

**National Organic Standards Board
Materials Subcommittee
Discussion Document
Confidential Business Information in Petitions**

Date of Vote: February 12, 2013

Introduction

The role of the NOSB under OFPA and the Federal Rule is to review substances for inclusion on the National List. The primary way for affected parties to bring something before the NOSB is by submitting a petition for it pursuant to 72 FR 2167 Petition Guidelines. These guidelines discuss the right and ability of petitioners to submit some information in a petition as Confidential Business Information (CBI) following the guidelines in 7 CFR 1.27 [d].

This procedure has not served either the petitioner or the NOSB particularly well. The petitioners do not realize and are not notified that the NOSB members do not have access to their CBI. The Technical Reviewers are able to ask for the full petition with the CBI but may not disclose the CBI in their Technical Evaluation Reports. For some petitions, NOSB members do not have key information they need to be able to classify a petitioned material as synthetic or non-synthetic, or to understand the formulation challenges around the petitioned material and the alternatives. Therefore very few petitions containing CBI have actually been approved for the National List by the NOSB because the board does not have enough information to make a positive decision. Yet the petitioners are not told in the petition guidelines that this is the case.

In addition, petitioners often do not follow the CBI procedures spelled out in the Petition Guidelines well and so petitions often are sent back to petitioners because they have not provided details on why information is claimed as CBI, they identified public information as CBI, or they did not submit in the correct format according to the petition guidelines.

The NOSB is in a unique position in being members of the public who advise a federal agency. NOSB operates in a transparent environment and all its documents are either publicly posted or can be shared under the Freedom of Information Act (FOIA). Ideally, petitions should comply with the openness required under FOIA. In this discussion document we are asking for input on whether CBI should still be allowed in petitions, and if so, what limitations should be placed on it. Further, if there is to be CBI in a petition, it needs to be made much clearer to petitioners, the NOSB, and the public who has access to that information and what outcome can be expected from CBI.

Background

On January 21, 2009, President Obama issued a memorandum for heads of departments and agencies that says:

A democracy requires accountability, and accountability requires transparency. As Justice Louis Brandeis wrote, "Sunlight is said to be the best of disinfectants." In our democracy, the Freedom of Information Act (FOIA), which encourages accountability through transparency, is the most prominent expression of a

profound national commitment to ensuring an open Government. At the heart of that commitment is the idea that accountability is in the interest of the Government and the citizenry alike.

.....

All agencies should adopt a presumption in favor of disclosure, in order to renew their commitment to the principles embodied in FOIA, and to usher in a new era of open Government. ... The presumption of disclosure also means that agencies should take affirmative steps to make information public.

The USDA and AMS have adopted regulations and directives relating to CBI that are addressed below:

What can and can't be claimed as CBI.

The considerable body of case law concerning Exemption 4 of FOIA, which includes CBI, has been reviewed by the Department of Justice in the DOJ Guide to the Freedom of Information Act,¹ It concludes, "[T]he Court of Appeals for the District of Columbia Circuit and nearly every court that has considered the issue has found the Trade Secrets Act and Exemption 4 to be 'coextensive.'"

The Trade Secrets Act defines trade secrets:

- (3) the term "trade secret" means all forms and types of financial, business, scientific, technical, economic, or engineering information, including patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing if—
 - (A) the owner thereof has taken reasonable measures to keep such information secret; and
 - (B) the information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, the public;

Under the Act, the tests for trade secrets are thus the following (all must be met):

1. Is the information secret? Particularly, is it secret from competitors?
2. Has the owner of the information taken measures to keep it secret?
3. Would a competitor gain advantage by knowing the information?

As a result, some kinds of information are not trade secrets:

1. Environmental and health effects of chemicals, because they are widely known and published.
2. Emissions data and other data that must be reported in publicly available forms, such as National Pollution Discharge Elimination System (NPDES) permits or Toxics Release Inventory (TRI) reports.
3. Published articles or other references that are publicly available.
4. Fertilizer ingredients, which are listed in publicly-available forms.

¹ Department of Justice, 2009. Guide to the Freedom of Information Act.
http://www.justice.gov/oip/foia_guide09.htm

5. Food ingredients.
6. Information about a manufacturing process that can be found in a patent.

It is generally accepted that proprietary manufacturing processes that are not revealed in a patent and are kept secret from competitors do qualify as trade secrets. Other examples are software code, business plans, and financial data, if kept secret.

The USDA has regulations relating to the release of information claimed as CBI that the agency decides is not CBI.² “[T]he policy of USDA is to obtain and consider the views of the submitter of the information and to provide the submitter an opportunity to object to any decision to disclose the information.” Some of the steps that are relevant to the petition process are described in the Petition Guidelines #13 (below).

Relevant areas in the Rule

The relevant areas here are in the Code of Federal Regulations 7 CFR 1.27[d] & [e], and in the Federal Register notice regarding Petition Guidelines, 72 FR 2167 from January 18, 2007.

7 CFR 1.27[d]

Title 7: Agriculture

1.27 - Rulemaking and other notice procedures.

