

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

[Document Number AMS-TM-09-0003; TM-08-06PR]

RIN 0581-AC91

National Organic Program; Proposed Amendments to the National List of Allowed and Prohibited Substances (Crops and Processing)

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the U.S. Department of Agriculture's (USDA's) National List of Allowed and Prohibited Substances (National List) 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 exemptions (uses) for six substances in organic crop production and organic processing. Consistent with the recommendations from the NOSB, this proposed rule would add six substances, along with any restrictive annotations, to the National List. This proposed rule would also remove one substance from the National List, as the exemption for use in organic crop production has expired.

DATES: Comments must be received by August 3, 2009.

ADDRESSES: Interested persons may comment on this proposed rule using the following procedures:

- *Internet:* <http://www.regulations.gov>.

- *Mail:* Comments may be submitted by mail to: Toni Strother, Agricultural Marketing Specialist, National Organic Program, USDA-AMS-TMP-NOP, Room 4004-So., Ag Stop 0268, 1400 Independence Ave., SW., Washington, DC 20250.

Written comments responding to this proposed rule should be identified with the document number AMS-TM-09-0003; TM-08-06. You should identify the topic and section number of this proposed rule to which your comment refers. You should clearly indicate whether or not you support the exemption for any or all of the substances in this proposed rule. You should clearly indicate the reason(s) for your position. You should also indicate recommended language changes as appropriate. Please include relevant information and data to support your position, (e.g. scientific, environmental, manufacturing, industry impact information, etc.). Only relevant material supporting your position should be submitted.

It is our intention to have all comments concerning this proposed rule, including names and addresses when provided, regardless of submission procedure used, available for viewing on the 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 4004-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

On December 21, 2000, the Secretary established, within the National Organic Program (NOP) [7 CFR part 205], the National List regulations §§ 205.600 through 205.607. This National List identifies the synthetic substances that may be used and the nonsynthetic (natural) substances that may not be used in organic production. The National List also identifies synthetic, nonsynthetic nonagricultural and nonorganic agricultural substances that

may be used in organic handling. The Organic Foods Production Act of 1990, as amended, (7 U.S.C. 6501 *et seq.*), (OFPA), and NOP regulations, in § 205.105, specifically prohibit the use of any synthetic substance in organic production and handling unless the synthetic substance is on the National List. Section 205.105 also requires that any nonorganic agricultural and any nonsynthetic nonagricultural substance used in organic handling be on the National List.

Under the authority of the OFPA, 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 eleven 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), December 12, 2007 (72 FR 70479), September 18, 2008 (73 FR 54057), and October 9, 2008 (73 FR 59479).

This proposed rule would amend the National List to reflect six recommendations submitted to the Secretary by the NOSB on November 30, 2007, and May 22, 2008. Based upon their evaluation of petitions submitted by industry participants, the NOSB recommended that the Secretary add two substances (aqueous potassium silicate and sodium carbonate peroxyhydrate) for organic crop production to § 205.601, one substance (gellan gum) for organic processing to § 205.605, and three substances (fortified cooking wine—marsala, fortified cooking wine—sherry, and tragacanth gum) for organic processing to § 205.606 of the National List. The use of each substance in organic production was evaluated by the NOSB using the evaluation criteria specified in OFPA (7 U.S.C. 6517-6518).

This proposed rule would also remove one substance (Glycerine Oleate (Glycerol monooleate)) from § 205.601 at paragraph (m)(2)(i). Glycerine Oleate (Glycerol monooleate) (CAS #s 37220-82-9) was added to the National List on September 11, 2006 (71 FR 53299), as an inert ingredient with the annotation, for use until December 31, 2006.

