

# Rules and Regulations

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## DEPARTMENT OF AGRICULTURE

### Agricultural Marketing Service

#### 7 CFR Part 205

[Docket No. AMS-TM-06-0223; TM-06-12]

#### National Organic Program— Submission of Petitions of Substances for Inclusion on or Removal From the National List of Substances Allowed and Prohibited in Organic Production and Handling

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Notice of Guidelines on Procedures for Submitting National List Petitions.

**SUMMARY:** This notice supersedes prior Department of Agriculture's (USDA) National Organic Program's (NOP) published guidelines used to submit petitions to amend the National List of Allowed and Prohibited Substances (National List). The National List identifies the synthetic substances that may be used and the non-synthetic substances that may not be used in organic production. The National List also identifies synthetic and non-synthetic substances that may be used in organic handling. This notice provides guidance on who may submit petitions, what substances may be petitioned and the information that is required to be included within a submitted petition. Additionally, this notice establishes new commercial availability evaluation criteria that will be applied during the petition review of non-organic agricultural substances for inclusion onto or removal from § 205.606 of the National List.

**DATES:** *Effective Date:* These guidelines will be in effect on January 19, 2007.

**ADDRESSES:** Petitions should be submitted in duplicate to: Program Manager, USDA/AMS/TM/NOP, Room 4008-So., Ag Stop 0268, 1400

Independence Ave., SW., Washington, DC 20250. Phone: (202) 720-3252. Fax: (202) 205-7808. To submit petitions electronically, contact the USDA NOP for additional instructions.

**FOR FURTHER INFORMATION CONTACT:** National List Coordinator, National Organic Program, USDA/AMS/TM/NOP, Room 4008-So., Ag Stop 0268, 1400 Independence Ave., SW., Washington, DC 20250. Phone: (202) 720-3252. Fax: (202) 720-3252.

#### SUPPLEMENTARY INFORMATION:

##### Background

The Organic Foods Production Act of 1990 (OFPA), as amended (7 U.S.C. 6501 *et seq.*), authorizes the establishment of the NOP regulations including the National List of Allowed and Prohibited Substances (National List). This National List identifies the synthetic substances that may be used and the non-synthetic substances that may not be used in organic production, and also identifies synthetic and non-synthetic substances that may be used in organic handling. The OFPA and NOP regulations, in § 205.105, specifically prohibit the use of any synthetic substance for organic production and handling unless the synthetic substance is on the National List. Section 205.105 also requires that any non-organic, non-synthetic substance used in organic handling must also be on the National List. Since the NOP regulations became effective on October 21, 2002, the National List can only be amended through rulemaking by either the National List Petition Process or the National List Sunset Process. The guidelines contained in this notice apply only to the National List Petition Process.

The ability for any person to petition to amend the National List is authorized by the OFPA (7 U.S.C. 6518(n)) and the NOP regulations, in § 205.607. This authorization provides that any person may petition the National Organic Standards Board (NOSB) for the purpose of having 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 specified evaluation criteria in OFPA (7 U.S.C. 6518(m)), and forward recommendations for amending the National List to the Secretary. Since the NOP regulations became effective in

October 2002, several petitions to include synthetic or non-synthetic substances in their respective sections of the National List have been reviewed by the NOSB. However, only a few of these petitions were for inclusion of non-organic agricultural substances onto the National List in § 205.606.

Until recently, some producers, handlers and certifiers may have misinterpreted § 205.606 to mean that any non-organic agricultural product which was determined by an accredited certifying agent to be not commercially available in organic form could be used in organic products, without being individually listed pursuant to the National List procedures. In January 2005, the First Circuit decision in *Harvey v. Johanns* held that such an interpretation is contrary to the plain meaning of the OFPA and ordered that 7 CFR 205.606 shall not be interpreted to create a blanket exemption to the National List requirements specified in §§ 6517 and 6518 of the OFPA (7 U.S.C. 6517-6518). Consistent with the district court's final judgment and order, dated June 9, 2005, on July 1, 2005, the NOP published a notice regarding § 205.606 (70 FR 38090), and on June 7, 2006, published a final rule revising § 205.606 to clarify that the section shall be interpreted to permit the use of a non-organically produced agricultural product only when the product has been listed in § 205.606 pursuant to National List procedures, and when an accredited certifying agent has determined that the organic form of the agricultural product is not commercially available (71 FR 32803). As a result, industry information provided to the NOP indicates that there may be many non-organic agricultural substances that are being used in organic products which will render currently certified products in non-compliance when the court final order and judgment on *Harvey v. Johanns* becomes fully effective on June 9, 2007.

This **Federal Register** Notice, developed in collaboration with the NOSB and based on its October 2006 recommendation, modifies the information to be included in a petition to provide for the review of non-organic agricultural substances to be included onto § 205.606. This notice also clarifies the information to be submitted for all types of petitions submitted to amend the National List.

