Formal Recommendation
From: National Organic Standards Board (NOSB)
To: the National Organic Program (NOP)

Date: May 2, 2014

Subject: Update of the Petition and Technical Review Process

Chair: Mac Stone

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: ☐

Guidance Statement: ☐

Other: ☑

Statement of Recommendation: Passed

Motion to accept the proposal on Updating the petition and TR process as described below in the attached document

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

The National Organic Program (NOP) asked the NOSB for advice on revising the procedures for petitions and technical reviews in an effort to make the petition submission procedures clearer for petitioners. The revised procedures (attached below) clarify how to submit complete petitions, explain to petitioners what to expect in the petition process, make the review process for the NOSB clearer and more consistent, and provide transparency about these processes to the public.

These procedures are encompassed by a 2007 Federal Register notice, 72 FR 2167, and sections of the NOSB Policy and Procedures Manual (PPM) appearing on pages 34, 35, 37 and 38 of the current version.

Committee Vote:

Moved: Zea Sonnabend

Seconded: Calvin Walker

Yes: 15 No: 0 Abstain: 0 Absent: 0 Recuse 0

National Organic Standards Board
Materials Subcommittee
Proposal: Update of the Petition and Technical Review Process
August 27, 2013
Reviewed December 10, 2013 - No revisions

Introduction

The National Organic Program (NOP) has asked the NOSB for input on revising the procedures for petitions and technical review. These procedures are encompassed by a 2007 Federal Register notice, 72 FR 2167, and sections of the NOSB Policy and Procedures Manual (PPM) appearing on pages 34, 35, 37 and 38 of the current version.

This effort is aimed at making it clearer for petitioners to submit complete petitions and to know what to expect in the petition process, for the NOSB to have clear policies for reviewing petitions in a consistent way, and for the public to have transparency in how petitions are received, evaluated and reviewed.

Subjects covered in this proposal include petitioning to add or remove substances to the National List, how such petitions proceed once they are received, and how the NOSB determines which substances are on the National List. Also covered is the subject of adding, removing or changing and annotation placed on a listed substance.

Used throughout this proposal is the ~~strikethrough~~ for old language to be removed, and an underline for new language to be added.

Part 1. Procedures for Submitting National List Petitions

Any person may submit a petition requesting a substance to be reviewed by the NOP and NOSB at any time. Each substance to be evaluated for the National List must be submitted in a separate petition. Only single substances may be petitioned for evaluation; formulated products cannot appear on the National List. When submitting petitions, an official petition contact should be designated for all correspondence and the petition should provide specific contact information including name, address, phone number, fax number and e-mail address.

To facilitate timely NOP review and NOSB consideration of petitions, petitioners must provide concise yet comprehensive responses to the required petition information items described under the guideline heading ‘‘Information to be included in a Petition.’’ Upon receipt, the NOP will review the petition for completeness of the required petition information. If the required petition information is incomplete, the petition will be returned to the petitioner with a request for additional information.

Petitions for substance evaluations to add a substance onto, remove a substance from, or amend a substance presently on the National List involves a public and open process. Confidential Business Information (CBI) is no longer accepted in petitions. ~~Petition information not categorized and accepted by USDA, pursuant to 7 CFR 1.27(d), as Confidential Business Information (CBI) will be considered available to the public for inspection. Published information usually cannot be claimed as confidential.~~ When a petition is considered complete and forwarded for NOSB evaluation, ~~except for CBI~~, the petition will be made available for public inspection. Substance petitions that are complete and under evaluation by the NOSB will be posted on the NOP Web site at: http://www.ams.usda.gov/nop. Public comments may be

submitted to either the NOSB or the NOP for any petitioned substance being evaluated by the NOSB. Comments also will be posted on the NOP Web site.

Information To Be Included in a Petition

The guidelines for required information to be included in a petition are as follows:

Item A—Please indicate which section or sections the petitioned substance will be included on and/or removed from the National List. For petitions to change or add an annotation to an already listed substance, please indicate in which category of OFPA §6517 (c)(1)(B)(i) the substance is listed.

