



October 25, 2016

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

**Docket:** AMS-NOP-16-0069

**RE:** National Organic Program: Notice of Interim Instruction on Material Review

Dear Mr. Lewis:

Thank you for this opportunity to provide comment on the National Organic Program's (NOP) Notice of Interim Instruction on Material Review. NOP is requesting comments on instruction for Accredited Certifying Agents (ACAs) that specifies the criteria and process that must be followed when approving substances for use in organic production and handling. This instruction is directed at certifiers, who must meet certain terms and conditions as part of their accreditation under USDA's organic program.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing organic businesses across 50 states. Its members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's Board of Directors is democratically elected by its members. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

### **Summary of OTA's Position**

OTA has long advocated for NOP accreditation of Material Review Organizations (MROs). We believe that every certifier and every MRO that takes on the responsibility of material review must operate under uniform standards and requirements, regardless of whether they are a government entity, Accredited Certification Agent (ACA), or third-party reviewer. While we appreciate the intermediate steps NOP has taken to provide material review instruction for ACAs, we do not believe that Interim Instruction 3012 adequately addresses the NOSB recommendations on material review that were unanimously passed in December 2011 (Accreditation for MROs) and May 2012 (Evaluation Criteria). Consistent with the 2011 NOSB recommendation that called for MRO accreditation, we continue to believe that NOP must establish formal accreditation that provides uniform oversight to ACAs and MROs and this must be done under the structure of NOP accreditation. We do not believe that the International Organization of Standardization (ISO) accreditation process will be able to provide the same level of oversight, enforcement and uniformity that NOP accreditation would. It is critical that a system is in place that will provide NOP with legal authority over MROs, including the ability to suspend accreditation, issue non-conformances, and provide appeal procedures.

OTA requests that NOP to take the steps necessary to adequately respond to NOSB's 2011 recommendation and establish accreditation for MROs. As an intermediate step, we urge NOP to accept our suggested revisions to NOP 3012 as explained below and to act further on NOSB's 2012 Recommendation on Evaluation of Criteria. ACAs and MROs need guidance that will bring greater consistency by delineating the material review procedures and expectations to follow with respect to depth and frequency of review, acceptability of verification documentation, and appropriate education and training. Finally, hand-in-hand with more detailed guidance on evaluation criteria, we urge NOP to finalize its Draft Guidance on Classification of Materials. OTA cannot emphasize enough the need for guidance on the Classification of Materials and the integral role it plays in the overall material review process.

**We offer the following more detailed comments on Interim Instruction 3012:**

OTA appreciates the efforts of NOP to provide instructions for certifiers when approving substances for use in organic production and handling. The NOP Policy Memorandum 11-4 (Evaluation of Materials used in Organic Crop, Livestock and Handling Operations) helped to gain clarity on review decisions and procedures as they apply to inconsistent interpretations by ACAs and MROs. Similarly, this Interim Instruction is helpful because it specifies the conditions that must be met for ACAs to consult with MROs. However, while we see value in the intermediate steps NOP has taken to provide material review instruction for ACAs, we believe the instruction falls short of MRO accreditation under NOP, and will not provide the uniform oversight and enforcement that is needed equally for both ACAs and MROs.

OTA believes that accreditation of MROs by NOP is the only solution that will achieve the following critical conditions:

- Provide adequate consistency among ACA and MRO criteria and decisions, which would benefit input manufacturers, organic operations and organic consumers;
- Support organic producers and handlers who use MRO decisions in production planning;
- Provide legal protection for MROs and product listing decisions;
- Provide NOP with legal authority over MROs, including the ability to suspend accreditation, issue non-conformances, and provide appeal procedures.

NOP 3012 Interim Instruction on Material Review is not effective to accomplish these goals, for the following reasons:

- NOP 3012 does not give NOP the authority to oversee and enforce compliance of MROs;
- NOP 3012 is directed at certifiers, and lacks instructions for MROs to conduct technical review of materials and communicate the compliance status and restrictions to the certifiers who accept their determinations;
- NOP 3012 does not require MROs to make their material review policies and procedures transparent to all stakeholders.

