

# Proposed Rules

Federal Register

Vol. 75, No. 215

Monday, November 8, 2010

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–NOP–10–0079; NOP–09–02PR]

RIN 0581–AD06

#### 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) 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 May 22, 2008, November 19, 2008, and May 6, 2009. The recommendations addressed in this proposed rule pertain to establishing exemptions (uses) for four substances in organic crop production and organic processing, amending an annotation for one allowed substance, and removing an exemption for one allowed substance. Consistent with the recommendations from the NOSB, this proposed rule would add the following four substances, along with any restrictive annotations, to the National List: Microcrystalline cheesewax; acidified sodium chlorite; dried orange pulp; and Pacific kombu seaweed. This proposed rule would also amend the annotation for lecithin—unbleached, and remove lecithin—bleached, from the National List.

**DATES:** Comments must be received by January 7, 2011.

**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–NOP, Room 2646–So., Ag Stop 0268, 1400 Independence Ave., SW., Washington, DC 20250–0268.

Written comments responding to this proposed rule should be identified with the document number AMS–NOP–10–0079; NOP–09–02. 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 action being proposed for any or all of the substances in this proposed rule. You should clearly indicate the reason(s) for your position. You should also offer any recommended language changes that would be appropriate for your position. 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 USDA's 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, 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 proposed rule are requested to make an appointment in advance by calling (202) 720–3252.

**FOR FURTHER INFORMATION CONTACT:** Melissa Bailey, Director, Standards Division, 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 the 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 thirteen 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), October 9, 2008 (73 FR 59479), July 6, 2010 (75 FR 38693), and August 24, 2010 (75 FR 51919).

This proposed rule would amend the National List to reflect six recommendations submitted to the Secretary by the NOSB on May 22, 2008, November 19, 2008, and May 6, 2009. Based upon their evaluation of petitions submitted by industry participants, the NOSB recommended that the Secretary add one substance (microcrystalline cheesewax (CAS #s 64742–42–3, 8009–03–08, and 8002–74–2)) for organic crop production to § 205.601, one substance (acidified sodium chlorite) for organic processing to § 205.605(b), and two substances (orange pulp, dried, and Pacific kombu seaweed) for organic processing to § 205.606 of the National List. This proposed rule would amend § 205.605(b) of the National List by removing one substance (lecithin—bleached). This proposed rule would also amend § 205.606 of the National List by amending one listing (lecithin—unbleached). The exemptions for use of each substance in organic production

were evaluated by the NOSB using the evaluation criteria specified in OFPA (7 U.S.C. §§ 6517–6518). In addition, the amendment of one substance and removal of one substance were also evaluated by the NOSB using NOP criteria on commercial availability (72 FR 2167).

## 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: Designating paragraph (o) for the purpose of adding the following substance as a production aid: Microcrystalline cheesewax (CAS #s 64742–42–3, 8009–03–08, and 8002–74–2). A petition to add microcrystalline cheesewax for use in organic crop production as a production aid in log grown mushroom culture was submitted in January 2007. Microcrystalline cheesewax is a colorless solid which is heated to its melting point and applied with a brush to inoculation sites on the mushroom production logs. This substance acts as a moisture barrier and is temporarily used to limit moisture loss from mushroom spawn inoculums and airborne contaminants from colonizing on the inoculation sites. On May 21, 2008, the NOSB recommended adding a blended form of microcrystalline cheesewax to the National List. This blended form is comprised of three synthetically-derived substances: Clay-treated microcrystalline wax (CAS # 64742–42–3), petrolatum (CAS # 8009–03–08), and paraffin wax (CAS # 8002–74–2). Clay-treated microcrystalline wax, petrolatum and paraffin waxes range from solid to semi-solid state at room temperature, depending on the oil content. These three components are recovered from crude oil through a series of crystallization, filtration, solidification, and solvent extraction steps. According to the petition, all of the solvent is recovered during the extraction process and none of the solvent remains in the final product. These substances are then decolorized, deodorized, blended, and a synthetic antioxidant preservative, Butylated hydroxytoluene (BHT) (CAS # 9010–79–

