

# Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF AGRICULTURE

### Agricultural Marketing Service

#### 7 CFR Part 205

[Doc. No. AMS–NOP–11–0003; NOP–10–13]

RIN 0581–AD13

#### National Organic Program, Sunset Review (2013)

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

**ACTION:** Advance notice of proposed rulemaking with request for comments.

**SUMMARY:** The Organic Foods Production Act of 1990 (OFPA) requires sunset (expiration) of the exempted or prohibited use of substances on the National List of Allowed and Prohibited Substances (National List) under the National Organic Program (NOP). The exemptions and prohibitions granted on the National List under the OFPA are required to be reviewed every 5 years by the National Organic Standards Board (NOSB). The Secretary of Agriculture has authority under the OFPA to renew such exemptions and prohibitions. If the substances are not reviewed by the NOSB and renewed by the Secretary within 5 years of their inclusion on the National List, then their authorized use or prohibition expires. As required by the OFPA, the allowed use of 11 synthetic and nonsynthetic substances in organic production and handling will expire on November 3, 2013. A prohibition on one nonsynthetic substance in organic production will expire on November 3, 2013. This advance notice of proposed rulemaking (ANPR) begins the public comment process on whether the identified existing exemptions or prohibition should be continued. This ANPR also establishes that the sunset review and renewal process must be concluded by November 3, 2013. Finally, this ANPR discusses how the NOP will manage the sunset review and renewal process.

**DATES:** Comments must be submitted on or before August 1, 2011.

**ADDRESSES:** Interested persons may submit written comments on this ANPR using one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Mail:* Toni Strother, Agricultural Marketing Specialist, National Organic Program, USDA–AMS–NOP, Room 2646–So., Ag Stop 0268, 1400 Independence Ave., SW., Washington, DC 20250–0268.

Written comments responding to this ANPR should be identified with the docket number AMS–NOP–11–0003; NOP–10–13. For detailed instructions on submitting comments and additional information on the rulemaking process, see the “Guidance on Submitting Your Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document. The NOP intends to have all comments concerning this ANPR, including names and addresses when provided, whether submitted by mail or internet, available for viewing on the Federal eRulemaking Portal internet site, <http://www.regulations.gov>.

Comments submitted in response to this ANPR will also be available for viewing in person at USDA–AMS, National Organic Program, Room 2646–South Building, 1400 Independence Ave., SW., Washington, DC, from 9 a.m. to 12 noon and from 1 p.m. to 4 p.m., Monday through Friday (except official Federal holidays). Persons wanting to visit the USDA South Building to view comments received in response to this ANPR are requested to make an appointment in advance by calling (202) 720–3252.

**FOR FURTHER INFORMATION CONTACT:** Melissa Bailey, Director, Standards Division, National Organic Program, USDA–AMS–NOP, 1400 Independence Ave., SW., Room 2646–So., Ag Stop 0268, Washington, DC 20250–0268. Telephone: (202) 720–3252.

#### SUPPLEMENTARY INFORMATION:

##### Background

The Organic Foods Production Act of 1990 (OFPA), 7 U.S.C. 6501 *et seq.*, authorizes the establishment of the National List. The National List identifies synthetic substances that are exempted (allowed) and nonsynthetic substances that are prohibited in organic crop and livestock production. The National List also identifies

nonsynthetic and synthetic substances that are exempted for use in organic handling. The exemptions and prohibitions granted under the OFPA are required to be reviewed every 5 years by the National Organic Standards Board (NOSB). The Secretary of Agriculture has authority under the OFPA to renew such exemptions and prohibitions. If the substances are not reviewed by the NOSB and renewed by the Secretary within 5 years of their inclusion on the National List, their authorized use or prohibition expires under OFPA’s sunset provision.

This ANPR announces the sunset of 11 exempted substances and 1 prohibition added to the National List on November 3, 2003 (68 FR 61987) and November 4, 2003 (68 FR 62215), and previously renewed under the sunset process on November 3, 2008 (73 FR 59479). This ANPR establishes November 3, 2013, as the date by which the sunset review and renewal process must be concluded. The exemptions and prohibitions not renewed by this date will be removed from the National List. This ANPR also begins the public comment process on whether the existing specific exemptions on the National List should be continued. This ANPR discusses how the NOP will manage the sunset review and renewal process.

