

# Proposed Rules

Federal Register

Vol. 75, No. 58

Friday, March 26, 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

[Doc. No. AMS–NOP–09–0074; NOP–09–01]

RIN 0581–AC96

#### National Organic Program, Sunset Review (2012)

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

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

**SUMMARY:** Sunset of the exempted or prohibited use of substances under the National Organic Program (NOP) is required by the Organic Foods Production Act of 1990 (OFPA). 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 and renewed by the Secretary within 5 years of their inclusion on the National List, their authorized use or prohibition expires. This advance notice of proposed rulemaking (ANPR) announces the sunset of 37 exempted substances added to the National List for use in organic handling on June 27, 2007; the sunset of 183 continued exemptions (use) and prohibitions of substances used in organic production and handling added to the list on October 21, 2007; the sunset of 2 exemptions of one substance for continued use in organic crop and livestock production added to the national list on December 11, 2007; and the sunset of 10 exempted substances for use in organic livestock production added to the national list on December 13, 2007. This ANPR establishes June 27, 2012, October 21, 2012, December 11, 2012, and December 13, 2012, as the respective dates by which the sunset review and renewal process must be concluded. The NOP may try to

conclude the sunset and renewal process for the 232 combined exempted and prohibited substances used in organic production and handling added to the National List in 2007 by the earliest respective date of June 27, 2012. This ANPR also begins the public comment process on whether the identified existing exemptions and prohibitions should be continued. Finally, this ANPR discusses how the NOP will manage the sunset review and renewal process.

**DATES:** Comments must be submitted on or before May 25, 2010.

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

- *Mail:* Comments may be sent by mail to: Toni Strother, Agricultural Marketing Specialist, National Organic Program, USDA–AMS–NOP, 1400 Independence Ave., SW., Room 2624–So., Ag Stop 0268, Washington, DC 20250–0268.

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

Written comments responding to this ANPR should be identified with the docket number AMS–NOP–09–0074; NOP–09–01. You should clearly indicate your position on continuing the allowance or prohibition of the substances identified in this ANPR and the reasons for your position. You should include relevant information and data to support your position (e.g., scientific, environmental, manufacturing, industry impact information, etc.). You should also supply information on alternative substances or alternative management practices, where applicable, that support a change from the current exemption of the substance. Only the supporting material relevant to your position will be considered.

It is our intention to have all comments concerning this ANPR, including names and addresses when provided, whether submitted by mail or Internet, available for viewing on the Regulations.gov (<http://www.regulations.gov>) internet site. Comments submitted in response to this ANPR will also be available for viewing in person at USDA–AMS, National Organic Program, Room 2646–South Building, 1400 Independence Ave., SW., Washington, DC, from 9 a.m. to 12 noon and from 1 p.m. to 4 p.m., Monday through Friday (except official Federal

holidays). Persons wanting to visit the USDA South Building to view comments received in response to this ANPR are requested to make an appointment in advance by calling (202) 720–3252.

#### FOR FURTHER INFORMATION CONTACT:

Shannon H. Nally, Acting Director, Standards Division, National Organic Program, USDA–AMS–NOP, 1400 Independence Ave., SW., Room 2646–So., Ag Stop 0268, Washington, DC 20250–0268. Telephone: (202) 720–3252.

#### SUPPLEMENTARY INFORMATION:

##### Background

The 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 and renewed by the Secretary within 5 years of their inclusion on the National List, their authorized use or prohibition expires.

The NOSB will review the continued exemption (use) of 37 agricultural products not commercially available as organic that are scheduled to expire after June 27, 2012. These products are allowed for use in organic handling in or on processed products based on final commercial availability determinations by accredited certifying agents. The NOSB will review the continued exemption (use) and prohibition of 183 substance listings used in organic production and handling scheduled to expire after October 21, 2012. The NOSB will review the continued exemption (use) of 2 listings for one substance for use in organic crop and livestock production scheduled to expire after December 11, 2012. The NOSB will review the continued exemption (use) of 10 substances for use

in organic livestock production scheduled to expire after December 13, 2012. Additionally, the NOP may try to conclude the sunset and renewal process for the 231 combined exempted and prohibited substances used in organic production and handling added to the National List in 2007 by the earliest respective date of June 27, 2012.

