



November 13, 2011

Ms. Lorraine Coke
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Avenue, SW
Room 2646-So, Mail Stop 0268
Washington, DC 20250-0268

Docket: AMS-NOP-11-0081; NOP-11-15

RE: Compliance, Accreditation, and Certification Committee (CACC): Material Review Organizations

Dear Ms. Lorraine Coke:

Thank you very much for this opportunity to provide comment on CACC's recommendation on Oversight of Material Review Organizations.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. 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, and its mission is to promote and protect the growth of organic trade to benefit the environment, farmers, the public and the economy (<http://www.ota.com/>).

In summary, OTA supports the CACC's recommendation and urges NOSB to pass the recommendation at this meeting with a few revisions that we have described below.

OTA is particularly supportive of the recommendation's overriding requirement that Material Review Organizations (MROs) become accredited or formally recognized under a newly created National Organic Program (NOP) scope. We believe every MRO that takes on the responsibility of material review, allowance, and/or certification must operate under uniform standards and requirements, regardless of whether they are a government entity, Accredited Certification Agent (ACA), or third-party reviewer. The industry needs NOP to establish those procedures and requirements, and to provide uniform oversight.

In order to strengthen the recommendation, OTA suggests revisions in two primary areas: 1) The recommendation needs a definition of a Material Review Organization (MRO); and 2) The recommendation should clearly state that once an entity is accredited as an MRO, its decisions must be accepted by other MROs and ACAs. OTA has suggested a definition of MRO along with associated language changes under section "**Material Review Organization Qualification**," and we have suggested a new section be added titled "**Equivalency among Accredited MROs**." Minor changes are

also requested under “*MRO operation and review criteria*” and “*Structure and Consistency of a Materials List.*”

Background and Overview: One of the tenets of trust in the organic claim is independent verification of organic production and handling by accredited agents of USDA. Current inspection requirements extend from seed to final product. Those non-organic materials required in organic production (farming) and handling (processing) have historically been reviewed by desk audit only. NOP oversight and USDA agent inspection are not required for these non-organic inputs with the notable exception of the requirements of NOP Guidance Document 5012 regarding liquid fertilizers issued September 14, 2009. The events surrounding the requirements for these additional requirements pointed up a gap in the audit trail that assures organic integrity and this potential risk to the organic sector. In addition, materials decisions are currently made without uniform procedures or equivalency recognition.

The current state of materials review can be compared to the state of organic certification before the implementation of NOP when certifiers did not recognize one another’s certificates and made conflicting decisions. In the 1990s, the industry attempted to harmonize materials decisions with the creation of the Organic Materials Review Institute (OMRI), but there is no formal mechanism in place for accrediting or recognizing OMRI, the new California Department of Food and Agriculture (CDFA) Assembly Bill (AB) 856 Program, or other materials review programs.

The CACC recommendation is particularly important to the fate of material review in California under AB 856. In January 2010, California passed AB 856 establishing oversight over organic input materials sold in the state in response to several companies allegedly selling fraudulent organic inputs to organic producers. Current interpretation of AB 856 by CDFA assumes that the law does not allow CDFA to recognize material reviews by reviewers outside of CDFA, although a majority of the AB 856 Organic Input Material Subcommittee, which is providing recommendations on the AB 856 policy, recommends some form of recognition of material reviews by other material review organizations. CDFA plans to review input materials in accordance with its interpretation of CA law that requires in-house reviews if this service is seen as one that a CA agency is able to provide. One of the primary concerns expressed by CDFA with respect to recognizing outside material reviews is that, without uniformity at the federal level, it would be giving away its authority to an unknown process.

OTA has several concerns about CDFA providing material reviews of inputs, including that the review process can be complex and demand expertise that may not currently be within that agency. Under the CACC Recommendation, if accepted, CDFA would be required to become accredited and accept reviews outside of its agency, avoiding duplicative and potentially conflicting and inconsistent decisions between CDFA and MROs/ACAs. OTA is 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 sector that uniform procedures for materials review be implemented as an integral part of NOP under an

accreditation or recognition system as quickly as possible. That being said, we offer the following specific comments on the recommendation:

Material Review Organization Qualification

OTA supports the recommendation that MROs become accredited under the National Organic Program. We're concerned, however, by the wording that "MROs become Accredited ***Certifying Agents*** (ACAs)." Instead, we believe that a Material Review Organization should be defined, and the recommendation should be revised to read as follows:

In order to facilitate adequate oversight and enforcement of the activities of MROs, the National Organic Program should require that MROs become ~~Accredited~~ **or formally recognized** ~~Certifying Agents (ACAs)~~ under **a newly formed Material Review scope**. MROs that only perform material review services should be ~~certified under a new accredited under scope which restricted s certification activities to material review~~ **activities**. ACAs who **currently** perform ~~other certification types would simply add the materials review~~ **would simply add the Material Review** scope to their existing accreditation. ~~Furthermore, the NOSB feels that v Materials review activities (providing a public "list" of approved NOP compliant inputs) should ultimately only be allowed by NOP accredited entities.~~

[Accepted: In order to facilitate adequate oversight and enforcement of the activities of MROs, the National Organic Program should require that MROs become accredited or formally recognized under a newly formed Material Review scope. MROs that only perform material review services should be restricted to material review activities. ACAs who currently perform materials review would simply add the Material Review scope to their existing accreditation. Materials review activities should only be allowed by NOP accredited entities.]

