Between the definition and Policy number 4 in section 4 (Policy), we understand that a MRO is **not a certifier** and ***must*** be accredited to ISO 17065. Since there are many certifiers that would also meet the definition as written, we request that it be expanded to include that MROs are not certifiers and that ISO accreditation is a requirement for MROs.

We also believe that more clarity is needed regarding oversight of MROs. In the background section, it's stated that the ISO accreditation process has been identified as being able to provide adequate oversight and enforcement of MROs to ensure consistency of material review by different organizations. ISO accreditation will ensure that policies and procedures are in place for the work *structure*, however we do still have questions and concerns about oversight for specific materials *decisions*. We question whether the decisions for review policies also would be evaluated for consistency with the National Organic Standards. We believe such oversight is necessary. This stated, we do support that certifiers are able to accept the determination of NOP recognized MROs.

Policy- We have several questions regarding the policies outlined in this section. We concur with the first policy. MOSA conducts many material reviews daily for products in use on the organic operations we certify. We also allow OMRI, CDFA, EPA and WSDA listed products. The second policy outlines that a certifier may consult with other certifiers and accept that certifier's determination, such as WSDA. Since WSDA is the only certifier specifically mentioned here, and since we recognize that WSDA has a high-profile materials review program, we question whether the reviews of other agencies could also be accepted. The third policy clarifies that the EPA's *for organic production* products are allowed for use. We are uncertain whether the EPA is a recognized MRO. The last policy in this first section addresses MROs, specifically naming CDFA and OMRI. We appreciate the recognition of other entities that provide materials review services for our organic community, but we question who oversees the policies in place at these organizations. Policy 4 states, *"these material review organizations must abide by USDA AMS guidance and policies on materials."* Who verifies that they do? We also question whether or not *any* ISO accredited organization is recognized, or if such recognition is only extended to CDFA and OMRI. We encourage the NOP to put in place a policy that requires NOP recognition of MROs prior to certifiers relying on the MRO's materials reviews.

Our hope is that the burden of our materials review work might decrease, however, the policies that follow in the next section (*"in all cases, a certifier must")* actually seem to require an increase in our work. ("*In all cases.. Certifiers must maintain documentation to support its determinations."*) We do maintain adequate documentation for products we review, but we do not maintain documentation regarding *the review* of materials for all of the products we allow, because some are WSDA, CDFA, EPA or OMRI listed. We request clarification regarding what the *"documentation to support its determinations"* entails when we allow products based on reputable and recognized third party approval. We propose to strike the second part of the policy stating, *"including those products that are approved based on prior determination by another certifier, MRO or the EPA*." Certifiers should maintain documentation to support their decisions, and that documentation can include a simple note regarding recognized third party approval. We request that any documentation in addition to *the determination* for materials

approved by third parties, be explained in the first part of the policy section, where the different options certifiers have available for determining whether materials may be used on an organic operation are described. When materials are approved based on prior determination by a third party, we do not believe that any additional documentation regarding *the review* of the material is necessary.

We also do not make synthetic/nonsynthetic and ag/nonag decisions for materials listed with other organizations because we expect that these decisions are being made by the other organization as part of their technical review of the material. We propose that the policy include this requirement only for materials reviewed by the certifier. When materials are listed with a third party, certifiers should not need to do this classification themselves. This policy also includes that certifiers should make these decisions based on *"NOP guidance regarding the classification of materials."* While we do consult NOP's *draft* guidance on classification of materials, we are unaware of any published guidance on this topic. We encourage publication of the final guidance.

Regarding the statement, *"In all cases, a certifier must demonstrate appropriate education, training, and experience levels for personnel conducting materials review,"* we would appreciate the NOP giving examples or criteria personnel need to meet.

