

**Formal Recommendation by the
National Organic Standards Board (NOSB)
to the National Organic Program (NOP)**

Date: May 22, 2012

Subject: Proposed Recommendation on Evaluation of Materials Review Organizations

Chair: Barry Flamm

The NOSB hereby recommends to the NOP the following:

Guidance Statement X

Statement of the Recommendation (Including Recount of Vote):

Recommendation to provide draft guidance language to NOP as per attached CACC Recommendation. Passed by a vote of 14 yes, 0 no, 1 recusal.

Rationale Supporting Recommendation (including consistency with OFPA and NOP):

CACC recommendation is attached.

Committee Vote:

Moved: Dickson **Second:** Richardson

Yes: 14 **No:** 0 **Abstain:** **Absent:** **Recusal:** 1

**National Organic Standards Board
Compliance, Accreditation and Certification Committee
Proposed Recommendation
Criteria for Material Review by Material Review Organizations**

May 22, 2012

Introduction

The assessment of specific substances for compliance with the National Organic Standards – known as “Materials Review” – is a foundational element in the organic supply chain. Certifiers and other materials review organizations regularly review materials as a service to their clients, and these decisions directly impact the organic integrity of growing, livestock and handling operations and ultimately the integrity of the USDA Organic label. The uniformity, consistency and integrity of materials review decisions is of paramount importance to the integrity of the entire organic supply chain, and the National Organic Program must play a primary role in supervising and monitoring these activities.

Following the NOP’s request for NOSB advice on this issue, the CACC prepared a discussion document for the April, 2011 NOSB meeting in Seattle. This document summarized the issue and the NOP request, and posed a number of specific questions about specific facets of this complex subject. The board received written and oral public comment from numerous stakeholders, including certifiers, materials review organizations, input manufacturers and others. The CACC presented a recommendation on the topic at the November, 2011 NOSB meeting in Savannah. This recommendation described specific criteria to be used by the NOP in evaluation and oversight Materials Review Organizations. During and following the Savannah NOSB meeting, a number of stakeholders pointed out that the recommendation failed to address *the specific criteria and procedures to be used by MROs in evaluating materials*. The present recommendation addresses those concerns by detailing such procedures.

Background

On January 18, 2011, the NOP Deputy Administrator requested the participation of the NOSB in developing a clearer NOP policy on the oversight of materials review organizations:

The NOP is interested in developing a more uniform and consistent procedure for evaluating the competency and quality of material evaluation programs, as approved by accredited certification agencies or by other third party organizations.

The NOP is requesting that the National Organic Standards Board (NOSB) develop a recommendation that delineates the criteria that should be used by certifying agents and third party organizations to evaluate materials used in

organic production and handling. The recommendation should include the criteria and process that should be used to determine the approval of input substances used in crop production (e.g. fertilizers, pest control materials, soil amendments, crop production aids), livestock production (e.g. feed supplements, feed additives, medications and livestock production aids), post-harvest handling and food processing (e.g. processing aids, sanitizers, facility pest control materials).

A number of organizations currently provide materials review services to producers and certifiers. At least one of those organizations is an independent organization that is not an Accredited Certifying Agent or under any NOP oversight. At least one other materials review organization is a formal subdivision of an ACA, and many ACAs provide some material review services to clients on a formal or informal basis. The CACC agrees with the NOP that there is a clear need for more uniform and consistent policies governing material review services, and we believe that all organic stakeholders would benefit from a clearly defined NOP guidance around the qualification and activities of these organizations.

Challenges

1. All certifying agents review input materials for compliance with the NOP regulations. Most certifying agents do not publish their list of approved inputs. This leads to a lack of transparency of what materials have been approved for use in organic production and handling.
2. There are numerous organizations reviewing materials for compliance with the NOP regulations. On limited occasions a material that is allowed by one certifying agent is prohibited by another. This lack of consistency in what materials are approved creates an uneven regulatory landscape, is unfair to organic producers and handlers, and leads to certifier shopping to find the certifying agent that allows more materials.
3. A universal list of approved substances is not currently available to organic producers and handlers. It is difficult for many organic producers and handlers to understand what materials are allowed and which materials are prohibited. This regulatory uncertainty causes reluctance by many potential organic producers and handlers to enter the organic trade.
4. OMRI and WSDA maintain a publically available list of approved materials. The process for removing substances from these approved lists is not consistent. There is not a consistent process for material input manufacturers to appeal decisions made by OMRI, WSDA or certifying agents.
5. The NOP does not have direct regulatory authority over material manufacturers. If material manufacturers violate the organic standards or fraudulently represent their product as approved for organic use the NOP does not have authority to issue civil penalties or propose adverse actions. Currently organic producers and handlers bear the risk of using substances that may not comply with the NOP regulations.

The CACC's November 2011 recommendation presented a framework for NOP oversight and evaluation of MROs. The present recommendation will set out specific review criteria to be used by such organizations (both independent MROs and ACAs performing materials review activities) in reviewing materials.

Relevant Areas in the Rule

While both OFPA and the Rule deal extensively with the review of materials as performed by NOSB, NOP and ACAs, neither provides any language that relates directly the work or oversight of materials review organizations.