The regulation defines "certifying agent" as, "*Any entity accredited by the Secretary as a certifying agent for the purpose of certifying a production or handling operation as a certified production or handling operation.*" A Material Review Organization would not be certifying a production or handling operation nor "certifying" an ingredient or product, but rather evaluating the compliance of a material for use by a certified production or handling operations. We believe this distinction is important because there is already a great deal of confusion between a certified organic input/ingredient certified by a certifying agency and a compliant input or ingredient approved by OMRI or WSDA. **We support the implementation of a separate procedure for authorizing or accrediting Materials Review and Approval, modeled after the existing accreditation categories.**

Therefore, OTA recommends the following definition of Material Review Organization:

Material Review Organization: Any entity accredited or authorized by the Secretary to review and approve materials as compliant with the National Organic Program for use in producing or handling certified organic products.

CACC acknowledges that a new accreditation scope is a complicated and potentially long-term undertaking. We agree, and we encourage NOP to provide detailed guidance to certifiers on the material review process in order to promote consistency and uniformity among currently operating

MROs while longer-term regulatory changes are undertaken. Guidance in the short term is very important, but guidance will not address the fundamental problems we are faced with, particularly the issue we have described with CDFA. While guidance and accreditation are both important, accreditation as outlined by CACC is far the most important. We do not want to see guidance take the place of **or delay** the development of an accreditation scope for materials review. **We believe they go hand in hand, and the development of both must begin as soon as possible.**

In our comments submitted on the Spring 2011 CACC Discussion document, we included a fairly comprehensive list of general requirements that an ACA or MRO would need to meet in order to review materials or be accredited. We acknowledge that our suggested criteria were incorporated into this recommendation, if not specifically then presumably under ISO 65 standards or general NOP accreditation requirements for ACAs. For the record, we are resubmitting our criteria (**see Appendix 1**).

OTA suggests a new next section be added to the recommendation:

Equivalency among Accredited MROs – OTA suggests that this new section be added.

We believe that once an entity is accredited as an MRO, its decisions must be accepted by other MROs and ACAs. We understand that under § 205.501(a)(13), a certifying agent must accept the certification decisions made by another certifying agent accredited by USDA. This requirement should also apply to MROs, and it's important to clearly communicate this intent to NOP. Therefore, we suggest the following be added:

Equivalency among Accredited MROs

We believe that once an entity is accredited as an MRO, its decisions must be accepted by other MROs and ACAs. If we develop a uniform, accredited, transparent material review program, at its core must be equivalency of review and decision-making among accredited MROs. Without equivalency, we will lose the trust and confidence of organic input manufacturers, which will certainly lead to fewer input options to the organic production community and create a disincentive to the development of new and innovative input materials.

In addition to accepting the decisions of other MROs and ACAs, the program must have a description of a transparent process to resolve conflicts between the MRO's decision and determinations with those of another MRO, ACA or the National Organic Program. We believe it will be critically important for the NOP to establish clear standards and requirements for how a MRO decision can be appealed.

MRO operation and review criteria - OTA supports this section with one minor change.

CACC has recommended the following operation and review criteria:

- MROs should use OFPA, the USDA National Organic Standards, NOP guidance and the National List as the base standards for their operations and activities.
- MROs should not make synthetic vs. non-synthetic and agricultural vs. nonagricultural determinations except as guided by NOP materials classification guidelines.
- MROs should be compliant with ISO 65 standards, which require the development of detailed

review protocols and policies.

- MROs must make their review process—including organizational hierarchies, procedures and governance structures related to materials decisions—transparent to all stakeholders.

OTA agrees with the above operational and review criteria, except that we request that “synthetic vs. non-synthetic” be revised to include agricultural and non-agricultural determinations.

In our comments submitted on the Spring 2011 CACC Discussion document, we included a list of criteria that should be used by Accredited Material Review Organizations (MRO) to evaluate materials. We acknowledge that many of our suggested criteria were incorporated into this recommendation, if not specifically, then presumably under ISO 65 standards or general NOP accreditation requirements for ACAs. For the record, we are resubmitting our criteria (**see Appendix 2**).

Structure and Consistency of a Materials List – OTA supports this section with one minor revision.

We agree with CACC that most effective way to ensure consistency among MROs is to ensure that all such organizations are operating by a consistent set of review protocols and procedures. We agree with the development of sub-categories and list structure, which reflects the review criteria to be used for each category, and we look forward to a category for post-harvest substances. OMRI procedures manual and generic list are a good starting point for identifying the categories and criteria. We also agree that NOP should maintain a single, national Generic Materials List that would be posted as a guidance document with the understanding that it is a living document that may not include every possible natural material that is allowed or prohibited. We’re please to see that OMRI and NOP have signed a contract to produce such guidance. A positive generic list will provide a uniform platform for MRO decisions, assist everyone from input suppliers to farmers, processors, and buyers to understand the regulations, facilitate trade, and assure consistency.

We agree that the Generic List should not include brand name products. That would be the purview of MROs, just as organic certification of specific companies and products is the responsibility of ACAs. We believe that when an accredited MRO takes a material review action, it must do so publicly and transparently. A separate brand name list of entities and products that accredited MROs have reviewed and approved as NOP-compliant should ideally be posted to a public place, and updated in real time. However, we do not believe that a Brand Name list should be managed by NOP.

Finance and Oversight – OTA supports this section

Again, we are in agreement with CACC. Audits and accreditation of MROs should be financed in the same way that ACA accreditation and audits are currently financed, through fees charged to the MRO for USDA audits.

We believe NOP oversight of MROs will best be facilitated by a uniform accreditation procedure. We believe that third-party MROs may be better positioned to handle certain aspects of material review, e.g., those that require specific expertise or may be uncommonly complex and ultimately can provide those services in the most economical and efficient manner.