#### June 27, 2012 Sunset Materials

The Handling Committee will review the continued exemption (use) of the nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic” in § 205.606 depending on final commercial availability determinations performed by accredited certifying agents scheduled to expire after June 27, 2012. They are as follows: Annatto extract color (pigment CAS #1393-63-1)—water and oil soluble; Beet juice extract color (pigment CAS #7659-95-2); Beta-Carotene extract color from carrots (CAS #1393-63-1); Black currant juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3); Black/Purple carrot juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3); Blueberry juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3); Carrot juice color (pigment CAS #1393-63-1); Cherry juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3); Chokeberry—Aronia juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3); Elderberry juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3); Grape juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3); Grape skin extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3); Paprika color—dried powder and vegetable oil extract (CAS #68917-78-2); Pumpkin juice color (pigment CAS #127-40-2); Purple potato juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3); Red cabbage extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3); Red radish extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3); Saffron extract color (pigment CAS #1393-63-1), and Turmeric extract color (CAS #458-37-7).

The following are allowed as ingredients or processing aids from

agricultural products per § 205.606: Casings, from processed intestines; Celery powder; Chia (*Salvia hispanica* L.); Dillweed oil (CAS #8006-75-5); Fish oil (Fatty acid CAS #'s: 10417-94-4, and 25167-62-8); Fructooligosaccharides (CAS #308066-66-2); Galangal, frozen; Gelatin (CAS #9000-70-8); Hops (*Humulus lupulus*); Inulin, oligofructose enriched (CAS #9005-80-5); Konjac flour (CAS #37220-17-0); Lemongrass, frozen; Orange shellac, unbleached (CAS #9000-59-3); Pepper, chipotle chile; Sweet potato starch, for bean thread production only; Turkish bay leaves; Wakame seaweed (*Undaria pinnatifida*); and Whey protein concentrate.

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 and renewed by the Secretary within 5 years of their inclusion on the National List, their authorized use or prohibition expires.

This means that the following color ingredients from agricultural products: Annatto extract color (pigment CAS #1393-63-1)—water and oil soluble; Beet juice extract color (pigment CAS #7659-95-2); Beta-Carotene extract color from carrots (CAS #1393-63-1); Black currant juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3); Black/Purple carrot juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3); Blueberry juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3); Carrot juice color (pigment CAS #1393-63-1); Cherry juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3); Chokeberry—Aronia juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3); Elderberry juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3); Grape juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3); Grape skin extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3); Paprika color—dried powder and vegetable oil extract (CAS #68917-78-2); Pumpkin juice color (pigment CAS #127-40-2); Purple potato juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3); Red cabbage extract color

(pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3); Red radish extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3); Saffron extract color (pigment CAS #1393-63-1), and Turmeric extract color (CAS #458-37-7), currently allowed for use in organic handling, will no longer be allowed for use after June 27, 2012.

This also means that the following ingredients or processing aids from nonorganic agricultural products: Casings, from processed intestines; Celery powder; Chia (*Salvia hispanica* L.); Dillweed oil (CAS #8006-75-5); Fish oil (Fatty acid CAS #'s: 10417-94-4, and 25167-62-8); Fructooligosaccharides (CAS #308066-66-2); Galangal, frozen; Gelatin (CAS #9000-70-8); Hops (*Humulus lupulus*); Inulin, oligofructose enriched (CAS #9005-80-5); Konjac flour (CAS #37220-17-0); Lemongrass, frozen; Orange shellac, unbleached (CAS #9000-59-3); Pepper, chipotle chile; Sweet potato starch, for bean thread production only; Turkish bay leaves; Wakame seaweed (*Undaria pinnatifida*); and Whey protein concentrate, currently allowed for use in organic handling, will no longer be allowed for use after June 27, 2012.