Because these substances may be critical to the production and handling of raw and processed organic agricultural products, their expiration could cause disruption of well-established and accepted organic production, handling, and processing systems. Therefore, the NOP is initiating the sunset review and renewal process now, to provide ample opportunity for the public to make their views known and to inform the decisions of the NOSB.

#### Crops Production Substances

The NOSB Crops Committee will review the continued exemption (use) of six listings of synthetic substances allowed for use in organic crop production on § 205.601: copper sulfate (2 listings), ozone gas, peracetic acid (2 listings), and EPA List 3 inert ingredients. These six listings are scheduled to sunset (expire) on November 3, 2013. The Crops Committee will also review the continued prohibition of one

nonsynthetic substance, calcium chloride, listed on § 205.602, scheduled to sunset on November 3, 2013. Table 1 contains the full listings of crop production substances to be reviewed under the 2013 sunset process.

TABLE 1—CROPS COMMITTEE SUNSET 2013 SUBSTANCES

National list section	Substance listing	Sunset date
Synthetic substances allowed for use in organic crop production.		
205.601(a)(3) .....	Copper sulfate—for use as an algicide in aquatic rice systems, is limited to one application per field during any 24-month period. Application rates are limited to those which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.	November 3, 2013.
205.601(a)(5) .....	Ozone gas—for use as an irrigation system cleaner only .....	November 3, 2013.
205.601(a)(6) .....	Peracetic acid—for use in disinfecting equipment, seed, and asexually propagated planting material.	November 3, 2013.
205.601(e)(4) .....	Copper sulfate—for use as tadpole shrimp control in aquatic rice production, is limited to one application per field during any 24-month period. Application rates are limited to levels which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.	November 3, 2013.
205.601(i)(8) .....	Peracetic acid—for use to control fire blight bacteria .....	November 3, 2013.
205.601(m)(2) .....	EPA List 3—Inerts of unknown toxicity—for use only in passive pheromone dispensers .....	November 3, 2013.
Nonsynthetic substances prohibited for use in organic crop production.		
205.602(c) .....	Calcium chloride, brine process is natural and prohibited for use except as a foliar spray to treat a physiological disorder associated with calcium uptake.	November 3, 2013.

### Handling Substances

The NOSB Handling Committee will review the continued exemption (use) of six nonagricultural (nonorganic), nonsynthetic substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food groups(s)).” The allowed uses of the

following six substances listed on § 205.605(a) are scheduled to expire on November 3, 2013: agar-agar, animal enzymes, calcium sulfate, carrageenan, glucono delta-lactone, and tartaric acid.

The Handling Committee will also review the continued exemption (use) of two nonagricultural (nonorganic), synthetic substances allowed as ingredients in or on processed products

labeled as “organic” or “made with organic (specified ingredients or food groups(s)).” The allowed uses of the following two substances listed on § 205.605(b) are scheduled to expire November 3, 2013: cellulose and tartaric acid. Table 2 contains the full listings of handling substances that will be reviewed under the 2013 sunset process.

TABLE 2—HANDLING COMMITTEE SUNSET 2013 SUBSTANCES

National list section	Substance listing	Sunset date
Nonsynthetics allowed:		
205.605(a) .....	Agar-agar .....	November 3, 2013.
205.605(a) .....	Animal enzymes—(Rennet-animal derived; Catalase-bovine liver; Animal lipase; Pancreatin; Pepsin; and Trypsin).	November 3, 2013.
205.605(a) .....	Calcium sulfate—mined .....	November 3, 2013.
205.605(a) .....	Carrageenan .....	November 3, 2013.
205.605(a) .....	Glucono delta-lactone—production by the oxidation of D-glucose with bromine water is prohibited.	November 3, 2013.
205.605(a) .....	Tartaric acid—made from grape wine .....	November 3, 2013.
Synthetics allowed:		
205.605(b) .....	Cellulose—for use in regenerative casings, as an anti-caking agent (non-chlorine bleached) and filtering aid.	November 3, 2013.
205.605(b) .....	Tartaric acid—made from malic acid .....	November 3, 2013.