The success of a material review program will be grounded in the audit of the MRO’s review program. Whether it is a third-party entity or an ACA, we believe that its accreditation hinges on the

organization's successful performance under audit against uniform standards and requirements. We believe that we need to strike a balanced approach to audits so that they are not unduly burdensome, yet they need to be thorough and at a level to assure competence and program credibility, thereby assuring continued trust of the program by the public. We believe that NOP should be funded and staffed to carry out this function.

Enforcement and Fraud – OTA supports this section

OTA agrees with CACC that NOP oversight of MROs, as ACAs, is the most effective way to ensure consistency and integrity in the organic input material supply chain, and it provides the most powerful set of tools to prevent fraud, monitor compliance, and enforce the National Organic Standards. We also recognize that NOP oversight and Accreditation of MROs will protect organic producers and handlers. If legitimately approved materials are used by a certified party, they should not be penalized if approval of such materials is later revoked.

Conclusion

OTA acknowledges that the organic sector is facing a serious challenge regarding material review. We believe that a lack of a uniform, accredited and transparent materials review program has, in fact, caused negative impacts both to organic production and to our marketplace in the United States. OTA understands that a new accreditation scope for material review will be historical, and that its complicated and long-term nature makes many stakeholders uncomfortable, particularly those in the early stages of a material review program. We strongly believe however that comprehensive NOP oversight of materials review is essential to the continuing success of the program, and that THE critical component of credible oversight of materials review is the accreditation or formal assessment and recognition of third-party MROs by NOP. Establishing material review criteria and issuing guidance is important, however guidance will not address the more challenging legal issues, such as AB 856, that are putting the entire organic supply chain at risk.

Again, on behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment and for carefully considering our comments.

Respectfully submitted,



Gwendolyn Wyard
Associate Director of Organic Standards and Industry Outreach
Organic Trade Association

CC: Laura Batcha
Executive Vice President
Organic Trade Association

Relevant References (attached)

- OTA comments on AB856
- Input Manufacturer Compliance Plan Guidance Document for Inputs Used in Organic Crop and Livestock Production
- NOP 5012 - Liquid Fertilizer

Appendix 1

In order to review materials or be accredited, the MRO or ACA would need to meet the following general requirements:

- The program must be ISO 65 accredited.
- Transparency - the program must provide and make public its policies and procedures and provide a clear description of the process it will follow to review the compliance of organic input material to the NOP Standards. This includes a description of the organizational structure and outside experts that may be consulted.
- The program must be able to efficiently search, find and track material decisions by material and by client.
- The program must have trained personnel to review materials; personnel must have a minimum of a bachelor's degree in science or equivalent. Organic Industry experience is preferred.
- The program must have sufficient personnel, resources, infrastructure, and documentation to engage in on-site inspections when required.
- The program should engage in a reasonable number of announced and unannounced inspections per year of the facilities producing the approved products to assure integrity of the list. Decisions about what facilities to inspect should include an emphasis on those categories and products that are at higher risk of potential problems or fraud.
- The program must communicate decisions regarding the compliance or non-compliance of brand-name inputs and the dates they made the decisions. Specifically, the program must make public the process for identifying and removing non-compliant products from its registration.
- For those products the program has found compliant and continues to publish as compliant, it must have a mechanism in place by which it confirms ongoing compliance of such products.
- The program must undergo regular audits that include material review as part of the audit scope.
- The program must have a description of a transparent process to resolve conflicts between the MRO's decision and determinations with those of another MRO, ACA or the National Organic Program.
- The program must have a description of the qualifications, expertise, obligations regarding conditions of confidentiality, and conflict of interest of any outside party that the MRO may or may not consult with in its review and decision-making.

- The program must have a description of a process in which an applicant can appeal a decision made by the MRO regarding whether an organic input material is compliant with National Organic Program standards.
- The program must have a description of a process in which the MRO will investigate, take action and notify interested parties regarding previously approved organic input materials when in receipt of information in regards to compliance to National Organic Program standards from the public, other state organic programs, accredited certifying agencies, or the National Organic Program

Appendix 2

Criteria that should be used by Accredited Material Review Organizations (MRO) to evaluate materials:

- The MRO must have a clear description of the process it will follow to review the compliance of organic input material to the NOP Standards. This includes a description of all internal committees and outside experts that may be consulted.
- Evaluation of the Compliance Plan. The input/material manufacturer must have a Compliance Plan describing all ingredients (active and inactive), manufacturing processes, process control information, testing, and other information as required by the material evaluation program.
 - OTA developed a guidance document intended for input manufacturers seeking to develop an Organic Systems Plan. The document titled “Input Manufacturer Compliance Plan Guidance Document for Inputs Used in Organic Crop and Livestock Production” can be found at the following link:
<http://www.ota.com/pp/regulatory/inputcompliance.html>
- The MRO must follow established criteria for making agricultural vs. non-agricultural determinations based on NOP or NOSB Guidance.
- The MRO must follow established criteria for making synthetic vs. non-synthetic determinations based on NOP or NOSB Guidance.
- Minimum Requirements for MRO Review Personnel. We believe that those actually charged with the evaluation of materials should have a minimum level of experience and education. Our initial recommendation is personnel must have a minimum of bachelor’s degree in science or equivalent professional experience. Organic Industry experience is preferred.
- Formal Public Communication of the Decision-Making process. We believe that when an accredited MRO takes a material review action, it must do so publicly and transparently. Currently, it is very difficult for input manufacturers and the organic production and certification community to have awareness of the status of any one input material across the entire spectrum of review entities and ACAs.

March 7, 2011

Amadou Ba, Chief
Fertilizing Materials Inspection Branch
California Department of Food and Agriculture
1220 N Street
Sacramento, CA 95814

Dear Mr. Ba:

As you know, the Organic Trade Association (OTA), representing businesses across the organic supply chain, has been actively engaged in the California Department of Food and Agriculture's (CDFA) Fertilizer Inspection Advisory Board AB 856 Subcommittee. OTA fully supports the objectives of AB856 to ascertain compliance of input materials for use in organic production and to investigate and prosecute fraudulent products marketed for use in organic agriculture. We appreciate the opportunity to be represented in the discussions on promulgating regulations for this important law.

