

# Proposed Rules

Federal Register

Vol. 73, No. 135

Monday, July 14, 2008

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

[Docket Number AMS-TM-07-0124; TM-07-12PR]

RIN 0581-AC76

#### National Organic Program (NOP); Sunset Review (2008)

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

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would amend the U.S. Department of Agriculture's (USDA) National List of Allowed and Prohibited Substances (National List) regulations to reflect recommendations submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB) on November 30, 2007, and May 22, 2008. The recommendations addressed in this proposed rule pertain to the continued exemption (use) and prohibition of 12 substances in organic production and handling. Consistent with the recommendations from the NOSB, this proposed rule would renew the 11 exemptions and 1 prohibition on the National List (along with any restrictive annotations) and correct the Tartaric acid listings by adding annotations originally recommended to the Secretary on November 1, 1995.

**DATES:** Comments must be received by August 13, 2008.

**ADDRESSES:** Interested persons may submit written comments on this proposed rule using the following addresses:

- *Mail:* Toni Strother, Agricultural Marketing Specialist, National Organic Program, USDA-AMS-TMP-NOP, 1400 Independence Ave., SW., Room 4008-So., Ag Stop 0268, Washington, DC 20250.

- *Internet:* [www.regulations.gov](http://www.regulations.gov).

Written comments responding to this proposed rule should be identified with the docket number AMS-TM-07-0124.

You should clearly indicate your position to continue the allowance or prohibition of the substances identified in this proposed rule 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.). You should also supply information on alternative substances or alternative management practices, where applicable, that support a change from the current exemption or prohibition of the substance. Only the supporting material relevant to your position will be considered.

It is our intention to have all comments concerning this proposed rule, including, names and addresses when provided, whether submitted by mail or internet available for viewing on the Regulations.gov ([www.regulations.gov](http://www.regulations.gov)) Internet site. Comments submitted in response to this proposed rule will also be available for viewing in person at USDA-AMS, Transportation and Marketing Programs, National Organic Program, Room 4008-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 proposed rule are requested to make an appointment in advance by calling (202) 720-3252.

**FOR FURTHER INFORMATION CONTACT:** Richard H. Mathews, Chief, Standards Development and Review Branch, *Telephone:* (202) 720-3252; *Fax:* (202) 205-7808.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The OFPA, 7 U.S.C. 6501 *et seq.*, authorizes the establishment of the National List of exempted and prohibited substances. The National List identifies synthetic substances (synthetics) that are exempted (allowed) and nonsynthetic substances (nonsynthetics) that are prohibited in organic crop and livestock production. The National List also identifies nonsynthetics and synthetics 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 they are not reviewed by the NOSB within 5 years of their inclusion on the National List and renewed by the Secretary, their authorized use or prohibition expires. This means that synthetic substances Copper sulfate, Ozone gas, Peracetic acid, and EPA List 3 Inerts, currently allowed for use in organic crop production, will no longer be allowed for use after November 3, 2008. Calcium chloride currently prohibited from use in organic crop production, except as a foliar spray to treat a physiological disorder associated with calcium uptake, will be allowed after November 3, 2008. This also means that Agar-agar, Carrageenan, and Tartaric acid, currently allowed for use in organic handling, will be prohibited after November 3, 2008. Finally, Animal enzymes, Calcium sulfate, Glucono delta lactone, and Cellulose, currently allowed for use in organic handling, will no longer be allowed for use after November 4, 2008.

In response to the sunset provisions in the OFPA, the Secretary published an Advanced Notice of Proposed Rulemaking (ANPR) (72 FR 73667) in the **Federal Register** on December 28, 2007, to announce the review of 11 exemptions and 1 prohibition authorized under the National Organic Program regulations. This ANPR also requested public comment on the continued use or prohibition of such exemptions and prohibition. The public comment period lasted 30 days.