#### October 21, 2012 Sunset Materials

The Crops Committee will review the continued exemption (use) of the following synthetic substances allowed for use in § 205.601 that are scheduled to expire after October 21, 2012, from use in organic crop production: Ethanol; Isopropanol; Calcium hypochlorite; Chlorine dioxide; Sodium hypochlorite; Hydrogen peroxide; Soap-based algicide/demossers; Herbicides, soap-based; Newspaper or other recycled paper, without glossy or colored inks (2 uses); Plastic mulch and covers; Soaps, ammonium; Ammonium carbonate; Boric acid; Elemental sulfur (3 uses); Lime sulfur (2 uses); Oils, horticultural-narrow range oils as dormant, suffocating, and summer oils (2 uses); Soaps, insecticidal; Sticky traps/barriers; Pheromones; Sulfur dioxide; Vitamin D<sub>3</sub>; Copper hydroxide; Copper oxide; Copper oxychloride; Copper sulfate (2 uses); Hydrated lime; Hydrogen peroxide; Potassium bicarbonate; Streptomycin; Aquatic plant extracts (other than hydrolyzed); Humic acids; Lignin sulfonate (2 uses); Magnesium sulfate; Soluble boron products; Sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt; Liquid fish products; Vitamin B<sub>1</sub>; Vitamin C; Vitamin E;

Ethylene gas; Sodium silicate; and EPA List 4—Inerts of Minimal Concern.

The Crops Committee will review the continued prohibition of the following nonsynthetic substances in § 205.602 which are scheduled to expire and be allowed for use after October 21, 2012, in organic crop production: Ash from manure burning; Arsenic; Lead salts; Potassium chloride; Sodium fluoaluminate (mined); Sodium nitrate; Strychnine; and Tobacco dust (nicotine sulfate).

The Livestock Committee will review the continued exemption (use) of the following synthetic substances allowed for use in organic livestock production in § 205.603 that are scheduled to expire after October 21, 2012: Ethanol; Isopropanol; Aspirin; Vaccines; Chlorhexidine; Calcium hypochlorite; Chlorine dioxide; Sodium hypochlorite; Electrolytes; Glucose; Glycerine; Hydrogen peroxide; Iodine (2 uses); Magnesium sulfate; Oxytocin; Ivermectin; Phosphoric acid; Copper sulfate; Lidocaine; Lime, hydrated; Mineral oil; Procaine; Trace minerals; Vitamins; and EPA List 4—Inerts of Minimal Concern.

The Livestock Committee will also review the continued prohibition of the following nonsynthetic substance in § 205.604 which is scheduled to expire and be allowed for use after October 21, 2012, in organic livestock production: Strychnine.

The Handling Committee will review the continued exemption (use) of the following nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” currently scheduled for expiration after October 21, 2012 from § 205.605 as (a) Nonsynthetics allowed: Acids (Alginic; Citric; and Lactic); Bentonite; Calcium carbonate; Calcium chloride; Dairy cultures; Diatomaceous earth; Enzymes; Flavors; Kaolin; Magnesium sulfate; Nitrogen; Oxygen; Perlite; Potassium chloride; Potassium iodide; Sodium bicarbonate; Sodium carbonate; Waxes; Yeast (Autolysate; Bakers; Brewers; Nutritional; and Smoked).

The Handling Committee will review the continued exemption (use) of the following nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” currently scheduled for expiration after October 21, 2012, listed on § 205.605 as (b) Synthetics allowed: Alginates; Ammonium bicarbonate; Ammonium carbonate; Ascorbic acid; Calcium citrate; Calcium hydroxide; Calcium

phosphates (monobasic, dibasic, and tribasic); Carbon dioxide; Chlorine materials (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite); Ethylene; Ferrous sulfate; Glycerides (mono and di); Glycerin; Hydrogen peroxide; Magnesium carbonate; Magnesium chloride; Magnesium stearate; Nutrient vitamins and minerals; Ozone; Pectin (low-methoxy); Phosphoric acid; Potassium acid tartrate; Potassium carbonate; Potassium citrate; Potassium hydroxide; Potassium iodide; Potassium phosphate; Silicon dioxide; Sodium citrate; Sodium hydroxide; Sodium phosphates; Sulfur dioxide; Tocopherols; and Xanthan gum.

The Handling Committee will review the continued exemption (use) of the nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic” in § 205.606 depending on final commercial availability determinations performed by accredited certifying agents that are scheduled to expire after October 21, 2012. They are as follows: Cornstarch (native); Gums-water extracted only (Arabic, Guar, Locust bean, Carob bean); Kelp; and Pectin (high-methoxy).

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 and renewed by the Secretary within 5 years of their inclusion on the National List, their authorized use or prohibition expires.