II. Overview of Proposed Amendments

The following provides an overview of the proposed amendments to designated sections of the National List regulations:

Section 205.601 Synthetic Substances Allowed for Use in Organic Crop Production

This proposed rule would amend § 205.601 of the National List regulations by: (1) Redesignating paragraphs (e)(2) through (e)(9) and (i)(1) through (i)(11) as paragraphs (e)(3) through (e)(10) and (i)(2) through (i)(12) respectively; and (2) adding new paragraphs (a)(8), (e)(2), and (i)(1) for the purpose of adding the following substances:

Aqueous potassium silicate (CAS #—1312–76–1). Aqueous potassium silicate was petitioned for two separate uses in organic crop production: As an insecticide and as plant disease control. Potassium silicate is manufactured by fusing the naturally occurring compounds, silica sand and potassium carbonate, into glass at a high temperature. The glass can be cooled and ground into a colorless or yellowish, fine powder and dissolved in water at a high temperature to produce an aqueous solution.

The Environmental Protection Agency (EPA) evaluated potassium silicate according to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and approved the unconditional registration of pesticide products containing potassium silicate as the sole active ingredient. The sites approved for the use of potassium silicate include agricultural crops, nuts, fruits, vines, turf and ornamentals. Potassium silicate functions as a desiccant and is used as a fungicide, insecticide or miticide. The target pests are mites, whiteflies and other insects, powdery mildew, botrytis, and root and turf diseases. Per the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), the EPA determined that potassium silicate is exempt from tolerance in or on food commodities when the application rate does not exceed 1 percent by weight in aqueous solution and when used in the context of good agricultural practices (40 CFR 180.1268). See also 71 FR 34267, June 14, 2006.

In its assessment of potassium silicate, the EPA concluded that toxicological risks to humans and non-target organisms, and the potential environmental/ecological effects from exposures to potassium silicate are negligible. The constituent materials,

potassium and silica, are present in the terrestrial and aquatic environment at levels which exceed projected applications of potassium silicate. The breakdown products of potassium silicate, potassium and silicon dioxide, are not hazardous or persistent byproducts, and are ubiquitous in the environment. Dermal, eye and respiratory irritation that may occur through occupational exposures can be mitigated by the use of protective personal equipment and observance of re-entry interval restrictions. References: Potassium Silicate for use in crop production, Technical Advisory Panel Review Report, compiled by University of California Sustainable Agriculture Research and Education Program, September 4, 2003, <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5057629>; EPA Biopesticides Registration Action Document, Potassium Silicate, September 7, 2006, http://www.epa.gov/oppbppd1/biopesticides/ingredients/tech_docs/brad_072606.pdf; Potassium Silicate; Exemption for the Requirement of a Tolerance, 71 FR 34267, June 14, 2006; NOSB final recommendations, November 30, 2007, <http://tinyurl.com/bacvg8>; NOSB meeting transcripts, November 2007, <http://tinyurl.com/bqqzv8>.

At its November 27–30, 2007, meeting in Arlington, VA, the NOSB recommended adding aqueous potassium silicate to the National List for use in organic crop production as an insecticide and plant disease control. In this open meeting, the NOSB evaluated aqueous potassium silicate against the evaluation criteria of 7 U.S.C. 6517 and 6518 of the OFPA, received public comment, and concluded that the substance is consistent with the OFPA evaluation criteria. The NOSB specified the use of potassium silicate in the aqueous form, in order to exclude silica from sources other than naturally occurring sand, such as slag. To clarify the NOSB intent, Agricultural Marketing Service (AMS) proposes adding an annotation providing that the silica, used in the manufacture of potassium silicate, must be sourced from naturally occurring sand.

The NOP engaged in consultations with the EPA and Food and Drug Administration (FDA). The EPA informed the NOP that the recommended use of aqueous potassium silicate is consistent with EPA regulations. Concerning the use of aqueous potassium silicate, the FDA deferred to EPA as the appropriate regulatory body. Therefore, after consultation with the EPA and FDA regarding NOSB's recommendation to

permit the use of aqueous potassium silicate in organic crop production, the Secretary is proposing to accept the NOSB's recommendation and amend § 205.601 of the National List by adding aqueous potassium silicate at new paragraphs (e)(2) and (i)(1) as an insecticide and as plant disease control, respectively, as follows:

Aqueous Potassium Silicate (CAS #—1312–76–1)—The silica, used in the manufacture of potassium silicate, must be sourced from naturally occurring sand.