We received 35 comments. Comments were received from producers, handlers, certifying agents, trade associations, organic associations, various industry groups, and a university. We received six comments urging that the current listings remain as they are currently stated. Most commenters provided specific support for substances that they promoted, represented, or relied upon. Specific support was received for the following substances (the number in parenthesis represents the number of specific support comments): Agar-agar (7), animal enzymes (2), calcium chloride (1), calcium sulfate (1), carrageenan (15), cellulose (10), List 3 inert ingredients in passive pheromone dispensers (1), ozone gas (3), and peracetic acid (1). One commenter

stated that they have found the standard of identity for passive pheromone dispenser to be undefined. As a result they requested, if the allowance for List 3 inerts in passive pheromone dispensers is renewed, that the AMS and the NOSB reexamine and clarify the meaning of "passive pheromone dispensers." The AMS is unaware of any problems with passive pheromone dispensers.

Six of the commenters supported relisting DL-Methionine, DL-Methionine-hydroxyl analog, and DL-Methionine-hydroxyl analog calcium (CAS #—59–51–8; 63–68–3; 348–67–4). These substances were added to the National List on November 3, 2003, for use in organic poultry production. Initially these substances carried an expiration date of October 21, 2005. Effective October 22, 2005, the expiration date was amended to October 1, 2008. Because these substances have an expiration date recommended by the NOSB and established by rulemaking, they are not included in this sunset review.

The Methionine Task Force, a commenter to the ANPR, submitted a petition on December 17, 2007, to amend § 205.603(d)(1) by removing the annotation date of October 1, 2008. Rulemaking on this request is handled through a separate rulemaking action.

The NOSB met November 27–30, 2007, in Arlington, VA, where they finalized recommendations to continue the listing of 11 of the 12 substances due to sunset. The NOSB met again May 20–22, 2008, in Baltimore, MD, where they finalized their recommendations to continue the listings for Tartaric acid. The NOSB also recommended correcting the Tartaric acid listings by adding annotations originally recommended to the Secretary on November 1, 1995. Having reviewed the comments received on the ANPR, the NOSB also at the May meeting reaffirmed their recommendations from November 30, 2007. Both meetings were open to the public and additional comments were received during the meetings.

As a result of the November 2007 and May 2008 NOSB meetings, and in consideration of the ANPR comments, the NOSB recommended that the Secretary renew the 11 exemptions and 1 prohibition on the National List (along with any restrictive annotations) and correct the Tartaric acid listings by adding annotations originally recommended to the Secretary on November 1, 1995. These recommendations are limited to the prohibition and exemptions originally included on the National List on

November 3 and 4, 2003. The Secretary is engaging in this proposed rulemaking to reflect the recommendations of the NOSB, from November 2007 and May 2008, and to request public comment.

Under the authority of the OFPA, as amended, (7 U.S.C. 6501 *et seq.*), the National List can be amended by the Secretary based on proposed amendments developed by the NOSB. Since established, the National List has been amended nine times, October 31, 2003 (68 FR 61987), November 3, 2003 (68 FR 62215), October 21, 2005 (70 FR 61217), June 7, 2006 (71 FR 32803), September 11, 2006 (71 FR 53299), June 27, 2007 (72 FR 35137), October 16, 2007 (72 FR 58469), December 10, 2007 (72 FR 69569), and December 12, 2007 (72 FR 70479).

## II. Overview of Proposed Amendments

From November 27, 2007, through May 22, 2008, the NOSB reviewed 11 exemptions and 1 prohibition that are authorized on the National List and set to expire on November 3 and 4, 2007. Using the evaluation criteria specified in the ANPR for sunset review, the NOSB reviewed these exemptions and prohibition for continued authorization in organic agricultural production and handling. As a result of the NOSB's review, the NOSB recommended that the Secretary renew the 11 exemptions and 1 prohibition on the National List (along with any restrictive annotations) and correct the Tartaric acid listings by adding annotations originally recommended to the Secretary on November 1, 1995.

