

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

Date:

Subject:

Chair:

The NOSB hereby recommends to the NOP the following:

Rulemaking Action:

Guidance Statement:

Other:

Statement of Recommendation: **ó a2ú2y l MÚ**

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

Committee Vote:

Moved:

Seconded:

Yes:

No:

Abstain:

Absent:

Recuse:

**National Organic Standards Board
Materials Subcommittee
Proposal: Confidential Business Information in Petitions**

**July 23, 2013
Reviewed February 25, 2014 - No revisions**

Introduction

In preparation for the Spring 2013 NOSB meeting, the Materials Subcommittee submitted for Board review and public input a discussion document "Confidential Business Information in Petitions". That document discussed the procedures currently being used to address Confidential Business Information (CBI) as it relates to petitions for materials for inclusion on the National List, and the challenges associated with evaluation of petitioned materials without full and complete information, some of which could be classified as CBI. The document put forth two possible recommendations for modification of the current CBI policy, along with the request for feedback from the public.

Possible Recommendation 1:

CBI is not allowed in petitions. Petitioners must provide complete information about manufacturing processes and ingredients so that the NOSB and the public can fully evaluate each petitioned material. A modified version of this choice would be to not allow CBI for manufacturing processes or ingredients but to allow back up research and references to be submitted as CBI to assist the TR development.

Possible Recommendation 2:

CBI be allowed in petitions with the following stakeholder responsibilities:

For the National Organic Program

- A. The NOP will allow only information meeting the strict definition of CBI to be deleted from petitions considered by the board and posted for public viewing.
- B. The NOP must make it clear to petitioners what happens to the CBI submitted and who does and does not have access to it, preferably by revising the Petition Guidelines. It should be very clear to petitioners that the NOSB does not see the confidential information.
- C. The Technical Review contractor will have access to the CBI upon request. The contractor may then evaluate the CBI and conduct additional research to verify similar information.
- D. The TR contractor will indicate that they looked at CBI in the course of their review.

For Petitioners

- E. Petitioners are highly urged to provide complete information in their petitions, and keep CBI to the absolute minimum.
- F. Petitions Guideline B.13 requires a statement of reasons for the CBI. This statement needs to be clearly stated, and is part of the public petition that will be seen by the NOSB.

- G. Petitions will not be considered unless the rules in the Petitions Guidelines for CBI are followed completely.
- H. Petitioners need to be aware that petitions containing CBI are rarely approved by the NOSB and the board reserves the right to reject such a petition that does not give complete manufacturing information. The NOSB may also send back a petition as incomplete if there is simply not enough information to make a decision.

For the National Organic Standards Board

- I. The Policy and Procedures Manual will be updated to reflect any changes to CBI procedures based on this recommendation and the NOP revising the petition guidelines.
- J. Petitions that come in with CBI will be looked at in the usual way by the subcommittees and any that have withheld too much information to allow the Board to make an informed decision may be returned to the petitioner. Others will move forward for a Technical Review.
- K. If a petition is rejected because of CBI, the petitioner may re-petition and disclose the CBI. However, the NOSB will treat this at the lower level of priority with other re-petitioned substances.

Summary of Public Comments

Not surprisingly, there were differences of opinion regarding the need for allowances for CBI. Generally, public comments expressed the need for sufficient information for the NOSB to make determinations regarding the classification of materials – synthetic/non-synthetic and or agricultural/non-agricultural, and to determine the impact on human health and the environment. The majority of commenters expressed the opinion that a full list of ingredients should be disclosed. However, some commenters expressed the need for complete transparency regarding the full list of ingredients and manufacturing processes in the petitioned material. Others had concerns about protection of manufacturing processes and/or recipes of petitioned materials, and the potential for impact to participation in the National Organic Program, should CBI not be protected. The proposal for an affidavit process was generally either rejected outright or the opinion was expressed that the affidavit process would need more detail before it could be determined whether or not it would be effective.

Feedback pointed out the administrative difficulty in maintaining confidentiality of CBI provided to the NOSB and not the public and further stated that the transparency of the petition process and the relationship of the NOSB to the public could be adversely affected if such a procedure was implemented.

In order for the NOSB to discharge its responsibility for the proper evaluation of a petitioned material, the following information should be provided:

1. A complete list of ingredients included in the petitioned material. The exact recipes or formulations are not required; only sufficient information so that the NOSB can evaluate the impact on human health and the agro-ecosystem;
2. Sufficient information regarding the manufacturing process to allow for determining the classification of that material as either synthetic or non-synthetic and/or agricultural/non-agricultural and sufficient information regarding the manufacturing process to allow for an assessment of adverse health and environment effects that may be associated with

the product's production. Detailed, proprietary information regarding the manufacturing process is not required, except as it relates to the statement above.

Petitioners are encouraged to review the Classification of Materials Draft Guidance (NOP 5033), the Synthetic/Non-Synthetic Decision Tree (NOP 5033-1), and the Agricultural/Non-Agricultural Decision Tree (NOP 5033-2) for draft guidance on what minimum information is necessary for determination of Classification of Petitioned Materials.

Conclusion and Recommendation

The NOSB recognizes the investment and risk associated with development of proprietary materials and processes. The board's intention is not to place petitioners at economic risk through information provided as part of a petition process. However, the importance of transparency of the petition process, the right of the public to fully know the materials included in or on certified organic products, and the potential for an untenable administrative burden of management of CBI precludes the provision of CBI in materials petitions.

For this reason, the Materials Subcommittee is recommending a revision to the Material Petition process to eliminate the provision for Confidential Business Information.

Subcommittee Vote

The Materials Subcommittee moves to accept this recommendation and present it for full Board discussion at the fall 2013 NOSB meeting.

Motion by: Tracy Favre

Seconded by: Jay Feldman

Yes: 7 No: 0 Absent: 0 Abstain: 0 Recuse: 0

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