Sodium carbonate peroxyhydrate (CAS #—15630–89–4). Sodium carbonate peroxyhydrate was petitioned for use in organic crop production as an algacide. This substance is a white, granular, crystalline powder which is extremely soluble in water and decomposes when heated. It is manufactured via a dry, wet or spray process from sodium carbonate and hydrogen peroxide, both of which are naturally occurring and chemically produced. Upon contact with water sodium carbonate peroxyhydrate dissociates into sodium carbonate and hydrogen peroxide. The hydrogen peroxide oxidizes critical cellular components of the target organisms and further breaks down into water and oxygen. Hydrogen peroxide is currently on the National List (§ 205.601) for use in organic crop production as an algacide, disinfectant and sanitizer, and as a plant disease control substance.

The EPA has classified sodium carbonate peroxyhydrate as a non-complex chemical that targets algae, moss, liverworts, slime molds and their spores. The EPA has indicated that sodium carbonate peroxyhydrate is effectively hydrogen peroxide when applied to water, but has not established a formal tolerance or exemption from tolerance for sodium carbonate peroxyhydrate. The EPA determines the applicability for use in food crop production on a product-by-product basis where sodium carbonate peroxyhydrate is the active ingredient. At the time of publication of this proposed rule, the EPA has registered products containing the technical grade of the active ingredient sodium carbonate peroxyhydrate for applications in aquaculture, rice/wild rice fields and paddies, turf grasses, terrestrial landscapes, as well as commercial greenhouses, nurseries and garden centers. References: Sodium Carbonate Peroxyhydrate (128860) Products, http://www.epa.gov/pesticides/biopesticides/ingredients/product/prod_128860.htm; EPA Pesticide Product Label System (PPLS), <http://oaspub.epa.gov/pestlabl/>

ppls.home, search by product registration numbers.

Due to the rapid breakdown of sodium carbonate peroxyhydrate in the environment, the EPA has determined that this substance does not present ecological hazards when applied in accordance with the label directions. The EPA also found that toxicological risks from human exposure to sodium carbonate peroxyhydrate were negligible. Sodium carbonate peroxyhydrate is a corrosive material and wearing protective gear during handling can prevent potential skin damage and eye irritation. References: Sodium Carbonate Peroxyhydrate Technical Evaluation Report compiled by ICF International for the NOP, August 11, 2006, <http://tinyurl.com/an8qmv>; EPA Biopesticides Registration Action Document, Sodium Carbonate Peroxyhydrate, September 16, 2002, http://www.epa.gov/pesticides/biopesticides/ingredients/tech_docs/brad_128860.pdf; NOSB final recommendation, November 30, 2007, <http://tinyurl.com/bacvg8>; NOSB meeting transcripts, November 2007, <http://tinyurl.com/bqzqv8>.

At its November 27–30, 2007, meeting in Arlington, VA, the NOSB recommended adding sodium carbonate peroxyhydrate to the National List for use in organic crop production as an algaecide. In this open meeting, the NOSB evaluated sodium carbonate peroxyhydrate against the evaluation criteria of 7 U.S.C. 6517 and 6518 of the OFPA, received public comment, and concluded that sodium carbonate peroxyhydrate is consistent with the OFPA evaluation criteria.

The NOP engaged in consultations with the EPA and FDA. The EPA informed the NOP that the use of this substance would be consistent with EPA regulations only when applied in accordance with the product label. Further, the EPA explained that applications in organic food crop production must be consistent with the approved food uses which are identified on a product label. Product labels for algaecides containing sodium carbonate peroxyhydrate are approved for use by the EPA. To clarify this requirement, AMS proposes adding an annotation providing that federal law restricts the use of this substance in food crop production to approved food uses identified on the product label.