**NOP 3012 is useful only as an interim solution**

OTA has long advocated for the accreditation of MROs under a new Material Review scope, and we continue to view it as the only viable solution if NOP is going to adequately facilitate consistent material review and exercise uniform oversight of material review decisions across the organic sector. OTA is fully aware and we are sensitive to the time and resources it will potentially take to develop a new accreditation scope. We support NOP in its efforts to provide instruction and detailed guidance to ACAs

and MROs on the material review process to promote consistency and uniformity while longer-term regulatory changes are undertaken. In the meantime, NOP 3012—in addition to more detailed guidance on specific review procedures—can be useful. However, we do not see NOP 3012 or further guidance as a substitute for MRO accreditation. Our following comments are meant to improve the clarity and enforceability of the NOP 3012 Instruction should it be used as an interim solution prior to the development of a new Material Review scope under NOP accreditation.

- ***Specify the requirements for MROs***—NOP 3012 states, “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.”

**OTA suggested revision:** The requirement for ISO Guide 17065 accreditation should specify that the accreditation scope must include material review to the USDA National Organic Program regulations.

- ***Clarify whether certifiers can consult with MROs that are not specifically identified in the instruction*** – NOP 3012 states, “Certifying agents may consult with material review organizations accredited to ISO Guide 17065.” One could read this statement to mean that *any* organization accredited to ISO Guide 17065 may be consulted. NOP 3012 lists CDFA and OMRI as organizations that may be consulted, but does not limit the options to *only* these two organizations. By limiting the eligible MROs to only those listed in the instruction, NOP can better maintain oversight of the specific MROs that ACAs are authorized to consult with.

**OTA suggested revision:** Revise the text as follows to implement the two points identified above and provide additional clarifications (underlined text is to be added):

Certifying agents may consult with material review organizations identified in this instruction that are accredited to ISO/IEC 17065 (formerly ISO Guide 65) for material review to 7 CFR Part 205 National Organic Program regulations. 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 its 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.

- ***Clarify documentation requirements for certifiers when accepting an MRO determination*** – NOP 3012 states “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.”

To document acceptance of OMRI’s review decisions for approved products, certifiers typically maintain a current OMRI certificate for the approved product, or otherwise document the practice of confirming the status of the product on OMRI.org. These documentation methods should continue to be sufficient to meet the requirements of NOP 3012.

**OTA suggested revision:** Revise the text as follows to implement this clarification (underlined text is to be added):

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 (e.g., MRO certificate or documentation that the status was verified on the MRO or certifier website);

- **Clarify classification requirements for certifiers when accepting an MRO's determination** – NOP 3012 states “In all cases, a certifier must... 2. Make synthetic vs. non-synthetic or agricultural vs. non-agricultural determinations in compliance with the USDA organic regulations and NOP guidance regarding the classification of materials.”

This requirement may be problematic when accepting decisions of other certifiers or MROs. It doesn't seem reasonable for certifiers to perform classification decisions on products they did not review themselves and for which they likely do not know the ingredients. Classification decisions by the certifier or MRO who performed the technical review of the material should be sufficient.

**OTA suggested revision:** Revise the text as follows to implement this clarification (underlined text is to be added):

2. If the certifier conducts the evaluation, the certifier must make synthetic vs. non-synthetic or agricultural vs. non-agricultural determinations in compliance with the USDA organic regulations and NOP guidance regarding the classification of materials;

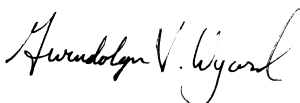
## **Conclusion**

We are confident that the review of materials for use in organic production and handling is currently quite rigorous as a part of the certification process, but there is need for improvement and harmonization of the system to facilitate trade and assure continued confidence and growth of the industry. Therefore, OTA believes that it is essential to the health and well-being of the organic industry that uniform material review procedures and oversight for ACAs and MROs be implemented as an integral part of NOP under the USDA-NOP accreditation system as quickly as possible.

Since the creation of an accreditation scope for MROs is a complicated and potentially long-term undertaking, we urge NOP to not delay in accepting our suggested revisions to NOP 3012, finalizing the Classification of Materials Guidance, and drafting more detailed guidance on material review criteria. This will promote greater consistency and uniformity among currently operating ACAs and MROs while longer-term regulatory changes are undertaken.

On behalf of our members across the supply chain and the country, OTA thanks the National Organic Program for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,





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Organic Trade Association

cc: Laura Batcha  
Executive Director/CEO  
Organic Trade Association