We strongly support the ways in which AB 856 and its proposed regulations:

- Address the need for inspections of facilities manufacturing inputs for organic production ;
- Give CDFA enforcement authority, including the ability to prosecute and fine suppliers making fraudulent inputs which do not comply with the National Organic Program (NOP) standards.

We also commend the Fertilizing Materials Inspection Program (FMIP) for establishing a transparent process for obtaining feedback on regulations as they are drafted, for developing a phase-in period of the law that allows for continued industry recommendations as the law is implemented, and for further researching blended input materials before making a determination on how best to regulate these products.

OTA would like to recommend that CDFA:

- Add language to its regulations, as agreed to at AB 856 Subcommittee meetings, to clarify the scope of the definition of Organic Input Materials (OIMs) to apply only to products that make claims of compliance to the NOP rule;
- Recognize inspections from ACAs and other NOP-recognized third parties;
- Recognize in-state and out-of-state material reviews by Accredited Certifying Agents or NOP-recognized third party reviewers by including language allowing for this in the regulations;
- Consider the Organic System Plan as a model for input producers to maintain their records;
- Not implement the regulation faster than staff capacity allows for uninterrupted business in compliant inputs;
- Revise the fee structure so that it is based on a fee per formula, not per label.

In our comments, we also recommend that CDFA consider other definitions and terms, and we request clarifications regarding some of the processes for implementing AB 856. Further, OTA is concerned that the proposed regulations will have adverse economic impacts on small businesses, and we recommend that the economic impacts be further evaluated.

Finally, OTA encourages CDFA and FIAB to maintain close dialog with USDA-NOP. The organic sector is accountable to a federal program for demonstrating compliance with organic standards and ultimately OTA seeks a nationally uniform solution to materials review, verification and enforcement of compliance to national organic standards.

Again, OTA thanks CDFA for its efforts to eliminate and prosecute fraud in organic compliant inputs used in California organic agriculture.

OTA respectfully submits the following more specific comments on the proposed regulations, to help CDFA facilitate the implementation of this new law:

General Comments.

1. Notice of Proposed Rulemaking & Initial Statement of Reasons.

A. Reasonable Alternatives to the Regulations & Consideration of Alternatives.

Discussion. The Department states that “no other alternatives were presented to or considered by the Department in regard to the proposed rulemaking as written” and that the Department determined no alternatives for consideration existed that were less burdensome to small business. We believe that several substantive alternatives were discussed and/or proposed during meetings and deliberations of the Fertilizer Inspection Advisory Board AB 856 Subcommittee meetings that occurred in and around June 9, 2010, July 13, 2010, August 3, 2010, September 15, 2010, October 21, 2010 and November 12, 2010 as so noted in the Technical, Theoretical, and/or Empirical Study, Reports or Documents of the rulemaking’s Initial Statement of Reasons. We believe the Department was presented with these alternatives to the scheme outlined in the proposed regulations and that, although they may or may not appear in the “minutes” of the meetings or in “recommendations” of the Subcommittee, this does not release the Department from their obligation to analyze and evaluate alternatives other than those found in the proposed regulation.

Recommendation. The Department should very carefully consider all alternatives that were raised during the meetings mentioned above and provide their evaluation and economic analysis of the alternatives discussed at the meetings, especially as they relate to their relief of the economic burden on applicants and end users, especially small businesses. We believe that alternatives were discussed at those meetings to include but not be limited to:

- a) **Recognition.** The National Organic Program (NOP) recognizes third-party materials review programs. Only NOP recognized and ISO65 accredited programs are authorized to assess an input materials compliance to the National Organic Standards. The issues of expertise, duplication, redundancy, cost of review and economic burden were discussed at the meetings and have not been evaluated or analyzed in this regulatory package. We believe that only approvals from NOP recognized materials review programs should be recognized by CDFA’s organic input material registration review process.
- b) **Third Party Inspections.** Allowing third party inspections of organic input material manufacturers in California was proposed during sub-committee meetings. The law is permissive in that it says the Department may conduct the annual inspections of organic input material manufacturers. We believe that the issues of expertise, duplication, redundancy, the cost of multiple inspections and economic burden were

discussed at the meetings and have not been evaluated or analyzed in this regulatory package. We believe that the Department is fully justified in the approval of NOP recognized third-parties including accredited certifying agents for the required annual inspection of organic input material manufacturers inside California, nationally and internationally;

- c) Scope.** The sub-committee voted to clarify the scope of OIM at the October, 2010 meeting, based on recommendations of a Scope Task Force. It was OTA's understanding that the Department had accepted this recommendations but it does not appear in the regulations. Specifically, the regulation should only require registration by those engaged in the manufacture or sale of commercial organic input materials that are "to be used in organic crop and food production", meaning that the product is intended for use and makes a claim of NOP compliance. This was discussed and has not been evaluated or analyzed by the Department. Further, we believe that the intent of the law and the regulation should not be targeted at individuals using organic inputs on their own properties but rather should be focused on commercial interests, i.e. registering organic input materials that are manufactured, distributed and sold through wholesale and retail marketplaces for use in organic production, and reviewed for compliance as a blended or branded product by an NOP recognized materials review program. Specifically, to capture the intent of the Scope task force recommendation passed by the sub-committee, we request that the following language be added to the regulations for clarification purposes:

"Organic Input Materials (OIM) that are required to be registered are those products to be used by organic producers which claim to be compliant to NOP as suitable for use in organic crop and food production." ;