Concerning the use of sodium carbonate peroxyhydrate, the FDA deferred to EPA as the appropriate regulatory body. Therefore, after consultation with the EPA and FDA regarding NOSB's recommendation to permit the use of sodium carbonate

peroxyhydrate in organic crop production, the Secretary is proposing to accept the NOSB's recommendation and amend § 205.601(a) of the National List by adding sodium carbonate peroxyhydrate at new paragraph (a)(8) as an algaecide as follows:

Sodium carbonate peroxyhydrate (CAS #—15630–89–4)—federal law restricts the use of this substance in food crop production to approved food uses identified on the product label.

This proposed rule would further amend § 205.601 of the National List by (1) removing the expired exemption at paragraph (m)(2)(i); and (2) redesignating current paragraph (m)(2)(ii) as (m)(2). Glycerine Oleate (Glycerol monooleate) (CAS#s 37220–82–9)—for use only until December 31, 2006, is currently listed at (m)(2)(i). Removal of this substance has no new regulatory effect. When this exemption was enacted on September 11, 2006 (71 FR 53299), Glycerine oleate was classified by EPA as a List 3 inert (Inerts of Unknown Toxicity). The EPA has not reclassified this form of Glycerine oleate as a List 4—Inerts of Minimal Concern, which are allowed in organic crop production unless individually prohibited, and therefore, this substance has been prohibited from use in organic crop production since December 31, 2006.

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))."

This proposed rule would amend paragraph (a) of § 205.605 of the National List regulations by adding the following substance:

Gellan gum (CAS #—71010–52–1). Gellan gum was petitioned for use as a food additive in organic processing. It is a water soluble, off-white powder that forms gels in the presence of positively charged ions. Gellan gum functions as a thickening agent to produce a wide range of textures in products, such as: Bakery fillings, confections, dairy products, dessert gels, frostings, icings and glazes, jams and jellies, puddings, sauces, and others. The gum is a high molecular weight polysaccharide which is produced through fermentation. The substance is deacylated and then precipitated from the fermentation medium with isopropyl alcohol. The thickness of the gel can be manipulated for specific functions by the addition of potassium, magnesium, calcium, and/or sodium salts. Reference: Technical Evaluation Report compiled by ICF International for the USDA NOP,

February 10, 2006, <http://tinyurl.com/bpuryq>.

The FDA has determined that gellan gum may be safely used in food in accordance with the prescribed conditions at 21 CFR 172.665. That regulation stipulates specific guidelines for the manufacturing process, specifications of the finished product, including maximum residual levels of isopropyl alcohol, and labeling requirements for its container. Gellan gum falls within FDA's definition of stabilizers and thickeners which may be used to achieve the technical and functional effects listed in 21 CFR 170.3(o)(28).

At its November 27–30, 2007, meeting in Arlington, VA, the NOSB recommended adding gellan gum as a nonsynthetic substance for use in organic handling. In this open meeting, the NOSB evaluated gellan gum against the evaluation criteria of 7 U.S.C. 6517 and 6518 of the OFPA, received public comment, and concluded that gellan gum is consistent with the OFPA evaluation criteria. In response to the NOSB recommendation regarding gellan gum in organic handling, the Secretary is proposing to amend § 205.605(a) of the National List regulations to allow the use of gellan gum as a nonsynthetic nonagricultural substance allowed as an ingredient in or on processed products labeled as "organic" or "made with organic specified ingredients or food group(s)" as follows:

Gellan gum (CAS #—71010–52–1).

Gellan gum was petitioned for addition to the National List as a synthetic substance. The NOSB handling committee recommended that the material be added to the National List in Section 205.605, as a synthetic substance due to parallels in the manufacturing processes between xanthan gum and gellan gum, specifically, the use of fermentation and isopropyl alcohol (IPA) extraction in the production processes. Xanthan gum is currently listed as a synthetic substance on the National List. At the November 2007 meeting, the full NOSB voted to recommend gellan gum as a nonsynthetic substance. In this decision, the majority of NOSB members accepted that a substance does not qualify as a synthetic based solely upon the use of synthetic processing aid, IPA, in its manufacture. Further, the majority of the NOSB members agreed that the decision regarding gellan gum was not predicated upon that for xanthan gum. References: NOSB recommendations, November 30, 2007, <http://tinyurl.com/ajnvbq>; NOSB meeting transcripts, March 2007 and

November 2007, <http://tinyurl.com/bqqzv8>.