With respect to the criteria used to make recommendations regarding the continued authorization of exemptions and prohibitions, that decision making is based on public comments and applicable supporting evidence that expresses a continued need for the use or prohibition of the substance(s).

Concerning criteria used to make recommendations regarding the discontinuation of an authorized exempted synthetic substance or prohibited nonsynthetic substance, that decision making, for the exempted synthetic substance, is based on public comments and applicable supporting evidence that demonstrates the currently authorized exempted substance is: (a) Harmful to human health or the environment, (b) not necessary to the production of the agricultural products because of the availability of wholly nonsynthetic substitute products, or (c) inconsistent with organic farming and handling.

In the case of recommendations to discontinue prohibitions of nonsynthetic substances, that decision

making is based on public comments and applicable supporting evidence demonstrating that the prohibited nonsynthetic substance is no longer harmful to human health or the environment and is consistent and compatible with organic practices.

## Renewals

After considering all public comments and supporting evidence, the NOSB determined that the 11 exemptions and 1 prohibition demonstrated a continued need for authorization in organic agricultural production and handling. On May 22, 2008, the NOSB finalized its recommendation on Tartaric acid and reaffirmed its recommendations of November 30, 2007, on the other 11 substances.

In addition to recommending the continued listing of Tartaric acid in paragraphs (a) and (b) of § 205.605, the NOSB recommended that the listings be corrected to include the annotations originally recommended by the NOSB on November 1, 1995. The NOSB recommended that the listing for Tartaric acid at § 205.605(a) be corrected to read, "Tartaric acid—made from organic grape wine." The NOSB recommended that the listing for tartaric acid at § 205.605(b) be corrected to read, "Tartaric acid—made from malic acid." These annotations were inadvertently left out of the rulemaking which added Tartaric acid to the National List on October 31, 2003 (68 FR 61987).

The Agricultural Marketing Service (AMS) has reviewed and concurs with the NOSB recommendations. Accordingly, this proposed rule would continue the 11 exemptions and 1 prohibition in 7 CFR 205.601, 205.602, and 205.605 of the following substances in organic agricultural production and handling and amend the USDA's national regulations (7 CFR part 205) to add annotations to the Tartaric acid listings of § 205.605:

### Section 205.601 Synthetic Substances Allowed for Use in Organic Crop Production

(a) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems.

(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.

(5) Ozone gas—for use as an irrigation system cleaner only.

(6) Peracetic acid—for use in disinfecting equipment, seed, and asexually propagated planting material.

(e) As insecticides (including acaricides or mite control).

(3) 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.

(i) As plant disease control.

(7) Peracetic acid—for use to control fire blight bacteria.

(m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

(2) EPA List 3—Inerts of unknown toxicity allowed:

(ii) Inerts used in passive pheromone dispensers.

#### Section 205.602 Nonsynthetic Substances Prohibited for Use in Organic Crop Production

(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.

#### Section 205.605 Nonagricultural (Nonorganic) Substances Allowed as Ingredients in or on Processed Products Labeled as “Organic” or “Made With Organic (Specified Ingredients or Food Group(s))”

(a) *Nonsynthetics allowed:*

Agar-agar.

Animal enzymes—(Rennet—animals derived; Catalase—bovine liver; Animal lipase; Pancreatin; Pepsin; and Trypsin).

Calcium sulfate—mined.

Carrageenan.

Glucono delta-lactone—production by the oxidation of D-glucose with bromine water is prohibited.

Tartaric acid—made from organic grape wine.

(b) *Synthetics allowed:*

Cellulose—for use in regenerative casings, as an anti-caking agent (non-chlorine bleached) and filtering aid.

Tartaric acid—made from malic acid.

#### Nonrenewals

The NOSB determined that the 11 exemptions and 1 prohibition demonstrated a continued need for authorization. Accordingly there are no nonrenewals.