This means that the following synthetic substances: Ethanol; Isopropanol; Calcium hypochlorite; Chlorine dioxide; Sodium hypochlorite; Hydrogen peroxide (2 uses); Soap-based algicide/demossers; Herbicides, soap-based; Newspaper or other recycled paper, without glossy or colored inks (2 uses); Plastic mulch and covers; Soaps, ammonium; Ammonium carbonate; Boric acid; Elemental sulfur (3 uses); Lime sulfur (2 uses); Oils, horticultural-narrow range oils as dormant, suffocating, and summer oils (2 uses); Soaps, insecticidal; Sticky traps/barriers; Pheromones; Sulfur dioxide; Vitamin D<sub>3</sub>; Copper hydroxide; Copper oxide; Copper oxychloride; Copper sulfate (2 uses); Hydrated lime; Hydrogen peroxide; Potassium bicarbonate; Streptomycin; Aquatic plant extracts (other than hydrolyzed); Humic acids; Lignin sulfonate (2 uses); Magnesium sulfate; Soluble boron products; Sulfates, carbonates, oxides,

or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt; Liquid fish products; Vitamin B<sub>1</sub>; Vitamin C; Vitamin E; Ethylene gas; Lignin sulfonate; Sodium silicate; and EPA List 4—Inerts of Minimal Concern; currently allowed for use in organic crop production, will no longer be allowed for use after October 21, 2012.

This also means that the following nonsynthetic substances: Ash from manure burning; Arsenic; Lead salts; Potassium chloride; Sodium fluoaluminate (mined); Sodium nitrate; Strychnine; and Tobacco dust (nicotine sulfate); currently prohibited from use in organic crop production, will be allowed for use after October 21, 2012.

This means that the following synthetic substances: Ethanol; Isopropanol; Aspirin; Vaccines; Chlorhexidine; Calcium hypochlorite; Chlorine dioxide; Sodium hypochlorite; Electrolytes; Glucose; Glycerine; Hydrogen peroxide; Iodine (2 uses); Magnesium sulfate; Oxytocin; Ivermectin; Phosphoric acid; Copper sulfate; Lidocaine; Lime, hydrated; Mineral oil; Procaine; Trace minerals; Vitamins; and EPA List 4—Inerts of Minimal Concern; currently allowed for use in organic livestock production, will no longer be allowed for use after October 21, 2012.

This also means that the following nonsynthetic substance: Strychnine; currently prohibited from use in organic livestock production, will be allowed for use after October 21, 2012.

This means that the following nonagricultural (nonorganic) substances: Acids (Alginic; Citric; and Lactic); Bentonite; Calcium carbonate; Calcium chloride; Dairy cultures; Diatomaceous earth; Enzymes; Flavors; Kaolin; Magnesium sulfate; Nitrogen; Oxygen; Perlite; Potassium chloride; Potassium iodide; Sodium bicarbonate; Sodium carbonate; Waxes; Yeast (Autolysate; Bakers; Brewers; Nutritional; and Smoked); currently allowed for use in organic handling, will no longer be allowed for use after October 21, 2012.

This means that the following synthetic substances: Alginates; Ammonium bicarbonate; Ammonium carbonate; Ascorbic acid; Calcium citrate; Calcium hydroxide; Calcium phosphates (monobasic, dibasic, and tribasic); Carbon dioxide; Chlorine materials (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite); Ethylene; Ferrous sulfate; Glycerides (mono and di); Glycerin; Hydrogen peroxide; Magnesium carbonate; Magnesium chloride; Magnesium stearate; Nutrient vitamins

and minerals; Ozone; Pectin (low-methoxy); Phosphoric acid; Potassium acid tartrate; Potassium carbonate; Potassium citrate; Potassium hydroxide; Potassium iodide; Potassium phosphate; Silicon dioxide; Sodium citrate; Sodium hydroxide; Sodium phosphates; Sulfur dioxide; Tocopherols; and Xanthan gum; currently allowed for use in organic handling, will no longer be allowed for use after October 21, 2012.

This also means that the following ingredients or processing aids from nonorganic agricultural products: Cornstarch (native); Gums-water extracted only (Arabic, Guar, Locust bean, Carob bean); Kelp; and Pectin (high-methoxy); currently allowed for use in organic handling, will no longer be allowed for use after October 21, 2012.

