

INFORMATION TO BE INCLUDED IN A PETITION

ITEM A

Please indicate within which of the following categories your substance is being petitioned for inclusion on or removal from the National List:

- Synthetic substance's allowed for use in organic crop production;
- Nonsynthetic substances prohibited for use in organic crop production;
- Synthetic substances allowed for use in organic livestock production;
- Nonsynthetic substances prohibited for use in organic livestock production; and
- Nonagricultural (nonorganic) substances allowed in or on processed products labeled as "organic" or "made with organic (specified ingredients)."

ITEM B

1. The substance's common name.
2. The manufacturer's name, address and telephone number.
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.
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 can follow the guidelines in the Instructions for Submitting Confidential Business Information (CBI) listed in #13.
6. A summary of any available previous reviews by State or private certification programs or other organizations of the petitioned substance.
7. Information regarding EPA, FDA, and State regulatory authority registrations, including registration numbers.
8. The Chemical Abstract Service (CAS) number or other product numbers of the substance and labels of products that contains the petitioned substance.
9. 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 or manufacture; (d) effects on human health; and, (e) effects on soil organisms, crops, or livestock.
10. Safety information about the substance including a Material Safety Data Sheet (MSDS) and a substance report from the National Institute of Environmental Health Studies.
11. 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.
12. A "Petition Justification Statement" which provides justification for one of the following actions requested in the petition:
 - When petitioning for the inclusion of a synthetic substance on the National List, the petition should state why the synthetic substance is necessary for the production or handling of an organic product. The petition should also describe the nonsynthetic substances or alternative cultural methods that could be used in place of the petitioned synthetic substance. Additionally, the petition should summarize the beneficial effects to the environment, human health, or farm ecosystem from use of the synthetic substance that support the use of it instead of the use of a nonsynthetic substance or alternative cultural methods.
 - When petitioning for the removal of a synthetic substance from the National List the petition must state why the synthetic substance is no longer necessary or appropriate for the production or handling of an organic product.
 - When petitioning for the inclusion on the National List of a nonsynthetic or nonagricultural substance as a prohibited substance the petition must state why the nonsynthetic or nonagricultural substance should not be permitted in the production or handling of an organic product.
 - When petitioning for the removal from the National List of a nonsynthetic or nonagricultural substance as a prohibited substance the petition must state why the nonsynthetic or nonagricultural substance should be permitted in the production or handling of an organic product.

ITEM B - CONTINUED....

13. A Commercial Confidential 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. Instructions for submitting CBI to the National List Petition process are presented in the instructions below:

- (a) Financial or commercial information the applicant does not want disclosed for competitive reasons can 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 usually cannot be claimed as confidential.

However, the National List substance evaluations will involve a public and open process. Nonconfidential information will be available for public inspection.

The NOP Program Manager may request additional information from the petitioner following receipt of the petition.

Source: "Notice of Guidelines and Call for National List Petitions: What Information Has to be Included in the Petition?" *Federal Register* 65:135 (13 July 2000) p. 43260-43261.