#### Technical Correction

This proposed rule would amend § 205.605(a) by changing “Carageenan” to “Carrageenan” to correct the spelling of this allowed substance.

#### III. Related Documents

One advanced notice of proposed rulemaking with request for comments was published in **Federal Register** Notice 72 FR 73667, December 28, 2007, to make the public aware that the allowance of 12 synthetic and non-synthetic substances in organic production and handling will expire, if not reviewed by the NOSB and renewed by the Secretary.

#### IV. Statutory and Regulatory Authority

The OFPA, as amended (7 U.S.C. 6501 *et seq.*), authorizes the Secretary to make amendments to the National List based on proposed amendments developed by the NOSB. Sections 6518(k)(2) and 6518(n) of OFPA authorize the NOSB to develop proposed amendments to the National List for submission to the Secretary and establish a petition process by which persons may petition the NOSB for the purpose of having substances evaluated for inclusion on or deletion from the National List. The National List petition process is implemented under § 205.607 of the NOP regulations. The current petition process (72 FR 2167, January 18, 2007) can be accessed through the NOP Web site at: <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5048809&acct=nopgeninfo>.

##### A. Executive Order 12866

This action has been determined not significant for purposes of Executive Order 12866, and therefore, has not been reviewed by the Office of Management and Budget.

##### B. Executive Order 12988

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. This proposed rule is not intended to have a retroactive effect.

States and local jurisdictions are preempted under the OFPA from creating programs of accreditation for private persons or State officials who want to become certifying agents of organic farms or handling operations. A governing State official would have to apply to USDA to be accredited as a certifying agent, as described in § 2115(b) of the OFPA (7 U.S.C. 6514(b)). States are also preempted under §§ 2104 through 2108 of the OFPA (7 U.S.C. 6503 through 6507)

from creating certification programs to certify organic farms or handling operations unless the State programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA.

Pursuant to § 2108(b)(2) of the OFPA (7 U.S.C. 6507(b)(2)), a State organic certification program may contain additional requirements for the production and handling of organically produced agricultural products that are produced in the State and for the certification of organic farm and handling operations located within the State under certain circumstances. Such additional requirements must: (a) further the purposes of the OFPA, (b) not be inconsistent with the OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

Pursuant to § 2120(f) of the OFPA (7 U.S.C. 6519(f)), this proposed rule would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspections Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*), concerning meat, poultry, and egg products, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 *et seq.*), nor the authority of the Administrator of EPA under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 *et seq.*).

Section 2121 of the OFPA (7 U.S.C. 6520) provides for the Secretary to establish an expedited administrative appeals procedure under which persons may appeal an action of the Secretary, the applicable governing State official, or a certifying agent under this title that adversely affects such person or is inconsistent with the organic certification program established under this title. The OFPA also provides that the U.S. District Court for the district in which a person is located has jurisdiction to review the Secretary's decision.

##### C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose is to fit regulatory actions to the scale of businesses subject to the action. Section

605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

Pursuant to the requirements set forth in the RFA, the AMS performed an economic impact analysis on small entities in the final rule published in the **Federal Register** on December 21, 2000 (65 FR 80548). The AMS has also considered the economic impact of this action on small entities. The impact on entities affected by this proposed rule would not be significant. The effect of this proposed rule would be to allow the continued use of substances currently listed for use in organic agricultural production and handling. The AMS concludes that this action would have minimal economic impact on small agricultural service firms. Accordingly, USDA certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Small agricultural service firms, which include producers, handlers, and accredited certifying agents, have been defined by the Small Business Administration (SBA) (13 CFR 121.201) as those having annual receipts of less than \$6,500,000 and small agricultural producers are defined as those having annual receipts of less than \$750,000. This proposed rule would have an impact on a substantial number of small entities.