1), is added in a quantity less than 100 parts per million.<sup>1</sup>

Each of the three components of microcrystalline cheesewax is classified by the Food and Drug Administration (FDA) as food-grade petroleum wax. The FDA defines petroleum wax as a mixture of solid hydrocarbons, paraffinic in nature, derived from petroleum, and refined to meet the specifications prescribed in 21 CFR 172.886(b). The FDA has approved food-grade petroleum wax for direct addition to chewing gum base, on cheese and raw fruits and vegetables, as a defoamer in food and as a component of microcapsules for spice-flavoring substances added to food for human consumption in accordance with 21 CFR 172.886. Petroleum wax, in accordance with 21 CFR 178.3710, is also FDA-approved for use as an indirect food additive, *i.e.*, a component of nonfood articles in contact with food. Occupational exposure to petroleum wax can result in dermal, eye, and respiratory irritation. This can be mitigated by the use of protective personal equipment and sufficient general local exhaust. References: NOSB final recommendations, May 21, 2008, <http://tiny.cc/rmmr3>; NOSB meeting transcripts, May 2008, <http://tinyurl.com/bqqzv8>; Petition and Addendum for cheesewax, April and December 2006, <http://tinyurl.com/34lp8to>.

At its May 20–22, 2008, meeting in Baltimore, MD, the NOSB recommended adding microcrystalline cheesewax to the National List for use in organic crop production as a production aid in log grown mushroom culture. In this open meeting, the NOSB evaluated microcrystalline cheesewax 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 recommendation also specified that the microcrystalline cheesewax must be made without either ethylene-propylene co-polymer, a thickener, or synthetic colors.

The Secretary has reviewed the NOSB recommendation and, consistent with this recommendation, proposes to add Microcrystalline cheesewax for organic crop production by amending § 205.601 of the National List by adding new paragraph (o) as follows:

(o) As production aids. Microcrystalline cheesewax (CAS #'s 64742–42–3, 8009–03–08, and 8002–74–

2)—for use in log grown mushroom culture. Must be made without either ethylene-propylene co-polymer or synthetic colors.

### *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 (b) of § 205.605 of the National List regulations by removing the exemption for the following substance:

Lecithin—bleached. Bleached lecithin was included in § 205.605(b) of the National List as originally published on December 21, 2000 (FR 65 80548), as an allowed synthetic ingredient in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

In June 2008, a petition was submitted to the NOSB for the removal of bleached lecithin from § 205.605(b). The petition claimed that certified organic lecithins had become available and could replace non-organic bleached lecithin. Specifically, the petition cited the adequate supply of domestically-grown organic soybeans, and the use of lighter colored raw materials, reduced processing temperatures, and reduction of color pigments by filter media that enabled the production of an organic equivalent to conventional bleached lecithin.

Lecithin is the primary emulsifier in a wide variety of organic products. Most commercial lecithin is made from soybeans. It can also be made from vegetable crops such as corn, canola and sunflower. Nonorganic soy lecithin is manufactured by using hexane to extract the oil from the soybeans. The fluid lecithin resulting from this extraction process can then be bleached with hydrogen peroxide or benzyl peroxide. Bleached lecithin is functionally equivalent to unbleached lecithin, but is used when a lighter color is preferred.

At its May 4–6, 2009, meeting in Washington, DC, the NOSB considered public comments and determined that organic light-colored lecithins are commercially available in the appropriate form, quality, and quantity to fulfill essential uses in organic handling. Additionally, the NOSB noted that there are conventional non-synthetic gums that can serve the same or similar functions as bleached lecithin.

The Secretary has reviewed the NOSB recommendation and, consistent with this recommendation, proposes to remove the exemption for lecithin—

<sup>1</sup> The U.S. Food and Drug Administration (FDA) permits the addition of antioxidants permitted in food to petroleum wax (21 CFR 172.886(c)).

bleached in paragraph (b) of § 206.605. The Board has recommended to continue to allow nonorganic de-oiled lecithin when an organic version is not commercially available—see § 205.606 discussion below. This proposed action would not prohibit nonorganic forms of bleached, de-oiled lecithin, nor would it prohibit bleaching of organic fluid lecithin with hydrogen peroxide, a bleaching agent, which is allowed for use in organic handling per § 205.605(b). References: NOSB recommendations, May 2009, <http://tiny.cc/9wgkpw>; NOSB meeting transcripts, May 2009, <http://tinyurl.com/bqqzv8>; Petition to remove bleached lecithin, June 2008, <http://tinyurl.com/32e638e>.