Section 205.606 Nonorganically Produced Agricultural Products Allowed as Ingredients in or on Processed Products Labeled as "Organic."

This proposed rule would amend § 205.606 of the National List regulations by (1) redesignating paragraphs (g) through (t) and (u) through (w) as paragraphs (h) through (u) and (w) through (y) respectively; and (2) adding new paragraphs (g) and (v) for the purpose of adding the following substances:

Fortified cooking wine—Marsala. Marsala cooking wine was petitioned for use as a nonorganic agricultural ingredient in or on processed products labeled as "organic." This ingredient is used to impart a unique flavor to a variety of foods. Marsala is a dessert, or fortified wine, which is produced by adding yeast to the juice of crushed and pressed grapes. The addition of grape spirits stops the fermentation process at the desired sugar level. The wine is then heated for a specific time to reach a certain temperature and salt is added to prevent or slow further fermentation that would turn the Marsala wine into vinegar. The Marsala wine becomes a non-beverage, cooking wine with the addition of salt. The production of non-beverage wines is regulated by the Alcohol and Tobacco Tax and Trade Bureau (27 CFR 24.215) and the labeling falls within the jurisdiction of the FDA.

At its May 20–22, 2008, meeting in Baltimore, MD, the NOSB recommended adding fortified cooking wine—Marsala, to the National List for use in organic handling as a nonorganic agricultural ingredient when the organic form of Marsala cooking wine is determined to be commercially unavailable. In this open meeting, the NOSB evaluated Marsala cooking wine against the evaluation criteria of 7 U.S.C. 6517 and 6518 of the OFPA and NOP criteria (72 FR 2167, January 18, 2007) on commercial availability, received public comment, and concluded that the use of the substance in organic handling is consistent with the OFPA evaluation criteria and NOP commercial availability criteria. Specifically in regard to commercial availability, the NOSB cited scarcity of production as determined by an extensive search among fortified wine producers and organic wine producers. Therefore, in response to the NOSB recommendation regarding Marsala cooking wine in organic handling, the Secretary is proposing to amend § 205.606 of the National List regulations to allow fortified cooking wine—Marsala, at new

paragraph (g) as a nonorganically produced agricultural product allowed as an ingredient in or on processed products labeled as "organic" as follows:

Fortified cooking wines.

(1) Marsala.

Fortified cooking wine—Sherry. Sherry cooking wine was petitioned for use as a nonorganic agricultural ingredient in or on processed products labeled as "organic." This ingredient is used to impart a unique flavor to a variety of foods such as soups and entrees. Sherry is a dessert or fortified wine that is produced with the addition of spirits after fermentation. Fining and filtering of the wine occurs both before and after it is heated or baked. The addition of salt prevents the wine from turning to vinegar and produces a non-beverage cooking wine. The production of non-beverage wines is regulated by the Alcohol and Tobacco Tax and Trade Bureau (27 CFR 24.215) and the labeling falls within the jurisdiction of the FDA.

At its May 20–22, 2008, meeting in Baltimore, MD, the NOSB recommended adding fortified cooking wine—Sherry, to the National List for use in organic handling as a nonorganic agricultural ingredient where the organic form of Sherry cooking wine is considered commercially unavailable. In this open meeting, the NOSB evaluated Sherry cooking wine against the evaluation criteria of 7 U.S.C. 6517 and 6518 of the OFPA and NOP criteria (72 FR 2167, January 18, 2007) on commercial availability, received public comment, and concluded that the use of the substance in organic handling is consistent with the OFPA evaluation criteria and NOP commercial availability criteria. Specifically in regard to commercial availability, the NOSB cited a dearth of production among an extensive list of fortified wine producers and organic wine producers. Therefore, in response to the NOSB recommendation regarding Sherry cooking wine in organic handling, the Secretary is proposing to amend § 205.606 of the National List regulations to allow fortified cooking wine—Sherry, at new paragraph (g) as a nonorganically produced agricultural product allowed as an ingredient in or on processed products labeled as "organic" as follows:

Fortified cooking wines.

