

**FORMAL RECOMMENDATION BY THE
NATIONAL ORGANIC STANDARDS BOARD (NOSB)
TO THE NATIONAL ORGANIC PROGRAM (NOP)**

Date: November 19, 2008

Subject: Procedures for Handling Technical Reviews

NOSB Chair: R. Delgado

Recommendation

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: _____

Guidance Statement: _____

Other: _____X_____

Summary Statement of the Recommendation (including Recount of Vote):

The recommendation provides clear guidance for the NOSB on securing advice from third party consultants in a clear and consistent manner.

Committee vote; Moved: R. Delgado, Second: H. Karreman Yes: 8 No 0 Abstain 0 Absent 1

NOSB Vote: Motion: D. Giacomini Second: B. Flamm

Board vote: Yes – 14 No- 0 Abstain- 0 Absent – 1

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

The recommendation provides guidance to Board committees on securing needed advice which is consistent with OFPA.

Response by the NOP:

**National Organic Standards Board
Joint Materials and Policy Development Committees
Recommendation for an addition to the NOSB Board Policy Manual:
Procedures for Handling Technical Reviews
September 23, 2008**

Introduction:

While reviewing specific petitions, the NOSB requires, at times, specialized expertise. This has been particularly important as the organic community has expanded and the number and complexity of issues has evolved. The goal of this document is to provide a clear guidance for the NOSB on securing advice from third party consultants in a clear and consistent manner.

The NOSB recognizes the challenge in finding and qualifying capable technical third-party experts, particularly when there is a need for specialized scientific know-how, or market availability. This recommendation assumes that there is a listing of third party experts available. For this purpose, the NOSB would like to encourage the NOP, with input from the NOSB, to seek and qualify individuals, institutions, and organizations in order to develop a database of potential technical reviewers.

The following addition to the PPM includes eliminations of current text in the Policy Manual for Section VIII in strike through, and additions in red font:

SECTION VIII

PROCEDURES OF THE NOSB

This section presents the procedures followed by the NOSB to evaluate petitions. First, the **National Organic Program (NOP)** material review process is presented. Second, a review of the NOSB process for selecting and reviewing the work of technical advisory panels is provided followed by a description needed in a formal petition. Third, the process for NOSB material review is provided.

MATERIALS REVIEW PROCESS

Evaluation Procedures for Substances Petitioned for Addition or Removal from the National List (NL). A petition to change the annotation to a listed material is in effect the addition or removal of one or more materials.

Definitions:

Technical Advisory Panel (TAP) - Group of third party experts ~~hire~~ convened by the Board to provide a technical review related to a material petition under review by the NOSB.

Technical Review – A report prepared by a third party expert under contract addressing the environmental, human, and industrial impact of a petitioned material per the OFPA and regulatory evaluation criteria to aid in the thorough evaluation of that material by the NOSB

Phase 1: Receipt of Petition and Examination of Petition for Completeness and Eligibility

During this phase the ~~National Organic Program (NOP)~~ will:

- Notify the petitioner via letter and/or electronic mail of receipt of the petition.
- Determine whether the petition is complete
- Determine if the petitioned substance is eligible for petition under the Organic Foods Production Act and its implementing regulations; document this review using the NOP-OFPA checklist.
- Determine whether the petitioned use is approved under the statutory and regulatory authority of the Environmental Protection Agency (EPA); the Food and Drug Administration (FDA); or other appropriate federal agency if applicable;
- Identify and secure any confidential business information (CBI) designated by the petitioner;
- Notify, as applicable, the petitioner via letter and/or electronic mail of determination of completeness and eligibility, and acknowledge the designation of certain information as CBI.
- Upon determination of completeness and eligibility, the following actions will be taken:
 - Publish the petition on NOP website; and
 - Notify the ~~National Organic Standards Board (NOSB)~~ materials committee chairperson and the chairperson of the committee that the substance is being petitioned for addition or prohibition from the National List (Crops, Livestock, Handling or other pertinent committees). This notification will be sent via letter and/or electronic mail and inform the chairs that the petition is complete, provide OFPA review and EPA/FDA determination checklist, and request identification of any questions the appropriate committee wishes to be specifically addressed in the contractor's report.