Discussion

The NOSB's Fall 2011 Recommendation detailed specific criteria to be used by the NOP in evaluation and oversight Materials Review Organizations. A number of commenters, including MROs and ACAs, noted that the CACC's recommendation failed to provide a concrete framework for the NOP to use in creating guidance for such organizations in the short term. This recommendation addresses that deficiency by adding a number of specific criteria and procedures to be used by such organizations in the evaluation of specific materials. A number of issues were discussed, including the following:

Depth of materials review.

At what depth should an input be reviewed (i.e. ingredients within ingredients OR ingredients within ingredients within ingredients)

Evaluation of synthetic/non-synthetic and agricultural/non-agricultural status of materials.

How should MROs make these determinations in a way that ensures consistency with NOP policy and consistency across MROs?

Duration and expiration of materials review determinations.

How long is a material review decision valid? How often must a substance or input be re-reviewed?

Procedures for monitoring ongoing compliance of approved products.

What are guidelines for surveillance, removal of noncompliant products from the list, documentation of formula changes, etc.?

Evaluation of potential use of prohibited methods.

Clarify whether and to what extent prohibited methods are permitted in the production of inputs. What level of verification is necessary for prohibited methods, especially GMO sourced inputs like corn gluten meal or soy meal?

Substantiation of label claims and other requirements.

i.e. pH in stabilized fish, purchase records to prove formulas, records for compost production, NPK label claims

Recommendation

In its November 2011 recommendation, the NOSB asked that the National Organic Program require that MROs become accredited or formally recognized under a newly formed Material Review scope, in order to facilitate adequate oversight and enforcement of the activities of MROs. The recommendation advocated that Materials review activities should ultimately only be allowed by NOP accredited entities.

Since the creation of a new accreditation scope is a complicated and potentially long-term undertaking, the NOSB also recommends a number of short term measures to support the consistency of decisions currently being made by MROs. In conjunction with, and parallel to, NOP's work in creating an accreditation scope for materials review. NOP should provide detailed guidance and criteria on the material review process in order to promote consistency and uniformity among currently operating MROs while longer term regulatory changes are undertaken.

We ask that the NOP provide detailed guidance to MROs and ACAs to ensure the consistency and integrity of materials review decisions. Such guidance should:

- Establish that material review organizations may not make synthetic vs. non-synthetic or agricultural vs. non-agricultural determinations except when made in strict compliance with NOP guidance. We urge the NOP to expedite the publication of clear guidance for making such determinations, based on earlier recommendations of the NOSB. The classification of materials is of foundational importance to the integrity of organic products, and such guidance is extremely critical, given the thousands of synthetic vs. non-synthetic and agricultural vs. non-agricultural determinations made by certifiers each year.
- Require that MROs who publish materials lists obtain and maintain ISO 65 accreditation, which will ensure MROs are meeting these strict guidelines regarding consistency and transparency. For ACAs or other entities who do not publish public lists, the NOP should still include similar criteria as part of the accreditation process.
- Require that MROs provide a clear and publically available description of its review criteria and decision-making procedures.
- Establish appropriate education, training, and experience levels for personnel conducting material review.
- Establish appropriate levels of personnel, resources, infrastructure, and documentation to engage in on-site inspections where needed. Establish need, frequency, and type of on-site inspections.

- Create clear expectations about the depth of the review, providing clear direction for the evaluation of ingredients, sub ingredients, and processing aids at various levels within a formulation.
- Create clear expectations for the frequency of material review, establishing how often and under what conditions approved products must be re-reviewed.
- Contain a mechanism to ensure consistency in decisions across MROs. Specifically, it should give direction to MROs about what action, if any, should be taken when making a decision it knows conflicts with another MRO's decision.
- Establish criteria for determining the acceptability of documentation for verifying compliance with certain material annotations or required conditions (e.g. pH in stabilized fish, purchase records to prove formulas, records for compost production, NPK labels claims).
- Give direction to MROs on verification of products derived from GMO risk crops (e.g. corn gluten meal, soy meal). What type of substantiation is sufficient to verify that an input has been produced without excluded methods?
- Provide procedures for ongoing monitoring of approved products, including market surveillance, testing, removal of noncompliant products from lists, etc.
- Give direction to MROs about what action should be taken when the NOP issues guidance or policy which contradicts an MRO's listing of an input or material, including the expected timeframe for the MRO's listing to be changed.
- Be developed with the input and participation of current MROs and ACAs, through the Accredited Certifiers Association, the Organic Materials Review Institute, and others, to draw on the considerable material review expertise of those organizations currently making such decisions. The NOP has noted that its 2012 accreditation audits of ACAs will include materials review processes as a focus; we hope that the NOP will use this information to inform the development of a policy which incorporates the best practices being currently used.
- Provide clear definitions of key terms, including the use of the term "certification" with regard to materials review activities.

Committee Vote

Motion by: Dickson

Second: Richardson

Yes: 8 No: 0

Absent: 0

Abstain: 0

Recuse: 0