### The Sunset Process

All substances currently on the National List have been previously evaluated by the NOSB for consistency

with OFPA and its implementing regulations. According to § 6517(e) of the OFPA, these substances must be reviewed by the NOSB and renewed by the Secretary for their use or prohibition

to continue after 5 years of their addition to the National List which will be November 3, 2013. All substances identified under this notice were previously renewed under the sunset

process on November 4, 2008 (73 FR 59479), and must be reviewed again by November 3, 2013.

This notice requests public comments about the continued use or prohibition of the substances identified. Public comments submitted will be considered in the review and renewal process. The NOP will forward comments received under this notice to the NOSB for review. The NOSB will review the listings of allowed and prohibited substances scheduled to sunset, including the public comments received during this review. The NOSB will review each of the substances listed in this notice and may determine that certain substances warrant a more in-depth review and require additional information or research that considers new scientific data and technological and market advances.

Following the NOSB's review, the NOSB will make a recommendation to the Secretary about the continuation of specific exemptions and prohibitions for the substances listed in this ANPR. After the Secretary receives and reviews the NOSB's recommendations, the NOP will publish a proposed rule regarding the NOSB recommendations. This proposed rule will provide an additional opportunity for the public to submit written comments. Comments received on the proposed rule will be used to develop a final rule. Because the sunset review and renewal process involves rulemaking, the NOP believes it is appropriate to initiate the process now for substances scheduled to sunset in 2013.

#### Guidance on Submitting Your Comments

Written comments responding to this ANPR should be identified with the docket number AMS-NOP-11-0003; NOP-10-13. You should clearly indicate your position on continuing the allowance or prohibition of the substances identified in this ANPR and the reasons for your position. You should include relevant information and data to support your position (e.g., scientific, environmental, manufacturing, industry impact information, etc.).

Comments, regardless of whether they support or do not support the continued use of a substance(s) listed within this ANPR, should provide evidence concerning the viability of alternatives for the substance under sunset review. Viable alternatives include, but are not limited to, alternative management practices that would eliminate the need for the specific substance; other currently exempted substances that are on the National List, which could eliminate the need for this specific substance; and other organic or nonorganic agricultural substances. Such evidence should adequately address whether any alternatives have a function and effect equivalent to or better than the specific exempted substance, and whether you want the substance to be renewed or do not want its use to be continued. Assertions about alternative substances, except for those alternatives that already appear on the National List, should, if possible, include the name and address of the manufacturer of the alternative. Further, your comments should include a copy or the specific source of any supportive literature, which could include product or practice descriptions; performance and test data; reference standards; names and addresses of producers or handlers who have used the alternative under similar conditions and the date of use; and an itemized comparison of the function and effect of the proposed alternative(s) with the substance under review. The information provided in Table 3 can help you describe recommended alternatives for different types of organic operations in place of a current exempted substance that you do not want to be continued.

An Appendix to this ANPR contains worksheets to assist you in gathering relevant information concerning these issues. These worksheets are not required to submit a comment. These worksheets are used by the NOSB to develop their recommendations to the Secretary to include an exempted substance on the National List. You do not have to answer the questions on the worksheets; they are intended only to help you provide substantive comments

to the NOSB when you provide comments on the specific substance.

#### Comments That Support Existing Exemptions and Prohibitions

Comments in support of a continued exemption of a substance should demonstrate that the substance is: (1) Not harmful to human health or the environment, (2) necessary to the production of the agricultural products because of the unavailability of wholly nonsynthetic substitute products, and (3) consistent with organic production and handling. Comments in support of a continued prohibition should explain how the use of the substance would continue to be: (1) harmful to human health or the environment, or (2) inconsistent with organic farming and handling.

#### Comments That DO NOT Support Continuing Existing Exemptions or Prohibitions

The current exemptions were originally recommended by the NOSB based on evidence available to the NOSB at the time of review which demonstrated that the substances were found to be: (1) Not harmful to human health or the environment, (2) necessary because of the unavailability of wholly nonsynthetic alternatives, and (3) consistent and compatible with organic practices.