(d)(1) Any written submission, pursuant to a notice, may be held confidential if the person making the submission requests that the submission be held confidential, the person making the submission has shown that the written submission may be withheld under the Freedom of Information Act, and the Department official authorized to issue the notice determines that the submission may be withheld under the Freedom of Information Act.

2) If a request is made in accordance with paragraph (d)(1) of this section for confidential treatment of a written submission, the person making the request shall be informed promptly in the event the request is denied and afforded an opportunity to withdraw the submission.

(3) If a determination is made to grant a request for confidential treatment under paragraph (d)(1) of this section, a statement of the specific basis for the determination that will not be susceptible of identifying the person making the request will be made available for public inspection.

(e) If the subject of the notice is such that meaningful submissions cannot be expected unless they disclose information that may be withheld under the Freedom of Information Act, the notice shall so indicate and contain a statement that written submissions pursuant to the notice will be treated as confidential and withheld under the Freedom of Information Act. Provided, That the policy regarding availability of written submissions set forth in this paragraph may only be used with the prior approval of the Secretary, or the Under Secretary or

² 7 CFR Part 1 § 1.12 Handling information from a private business.

Assistant Secretary that administers the program that is the subject of the notice.

72 FR 2167 from January 18, 2007

Procedures for Submitting National List Petitions

..... 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. 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.

Information to be included in a Petition

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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....

The above information is repeated in detail in the NOSB Policy and Procedures Manual on page 48.³

Discussion

There are four groups who have needs regarding the issue of CBI:

1. The petitioner may have valid trade secrets that they do not wish to disclose publicly because they do not want competitors to get their formula or other details.
2. The USDA and their contracted Technical Reviewers must honor the CBI regulations while at the same time provide a clear and consistent process for petitions and their review.
3. The NOSB must learn as much as it can about each petitioned substance in order to classify it properly on the National List and to determine whether it is compatible with organic production and handling.

³ National Organic Standards Board Policies and Procedures Manual.
<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELDEV3013893>

4. The public has the right to know that the NOSB has used a fair and transparent process in reviewing petitions and making recommendations.

The NOSB makes decisions about generic materials and not formulated products, and in order to do this, the NOSB needs to know how each petitioned material is made and what all the components are. The NOSB looks at everything that goes into a material, including growth media, processing aids, carriers and the ecological interactions and environmental fate of each material. The NOSB has the discretion to reject a petition if the CBI makes it such that either the manufacturing process or the components are not disclosed. However, the board does not want to do this if possible and is proposing this discussion document as a series of solutions so that all the affected parties have confidence in the review process. There may still be cases where the NOSB will have to either deny or vote down the petition if the CBI is too critical to making a good decision.

Any recommendation on this subject needs to include the following components:

- What explanation the petitioners receive about the impact of their CBI.
- What happens to CBI and who has access to it.
- How the NOSB can gain assurance about the portion of the CBI that is instrumental to their deliberations.

The possible recommendations presented here recognize that CBI may be necessary in some petitions. However the subcommittee is also posing the question to see whether stakeholders think it is necessary to have CBI. The NOP needs to work with the petitioners to keep the CBI to a minimum, to give access to necessary information in the preparation of the Technical Evaluation Reports (TERs), and to let petitioners know what to expect from the process.

Recommendations for Discussion Purposes

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.
- I. (optional) The petitioner may be given the option to affirm that the information withheld as CBI is consistent with the review criteria by affidavit. For instance if a manufacturing process is CBI the affidavit would contain legally binding language that states something like:
"The manufacturing process of _____ does not include additional ingredients that are not disclosed in the petition. The process involves only mechanical, physical or biological steps."

The affirmation would not take the place of an objective TR to verify the stated information. Petitioners could be given the opportunity to cite similar materials or processes that are public.

This affirmation will be easier to develop once the Classification of Materials Guidance is issued so there are more comprehensive definitions for it to be based on. There could be other affidavits created for synthetic substances or for handling situations that involve CBI.

For the National Organic Standards Board

- J. 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.

- K. 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.
- L. If a petition is rejected because of CBI, the petitioner may re-petition and disclose the CBI, however, the NOSB will treat this at a lower priority level with other re-petitioned substances.

Discussion Questions

1. Should Confidential Business Information be allowed in petitions? Please explain your answer.
2. If CBI is allowed, should it be limited so that it does not involve ingredients or manufacturing processes?
3. Do the provisions in Possible Recommendation 2 make sense and are there others that the board should consider?
4. Provision I in Possible Recommendation 2 is about using an affidavit to supplement a CBI petition. Comment on whether this is valuable.
5. Should procedures, such as a Confidentiality Agreement, be developed that would allow the NOSB, but not the public, to see any CBI?

Subcommittee Vote

Motion: The Materials Subcommittee moves to accept this discussion document and present it for full Board discussion at the spring 2013 NOSB meeting.

Motion by: Zea Sonnabend Second: Calvin Walker
Yes: 5 No: 0 Absent: 2 Abstain: 0 Recuse: 0