### 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. 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.

### Overview of Petition Review by the NOSB

For each completed petition, the responsible NOSB committee reviews petition information, technical reports and public comments, then develops the recommendation for full NOSB consideration at a scheduled public meeting. The NOSB determines when petitions will be reviewed at their public meetings and when

recommendations are forwarded to the Secretary.

As provided for in OFPA (7 U.S.C 6518(m)), when evaluating petitioned substances for amendment of the National List, the NOSB shall consider:

- (1) The potential of such substances 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 such 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.

If an agricultural substance is petitioned for amendment onto § 205.606 of the National List, the NOSB shall verify that the material is agricultural. Once the substance is verified to be agricultural, the NOSB will determine if the substance is potentially commercially unavailable. The NOSB will consider:

- (A) Why the substance should be permitted in the production or handling of an organic product;
- (B) The current industry information regarding availability of and history of unavailability of an organic form in the appropriate form, quality, or quantity of the substance. Industry information includes, but is not limited to the following: (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.

After considering the petition at a scheduled public meeting, the NOSB will forward its recommendation to the Secretary. Upon receipt, the Secretary will evaluate the recommendation for

inclusion onto or removal from the National List. Proposed amendments to the National List are published in the **Federal Register** as a Proposed Rule. After considering and responding to public comments on the proposed rule, amendments to the National List are effective only after publication in the **Federal Register** as a Final Rule. A substance that has been petitioned and recommended to be allowed for use by the NOSB is not allowed for use in organic production or handling until the final rule for amending the National List, if any, is effective.

When a substance is added onto the National List, it will remain on the List for 5 years after final rule becomes effective. As required by the Sunset provision in OFPA (7 U.S.C 6517(e)), the NOSB must review substances added to the National List at least once every 5 years per the National List Sunset Process, to reaffirm or not reaffirm, the status of each substance on the National List. Petitions to reevaluate prior NOSB recommendations to include a substance onto or remove a substance from the National List will be considered by the NOSB when substantial new petition substance information is provided.

### Submitting Petitions for § 205.606

When submitting petitions to include a non-organic agricultural substance onto § 205.606, the petitioner must state in the petition justification statement, why the substance should be permitted in the production or handling of an organic product. Specifically, the petition must include current industry information on availability of, and history of unavailability of an organic form of the substance. When providing information on commercial availability of the organic form of an agricultural product, petitioners must be aware that the global market is the universe of supply; commercial availability is not dependent upon geographic location or local market conditions.

For petitions to remove a non-organic agricultural substance from § 205.606, the petitioner must state why the substance should be prohibited from use in a non-organic form. Any information acquired since the original petition to add the substance to the National List should be provided.

### 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.

- 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:

1. The substance’s chemical or material common name.

2. The manufacturer’s or producer’s name, address and telephone number 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. 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.

7. Information regarding EPA, FDA, and State regulatory authority registrations, including registration numbers. If this information does not exist, the petitioner should state so in the petition.

8. 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.

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 and/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. If this information does not exist, the petitioner should state so in the petition.

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. For petitions to include non-organic agricultural substances onto the National List, 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, the petitioner should state so in the petition.

12. 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 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.

- 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.

*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.

- 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.

*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.

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.

No additional collection or recordkeeping requirements are imposed on the public by this rule.

Accordingly, OMB clearance is not required by § 305(h) of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, *et seq.*, or OMB's implementation regulation at 5 CFR, part 1320.

**Authority:** 7 U.S.C. 6501-6522.

Dated: January 10, 2007.

**Lloyd C. Day,**

*Administrator, Agricultural Marketing Service.*

[FR Doc. E7-596 Filed 1-17-07; 8:45 am]

**BILLING CODE 3410-02-P**

## DEPARTMENT OF AGRICULTURE

### Agricultural Marketing Service

#### 7 CFR Part 980

[Docket No. FV06-980-1 FR]

#### **Vegetables, Import Regulations; Partial Exemption to the Minimum Grade Requirements for Fresh Tomatoes**

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** This rule provides a partial exemption to the minimum grade requirements under the tomato import regulation. The import regulation is authorized under section 8e of the Agricultural Marketing Agreement Act of 1937 (Act). Section 8e requires imported tomatoes to meet the same or comparable grade and size requirements as those in effect under Federal Marketing Order No. 966 (order). The order regulates the handling of tomatoes grown in Florida. A separate rule to amend the rules and regulations under the order to exempt UglyRipe™ (UglyRipe) tomatoes from the shape requirements associated with the U.S. No. 2 grade is being issued by Department of Agriculture (USDA). This rule provides the same partial exemption under the import regulation so it will conform to the regulations for Florida tomatoes under the order.

**DATES:** *Effective Date:* This final rule becomes effective January 19, 2007.