- d) Inputs vs. labels.** The issue of economic burden of paying for the registration of each unique "label" containing organic input materials was discussed numerous times. One alternative that was discussed was a registration scheme based on the Department reviewing and approving the organic input materials, themselves that could subsequently be the derivative for any number of "labels." The Department's fee would be based in the review of the organic material input, not each unique label that contained an approved organic material input. We believe that the Department can provide a process to approve a manufacturer's "formulation" that can be used in the formulation of any number of "labels" registered by the Department. In fact, the Food and Agriculture Code supports a registration fee per "product" that refers to the input itself. The fact that an input can be combined with other approved inputs into a labeled product does not require a "registration" fee to be charged for each label. While the initial registration cost for an OIM is appropriate, based on the time and staff required of an initial application review, we do not foresee that the same amount of departmental resources will be required of a review of product renewals that have no changes. We, therefore, request that the cost of renewing a registration for an unchanged product be reduced.

B. Evidence of Supporting Finding of No Significant Statewide Adverse Economic Impact Directly Affecting Business.

Discussion. The Department states it has initially determined that the proposed changes in regulation would result in no added cost to small businesses. The Department does not provide any analysis to support this finding.

Recommendation. The Department is required to provide an economic impact analysis of all parties to this proposed regulation; those potentially impacted include but are not limited to organic input manufacturers, distributors, accredited certifying agents, organic farmers, composting operations, and consumers. Several OTA members anticipate that the regulations will likely limit sales of OIMs in California, including fertilizers, soil amendments, and compost used in organic production, and their availability to organic producers.

Section 2303. Labeling Requirements.

Section 2303(w).

1. Consideration of other accepted definitions and terms.

Discussion. The Department proposes – for consideration with labeling requirements the accepted definitions and other official terms in the 2010 American Association of Plant Food Control Officials Publication (AAPFCO), volume 63. While many organic material inputs are used in traditional fertilizer formulations, there are many that have not been defined, described or currently contemplated by the AAPFCO.

Recommendation. We recommend the inclusion of the definitions and terms from the National Organic Program, the National Organic Standards Board, the Organic Materials Review Institute’s generic materials list, and the American Association of Feed Control Officials. These definitions and terms will provide applicants and the Department with additional flexibility so that the organic input material labels contain terms and definitions that are widely used and easily understood by the trade and the public. In addition, we would recommend that the Department not specify the year or volume number of a document. Instead, identify it by the latest policy position or publication of the authoritative organization.

Section 2320.2. Registration Application for Organic Input Material Product Label.

Application.

1. Form.

Discussion. The Department has provided a description of the information it requires in its application for registration of an organic input material. The proposed regulation does not

provide an actual reference to the form the Department is using for its registration process; i.e. the form number, edition and date last amended.

Recommendation. We recommend that the Department provide a standard name for the form and identify where the most current edition can be found.

Section 2320.2 (a).

1. Compliance with National Organic Program Standards.

Discussion. The Department has indicated that organic materials submitted for registration shall comply with the requirements of the National Organic Program standards. While the Department has provided the application for registration of an organic input material, the Department has not provided any transparency into their process to determine whether a material is in compliance with National Organic Program standards. The proposed regulation should:

- a) Provide a description of a transparent process that the Department will follow in its review and decision making;
- b) Provide recognition of the other established programs in the United States that provide review of organic input material for their compliance with National Organic Program standards;
- c) Provide a description of a transparent process to resolve conflicts between the Department's review and determinations with those of an established review program, state organic program or the National Organic Program;
- d) Provide a description of a transparent process that the Department will follow in its review and decision making for materials that the Department does not have expertise or experience;
- e) Provide a description of the qualifications, expertise, obligations regarding conditions of confidentiality, and conflict of interest of any outside party that the Department may or may not consult with in their review and decision making;
- f) Provide a description of a process in which an applicant can appeal a registration decision made by the Department in regards to whether an organic input material is compliant with National Organic Program standards; and,
- g) Provide a description of a process in which the Department will investigate, take action and notify interested parties regarding previously approved organic input materials when in receipt of information in regards to compliance to National Organic Program standards from

the public, other state organic programs, accredited certifying agents, or the National Organic Program.

Recommendation. We recommend that:

- a) Only programs recognized by NOP conduct materials review, and thus CDFA should not commence materials review until such time as CDFA/FMIP is recognized by NOP for such purpose;
- b) The Department recognize the review and approval of organic input materials by the other NOP recognized organic input material review programs, specifically ACA's, OMRI and WSDA. Recognition of other review programs will reduce redundancy and economic burden on applicants;
- c) The Department focus implementation activity on registration of products deemed compliant by third-party review, and require annual inspections of facilities based on risk, and conduct investigations when fraud is suspected;

(b) (5). The source or supplier of all ingredients.

1. Source or Supplier of All Ingredients.

Discussion. The Department indicates that it will require an applicant to provide the source or supplier of all ingredients during the application process. While it is acceptable for the Department to require the source or supplier information, many organic input material manufacturers have developed supply chain relationships that are of a very sensitive business nature.

Recommendation. We recommend that the Department clearly provide an application process that provides the necessary information for their registration of an organic input material but also provide for confidentiality of business information.

Section 2323. On Site Inspection of Organic Input Material Manufacturers.

1. Cost of Inspection.

Discussion. The in-state and out-of-state facilities of registered organic input material manufacturers are required to be inspected on an annual basis. However, the Department has not outlined a fee schedule for the cost of inspection or how an in-state or out-of-state manufacturer will pay for the inspections.

Recommendation. We recommend that the Department identify its authority to charge fees for the inspection of in-state and out-of-state facilities and establish a fee schedule based on an hourly charge.

