



Interim Instruction Material Review

1. Purpose and Scope

This instruction specifies the criteria and process that accredited certifying agents (certifiers) must follow 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 (see 7 CFR 205.501(a)(21)).

2. Definitions

Material Review Organization (MRO). An entity with expertise in verifying compliance of production and handling materials with the U.S. Department of Agriculture (USDA) organic regulations. MROs provide certifiers, input manufacturers, suppliers, and organic operations with an independent review and assessment of materials intended for use in organic production and handling.

Materials. Substances to be used as an input in organic production and handling. Materials include, but are not limited to: 1) fertilizers, soil amendments, potting soil, crop production aids, and pest control materials used in crop production; 2) feed supplements, feed additives, medications, and livestock production aids used in livestock production; and 3) ingredients, processing aids, post-harvest handling substances, sanitizers, and facility pest control materials used in processing and handling.

3. Background

The National Organic Standards Board (NOSB) and organic community have historically supported the accreditation of MROs to ensure consistency, uniformity, and predictability of review programs for materials used in organic production and handling. The Organic Foods Production Act of 1990, as amended, (7 U.S.C. § 6501) does not provide authority to accredit MROs; the International Organization of Standardization (ISO) accreditation process has, however, been identified as being able to provide adequate oversight and enforcement of MROs to ensure consistency of material review by different organizations.

Section 205.201 of the USDA organic regulations requires organic producers and handlers to provide a list of each material in their Organic System Plans (OSP).

Certifiers must evaluate this list to determine compliance with the USDA organic regulations. Certifiers either approve or reject a material and communicate their findings to the applicant for certification or the certified operation. Prior to a material being used in organic production or handling by an applicant or certified operation, the certifier must approve the use of the material in the context of the operation's OSP.



In January 2011, the NOP requested that the NOSB provide recommendations on the review of materials by certifiers and MROs. In July 2011, the NOP issued Policy Memorandum 11-4 that outlined criteria for MROs.

In December 2011, the NOSB recommended that:

- MROs be defined as entities accredited or authorized to review and approve materials as compliant with the USDA organic regulations;
- The NOP provide guidance and criteria on the material review process;
- The NOP require MROs to make their review processes transparent;
- Certifiers accept decisions made by other certifiers and MROs;
- The NOP maintain a single, national, generic materials list;
- The NOP maintain a consolidated brand name materials list as an aggregation of materials approved by certifiers and MROs;
- Manufacturers and suppliers of materials partially fund the cost of managing MROs; and
- The NOP hold MROs and material manufacturers/suppliers accountable for violations of the USDA organic regulations.

In May 2012, the NOSB made additional recommendations related to MROs, specifically that:

- Material decisions should only be made by NOP-authorized entities;
- MROs should only make synthetic vs. nonsynthetic determinations based on NOP guidance;
- ISO Guide 65: 1996 General requirements for bodies operating product certification systems (now ISO 17065: 2012 Conformity assessment—requirements for bodies certifying products, processes and services) accreditation should be required for all MROs; and
- The NOP should approve a specific number of criteria for MROs.

In August 2013, the NOP revised Policy Memorandum 11-4 to include procedures for addressing inconsistent interpretations by certifiers and MROs of allowed materials.

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).

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.

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

Some manufacturers may submit their products for review to more than one certifying agent or MRO. In the majority of cases, certifying agents and MROs reach the same determination regarding the allowance or prohibition of a product. On rare occasions, certifying agents and



MROs reach different conclusions on whether the product complies with the USDA organic regulations.

In cases where different certifying agents, alone or in consultation with MROs, reach different conclusions on the allowance of a material, the NOP must be notified for a final determination on proper application of the regulations according to the following steps:

1. When a certifying agent concludes that a product may not comply with the regulations, and that product is allowed by another certifying agent, the certifying agent must notify the NOP at NOP.Guidance@ams.usda.gov.
2. The NOP will review information from both parties and determine whether the regulations have been properly applied. 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.
3. If the NOP determines that the regulations have not been properly applied and, therefore, the product does not comply with the regulations, the NOP will instruct the certifying agent to rescind its approval of the product.
4. The NOP will communicate the determination to all certifying agents and MROs with a timeline, if appropriate, for the discontinuation of product use by organic operations.

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

5. References

USDA Organic Regulations ([7 CFR Part 205](#))

7 CFR 205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.

7 CFR 205.201 Organic production and handling system plan.

7 CFR 205.203 Soil fertility and crop nutrient management practice standard.

7 CFR 205.600-607 The National List of Allowed and Prohibited Substances

NOSB Recommendations

NOSB Formal Recommendation, Proposed Recommendation on Evaluation of Materials Review, May 22, 2012.

NOSB Formal Recommendation, Evaluation of Material Review Organizations, December 2, 2011.



Other Laws and Regulations

[Pesticide Registration Number 2003-1: Labeling of Pesticide Products under the National Organic Program](#)

International Standards

ISO 17065: 2012 Conformity assessment—requirements for bodies certifying products, processes and services

Document Control: This document supersedes Policy Memorandum 11-4 Evaluation of Materials used in Organic Crop, Livestock and Handling Operations, dated January 21, 2011, and the revisions dated October 31, 2011 and April 6, 2013. This document also supersedes “Verification of Materials Memo” dated March 5, 2008, and “Documented Source of Approved & Prohibited Materials for Use in Organic Operations” dated July 16, 2004. These documents are now obsolete.