Phase 2: Determine if a Third Party Technical Review is Required

During this phase:

- The NOSB materials committee, working with other applicable NOSB committees, has **60** days to submit any questions to the NOP. The questions requested by the committee should include items that need specific background information, **recommended technical expertise, and be based on the OFPA criteria.**
- **Per the NOP materials review process, the NOSB should review the petition and using the NOP checklists for the material determine the following:**
 - 1) If the material is deemed appropriate for consideration on the National List (pending criteria). If the answer is no to this question, an explanation is required.**
 - 2) If the answer to question #1 is yes, the NOSB committee assigned for the review (as identified by the Materials Committee Chair) must decide if**
 - a. there is sufficient information in the petition,**
 - b. the committee can reasonably research any pending technical information, or**
 - c. there is the need to secure a technical review from a third party expert (see section titled *Procedures for Handling Technical Reviews*)**

3) If the answer to question #1 is no, the Materials Committee Chair will inform the NOP that the petition is incomplete and will include an explanation. If the reviewing committee concludes there is a need for a third party technical review, the Materials Committee Chair will proceed to make the request to the Program.

- Notify the petitioner, via letter and/or electronic mail, that the petition is incomplete or ineligible; or

Phase 3: Evaluation by a Third Party Expert

During this phase the NOP will:

- Notify the third party expert of the petition's determination of completeness and eligibility. This third party will have technical expertise relevant to the petition and the notification will constitute official notice of the need for a technical review.

During this phase the **Third Party Expert** will:

- Conduct activities necessary to provide responses to evaluation questions contained in the Statement of Work (SOW) and any additional questions identified by the NOSB as described above;
- Use the TR template to prepare and distribute to the NOP a draft technical report (TR) in electronic format.

Phase 4: Sufficiency Determination

During this phase the NOP will:

- Submit a copy of the draft TR for review to the NOSB materials committee and the committee that the substance is being petitioned for addition or prohibition from the National List (Crops, Livestock or Handling);
- Review the draft TR against the following performance criteria. The report will be acceptable when it:
 - Is consistent in format, level of detail and tone;
 - Is technically objective and free from opinions or conjecture;
 - Is written in a style appropriate for non-technical readers (e.g. free of technical jargon);
 - Is prepared using a well-defined and consistent procedure consisting of information gathering, information synthesis and document preparation, and quality assurance;
 - Is based on the best available information that can be obtained within the designated time frame;
 - Is thoroughly supported using literature citations; and,
 - Addresses all evaluation questions as set out in the SOW.

During this phase the NOSB materials committee and the committee that the substance is being petitioned for addition or prohibition from the National List (Crops, Livestock or Handling) will:

- Review the draft TR against the following performance criteria. The report will be acceptable when it:
 - Is consistent in format, level of detail and tone;
 - Is technically objective and free from opinions or conjecture;
 - Is written in a style appropriate for non-technical readers (e.g. free of technical jargon);
 - Is prepared using a well-defined and consistent procedure consisting of information gathering, information synthesis and document preparation, and quality assurance;
 - Is based on the best available information that can be obtained within the designated time frame;
 - Is thoroughly supported using literature citations; and,
 - Addresses all evaluation questions as set out in the SOW.

- Notify the NOP in letter and/or electronic mail the acceptance of the TR within 60 days of receiving the TR. If the TR is not accepted by the NOSB materials and the committee that the substance is being petitioned for addition or prohibition from the National List (Crops, Livestock or Handling), the committees must provide to the NOP in letter and/or electronic mail the specific areas of the TR that were concluded to be insufficient, the rationale for drawing such a conclusion and the improvements to be made so that the document can be determined sufficient.

- Upon concurrence by the NOP that the TR is insufficient, the NOP will notify the contractor by letter and/or electronic mail of the areas of the TR that are insufficient, the rationale for drawing such a conclusion and the improvements to be made so that the document can be determined sufficient. The time frame required for the completion of the changes will be determined through mutual agreement between the contractor and the NOP.