(2) Sherry.

Tragacanth gum (CAS #—9000–65–1). Tragacanth gum was petitioned for use as a nonorganic agricultural ingredient in or on processed products labeled as "organic." Tragacanth gum is used to provide texture, viscosity and emulsion stability in foods such as salad dressings

and sauces. Tragacanth gum has superior stability in acidic conditions and over a broader temperature range than other water-soluble gums. Tragacanth gum is harvested from the stems and branches of *Astragalus gummifer* Labillardiere and other Asiatic species of *Astragalus* (Fam. *Leguminosae*) in the desert and arid areas of the Middle East, specifically Iran and neighboring countries. The dried gum that exudes from the plant is cleaned, mechanically cut, dissolved in water and filtered. Tragacanth gum is a polysaccharide composed of 2 fractions, one of which is water soluble. It is typically available as a spray-dried powder which forms a gel when rehydrated with water, or oil prior to water, and agitated. The FDA has affirmed that tragacanth gum is a generally regarded as safe (GRAS) substance and established maximum usage levels according to the type of food (21 CFR 184.1351).

At its May 20–22, 2008, meeting in Baltimore, MD, the NOSB recommended adding tragacanth gum to the National List for use in organic handling as a nonorganic agricultural ingredient where the organic form of tragacanth gum is considered commercially unavailable. In this open meeting, the NOSB evaluated tragacanth gum against the evaluation criteria of 7 U.S.C. 6517 and 6518 of the OFPA and NOP criteria (72 FR 2167, January 18, 2007) on commercial availability, received public comment, and concluded that the use of the substance in organic handling is consistent with the OFPA evaluation criteria and NOP commercial availability criteria. Specifically with regard to the commercial availability criteria, the NOSB cited trade difficulties as the major challenge to a consistent supply, as the global supply of this ingredient is produced in Iran and neighboring countries. The NOSB recommended placement of tragacanth gum on the National List at § 205.606(j), Gums—water extracted only. As an exudate, the raw tragacanth gum is not harvested or processed using extraction. Accordingly, the NOP has determined that tragacanth gum does not belong in paragraph (j) but should have its own paragraph. Therefore, in response to the NOSB recommendation regarding tragacanth gum in organic handling, the Secretary is proposing to amend § 205.606 of the National List regulations to allow tragacanth gum at new paragraph (v) as a nonorganically produced agricultural product allowed as an ingredient in or on processed products labeled as "organic" as follows:

Tragacanth gum (CAS #—9000–65–1).

III. Related Documents

Three notices were published regarding the meetings of the NOSB and its deliberations on recommendations and substances petitioned for amending the National List. Substances and recommendations included in this proposed rule were announced for NOSB deliberation in the following **Federal Register** Notices: (1) 72 FR 10972, March 12, 2007, (Gellan gum); (2) 72 FR 58046, October 12, 2007, (Potassium silicate, Sodium carbonate peroxyhydrate, Gellan gum); and (3) 73 FR 18491, April 4, 2008, (Marsala cooking wine, Sherry cooking wine, Tragacanth gum).

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 the 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 (OMB).

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 section 2115(b) of the OFPA (7 U.S.C. 6514(b)). States are also preempted under section 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 section 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 section 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 the 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 use of additional substances in agricultural production and handling. This action would relax the regulations published in the final rule and would provide small entities with more tools to use in day-to-day operations. The AMS concludes that the economic impact of this addition of allowed substances, if any, would be minimal and beneficial to 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 \$7,000,000 and small agricultural producers are defined as those having annual receipts of less than \$750,000.