If you provide comments that do not support continuing an existing exemption or prohibition, you should provide reasons why the use of the substance should no longer be allowed or prohibited in organic agricultural production and handling. Specifically, comments that support the removal of a substance from the National List should provide information to demonstrate that the substance is: (1) Harmful to human health or the environment; (2) unnecessary because of the availability of alternatives; or (3) inconsistent with organic farming or handling. Comments that do not support a continued prohibition should explain how the use of the substance would not be: (1) harmful to human health or the environment, or (2) inconsistent with organic farming and handling.

TABLE 3—GUIDANCE ON SUBMITTING COMMENTS FOR ALTERNATIVES TO SUBSTANCES ON THE NATIONAL LIST.

If the currently listed substance is used in . . .	And is a . . .	Then the recommended alternative should be a (an) . . .
Crop Production .....	Synthetic substance .....	—Another currently listed synthetic substance; —Nonsynthetic substance; or —Management practice.

TABLE 3—GUIDANCE ON SUBMITTING COMMENTS FOR ALTERNATIVES TO SUBSTANCES ON THE NATIONAL LIST.—  
Continued

If the currently listed substance is used in . . .	And is a . . .	Then the recommended alternative should be a (an) . . .
Crop Production .....	Synthetic inert substance (pesticidal) .....	—Another currently listed synthetic substance; or
Handling .....	Nonsynthetic (non-agricultural) substance .....	—Nonsynthetic substance.
Handling .....	Synthetic substance .....	—Agricultural substance; or
		—Management practice.
		—Another currently listed synthetic substance;
		—Nonsynthetic (non-agricultural) substance; or
		—Management practice.

The NOP understands that supportive technical or scientific information for synthetic alternatives not currently on the National List may not be easily available to organic producers and handlers. Such information may, however, be available from the research community including universities, or other sources, including international organic programs.

#### Request for Comments

The NOP requests that you comment whether the NOSB should continue to recommend the exemptions and prohibitions listed above on the

National List of Allowed and Prohibited Substances for organic agricultural production and handling. All comments will be considered in the development of the NOSB's recommendations to the Secretary.

**Authority:** 7 U.S.C. 6501–6522 and 7 CFR part 205

Dated: May 24, 2011.

**Rayne Pegg,**  
*Administrator, Agricultural Marketing Service.*

#### Appendix

This Appendix contains worksheets to assist you in gathering relevant

information concerning the compatibility of substances with evaluation criteria of the OFPA. These worksheets are not required to submit a comment. These worksheets are used by the NOSB to develop their recommendations to the Secretary to include an exempted or prohibited substance on the National List. You do not have to answer the questions on the worksheets; they are intended only to help you provide substantive comments to the NOSB when you provide comments on the specific substance.

#### NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Question	Yes	No	N/A <sup>1</sup>	Documentation (TAP; petition; regulatory agency; other)
<b>Category 1. Adverse impacts on humans or the environment?</b>				
1. Are there adverse effects on environment from manufacture, use, or disposal? [§ 205.600 b.2].				
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§ 6518 m.3].				
3. Is the substance harmful to the environment? [§ 6517(c)(1)(A)(i); 6517(c)(2)(A)(i)].				
4. Does the substance contain List 1, 2, or 3 inerts? [§ 6517(c)(1)(B)(ii); § 205.601(m)(2)].				
5. Is there potential for detrimental chemical interaction with other materials used? [§ 6518(m)(1)].				
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§ 6518(m)(5)].				
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§ 6518(m)(5)].				
8. Is there a toxic or other adverse action of the material or its breakdown products? [§ 6518(m)(2)].				
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§ 6518(m)(2)].				
10. Is there any harmful effect on human health? [§ 6517(c)(1)(A)(i); § 6517(c)(2)(A)(i); § 6518(m)(4)].				
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [§ 205.600(b)(3)].				
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§ 205.600(b)(5)].				
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§ 205.600(b)(5)].				

<sup>1</sup> If the substance under review is for crop or livestock production, all of the questions from § 205.600(b) are N/A—not applicable.