Phase 5: Action by NOSB Materials Chair and the Committee that the Substance Is Being Petitioned for Addition or Prohibition from the National List (Crops, Livestock or Handling)

During this phase the NOSB materials Chair and the committee that the substance is being petitioned for addition or prohibition from the National List (Crops, Livestock or Handling) will:

- Convene at a mutually convenient time to review, discuss and recommend an action on the petitioned substance. The committee may convene as the TAP by electronic mail or conference call to provide complete evaluation of the petitioned substance, as provided by OFPA 6518(k)(3). The NOSB materials committee or delegated committee must convene and recommend an action on the petitioned substance no later than 60 days before a scheduled meeting of the full NOSB.

Phase 6: Action by Full NOSB

During this phase the NOP will:

- Publish the recommendation of the NOSB materials committee and the committee that the substance is being petitioned for addition or prohibition from the National List (Crops, Livestock or Handling) on the NOP website and request a minimum of 60 days of written public comment on the recommendation prior to the public NOSB business meeting.
- Set as an agenda item for the next meeting of the NOSB time sufficient to discuss and make a recommendation by the full NOSB on the petitioned substance.

PROCEDURES FOR HANDLING TECHNICAL REVIEWS

The NOSB's role involves reviewing specific materials; however, a petition could involve a wide range of topics. Although members of the Board represent several areas of the organic community and hold advanced degrees in different scientific areas, they might lack the expertise, or time, required to address the data needs of a petition. In such cases the Board has the option of requesting the assistance of third party experts and expecting from these experts a written technical review or report.

Third party experts can consist of the following:

1. Employees of the USDA such as AMS Science & Technology, Agriculture Research Service, or other federal agencies with appropriate expertise, as needed.
2. Consultants or contractors.

A committee should follow these steps in deciding the need for third party expert:

1. Define if the committee has the expertise needed to address the questions related to the petition, mainly:
 - a. Impact on the environment
 - b. Impact to human health
 - c. Sustainability and compatibility with organic principles.
2. If the committee does not have the expertise or resources (e.g., time), the Committee chair should make a request to the Chair of the Materials Committee for a third party expert specifying:
 - a. The third party expert's required background and level of expertise
 - b. Existence of potential sources of conflict that could result in biased reviews.

When requesting the assistance of a third party expert to evaluate a material, a committee must identify the main technical issues needed to be addressed including, but no limited to:

- a. All uses of the petitioned material beyond what the petitioner has requested
- b. All uses of the petitioned material in combination with other material(s) that have been already approved on the same section of the National List

- c. Interactions of the petitioned material, not addressed by the petitioner, and that may involve materials currently on the same section of the National List.
- d. All possible manufacturing methods for a petitioned material.
- e. Potential effects on public health and biodiversity
- f. Environmental risks and hazards including, but not limited to potential for developing pesticide resistance, or long-term effects on sustainability

If required, the committee should conduct a final review of the technical report and complete an assessment on the quality of work performed by the third party expert.

These are basic principles that should be considered when dealing with a third party expert:

1. A committee cannot proceed with a recommendation on a material if it is determined that there is limited valid scientific information on that material's impact on the environment, human health and its compatibility with organic principles.
2. The decision to request third party expert needs to be made independent of the availability of funds. If there is a lack of funding to secure third party expert advice, the review of the material should be placed on hold.
3. Although the Board has the final word on the approval or rejection of a petition, the decision to request a third party expert is the responsibility of the committee reviewing the material. In some cases the Materials Committee can take the initiative to request a third party expert. The logic is that a material review is an issue assigned to a committee and it is up to the committee to decide on the need for a third party expert.
4. The decision to define the expertise needed in the third party expert is the responsibility of the committee reviewing the material or issue.
5. To incorporate a diversity of opinions and to minimize the risk of bias, a committee should aim to work with a range of technical experts (individuals, or institutions).

Committee vote:

Moved: R Delgado Second: H Karreman
Yes-8 No-0 Abstain-0 Absent-1