2. Third-Party Organizations.

Discussion. Food and Agriculture Code Section 14601(f) establishes that manufacturers shall be inspected at least once a year. The code also states that the Secretary “may” perform site inspections and “may” accept inspections performed by third-party organizations for out-of-state manufacturers; each is permissive. The permissive nature of the code clearly indicates the legislature’s intent that the Department “may” be the body that performs the annual inspection – not the sole organization. If that were the case, the legislature would have made the law mandatory in regards to the Secretary performing the site inspections, i.e. “shall” perform the inspection vs. “may” perform the inspection. In addition, the fact that the legislature authorized third-party organizations to inspect out-of-state manufacturers is simple and has no bearing on the use of third-party organization to conduct in-state inspections. In addition, currently the National Organic Program requires annual site inspections and approval of certain fertilizer manufacturers by accredited certifying agents before their materials can be used in certified organic farming operations.

Recommendation. We recommend that the Department provide for inspections by third party organizations for both in-state and out-of-state and international manufacturers.

3. Audit Standards.

Discussion. The proposed regulation does not provide a description of the standards upon which they are basing the annual onsite inspection of fertilizer manufacturers. This will be especially important for third party organizations and accredited certifying agents.

Recommendation. We recommend that:

- a) The Department establish in regulation the standards by which a manufacturer will be inspected for compliance with National Organic Program standards and nutrient guarantee and/or claim; and,
- b) The Department consult with the United States Department of Agriculture’s National Organic Program and interested parties to produce a uniform and consistent set of inspection standards especially as it relates to compliance with their program.

Section 2323(d).

1. Records.

Discussion. The proposed regulation provides a very general catch-all for the records that a manufacturer will be required to maintain. While the record requirement refers to very critical records for oversight of compliance, the records themselves do not provide a platform for efficient and effective audit of a manufacturer’s facility or of a continued approval or registration of an organic input. We believe a “plan” requirement is more consistent with the

functioning of the National Organic Program. We believe a good model for the Department to consider would be the “Organic System Plans” that are currently in use and are the foundation for the audit and oversight by Accredited Certification Agents. We believe that an “Input Compliance Plan” should be considered by the Department that may include but not be limited to: Facility Information (Location, Facility, and Equipment); Flow Charts (Compliance Control Points, Processing, Lot Tracking); Inventory Management Records (Purchasing, Manufacturing and Shipping Records); Standard Operating Procedures (Receiving, Storage, Segregation, and Shipping; Equipment: Cleanout and Lockouts; and Sampling / Testing: Retains and Testing Protocols); and Personnel Training.

Recommendation. We recommend that:

- a) The Department require that manufacturers submit an Input Compliance Plan with their application and maintain it at their facility for inspection by the Department and third-party organizations; and,
- b) The Department consult with the United States Department of Agriculture’s National Organic Program and interested parties to develop the standards for an Input Compliance Plan.

Section 2323(e).

1. Samples.

Discussion. The proposed regulation indicates that the Department “shall” take samples and make analysis/examinations of input materials. While it is appropriate for the Department to take samples when necessary to determine compliance, it appears that the use of the term “shall” indicates that mandatory sampling and analysis will occur during annual site inspections. The proposed regulation does not include its process and procedures for taking a sample, notifying a manufacturer that a sample is being taken, or requiring a split sample be produced for retention by the manufacturer for their own analysis. The proposed regulation also does not refer to the laboratory certification, standards or testing methods/protocols it will require for testing purposes. We also note that the proposed regulation does not refer to federal law, regulation or policy in regards to the National Organic Program and sampling, testing and actions due to a finding of prohibited substance in an organic input material. The proposed regulation also lacks a process for the disposition of organic input materials that are considered adulterated for no other reason other than non-compliance with National Organic Program standards and can safely be used as a conventional fertilizing material without posing harm to a crop, the public or the environment.

Recommendation. We recommend that:

- a) The Department indicate their intent to conduct mandatory sampling during annual site visits or that samples may be taken to confirm compliance;

- b) The Department provide for sampling procedures and provide for split sampling whenever official samples are taken, for retention by the manufacturer;
- c) The Department provide for requirements for laboratory certification, standards and testing methods/protocols for testing of official samples;
- d) The Department provide for direct reference to federal law, regulation and policy in regards to the National Organic Program and the sampling, testing, and actions due to findings of a prohibited substances in an organic material; and,
- e) The Department provide for disposition of organic input materials that are considered adulterated for no other reason other than non-compliance with National Organic Program standards.

In summary, we recommend that CDFA add to its regulations that the definition of Organic Input Materials applies only to products of companies who make the claim that their products meet the NOP rule; recognize in-state and out-of-state inspections from other NOP accredited or recognized parties; recognize material reviewers currently recognized by the NOP ; consider the Organic System Plan as a model for input producers to maintain their records; adjust the fee structure to base it on per formula, not per label; and make clarifications on processes, as noted above, for implementing AB 856.

We look forward to our continued collaboration with you in developing clear and effective regulations to implement AB 856, to ensure the integrity of inputs for organic production.

Sincerely,



Laura Batcha
Chief of Policy and External Relations
Organic Trade Association



Compliance Plan Guidance Document For Inputs Used in Organic Crop and Livestock Production

Introduction

The following outline provides guidance on the essential components needed to create and maintain a Compliance Plan for input manufacturers of products used in organic production. This is intended to be a guidance document for input manufacturers and not every facility will require all components.

Inputs for use in organic production must meet the requirements of the USDA National Organic Program (NOP) regulations, 7 CFR Part 205. Companies supplying organic producers with fertilizers and soil amendments need to maintain all the records necessary to document compliance to the NOP. Third-party reviewers, including certification agents, are implementing comprehensive due diligence in approving not only high-nitrogen liquid fertilizers but all inputs for use in organic production.