**Category 2. Is the substance essential for organic production?**

- |  |  |  |  |  |
|--|--|--|--|--|
| 1. Is the substance formulated or manufactured by a chemical process? [§ 6502(21)].  |  |  |  |  |
| 2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [§ 6502(21)]. |  |  |  |  |
| 3. Is the substance created by naturally occurring biological processes? [§ 6502(21)].   |  |  |  |  |
| 4. Is there a natural source of the substance? [§ 205.600(b)(1)] .....   |  |  |  |  |
| 5. Is there an organic substitute? [§ 205.600(b)(1)] .....   |  |  |  |  |
| 6. Is the substance essential for handling of organically produced agricultural products? [§ 205.600(b)(6)].   |  |  |  |  |
| 7. Is there a wholly natural substitute product? [§ 6517(c)(1)(A)(ii)] .....   |  |  |  |  |
| 8. Is the substance used in handling, not synthetic, but not organically produced? [§ 6517(c)(1)(B)(iii)].   |  |  |  |  |
| 9. Is there any alternative substances? [§ 6518(m)(6)] .....   |  |  |  |  |
| 10. Is there another practice that would make the substance unnecessary? [§ 6518(m)(6)].   |  |  |  |  |

<sup>1</sup> If the substance under review is for crop or livestock production, all of the questions from § 205.600(b) are N/A—not applicable.

**Category 3. Is the substance compatible with organic production practices?**

- |   |  |  |  |  |
|---|--|--|--|--|
| 1. Is the substance compatible with organic handling? [§ 205.600(b)(2)] ...   |  |  |  |  |
| 2. Is the substance consistent with organic farming and handling? [§ 6517(c)(1)(A)(iii); § 6517(c)(2)(A)(ii)].  |  |  |  |  |
| 3. Is the substance compatible with a system of sustainable agriculture? [§ 6518(m)(7)].  |  |  |  |  |
| 4. Is the nutritional quality of the food maintained with the substance? [§ 205.600(b)(3)].   |  |  |  |  |
| 5. Is the primary use as a preservative? [§ 205.600(b)(4)] .....  |  |  |  |  |
| 6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [§ 205.600(b)(4)]. |  |  |  |  |
| 7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:   |  |  |  |  |
| a. copper and sulfur compounds; .....   |  |  |  |  |
| b. toxins derived from bacteria; .....  |  |  |  |  |
| c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?  |  |  |  |  |
| d. livestock parasiticides and medicines? .....   |  |  |  |  |
| e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?  |  |  |  |  |

<sup>1</sup> If the substance under review is for crop or livestock production, all of the questions from 205.600(b) are N/A—not applicable.

[FR Doc. 2011-13496 Filed 5-31-11; 8:45 am]

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**DEPARTMENT OF AGRICULTURE****Animal and Plant Health Inspection Service****9 CFR Parts 92, 93, 94, 96, and 98**

[Docket No. APHIS-2009-0035]

RIN 0579-AD05

**Lists of Regions Classified With Respect to Certain Animal Diseases and States Approved To Receive Certain Imported Horses**

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Proposed rule.

**SUMMARY:** We are proposing to remove lists of regions classified with respect to certain animal diseases and pests from

our animal and animal product import regulations and, instead, post them to the Animal and Plant Health Inspection Service's (APHIS') Web site. The regulations would provide the Web address and would explain APHIS' criteria and process for adding a region to, or removing a region from, each of the lists. The technical criteria APHIS uses to evaluate whether a region should be added to or removed from a list would not change. We are also proposing to remove lists of States approved to receive horses imported from foreign regions where we consider contagious equine metritis to exist and, instead, post approved States to our Web site. The criteria for approving a State would not change. We would continue to provide an opportunity for public comment on changes to the lists. This action would enable the Agency to respond more quickly to changes in the disease status of regions.

**DATES:** We will consider all comments that we receive on or before August 1, 2011.

**ADDRESSES:** You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2009-0035> to submit or view comments and to view supporting and related materials available electronically.

- *Postal Mail/Commercial Delivery:* Please send one copy of your comment to Docket No. APHIS-2009-0035, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comment refers to Docket No. APHIS-2009-0035.

*Reading Room:* You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the