- Synthetic substances allowed for use in organic crop production, § 205.601.
- Non-synthetic substances prohibited for use in organic crop production, § 205.602.
- Synthetic substances allowed for use in organic livestock production, § 205.603.
- Non-synthetic substances prohibited for use in organic livestock production, § 205.604.
- Non-agricultural (non-organic) substances allowed in or on processed products labeled as ''organic'' or ''made with organic (specified ingredients),'' § 205.605.
- Non-organic agricultural substances allowed in or on processed products labeled as ''organic,'' § 205.606.

Item B—Please provide concise and comprehensive responses in providing all of the following information items on the substance being petitioned (petitions to change annotations for an already listed substance need only complete #s 1, 2 (contact name), 3, 4, 12 (research backing up the change) & 13 (petition justification statement):

1. The substance's chemical and/or material common name.
2. The petitioners name address and telephone number, the manufacturer's or producer's name, address and telephone number (if different) and other contact information of the manufacturer/producer of the substance listed in the petition.
3. The intended or current use of the substance such as use as a pesticide, animal feed additive, processing aid, nonagricultural ingredient, sanitizer or disinfectant. If the substance is an agricultural ingredient, the petition must provide a list of the types of product(s) (*e.g.*, cereals, salad dressings) for which the substance will be used and a description of the substance's function in the product(s) (*e.g.,* ingredient, flavoring agent, emulsifier, processing aid).
4. A list of the crop, livestock or handling activities for which the substance will be used. If used for crops or livestock, the substance's rate and method of application must be described. ~~If used for handling (including processing), the substance's mode of action must be described.~~
5. The source of the substance and a detailed description of its manufacturing or processing procedures from the basic component(s) to the final product. ~~Petitioners with concerns for confidential business information may follow the guidelines in the Instructions for Submitting CBI listed in #13.~~
6. For Handling substances provide information about the ancillary substances (such as, but not limited to, carriers, emulsifiers or stabilizers) that may be included with the petitioned substance, including function, type of substance, and source if known.
7. A summary of any available previous reviews by State or private certification programs or other organizations of the petitioned substance. If this information is not available, the petitioner should state so in the petition.
8. Information regarding EPA, FDA, and State regulatory authority registrations, including registration numbers. The information provided must confirm that the intended use of the substance is permitted under EPA or FDA regulations, as applicable. If this information does not exist or is not applicable, the petitioner should state so in the petition.
9. The Chemical Abstract Service (CAS) number or other product numbers of the substance and labels of products that contains the petitioned substance. If the substance does not have an assigned product number, the petitioner should state so in the petition.
10. The substance's physical properties and chemical mode of action including

(a) Chemical interactions with other substances, especially substances used in organic production;
(b) toxicity and environmental persistence;
(c) environmental impacts from its use and/ or manufacture;
(d) effects on human health; and,
(e) effects on soil organisms, crops, or livestock.

11. Safety information about the substance including a Material Safety Data Sheet (MSDS) and a substance report from the National Institute of Environmental Health Studies. If this information does not exist, the petitioner should state so in the petition.

12. Research information about the substance which includes comprehensive substance research reviews and research bibliographies, including reviews and bibliographies which present contrasting positions to those presented by the petitioner in supporting the substance's inclusion on or removal from the National List. For petitions to include substances onto the National List for organic handling, this information item should include research concerning why the substance should be permitted in the production or handling of an organic product, including the availability of organic alternatives. ~~Commercial availability does not depend upon geographic location or local market conditions.~~ If research information does not exist for the petitioned substance or for the contrasting position, the petitioner should state so in the petition.

13. A ''Petition Justification Statement'' which provides justification for any of the following actions requested in the petition:

A. Inclusion of a Synthetic on the National List, §§ 205.601, 205.603, 205.605(b)

. • Explain why the synthetic substance is necessary for the production or handling of an organic product.

. • Describe any non-synthetic substances, synthetic substances on the National List or alternative cultural methods[1] that could be used in place of the petitioned synthetic substance.

. • Describe the beneficial effects to the environment, human health, or farm ecosystem from use of the synthetic substance that support its use instead of the use of a non-synthetic substance or alternative cultural methods.

B. Removal of a Synthetic From the National List, §§ 205.601, 205.603, 205.605(b)

. • Explain why the synthetic substance is no longer necessary or appropriate for the production or handling of an organic product, making sure to cover all uses of the listed substance.