The U.S. organic industry at the end of 2001 included nearly 6,949 certified organic crop and livestock operations. These operations reported certified acreage totaling more than 2.09 million acres of organic farm production. Data on the numbers of certified organic handling operations (any operation that transforms raw product into processed products using organic ingredients) were not available at the time of survey in 2001; but they were estimated to be in the thousands. By the end of 2005, the number of U.S. certified organic crop, livestock, and handling operations totaled about 8,500. Based on 2005 USDA, Economic Research Service, data from USDA-accredited certifying agents, U.S. certified organic acreage increased to 4 million acres.

The U.S. sales of organic food and beverages have grown from \$1 billion in 1990 to nearly \$17 billion in 2006. The organic industry is viewed as the fastest growing sector of agriculture, representing almost 3 percent of overall food and beverage sales. Since 1990, organic retail sales have historically demonstrated a growth rate between 20 to 24 percent each year, including a 22 percent increase in 2006.

In addition, USDA has 95 accredited certifying agents who provide certification services to producers and handlers. A complete list of names and addresses of accredited certifying agents may be found on the AMS NOP Web site, at <http://www.ams.usda.gov/nop>. AMS believes that most of these entities would be considered small entities under the criteria established by the SBA.

#### *D. Paperwork Reduction Act*

No additional collection or recordkeeping requirements are imposed on the public by this proposed rule. Accordingly, OMB clearance is not required by section 350(h) of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, *et seq.*, or OMB's implementing regulations at 5 CFR part 1320.

The AMS is committed to compliance with the Government Paperwork Elimination Act (GPEA), which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible.

The AMS is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

#### *E. General Notice of Public Rulemaking*

This proposed rule reflects recommendations submitted to the Secretary by the NOSB for the continuation of 11 exemptions and 1 prohibition contained on the National List of Allowed and Prohibited Substances. A 30-day period for interested persons to comment on this rule is provided. Thirty days is deemed appropriate because the expiration of these 12 substances has been widely publicized, their continued use or prohibition is critical to organic production, and this rulemaking should be completed before November 3, 2008.

#### **List of Subjects in 7 CFR Part 205**

Administrative practice and procedure, Agriculture, Animals, Archives and records, Imports, Labeling, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

For the reasons set forth in the preamble, 7 CFR part 205, Subpart G is proposed to be amended as follows:

## **PART 205—NATIONAL ORGANIC PROGRAM**

1. The authority citation for 7 CFR part 205 continues to read as follows:

**Authority:** 7 U.S.C. 6501–6522.

### **§ 205.605 [Amended]**

2. Section 205.605(a) is amended by removing “Carageenan” and adding “Carrageenan” in its place, and by removing “Tartaric acid” and adding “Tartaric acid—made from grape wine” in its place.

3. Section 205.605(b) is amended by removing “Tartaric acid” and adding “Tartaric acid—made from malic acid” in its place.

Dated: July 1, 2008.

**Lloyd C. Day,**

*Administrator, Agricultural Marketing Service.*

[FR Doc. E8–15389 Filed 7–11–08; 8:45 am]

**BILLING CODE 3410–02–P**

## **DEPARTMENT OF AGRICULTURE**

### **Agriculture Marketing Service**

#### **7 CFR Part 205**

[Docket Number AMS–TM–08–0025; TM–08–05PR]

**RIN 0581–AC81**

### **National Organic Program; Proposed Amendment to the National List of Allowed and Prohibited Substances (Livestock)**

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

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would amend the U.S. Department of Agriculture's (USDA) National List of Allowed and Prohibited Substances (National List) to reflect one recommendation submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB) on May 22, 2008. Consistent with the recommendation from the NOSB, this proposed rule would revise the annotation of one substance on the National List, Methionine, to extend its use in organic poultry production until October 1, 2010.

**DATES:** Comments must be received by August 13, 2008.

**ADDRESSES:** Interested persons may submit written comments on this proposed rule using the following addresses:

- *Mail:* Toni Strother, Agricultural Marketing Specialist, National Organic Program, USDA–AMS–TMP–NOP, 1400