



Procedure

National List Petition Guidelines

1. Purpose and Scope

This procedure provides guidelines on submitting a petition to amend the National List of Allowed and Prohibited Substances (National List) at 7 C.F.R. §§ 205.600-205.606. These guidelines, developed in collaboration with the National Organic Standards Board (NOSB), and based on the NOSB's April 2014 recommendations, describe the information to be included in all types of petitions submitted to amend the National List.

2. Background

The Organic Foods Production Act of 1990, as amended (7 U.S.C. §§ 6501-6523) (OFPA), authorizes the establishment of the U.S. Department of Agriculture (USDA) organic regulations, including the National List. The National List identifies the synthetic substances that may be used and the nonsynthetic substances that may not be used in organic production, and also identifies synthetic and nonsynthetic substances that may be used in organic handling. The OFPA and USDA organic regulations specifically prohibit the use of any synthetic substance for organic production and handling unless the synthetic substance is on the National List. (See 7 C.F.R. § 205.105.) Section 205.105 of the regulations also requires that any nonorganic, nonsynthetic substance used in organic handling be on the National List. The National List can be amended through rulemaking using the National List Petition Process or the National List Sunset Process. These guidelines apply only to the National List Petition Process.

The ability for any person to petition to amend the National List is authorized by § 6518(n) of the OFPA and § 205.607 of the USDA organic regulations. This authorization provides that any person may petition the NOSB to have a substance evaluated by the NOSB for recommendation to the Secretary for inclusion on or removal from the National List. The NOSB is authorized to review petitions under evaluation criteria specified in § 6518(m) of the OFPA, and forward recommendations for amending the National List to the Secretary.

3. Policy

3.1 Who can submit a petition?

Any person may submit a petition to have a substance evaluated by the NOSB (See 7 C.F.R. § 205.607(a)).

3.2 What can be petitioned?

Generic substances are eligible for petition; formulated (brand name) products are not eligible.



3.3 What is the National Organic Program's role?

The National Organic Program (NOP) accepts petitions, solicits public comments, and manages all communication with petitioners. If the substance is eligible for petition and the petition meets the guidelines referenced in [section 4](#) below, the petition is posted on the NOP website for review by the NOSB.

The NOP's acceptance of the petition for NOSB review is an administrative matter and does not reflect a decision by the NOP on the substantive merits of the petition.

3.4 What is the NOSB's role?

The NOSB, a Federal Advisory Committee, reviews petitions based on specific criteria in the OFPA.

One of the NOSB Subcommittees (crops, livestock, or handling) reviews petitions against the criteria in the OFPA. Prior to one of the semiannual NOSB public meetings, the NOP will publish the NOSB Subcommittee proposals with request for public comments.

At a public meeting, the NOSB will complete the review of the petition and submit a final recommendation to the NOP. The NOSB's meeting schedule and agenda can be found at <http://www.ams.usda.gov/nosb>.

3.5 What criteria does the NOSB use to evaluate petitions?

Pursuant to § 6518(m) of the OFPA, when evaluating a petitioned substance for amendment of the National List, the NOSB shall consider:

- (1) The potential of the substance for detrimental chemical interactions with other materials used in organic farming systems;
- (2) The toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment;
- (3) The probability of environmental contamination during manufacture, use, misuse or disposal of the substance;
- (4) The effect of the substance on human health;
- (5) The effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops, and livestock;
- (6) The alternatives to using the substance in terms of practices or other available materials; and
- (7) Its compatibility with a system of sustainable agriculture.

Synthetic substances petitioned for use in organic processing are evaluated pursuant to additional criteria in 7 C.F.R. § 205.600(b):

- (1) The substance cannot be produced from a natural source and there are no organic substitutes;



- (2) The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling;
- (3) The nutritional quality of the food is maintained when the substance is used, and the substance itself, or its breakdown products do not have an adverse effect on human health as defined by applicable Federal regulations;
- (4) The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law;
- (5) The substance is listed as generally recognized as safe (GRAS) by the Food and Drug Administration (FDA) when used in accordance with FDA's good manufacturing practices (GMP) and contains no residues of heavy metals or other contaminants in excess of tolerances set by FDA; and
- (6) The substance is essential for the handling of organically produced agricultural products.