This proposed rule would further amend paragraph (b) of § 205.605 of the National List regulations to add the following substance:

Acidified sodium chlorite. In October 2006, a petition was submitted to the NOSB for the use of acidified sodium chlorite as a synthetic processing aid in organic handling in wash and rinse water, as well as, for direct food contact and food contact surfaces. This substance contains an aqueous solution of sodium chlorite and citric acid, both of which are listed as generally recognized as safe (GRAS) in 21 CFR 186.1750 and 21 CFR 184.1033, respectively. Acidified sodium chlorite solution is a colorless to light green solution that has a slight chlorine-like odor.

The use of acidified sodium chlorite is regulated by other Federal agencies. The FDA permits uses of acidified sodium chlorite as a secondary direct food additive in accordance with the concentrations and other specified conditions in 21 CFR 173.325.<sup>2</sup> The FDA-approved uses for acidified sodium chlorite as secondary direct antimicrobial food treatment include the processing of poultry, red meat, comminuted and formed meat products, seafood, and raw and processed fruits and vegetables. Acidified sodium chlorite is also permitted as a sanitizing agent on food-processing equipment, utensils and other food contact surfaces including dairy-processing equipment (21 CFR 178.1010(b)(46)). The EPA has approved the use of acidified sodium chlorite (as an oxychloro species) as an ingredient in antimicrobial pesticide formulations applied to dairy-processing equipment, food-processing

equipment and utensils, if the end-use concentration does not exceed 200 ppm chlorine dioxide, per 40 CFR 180.940(b) and (c). Finally, the USDA Food Safety and Inspection Service (FSIS) recognizes the use of acidified sodium chlorite for processing red meat and poultry. The FSIS Directive 7120.1 specifies that acidified sodium chlorite applied as spray or dip in red meat processing, must have pH of 5.0–7.5 and concentrations of sodium chlorite and chlorine dioxide must not exceed 1200 and 300 ppm respectively.<sup>3</sup> References: NOSB recommendations, May 2009, <http://tiny.cc/lq2gx>; NOSB meeting transcripts, May 2009, <http://tinyurl.com/bqqzv8>; Petition for acidified sodium chlorite, October 2006, <http://tinyurl.com/3x2wxpk>; Acidified Sodium Chlorite Technical Advisory Panel Report compiled by AMS Science and Technology Program, July 21, 2008, <http://tinyurl.com/359zdk>.

At its May 4–6, 2009, meeting in Washington, DC, the NOSB recommended adding acidified sodium chlorite to § 205.605(b) of the National List regulations for secondary direct antimicrobial food treatment and indirect food contact surface sanitizing, with the restriction that only citric acid can be used for acidification. The Board considered that acidified sodium chlorite can have a short contact time with the product being treated, does not produce chloromethanes or chlorohalogen, and breaks down upon use to water, citric acid and sodium chloride with no resulting residual chlorine levels in water. During this open meeting, the NOSB evaluated acidified sodium chlorite 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 Secretary has reviewed the NOSB recommendation and, consistent with this recommendation, proposes to accept the NOSB's recommendation and amend § 205.605(b) of the National List by adding acidified sodium chlorite as follows:

Acidified sodium chlorite—Secondary direct antimicrobial food treatment and indirect food contact surface sanitizing. Acidified with citric acid only.<sup>4</sup>

<sup>3</sup> For other uses of acidified sodium chlorite in poultry and red meat processing, the FSIS Directive 7120.1 refers to the concentration and pH requirements provided in FDA regulation 21 CFR 173.325.

<sup>4</sup> The NOSB recommended the listing of this substance as sodium chlorite, acidified. In this proposed rule, “acidified” was moved to precede sodium chlorite for consistency with the use of this term in other Federal regulations.

#### *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) Revising the annotation at paragraph (p); (2) redesignating paragraphs (r) through (t) and paragraphs (u) through (y), as paragraphs (s) through (u) and (w) through (aa) respectively; and (3) adding new paragraphs (r) and (v) for the purpose of amending and adding the following substances:

Lecithin—unbleached. Unbleached lecithin was included in § 205.606 of the National List as originally published on December 21, 2000 (65 FR 80548), as an allowed nonorganic agricultural ingredient in “organic” products, when the organic version is not commercially available. In August 2008, a petition was submitted to amend the listing for unbleached lecithin to reflect the availability of organic fluid lecithins. Lecithin is available in fluid or de-oiled form. After extraction from the raw material, fluid lecithin can further be de-oiled with acetone as the solvent. Both fluid and de-oiled lecithin may be bleached or unbleached. De-oiled lecithin imparts crumb softening and dough lubricating and conditioning characteristics. De-oiled lecithin is the only form of lecithin appropriate for certain products such as cakes, cookies, doughs, sauces, chocolates, frostings, and canned meat products. References: NOSB recommendations, May 2009, <http://tiny.cc/6jmsq>; NOSB meeting transcripts, May 2009, <http://tinyurl.com/bqqzv8>; Petition to remove fluid lecithin from the general category of unbleached lecithin, August 2008, <http://tinyurl.com/25zcry9>.

At its May 4–6, 2009, meeting in Washington, DC, the NOSB evaluated lecithin 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 de-oiled lecithin is consistent with the OFPA evaluation criteria. The NOSB acknowledged that the de-oiling process, rather than bleaching, differentiates the types of lecithin. Based upon the petition and public comments, the NOSB determined that de-oiled lecithin is not commercially available in organic form and recommended revising the annotation of the listing for Lecithin—unbleached in § 205.606 to Lecithin—de-oiled. This proposed action would prohibit the use of nonorganic fluid lecithin and allow the use of bleached

<sup>2</sup> The FDA states that acidified sodium chlorite solutions are produced by mixing an aqueous solution of sodium chlorite and any GRAS acid. For the purposes of the NOP, only citric acid is permitted in acidified sodium chlorite for use in organic handling.

or unbleached nonorganic de-oiled lecithin when an organic version is not commercially available.

The Secretary has reviewed the NOSB recommendation and, consistent with this recommendation, proposes to amend § 205.606 of the National List regulations to allow the use of de-oiled lecithin as a nonorganically produced agricultural substance allowed as an ingredient in or on processed products labeled as “organic” as follows:

**Lecithin—de-oiled.**

Orange pulp, dried. In February 2008, dried orange pulp was petitioned for use as a nonorganic agricultural ingredient in or on processed products labeled as “organic.” Dried orange pulp, which may also be identified as citrus flour or citrus fiber, is used in various processed products including fresh and frozen baked goods, pastas, salad dressings, confectionery, processed cheese spreads, frozen food entrees, and processed meat and poultry products. Dried orange pulp is a yellowish light and fluffy powder. It is a byproduct of the extraction of raw oranges for orange juice production. The remaining raw pulp is washed with water, stabilized with heat, mixed, dried and milled. No chemical extraction or treatment is used in its manufacture. It functions to retain moisture in baked goods, pastas, salad dressings, confectionery, processed cheese spreads, frozen food entrees, processed meat and poultry products and seasoning brines for meat and poultry products. It also functions as a flavor enhancing agent in non-carbonated beverages and fruit drinks. In June 2004, the petitioner informed the FDA that this material is GRAS (GRAS Notice no. GRN000154). Dried orange pulp is also considered a moisture retention agent and binder for use in ground meat and poultry products. The USDA FSIS permits the use of dried orange pulp as a binder provided it does not exceed 3.5% of the product formulation. Dried orange pulp may also be used in various ground meat and poultry products where binders are permitted as described in USDA, FSIS Directive 7120.1.

References: NOSB recommendations, November 2008, <http://tiny.cc/agsu7>; NOSB meeting transcripts, November 2008, <http://tinyurl.com/bqqzv8>; Petition for dried orange pulp, January 2008, <http://tinyurl.com/238e7lj>.

At its November 17–19, 2008, meeting in Washington, DC, the NOSB recommended adding dried orange pulp to § 205.606 of the National List regulations for use in organic handling as a nonorganic agricultural ingredient when the organic form of dried orange pulp is determined to be commercially

unavailable. The Board determined that the demand for the organic dried orange pulp exceeded the availability of organic oranges in quantities to yield sufficient organic dried orange pulp. Specifically, the NOSB considered that most pulp is incorporated into orange juice and the low yield ratio of raw to dried pulp. The Board also considered the potential for this substance to replace certain synthetic substances which are allowed in organic handling. In this open meeting, the NOSB evaluated dried orange pulp against the evaluation criteria of 7 U.S.C. 6517 and 6518 of the OFPA and the NOP criteria (72 FR 2167, January 18, 2007) on commercial availability, received public comment, and concluded that the substance is consistent with the OFPA evaluation criteria.