According to USDA, Economic Research Service (ERS) data based on information from USDA-accredited certifying agents, the U.S. organic industry included nearly 6,949 certified organic crop and livestock operations at the end of 2001. These operations reported certified acreage totaling more than 2.09 million acres of organic farm production. By the end of 2005, the number of U.S. certified organic crop and livestock operations totaled about 8,500 and certified organic acreage exceeded 4 million acres. ERS, based upon information provided by domestic accredited certifying agents, estimated the number of certified handling operations as exceeding 2,790 in 2004. AMS believes that most of these entities would be considered small entities under the criteria established by the SBA.

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 97 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 accredited certifying agents 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 regulation 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.

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.

2. Section 205.601 is amended by:

- A. Adding new paragraph (a)(8);
B. Redesignating paragraphs (e)(2) through (e)(9) as (e)(3) through (e)(10) and adding new paragraph (e)(2);
C. Redesignating paragraphs (i)(1) through (i)(11) as (i)(2) through (i)(12); and adding new paragraph (i)(1); and
D. Revising paragraph (m)(2).

The additions and revision read as follows:

§ 205.601 Synthetic substances allowed for use in organic crop production.

* * * * *

(a) * * *

(8) Sodium carbonate peroxyhydrate (CAS #—15630–89–4)—federal law restricts the use of this substance in food crop production to approved food uses identified on the product label.

* * * * *

(e) * * *

(2) Aqueous potassium silicate (CAS #—1312–76–1)—The silica, used in the manufacture of potassium silicate, must be sourced from naturally occurring sand.

* * * * *

(i) * * *

(1) Aqueous potassium silicate (CAS #—1312–76–1)—The silica, used in the manufacture of potassium silicate, must be sourced from naturally occurring sand.

* * * * *

(m) * * *

(2) EPA List 3—Inerts of unknown toxicity—for use only in passive pheromone dispensers.

* * * * *

2. Section 205.605 is amended by adding one new substance in alphabetical order to paragraph (a) to read as follows:

§ 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) * * *

* * * * *

Gellan gum (CAS #—71010–52–1)

* * * * *

3. Section 205.606 is amended by:

A. Redesignating paragraphs (g) through (t) and (u) through (w) as paragraphs (h) through (u) and (w) through (y) respectively;

B. Adding new paragraphs (g) and (v) to read as follows:

§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."

* * * * *

(g) Fortified cooking wines.

(1) Marsala.

(2) Sherry.

* * * * *

(v) Tragacanth gum (CAS #—9000–65–1).

* * * * *

Dated: May 28, 2009.

Robert C. Keeney,

Acting Associate Administrator.

[FR Doc. E9–12818 Filed 6–2–09; 8:45 am]

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DEPARTMENT OF ENERGY

10 CFR Part 431

[Docket No. EERE–2008–BT–STD–0013]

RIN 1904–AB83

Energy Conservation Program for Certain Industrial Equipment: Energy Conservation Standards for Commercial Heating, Air-Conditioning, and Water-Heating Equipment

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of data availability and request for public comment.

SUMMARY: The U.S. Department of Energy (DOE) is announcing the availability of an environmental assessment (EA) to accompany its notice of proposed rulemaking (NOPR) considering potential energy conservation standards for certain commercial and industrial equipment, including commercial heating, air-conditioning, and water-heating equipment, published in the Federal Register on March 20, 2009. Specifically, this EA includes a concise examination of the impacts of emission reductions likely to result from the proposed standards for commercial packaged boilers and water-cooled and evaporatively-cooled commercial package air conditioners and heat pumps with a cooling capacity at or above 240,000 Btu/h and less than 760,000 Btu/h. The EA has been incorporated as Chapter 8 in the NOPR technical support document (TSD). In addition, Chapter 9 of the NOPR TSD provides the results of DOE's monetization analysis of these potential emission reductions. These materials are available online (see ADDRESSES). DOE specifically requests that interested members of the public, Tribes, and States comment on the EA.

DATES: DOE will accept comments, data, and information regarding the subject matter of this NODA submitted no later than June 18, 2009.

ADDRESSES: Any comments submitted must identify the NODA for Energy Conservation Standards for ASHRAE Products, and provide the docket number EERE–2008–BT–STD–0013 and/or Regulatory Information Number