Pursuant to 7 C.F.R. § 205.600(c), nonsynthetic substances petitioned for use in organic processing are evaluated against criteria specified in §§ 6517 and 6518 of the OFPA.

3.6 Is a specific form needed?

No. There is no form that must be submitted with the petition. However, certain information must be included in the petition as described in [section 4.2](#) below.

3.7 How long does the petition process take?

The petition process can take a year or more, depending on the complexity associated with the petition, amount of public participation, and other projects on the NOSB work agenda. To facilitate NOP review and NOSB consideration of petitions, petitions should provide concise yet comprehensive responses to the required petition information.

The majority of petitions are reviewed by the NOP for eligibility and completion within 30 days of receipt. Petitions are typically reviewed at an NOSB meeting within two years of the determination by NOP that the petition is eligible for NOSB review.

If the NOSB recommends the addition of a petitioned substance to the National List, the NOP will consider the NOSB recommendation for a future rulemaking action. Petitioned substances may not be used in production or handling unless the substance has been added to the National List.

3.8 Is there a cost or fee for submitting a petition?

No. There is no cost or fee for submitting a petition.



3.9 Are petitions available online?

Yes. Complete and eligible petitions are posted for the public on the NOP website at <http://www.ams.usda.gov/nop>.

3.10 Can I submit confidential business information or a redacted version that can be posted online?

No. Confidential business information is no longer accepted as part of the National List petition process. Petitions to amend the National List involve a public and open evaluation process.

3.11 How do I submit new information if my petition is under review by the NOSB?

Petitioners may update their petitions at any time. Submissions will be posted as an addendum to the petition for public access on the NOP website. If the entire petition is to be replaced, please contact the NOP prior to submission.

3.12 How do I submit comments about a petition that was submitted by another party?

To be notified of public comment opportunities, you can register for the National Organic Program's email notification service at <http://bit.ly/NOPOrganicInsiderRegistration>. Written comments on petitions under NOSB review may be submitted via www.regulations.gov during a public comment period that precedes each NOSB meeting. NOSB meetings also offer opportunities for in-person public comments.

3.13 How do I withdraw my petition?

Petitions may be withdrawn according to the guidelines in the most current version of the [NOSB Policy and Procedures Manual](#).

4. Procedures

4.1 Petition Submission

Petitions may be submitted by email, disk, or hard copy. Electronic submission (by disk or email) is strongly encouraged to facilitate posting of petitions on the NOP website.

Email submission. Send petitions as a single PDF file to nosb@ams.usda.gov.

Mail. Disks or hard copies may be submitted via mail to:

USDA/AMS/NOP, Standards Division
Attention: National List Manager
1400 Independence Ave. SW



Room 2642-So., Ag Stop 0268
Washington, DC 20250-0268

4.2 Items to be Included in a Petition

The following information must be submitted in a petition. For each item in the petition, reference the letter and/or number indicated below. Supporting documents may be provided as numbered appendices. Petitions should provide concise yet comprehensive responses.

Item A.1 — Indicate which section or sections the petitioned substance will be included on and/or removed from the National List. The current National List may be viewed at www.ams.usda.gov/NOPNationalList.

- Synthetic substances allowed for use in organic crop production (§ 205.601).
- Nonsynthetic substances prohibited for use in organic crop production (§ 205.602).
- Synthetic substances allowed for use in organic livestock production (§ 205.603).
- Nonsynthetic substances prohibited for use in organic livestock production (§ 205.604).
- Nonagricultural (nonorganic) substances allowed in or on processed products labeled as “organic” or “made with organic (specified ingredients)” (§ 205.605).
- Nonorganic agricultural substances allowed in or on processed products labeled as “organic” (§ 205.606).