The Secretary has reviewed the NOSB recommendation and, consistent with this recommendation, proposes to amend § 205.606 of the National List regulations to allow dried orange pulp, at new paragraph (r) as a nonorganically produced agricultural product allowed as an ingredient in or on processed products labeled as “organic” as follows:

**Orange pulp, dried.**

Seaweed, Pacific kombu. Pacific kombu seaweed was petitioned in August 2007, for use as a nonorganic agricultural ingredient in or on processed products labeled as “organic.” Pacific kombu seaweed has been consumed for centuries in Japan and is used for stock in traditional Japanese foods. Pacific kombu species impart a unique flavor, which is attributed to the glutamic acid content, and which is not achievable with other seaweed species or sea vegetables. Pacific kombu seaweed is wild harvested along the coast of Japan. After harvest, the seaweed is hot water extracted, condensed, heat sterilized and filtered. The FDA has classified Pacific kombu as brown algae and affirmed that brown algae is a GRAS direct food substance. Its use in spices, seasonings, and flavorings as a flavor enhancer and flavor adjuvant in food is regulated by the FDA at 21 CFR 184.1120.

References: NOSB recommendations, May 2008, <http://tiny.cc/0e1xo>; NOSB meeting transcripts, May 2008, <http://tinyurl.com/bqqzv8>; Petition for kombu seaweed, August 2007, <http://tinyurl.com/29l4oug>.

At its May 20–22, 2008, meeting in Baltimore, MD, the NOSB recommended adding Pacific kombu seaweed to § 205.606 of the National List regulations for use in organic handling as a nonorganic agricultural ingredient when the organic form of Pacific kombu seaweed is determined to be

commercially unavailable. In this open meeting, the NOSB evaluated Pacific kombu seaweed 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 substance is consistent with the OFPA evaluation criteria.

The Secretary has reviewed the NOSB recommendation and, consistent with this recommendation, proposes to amend § 205.606 of the National List regulations to allow Pacific kombu seaweed, at new paragraph (v) as a nonorganically produced agricultural product allowed as an ingredient in or on processed products labeled as “organic” as follows:

Seaweed, Pacific kombu.

### 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) 74 FR 11904, March 20, 2009, (bleached lecithin, acidified sodium chlorite, unbleached fluid lecithin); (2) 73 FR 54781, September 23, 2008, (dried orange pulp, acidified sodium chlorite); and (3) 73 FR 18491, April 4, 2008, (microcrystalline cheesewax, acidified sodium chlorite, Pacific kombu seaweed).

### 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/nop>.

#### 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 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 removal of lecithin-bleached is not expected to have a significant economic impact on small entities as alternative forms of lecithin are commercially available. 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 number of certified U.S. organic crop and livestock operations totaled nearly 13,000 and certified organic acreage exceeded 4.8 million acres in 2008.<sup>5</sup> ERS, based upon the list of certified operations maintained by the National Organic Program, estimated the number of certified handling operations was 3,225 in 2007.<sup>6</sup> 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 \$3.6 billion in 1997 to nearly \$21.1 billion in 2008.<sup>7</sup> The organic industry is viewed as the fastest growing sector of agriculture, representing over 3 percent of overall food sales in 2009. Between 1990 and 2008, organic food sales have historically demonstrated a growth rate between 15 to 24 percent each year. In 2009, organic food sales grew 5.1%.<sup>8</sup>

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

<sup>5</sup> U.S. Department of Agriculture, Economic Research Service. 2009. *Data Sets: U.S. Certified Organic Farmland Acreage, Livestock Numbers and Farm Operations, 1992–2008*. <http://www.ers.usda.gov/Data/Organic/>.

<sup>6</sup> U.S. Department of Agriculture, Economic Research Service. 2009. *Data Sets: Procurement and Contracting by Organic Handlers: Documentation*. <http://www.ers.usda.gov/Data/OrganicHandlers/Documentation.htm>.

<sup>7</sup> Dimitri, C., and L. Oberholtzer. 2009. *Marketing U.S. Organic Foods: Recent Trends from Farms to Consumers*, Economic Information Bulletin No. 58, U.S. Department of Agriculture, Economic Research Service, <http://www.ers.usda.gov/Publications/EIB58>.

<sup>8</sup> Organic Trade Association's 2010 Organic Industry Survey, <http://www.ota.com>.