In addition to formal regulations, the NOP issued a policy on December 14, 2009, titled "Approval of Liquid Fertilizers for use in Organic Production", which states that manufacturers seeking approval of products for use in organic production must:

1. Maintain complete records sufficient to demonstrate compliance with the NOP regulations.
2. Submit complete documentation describing all ingredients (active and inactive), manufacturing processes, process control information, testing, and other information as required by the material evaluation program.

The following guidance will serve as an aid to manufacturers seeking to develop an organic compliance plan. Once a plan is developed, it can be used to provide information as requested by a materials evaluation program and aid in on-site inspections. .

Part I: General information

A. Company Information

1. Contacts (including title of each contact, addresses, telephone numbers, fax numbers, and email addresses of personnel authorized to handle confidential, public or other information)
2. Legal structure and ownership of the company
3. Co-packer or contract manufacturer information, if appropriate
4. Brief description of the business and the procedures in place for compliance to the National Organic Program and other organic regulations if applicable
5. Procedures for training staff about organic regulations

B. Product General information

1. Timing of manufacture (seasonal, continuous, intermittent, etc)
2. Other non-organic products produced in the same facility, if any
3. Location of facility (ies)
4. Facility contact personnel, titles

Part II: Raw Ingredients

A. List of all Incoming Raw Ingredients, including:

1. Sources
2. Analysis
3. Storage Location
4. Reviews by Independent Third-Party Auditors, if applicable

Part III: Manufacturing Process

US organic regulations require that the final input be non-synthetic or on the National List of Allowed Synthetics Section 205.601. To understand whether your process uses or creates synthetic ingredients or inputs, the following information is needed:

A. Facility map – locations of all facilities relevant to manufacture of your product

B. Equipment list – all equipment used in handling and manufacturing your product

C. Production Process Description

1. Production Flow chart – all steps from initial ingredients until there is a final product ready for storage or shipping
2. Written Description of the Manufacturing Process - including ingredient amounts and processing aids, sequence and duration of events, temperatures, and processes such as digestion, fermentation, extraction, or any chemical reactions, etc.
3. Typical yields – the quantities you produce in a specified period of time. Consider this from a third party’s point of view. What is understandable and able to be confirmed during a single site visit? Be prepared to explain discrepancies in the results or anticipated losses during the manufacturing of the final product.
4. Batch capacity – What will one batch produce, and how often is a batch completed.
5. Sampling performed (testing performed, labs used, frequency of testing, etc.) – Tests related to your quality control.
6. Process Validation by Third-Party Audit - Any outside confirmation of aspects of your process. (ISO accreditation, OMRI, WSDA or other outside inspection)

D. Compliance Control Points (CCPs)

1. Pest control – Where necessary, what system do you provide to prevent pests from contaminating your system (thus your product)

2. Contamination prevention – How do you prevent prohibited materials in any quantity from being added to your products? Examples: Clean out systems between production of other products, Lockout systems to prevent unintentional addition of other ingredients, Sanitation systems where necessary (with removal of prohibited sanitizers where necessary), and segregation systems to prevent contamination which might occur from the manufacture of non-compliant products.
 3. Employee training – describe training to assure that employees follow the control system
 4. Split operations: If the facility produces products for both organic and non-organic use, describe steps taken to prevent commingling of ingredients or products.
- E. Storage facilities/capacity – a description of your facilities for storing both the ingredients to manufacture your product and the final product. Also include the facilities used if there is storage used intermediate to the process of manufacture (e.g. storage of blended ingredients used in manufacture of product). Capacities available and alternate uses should be noted.

Part IV: Finished Goods

- A. A list of all products manufactured in this facility, including any conventional products as well as those allowed for organic use. The list should provide:
1. Copy of all labels
 2. MSDSs, if applicable

Part V: Documentation

- A. Inventory Management
1. Raw Ingredients
 - a. Receipts, Purchase Orders, Bills of Lading
 - b. MSDSs, if applicable
 - c. Spec sheets, if applicable
 - d. Make sure to obtain “current” information from the ingredient supplier – suppliers can change their own formulations, placing the compliance of a final product at risk.
 - e. Live organism listing including species and quantity, if applicable
 - f. NOP compliance documentation
 - i. Organic certifications for applicable inputs
 - ii. Disclosure of any presence or use of Genetic Engineering, Sewage Sludge or Irradiation.
 - g. Sampling records/analyses – Results of any and all analyses for quality control and to meet compliance requirements i.e.; Heavy metal tests, nutrient analyses, contamination tests, etc.
 2. Storage Location and Quantities of All Inventory Items
 3. Production - Volume in-volume out record (Yield estimates & records.) Both your anticipated results and your actual results.

4. Work in Process records
 5. Finished goods
 - a. MSDS, if applicable
 - b. Spec sheets, if applicable
 - c. Sampling records/analyses – the tests you use to assure the quality of your final product
 6. Sales and Shipping Records
- B. Lot Tracking Records
1. Raw Ingredients
 2. Work in Process (WIP)
 3. Finished Goods
 4. Flow charts for Lot Tracking (Lot tracking pathways)
 5. Description of lot numbering system, or other tracking system
- C. Standard Operating Procedures (SOPs) (**These are optional** and may be helpful for various manufacturing operations)
1. General Recordkeeping / Document Flow
 2. Purchasing
 3. Documenting receipt of incoming ingredients
 4. Lab testing of incoming ingredients
 5. Ingredient storage
 - a. Lot Number Assignments
 - b. Segregation of allowed vs. prohibited materials
 6. Equipment Cleaning / Purging
 7. In-Process Storage
 8. Staging and Batch Mixing
 9. Packaging
 10. Storage of final product
 11. Order Processing
 12. Shipping
 13. Pest Control
 14. Training and Safety Protocols

D. Formulas

1. Confidential Statement of Formula - recipes that include quantities and quality specifications significant to the quality of the Final product

E. Registrations and Certifications

1. Other entities which license, inspect, or otherwise regulate the facilities used for the manufacture of this product
 - a. Other certification for organic input compliance, or certificates for compliance of ingredients
 - b. Non-governmental third party inspection/audit results/reports (quality systems, ISO, HACCP, etc.)
 - c. State or other government licenses, registrations, inspection reports, etc.