Item A.2 — OFPA Category - Crop and Livestock Materials

For substances petitioned for use in crop or livestock production, eligible substances must contain an active synthetic ingredient in one of the following OFPA categories (7 U.S.C. § 6517(c)(1)(B)(i)):

- Copper and sulfur compounds;
- Toxins derived from bacteria;
- Pheromones;
- Soaps;
- Horticultural oils;
- Fish emulsions;
- Treated seed;
- Vitamins and minerals;
- Livestock parasiticides and medicines; and
- Production aids.

Petitioners should indicate which OFPA category applies to their petitioned material. The OFPA categories referenced above do not apply to materials petitioned for use in organic handling or processing.



Item A.3 — Inert Ingredients

If the substance is a synthetic inert ingredient intended for use in a pesticide product, please see [NOP Notice 11-6](#) for more information.

Item B—Provide concise and comprehensive responses in providing all of the following information on the substance being petitioned.

For petitions to add or change an annotation for a substance that is already on the National List, items 5-11 are optional. Petitioners are encouraged to address these items if the information has changed since the NOSB's original review of the substance.

1. Substance Name

Provide the substance's chemical and/or material common name. The name of the petitioned substance should be consistent with any name(s) used by other Federal agencies (e.g., FDA, EPA, etc.)

2. Petitioner and Manufacturer Information

Provide the name, address, and telephone number for the petitioner and manufacturer (if different).

3. Intended or Current Use

Describe the intended or current use of the substance, e.g., 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. Intended Activities and Application Rate

Provide 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.

5. Manufacturing Process

Provide the source of the substance and a detailed description of its manufacturing or processing procedures from the basic component(s) to the final product.

6. Ancillary Substances

For substances petitioned for use in organic handling or processing, provide information about the ancillary substances (including, 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. Previous Reviews

Provide a summary of any available previous reviews of the petitioned substance by State or private certification programs or other organizations. If this information is not available, this should be stated in the petition.

If the substance has been previously reviewed and rejected by the NOSB, the petition must provide new information that was not submitted in an earlier petition or provided for in the previous technical reports for the substance.

8. Regulatory Authority

Provide 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.

For food ingredients and processing aids, the substance must be approved by FDA for the petitioned use. For pesticide active ingredients, the substance must have an EPA tolerance or tolerance exemption, as applicable. If this information does not exist or is not applicable, the petitioner should state this in the petition.

9. Chemical Abstracts Service (CAS) Number and Product Labels

Provide the CAS number or other product numbers of the substance. If the substance does not have an assigned product number, the petitioner should state so in the petition. For food additives, the International Numbering System (INS) number should also be provided.

This item should also include labels of products that contain the petitioned substance. If a product label does not apply to this substance, please provide a brief explanation. Product specification sheets, product data sheets, non-retail labels, or other product information may be substituted for the product label, if appropriate.

10. Physical and Chemical Properties

Provide the substance's physical properties and chemical mode of action including the following:

- (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

Provide 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 or is not applicable, the petitioner should state so in the petition.

12. Research Information

This item should include research information about the substance. The research should include comprehensive substance research reviews and research bibliographies, including reviews and bibliographies that 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 nonorganic agricultural substances on the National List for organic handling, this information should include research on why the substance should be permitted in the handling of an organic product, including the availability of organic alternatives.

If research information does not exist for the petitioned substance or for the contrasting position, the petitioner should state so in the petition.

13. Petition Justification Statement

Provide 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 (7 C.F.R. §§ 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 nonsynthetic substances, synthetic substances on the National List, or alternative cultural method 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 nonsynthetic substance or alternative cultural method.