#### December 11, 2012 Sunset Materials

The Crops Committee will review the continued exemption (use) of the following synthetic substance allowed for use in organic crop production in § 205.601 that is scheduled to expire after December 11, 2012: Sucrose octanoate esters. The Livestock Committee will review the continued use of the following synthetic substance allowed for use in organic livestock production in § 205.603 that is scheduled to expire after December 11, 2012: Sucrose octanoate esters.

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 and renewed by the Secretary within 5 years of their inclusion on the National List, their authorized use or prohibition expires.

This means that the following listings of the synthetic substance: Sucrose octanoate esters (2 uses); currently allowed for use in organic crop and livestock production, will no longer be allowed for use after December 11, 2012.

#### December 13, 2012 Sunset Materials

The Livestock Committee will review the continued exemptions (use) of the following synthetic substances for use in organic livestock production in § 205.603 that are scheduled to expire after December 13, 2012: Atropine (CAS #–51–55–8); Butorphanol (CAS #–42408–82–2); Flunixin (CAS #–38677–85–9); Furosemide (CAS #–54–31–9); Magnesium hydroxide (CAS #–1309–42–8); Peroxyacetic/Peracetic acid (CAS #–79–21–0); Poloxalene (CAS #–9003–11–6); Tolazoline (CAS #–59–98–3);

Xylazine (CAS #–7361–61–7); and Excipients.

The exemptions and prohibitions granted under the OFPA are required to be reviewed every 5 years by the NOSB. The Secretary of Agriculture has authority under the OFPA to renew such exemptions and prohibitions. If they are not reviewed by the NOSB and renewed by the Secretary within 5 years of their inclusion on the National List, their authorized use or prohibition expires.

This means that the following synthetic substances: Atropine (CAS #–51–55–8); Butorphanol (CAS #–42408–82–2); Flunixin (CAS #–38677–85–9); Furosemide (CAS #–54–31–9); Magnesium hydroxide (CAS #–1309–42–8); Peroxyacetic/Peracetic acid (CAS #–79–21–0); Poloxalene (CAS #–9003–11–6); Tolazoline (CAS #–59–98–3); Xylazine (CAS #–7361–61–7); and Excipients; currently allowed for use in organic livestock production, will no longer be allowed for use after December 13, 2012.

Expiration of the exempted or prohibited use of substances is provided for under the OFPA's sunset provision. This ANPR announces the sunset of 37 exempted substances added to the National List for use in organic handling on June 27, 2007; the sunset of 183 continued exemptions (use) and prohibitions of substances used in organic production and handling added to the list on October 21, 2007; the sunset of two exemptions of one substance for use in organic crop and livestock production added to the national list on December 11, 2007; and the sunset of 10 exempted substances for use in organic livestock production added to the national list on December 13, 2007. This ANPR establishes June 27, 2012, October 21, 2012, December 11, 2012, and December 13, 2012, as the respective dates by which the sunset review and renewal process must be concluded. Additionally, the NOP may try to conclude the sunset and renewal process for the 232 combined exempted and prohibited listings used in organic production and handling added to the National List in 2007 by the earliest respective date of June 27, 2012. The exemptions and prohibitions not renewed by their respective dates will be removed from the National List. This ANPR also begins the public comment process on whether the existing specific exemptions on the National List should be continued. This ANPR discusses how the NOP will manage the sunset review and renewal process.

Because these substances may be critical to the production and handling of a wide array of raw and processed

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

#### The Sunset Process

As the first step in this process, we invite public comment on the specific exemptions currently on the National List that are described in this document. All substances currently on the National List have been previously evaluated and determined by the NOSB for consistency with OFPA and its implementing regulations. According to § 6517(e) of the OFPA, these substances must be reviewed by the NOSB and renewed by the Secretary for their use to continue after 5 years of their addition to the National List which will be June 27, 2012, October 21, 2012, December 11, 2012, and December 13, 2012, respectively. The NOP may try to conclude the sunset and renewal process for the 232 combined exempted and prohibited listings used in organic production and handling added to the National List in 2007 by the earliest respective date of June 27, 2012. Public comments submitted will be considered in the review and renewal process.

The NOP will forward comments received under this ANPR to the NOSB for review. The NOSB will review the exemptions and prohibitions of the listings designated to sunset, including the public comments received during this review. The NOSB will review each of the substances listed in this ANPR and may determine that certain substances warrant a more in-depth review and require additional information or research that considers new scientific data and technological and market advances.