MOSA has clear written protocols and procedures outlining the requirements and policies we have in place for materials review, but we request the NOP to provide further guidance on specific criteria to be followed when conducting a review. We acknowledge that policies and procedures are not consistent among all agencies, MROs, and the EPA. This section should also more clearly state "*have in place* ~~*create*~~ *clear written protocols and procedures."* Certifiers should have the policies and procedures *in place*, rather than *create* them when conducting materials review.

It would seem that this section of the instruction requires documentation *of the review* in all cases, whether or not a material has been reviewed and approved by another organization. We ask that the NOP revise this policy section to specify the individual requirements for documentation for *each* option available to certifiers for determining whether or not materials may be used on the organic operation.

We suggest additional revisions to the policy section as below:
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). Certifiers must maintain documentation to support their ~~its~~ determinations about the status of a product's compliance with the regulations. Certifiers must make synthetic vs nonsynthetic or agricultural vs nonagricultural determinations as appropriate. Personnel conducting reviews must have adequate ~~appropriate~~ education, training, and/or experience ~~levels.~~ Certifiers must have in place clear written protocols and procedures outlining their 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. 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~~ accept the determinations of material review organizations accredited to ISO Guide 17065 (formerly ISO Guide 65) and recognized by the NOP. These material review organizations must abide by USDA Agricultural Marketing Service (AMS) guidance and policies on materials. The NOP recognizes the California Department of Food and Agriculture (CDFA) Organic Input Material (OIM) program ~~may be consulted~~ for their review of organic crop materials and the Organic Materials Review Institute (OMRI) ~~may be consulted~~ for crop and livestock materials, as well as for materials used in organic handling.

~~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;~~

~~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;~~

~~3. Demonstrate appropriate education, training, and experience levels for personnel conducting material reviews; and~~

~~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.~~

Products with Multiple Reviews- We want to thank the NOP for helping ACAs achieve consistency when review decisions differ. We concur that most of the time agencies and MROs reach the same conclusion regarding the allowance or prohibition of a product. On the occasion when we find we differ in decision with another certifier, we seek to resolve the issue by working directly with them **first**. In all situations to date we've been able to resolve our differences by simply communicating about the material being reviewed. We find that most differences happen because the manufacturer has not provided one of us with complete information, or that the information submitted is different. We do not believe the NOP *must be notified* when certifiers are working together to resolve the discrepancy.

In this section, the EPA is not included, and we're not clear whether they are an MRO. Please revise this section to include the EPA and to clarify that MROs, the EPA, and certifiers are equivalent. Anytime there is a discrepancy between *any recognized organizations* conducting reviews of materials, the NOP will help resolve the discrepancy. Sentence choices throughout this section presently confuse whether or not MROs or the EPA can notify the NOP in the instance of a discrepancy.

We pondered on the statement that *"the NOP's determination will be limited to the application of the USDA organic regulations for generic materials; the NOP does not approve or endorse branded (formulated) input products."* We recently received notification that Zumsil was prohibited. There was no information regarding the manufacturer of the product or which generic material caused the prohibition. Other similar prohibitions have been sent in the past. When there is a material that has been determined as not allowed, we would appreciate being informed of the generic material which affected the material's compliance with the NOS.

The instruction concludes with, *"A decision made by certifying agents about the status of branded (formulated) product remains in effect until the NOP notifies all certifying agents about the status of a material under the regulations."* This sentence implies that a decision discovered to be incorrect should remain in place until the NOP concludes their process. If, during this process, MOSA determines that we have made an incorrect conclusion during the review of the material, we'll plan to make a correction immediately. This sentence could more appropriately state *"may remain in effect."* NOP timeliness is also a concern. The process for the review of Zumsil, for example, began in February of 2014 and was not concluded until August of 2016.

We appreciate your consideration of this difficult and complex topic and look forward to reviewing the final instruction, with revisions and clarifications, and to receiving additional guidance in the area of materials review. MOSA's Certification Policy Manager, Jackie DeMinter jdeminter@mosaorganic.org, is available for any questions you may have.

Respectfully submitted,

The MOSA Certification Team