B. Removal of a Synthetic from the National List (7 C.F.R. §§ 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 nonsynthetic 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 Nonsynthetic (7 C.F.R. §§ 205.602 and 205.604)

- Explain why the nonsynthetic substance should not be permitted in the production of an organic product.
- Describe other nonsynthetic 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 Nonsynthetic from the National List (7 C.F.R. §§ 205.602 and 205.604)

- Explain why the nonsynthetic substance should be permitted in the production of an organic product.
- Describe the beneficial effects to the environment, human health, or farm ecosystem from use of the nonsynthetic substance that supports its use instead of the use of other nonsynthetic or synthetic substances on the National List or alternative [cultural methods](#).

E. Inclusion of a Nonsynthetic, Nonagricultural Substance on the National List (7 C.F.R. § 205.605(a))

- Explain why the substance is necessary for use in organic handling.
- Describe nonsynthetic 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 nonsynthetic or synthetic substances on the National List or alternative cultural methods.

F. Removal of a Nonsynthetic, Nonagricultural Substance from the National List (7 C.F.R. § 205.605(a))

- Explain why the substance is no longer necessary for use in organic handling.
- Describe any nonsynthetic 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 Nonorganically Produced Agricultural Substance on the National List (7 C.F.R. § 205.606)

- Provide a comparative description on why the nonorganic 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, quality, and quantity to fulfill an essential function in a system of organic handling.



- Describe industry information on the non-availability of organic sources of the substance, including, but not limited to, the following guidance regarding commercial availability evaluation criteria:
 - a) Regions of production, including factors such as climate and number of regions;
 - b) Number of suppliers and amount produced;
 - c) Current and historical supplies related to weather events such as hurricanes, floods, or droughts that temporarily halt production or destroy crops or supplies;
 - d) Trade related issues such as evidence of hoarding, war, trade barriers, and civil unrest that may temporarily restrict supplies; and
 - e) Any other issues that may present a challenge to a consistent supply.

H. Removal of a Nonorganically Produced Agricultural Substance from the National List (7 C.F.R. § 205.606)

- Provide a comparative description as to why the nonorganic 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, quality, and quantity to fulfill an essential function in a system of organic handling.
- Provide new industry information on the availability of organic sources of the substance, including, but not limited to, the following guidance on commercial availability evaluation criteria:
 - a. Regions of production, including factors such as climate and number of regions;
 - b. Number of suppliers and amount produced;
 - c. Current and historical supplies related to weather events such as hurricanes, floods, or droughts that temporarily halt production or destroy crops or supplies;
 - d. Trade-related issues such as evidence of hoarding, war, trade barriers, and civil unrest that may temporarily restrict supplies; and
 - e. Any other issues that may present a challenge to a consistent supply.

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

- Provide detailed information on why a new annotation is needed, with reference to the review criteria described in [section 3.5](#) above.
- Provide evidence that the current annotation is flawed, unnecessary, or outdated.

14. References

Organic Foods Production Act of 1990, as amended

7 U.S.C. § 6508 Prohibited Crop Production Practices and Materials.

7 U.S.C. § 6510 Handling.

7 U.S.C. § 6518(m) National Organic Standards Board; Evaluation.

7 U.S.C. § 6518(n) National Organic Standards Board; Petitions.

USDA Organic Regulations ([7 C.F.R. Part 205](#))



7 C.F.R. § 205.2 Terms defined.

Commercially available. The ability to obtain a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling, as determined by the certifying agent in the course of reviewing the organic plan.

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.

Petition. A request to amend the National List that is submitted by any person in accordance with this part.

7 C.F.R. § 205.607 Amending the National List.

NOSB Recommendations

[NOSB Recommendation: Update of the Petition and Technical Review Process, May 2, 2014](#)

[NOSB Recommendation: Confidential Business Information in Petitions, May 2, 2014](#)

Document Control: This document supersedes the notice “Submission of Petitions of Substances for Inclusion on or Removal From the National List of Substances Allowed and Prohibited in Organic Production and Handling,” published January 18, 2007 in the Federal Register (72 FR 2167), which is now obsolete.