. • Describe any non-synthetic substances, synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned synthetic substance, and their availability and applicability to all situations where the substance is used.

C. Inclusion of a Prohibition of a Non-Synthetic, §§ 205.602 and 205.604

. • Explain why the non-synthetic substance should not be permitted in the production of an organic product.

. • Describe other non-synthetic substances or synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned substance.

D. Removal of a Prohibited Non-Synthetic From the National List, §§ 205.602 and 205.604

. • Explain why the non-synthetic substance should be permitted in the production of an organic product.

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[1] *Cultural methods.* Methods used to enhance crop health and prevent weed, pest, or disease problems without the use of substances; examples include the selection of appropriate varieties and planting sites; proper timing and density of plantings; irrigation; and extending a growing season by manipulating the microclimate with green houses, cold frames, or wind breaks.

. • Describe the beneficial effects to the environment, human health, or farm ecosystem from use of the non-synthetic substance that supports its use instead of the use of other non-synthetic or synthetic substances on the National List or alternative cultural methods.

E. Inclusion of a Non-Synthetic, Non-Agricultural Substance Onto the National List, § 205.605(a)

. • Explain why the substance is necessary for use in organic handling.
. • Describe non-synthetic or synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned synthetic substance.
. • Describe any beneficial effects on the environment, or human health from the use of the substance that support its use instead of the use of non-synthetic or synthetic substances on the National List or alternative cultural methods.

F. Removal of a Non-Synthetic, Non-Agricultural Substance From the National List, § 205.605(a)

. • Explain why the substance is no longer necessary for use in organic handling.
. • Describe any non-synthetic or synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned substance, making sure to cover all uses.

G. Inclusion of a Non-Organically Produced Agricultural Substance Onto the National List, § 205.606

. • Provide a comparative description on why the non-organic form of the substance is necessary for use in organic handling.
. • Provide current and historical industry information/research/evidence that explains how or why the substance cannot be obtained organically in the *appropriate form, appropriate quality, and appropriate quantity* to fulfill an essential function in a system of organic handling.
• Describe industry information on substance non-availability of organic sources including but not limited to the following guidance regarding commercial availability evaluation criteria: (1) Regions of production, including factors such as climate and number of regions; (2) Number of suppliers and amount produced; (3) Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies; (4) Trade related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies, and
(5) Other issues which may present a challenge to a consistent supply.

H. Removal of a Non-Organically Produced Agricultural Substance From the National List, § 205.606

- Provide a comparative description as to why the non-organic form of the substance is not necessary for use in organic handling.
- Provide current and historical industry information/research/evidence that explains how or why the substance can be obtained organically in the *appropriate form, appropriate quality, and appropriate quantity* to fulfill an essential function in a system of organic handling.
- Provide new industry information on substance availability of organic sources including but not limited to the following guidance commercial availability evaluation criteria:
  (1) Region of production, including factors such as climate and number of regions;
  (2) Number of suppliers and amount produced;
  (3) Current and historical supplies related to weather events such as hurricanes, floods, or droughts that temporarily halt production or destroy crops or supplies;
  (4) Trade related issues such as evidence of hoarding, war, trade barriers, and civil unrest that may temporarily restrict supplies and;
  (5) Any other issues which may present a challenge to a consistent supply.

I. Adding, amending, or removing an annotation for a listed substance in all sections

- Provide evidence that the existing annotation is flawed, unnecessary, or outdated.
- Indicate why an annotation is needed or a change to existing one is needed.
- Explain what revision is needed to the annotation and why, with reference to the review criteria.