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 adding paragraph (o) to read as follows:

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

\* \* \* \* \*

(o) As production aids. Microcrystalline cheesewax (CAS #'s 64742–42–3, 8009–03–08, and 8002–74–2)—for use in log grown mushroom culture. Must be made without either ethylene-propylene co-polymer or synthetic colors.

\* \* \* \* \*

3. Section 205.605, paragraph (b), is amended by:

A. Removing “Lecithin—bleached.”; and

B. Adding one new substance to paragraph (b) 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)).”

\* \* \* \* \*

(b) \* \* \*

Acidified sodium chlorite—Secondary direct antimicrobial food treatment and indirect food contact surface sanitizing. Acidified with citric acid only.

\* \* \* \* \*

4. Section 205.606 is amended by:

A. Revising paragraph (p);  
B. Redesignating paragraphs (r) through (t) and paragraphs (u) through (y) as paragraphs (s) through (u) and (w) through (aa) respectively; and

C. Adding new paragraphs (r) and (v) to read as follows:

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

\* \* \* \* \*

(p) Lecithin—de-oiled.

\* \* \* \* \*

(r) Orange pulp, dried.

\* \* \* \* \*

(v) Seaweed, Pacific kombu.

\* \* \* \* \*

Dated: November 2, 2010.

**David R. Shipman,**

*Acting Administrator.*

[FR Doc. 2010–28042 Filed 11–5–10; 8:45 am]

**BILLING CODE 3410–02–P**

#### DEPARTMENT OF AGRICULTURE

##### Agricultural Marketing Service

##### 7 CFR Part 924

[Doc. No. AMS–FV–10–0053; FV10–924–1 PR]

##### Fresh Prunes Grown in Designated Counties in Washington and in Umatilla County, OR; Termination of Marketing Order 924

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

**ACTION:** Proposed rule.

**SUMMARY:** This rule invites comments on the proposed termination of the Federal marketing order regulating the handling of fresh prunes grown in designated counties in Washington and in Umatilla County, Oregon, and the rules and regulations issued thereunder. Marketing Order No. 924 is administered locally by the Washington-Oregon Fresh Prune Marketing Committee (Committee), which unanimously recommended termination of the marketing order at a meeting held on June 1, 2010. This recommendation is based on the Committee's determination that this order is no longer an effective marketing tool for the fresh prune industry, and that termination would best serve the current needs of the industry while also eliminating the costs associated with the operation of the marketing order.

**DATES:** Comments must be received by January 7, 2011.

**ADDRESSES:** Interested persons are invited to submit written comments concerning this proposal. Comments must be sent to the Docket Clerk, Marketing Order Administration Branch, Fruit and Vegetable Programs,

AMS, USDA, 1400 Independence Avenue, SW., STOP 0237, Washington, DC 20250–0237; Fax: (202) 720–8938; or Internet: <http://www.regulations.gov>. All comments should reference the document number and the date and page number of this issue of the **Federal Register** and will be made available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: <http://www.regulations.gov>. All comments submitted in response to this rule will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting the comments will be made public on the Internet at the address provided above.

##### FOR FURTHER INFORMATION CONTACT:

Martin Engeler, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 2202 Monterey Street, Suite 102–B, Fresno, California 93721, Telephone: (559) 487–5110, Fax: (559) 487–5906, or E-mail: [Martin.Engeler@ams.usda.gov](mailto:Martin.Engeler@ams.usda.gov); or Robert Curry, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1220 SW Third Avenue, Suite 385, Portland, Oregon 97068, Telephone: (503) 326–2724, Fax: (503) 326–7440, or E-mail: [Robert.Curry@ams.usda.gov](mailto:Robert.Curry@ams.usda.gov).

Small businesses may request information on complying with this regulation by contacting Antoinette Carter, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., STOP 0237, Washington, DC 20250–0237; telephone: (202) 720–2491, Fax: (202) 720–8938, or E-mail: [Antoinette.Carter@ams.usda.gov](mailto:Antoinette.Carter@ams.usda.gov).

**SUPPLEMENTARY INFORMATION:** This proposed rule is governed by § 608c(16)(A) of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the “Act”, and § 924.64 of Marketing Agreement and Order No. 924, both as amended (7 CFR part 924), effective under the Act and hereinafter referred to as the “order”.

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Order 12866.

This proposal to terminate the order has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have retroactive effect.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file