F. Other Documentation

1. Sanitation Logs
2. Pest Control Logs
3. Personnel Training Logs



Approval of Liquid Fertilizers for use in Organic Production

Background

On February 20, 2009, the National Organic Program (NOP) issued a notice to its accredited certifying agents (ACA) that it was no longer confident that the following liquid fertilizer products can be shown to be compliant with the NOP regulations: Marizyme™ and Agrolizer™. Both of these products were manufactured by Port Organic, Ltd., which was no longer operating at that time. The notice further advised that continued use of the products Marizyme™ and Agrolizer™ without the ability to prove they are in full compliance with the NOP standards could jeopardize the organic status of operations, including land and products.

NOP announced it will focus increased scrutiny on how inputs are approved for use by certified organic operations during accreditation audits of ACAs conducted beginning in 2009, beginning with an emphasis on liquid nitrogen fertilizers. Further, the NOP advised vigilance in the approval of all liquid fertilizer products and other inputs and advised ACA's of steps to be taken by October 1, 2009 for the review of all nitrogen liquid fertilizers with a nitrogen analysis of greater than 3 percent. Included in this announcement, NOP required that reviews must verify that no synthetic nitrogen equipment, tanks, or supplies must be present within 100 yards of the facility that produces the organic approved inputs at any time of the year.

On March 4, 2009, the NOP issued an amendment to the previous notice to clarify that while fertilizer producers were required to obtain third-party verification of their ingredients by October 1, 2009, all fertilizers were expected to be in compliance at the time of the notice. The amendment further clarified that manufacturers who do not produce liquid fertilizers with nitrogen analysis content greater than 3 percent are not required to undergo third-party inspections unless further advised by the NOP.

Terms Defined

For the purpose of this instruction, the following definitions shall apply:

Material evaluation program: An organic certification or other program, independent from the crop producer or the input manufacturer, with the expertise to verify compliance of inputs used in organic production and handling with the NOP regulations. The expertise and approval of material evaluation programs will be a component of the NOP accreditation program. Approved material evaluation programs include NOP accredited certifying agents and the Organic Materials Review Institute (OMRI). ACAs and OMRI are audited regularly to evaluate their compliance with the NOP regulations and this policy.

Policy

All liquid fertilizers with a nitrogen analysis greater than 3 percent must be approved by a material evaluation program to be used in organic production. When approving organic systems plans (OSP), ACA's must verify and document that all liquid fertilizers with a nitrogen analysis greater than 3 percent have been approved by a material evaluation program. It is a violation of the NOP regulations to apply unapproved liquid fertilizers to certified organic or transitional land.

Procedures for approving liquid fertilizers with a nitrogen analysis greater than 3 percent

Manufacturers seeking approval of liquid fertilizers with a nitrogen analysis greater than 3 percent for use in organic production must:

1. Produce inputs that comply with all NOP and other regulatory requirements.
2. Maintain complete records sufficient to demonstrate compliance with the NOP regulations.



3. Submit complete documentation describing all ingredients (active and inactive), manufacturing processes, process control information, testing, and other information as required by the material evaluation program.
4. Request and complete an onsite audit by a material evaluation program.

Approval. Upon receipt of complete documentation and request for an onsite audit, the material evaluation program must:

1. Conduct a complete review of all documented processes by a qualified inspector.
2. Conduct annual onsite audits of manufacturing facilities and processing by a qualified, experienced inspector to verify compliance with NOP requirements and stated procedures.
3. Conduct a balance-in / balance-out analysis of all ingredients and finished products including, when appropriate, by nitrogen content.
4. Prepare and issue a complete report of all observations and findings to the manufacturer and retain for review by the NOP.
5. Issue a signed certificate or other instrument which specifically lists all products approved under the scope of the material evaluation program. Document must state "Approved for use in NOP organic production by [name of material evaluation program who conducted the material review and onsite inspection]."
6. Conduct at least one annual unannounced inspection during manufacturing to ensure ongoing compliance.
7. Not issue approval for any fertilizer or other input which does not fully comply with the regulations.

Criteria for approval of fertilizer manufacturers. A material evaluation program may issue written approval of the fertilizer manufacturing process if:

1. Written procedures fully describe the manufacturing process.
2. Procedures fully account for product plant nutrient content and other attributes.
3. On-site inspections confirm that all NOP requirements are met and there is no evidence of fraud in formulation,
4. The infrastructure necessary to produce the approved finished product is present and complete. This may include dry and liquid storage areas, conveyances (such as forklifts, trucks, piping), finished product storage, and both the ingredient and finished product transportation infrastructure.
5. Shipping and receiving balances for ingredients and finished products support findings of product compliance.
6. Unannounced inspections and analytical testing verify compliance.

With this notice, the NOP removes the requirement for a minimum of 100 yards of separation between synthetic nitrogen storage facilities and organic fertilizer production areas.

Document Control

This document supersedes NOP Notices to Certifiers on this subject dated February 20, 2009 and March 4, 2009, which are now obsolete.

Approval

Miles V. McEvoy
Deputy Administrator
National Organic Program