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

### Guidance on Submitting Your Comments

If you provide comments that support the renewal of any or all existing exemptions and/or prohibitions included within this ANPR, you should clearly indicate this and provide your reasons and any relevant documentation that supports your position.

### Comments That Support Existing Exemptions and Prohibitions

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

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

If you provide comments that do not support continuing an existing exemption and/or prohibition, you should provide reasons why the use of the substance should no longer be allowed/prohibited in organic agricultural production and handling. Specifically, comments that support the removal of a substance from the National List should provide information to demonstrate that the substance is: (1) Harmful to human health or the environment; (2)

unnecessary because of the availability of alternatives; or (3) inconsistent with organic farming or handling. Comments that do not support a continued prohibition should explain how the use of the substance would not be: (1) Harmful to human health or the environment, or (2) inconsistent with organic farming and handling.

The current exemptions were originally recommended by the NOSB based on evidence available to the NOSB at the time of review which demonstrated that the substances were found to be: (1) Not harmful to human health or the environment, (2) necessary because of the unavailability of wholly nonsynthetic alternatives, and (3) consistent and compatible with organic practices. Therefore, comments against the continued exemption or supporting the continued prohibition of a substance should demonstrate how the current substance is: (1) Harmful to human health or the environment, (2) not necessary to the production of the agricultural products because of the availability of wholly nonsynthetic substitute products, or (3) inconsistent with organic farming and handling.

### All Comments

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

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

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

The NOP understands that supportive technical or scientific information for synthetic alternatives not currently on the National List may not be easily available to organic producers and handlers. Such information may,

however, be available from the research community including universities, or other sources, including international organic programs.

### Request for Comments

The NOP requests that you comment whether the NOSB should continue to recommend the following exemptions and prohibitions on the National List of

Allowed and Prohibited Substances for organic agricultural production and handling. Comments must be submitted on or before May 25, 2010.

Synthetic substances allowed for use in organic crop production.

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

Alcohols.

(1) Ethanol.

(2) Isopropanol.

Chlorine materials—*Except*, That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

(3) Calcium hypochlorite.

(4) Chlorine dioxide.

(5) Sodium hypochlorite.

(6) Hydrogen peroxide.

(7) Soap-based algicide/demossers.

As herbicides, weed barriers, as applicable.

(8) Herbicides, soap-based—for use in farmstead maintenance (roadways, ditches, rights of way, building perimeters) and ornamental crops.

Mulches.

(9) Newspaper or other recycled paper, without glossy or colored inks.

(10) Plastic mulch and covers (petroleum-based other than polyvinyl chloride (PVC)).

As compost feedstocks.

(11) Newspapers or other recycled paper, without glossy or colored inks.

As animal repellents.

(12) Soaps, ammonium—for use as a large animal repellent only, no contact with soil or edible portion of crop.

As insecticides (including acaricides or mite control).

(13) Ammonium carbonate—for use as bait in insect traps only, no direct contact with crop or soil.

(14) Boric acid—structural pest control, no direct contact with organic food or crops.

(15) Elemental sulfur.

(16) Lime sulfur—including calcium polysulfide.

(17) Oils, horticultural—narrow range oils as dormant, suffocating, and summer oils.

(18) Soaps, insecticidal.

(19) Sticky traps/barriers.

(20) Sucrose octanoate esters (CAS #s-42944-74-7; 58064-47-4)—in accordance with approved labeling.

As insect management.

(21) Pheromones.

As rodenticides.

(22) Sulfur dioxide—underground rodent control only (smoke bombs).

(23) Vitamin D<sub>3</sub>.

As plant disease control.

Coppers, fixed

(24) copper hydroxide

(25) copper oxide

(26) copper oxychloride

(27) Copper sulfate—Substance must be used in a manner that minimizes accumulation of copper in the soil.

(28) Hydrated lime.

(29) Hydrogen peroxide.

(30) Lime sulfur.

(31) Oils, horticultural, narrow range oils as dormant, suffocating, and summer oils.

(32) Potassium bicarbonate.

(33) Elemental sulfur.

(34) Streptomycin, for fire blight control in apples and pears only.

As plant or soil amendments.

(35) Aquatic plant extracts (other than hydrolyzed)—Extraction process is limited to the use of potassium hydroxide or sodium hydroxide; solvent amount used is limited to that amount necessary for extraction.