~~13. A Confidential Business Information Statement which describes the specific required information contained in the petition that is considered to be Confidential Business Information (CBI) or confidential commercial information and the basis for that determination. Petitioners should limit their submission of confidential information to that needed to address the areas for which this notice requests information. Final determination regarding whether to afford CBI treatment to submitted petitions will be made by USDA pursuant to 7 CFR 1.27(d). Instructions for submitting CBI to the National List Petition process are presented in the instructions below:~~
~~.(a) Financial or commercial information the petitioner does not want disclosed for competitive reasons may be claimed as CBI. Applicants must submit a written justification to support each claim.~~
~~.(b) ''Trade secrets'' (information relating to the production process, such as formulas, processes, quality control tests and data, and research methodology) may be claimed as CBI. This information must be (1) commercially valuable, (2) used in the applicant's business, and (3) maintained in secrecy.~~
~~.(c) Each page containing CBI material must have ''CBI Copy'' marked in the upper right corner of the page. In the right margin, mark the CBI information with a bracket and ''CBI.''~~
~~.(d) The CBI-deleted copy should be a facsimile of the CBI copy, except for spaces occurring in the text where CBI has been deleted. Be sure that the CBI-deleted copy is paginated the same as the CBI copy (The CBI-deleted copy of the application should be made from the same copy of the application which originally contained CBI). Additional material (transitions, paraphrasing, or generic substitutions, etc.) should not be included in the CBI-deleted copy.~~
~~.(e) Each page with CBI-deletions should be marked ''CBI-deleted'' at the upper right corner of the page. In the right margin, mark the place where the CBI material has been deleted with a bracket and ''CBI-deleted.''~~
~~.(f) If several pages are CBI-deleted, a single page designating the numbers of deleted pages may be substituted for blank pages. (For example, ''pages 7 through 10 have been CBI-deleted.'')~~
~~.(g) All published references that appear in the CBI copy should be included in the reference list of the CBI-deleted copy. Published information cannot be claimed as confidential.~~
~~(h) Final determination regarding whether to afford CBI treatment to submitted petitions will be made by USDA pursuant to 7 CFR 1.27(d). If a determination is made to deny CBI treatment, the petitioner will be afforded an opportunity to withdraw the submission.~~

Part 2. NOSB Policy and Procedures Manual proposed revisions

PPM, pp. 34-35:

MATERIALS REVIEW PROCESS

This section presents the procedures followed by the NOSB to evaluate petitions. First, the 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. This section concludes by providing a graphical description of the sunset review process.

Evaluation Procedures for Substances Petitioned for Addition or Removal from the National List.

The petition process is open to all, including members of the NOSB. The priority system for determining in which order petitions are reviewed will be applied to all petitions (Section VIII). These procedures also apply to petitions to add, remove, or change an annotation to an already listed substance.

Phase 1: Receipt of Petition and Examination of Petition for Completeness and Eligibility
During this phase the NOP will:
• Notify the petitioner via letter and/or electronic mail of receipt of the petition. Determine whether the petition is complete
• Determine whether 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:
o Publish the petition on NOP website; and
o 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 and 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.~~

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Phase 2: Determine whether a Third Party Technical Review is Required
During this phase:
• The ~~NOSB materials committee, working with other~~ applicable NOSB committee 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) Whether 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 whether
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 appropriate sub ~~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 *(proceed to Phase 3: Evaluation by a Third Party Expert)*

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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 subcommittee should follow these steps in deciding the need for third party expert:
1. Define whether the subcommittee 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 subcommittee does not have the expertise or resources (e.g., time), the Subcommittee 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.

3. When requesting the assistance of a third party expert to evaluate a material, a subcommittee must identify the main technical issues needed to be addressed including, but not 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
g. Ancillary substances that may be used in conjunction with handling materials, such are carriers, stabilizers or emulsifiers.

4. ~~If required~~, The Subcommittee 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 Subcommittee cannot proceed with a recommendation on a material if it is determined that there is insufficient ~~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 subcommittee reviewing the material.

4. The decision to define the expertise needed in the third party expert is the responsibility of the subcommittee reviewing the material or issue.

5. To incorporate a diversity of opinions and to minimize the risk of bias, a subcommittee should aim to work with a range of technical experts (individuals, or institutions).

Once the Technical Reports are submitted to the requesting subcommittee, that committee determines if the issues have been addressed sufficiently. If there are remaining questions, the subcommittee can go back for further clarification and expansion of the technical report. Once the information is deemed sufficient, the report is acceptable for public posting.

Subcommittee Vote

Motion to accept the proposal on Updating the petition and TR process as described above and voted on August 27

Motion by: Zea Sonnabend
Seconded by: Tracy Favre
Yes: 7 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Approved by Zea Sonnabend, Subcommittee Chair, to transmit to NOSB August 27, 2013