(36) Elemental sulfur.

(37) Humic acids—naturally occurring deposits, water and alkali extracts only.

(38) Lignin sulfonate—chelating agent, dust suppressant, flotation agent.

(39) Magnesium sulfate—allowed with a documented soil deficiency.

Micronutrients—not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Soil deficiency must be documented by testing.

(40) Soluble boron products.

(41) Sulfates of zinc

(42) Sulfates of copper

(43) Sulfates of iron

(44) Sulfates of manganese

(45) Sulfates of molybdenum

(46) Sulfates of selenium

(47) Sulfates of cobalt

(48) Carbonates of zinc

(49) Carbonates of copper

(50) Carbonates of iron

(51) Carbonates of manganese

(52) Carbonates of molybdenum

(53) Carbonates of selenium

(54) Carbonates of cobalt

(55) Oxides of zinc

(56) Oxides of copper

(57) Oxides of iron

(58) Oxides of manganese

(59) Oxides of molybdenum

(60) Oxides of selenium

(61) Oxides of cobalt

(62) Silicates of zinc

(63) Silicates of copper

(64) Silicates of iron

(65) Silicates of manganese

(66) Silicates of molybdenum

(67) Silicates of selenium

(68) Silicates of cobalt.

(69) Liquid fish products—can be pH adjusted with sulfuric, citric or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5.

(70) Vitamin B<sub>1</sub>

(71) Vitamin C

(72) Vitamin E

As plant growth regulators.

(73) Ethylene gas—for regulation of pineapple flowering.

As floating agents in postharvest handling.

(74) Lignin sulfonate.

(75) Sodium silicate—for tree fruit and fiber processing.

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.

(76) EPA List 4—Inerts of Minimal Concern.

Nonsynthetic substances prohibited for use in organic crop production.

(77) Ash from manure burning.

(78) Arsenic.

(79) Lead salts.

(80) Potassium chloride—unless derived from a mined source and applied in a manner that minimizes chloride accumulation in the soil.

(81) Sodium fluoaluminate (mined).

(82) Sodium nitrate—unless use is restricted to no more than 20% of the crop's total nitrogen requirement.

(83) Strychnine.

(84) Tobacco dust (nicotine sulfate).

Synthetic substances allowed for use in organic livestock production.

As disinfectants, sanitizer, and medical treatments as applicable.

Alcohols.

(85) Ethanol-disinfectant and sanitizer only, prohibited as a feed additive.

(86) Isopropanol-disinfectant only.

(87) Aspirin—approved for health care use to reduce inflammation.

(88) Atropine (CAS #–51–55–8)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires: (i) Use by or on the lawful written order of a licensed veterinarian; and (ii) A meat withdrawal period of at least 56 days after administering to livestock intended for slaughter; and a milk discard period of at least 12 days after administering to dairy animals.

Biologics.

(89) Vaccines.

(90) Butorphanol (CAS #–42408–82–2)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for

use under 7 CFR part 205, the NOP requires: (i) Use by or on the lawful written order of a licensed veterinarian; and (ii) A meat withdrawal period of at least 42 days after administering to livestock intended for slaughter; and a milk discard period of at least 8 days after administering to dairy animals.

(91) Chlorhexidine—Allowed for surgical procedures conducted by a veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.

Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

(92) Calcium hypochlorite.

(93) Chlorine dioxide.

(94) Sodium hypochlorite.

(95) Electrolytes—without antibiotics.

(96) Flunixin (CAS #—38677–85–9)—in accordance with approved labeling; except that for use under 7 CFR part 205, the NOP requires a withdrawal period of at least two-times that required by the FDA.

(97) Furosemide (CAS #—54–31–9)—in accordance with approved labeling; except that for use under 7 CFR part 205, the NOP requires a withdrawal period of at least two-times that required that required by the FDA.

(98) Glucose.

(99) Glycerine—Allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils.

(100) Hydrogen peroxide.

(101) Iodine.

(102) Magnesium hydroxide (CAS #—1309–42–8)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires use by or on the lawful written order of a licensed veterinarian.

(103) Magnesium sulfate.

(104) Oxytocin—use in postparturition therapeutic applications. Paracitides.

(105) Ivermectin—prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock.

(106) Peroxyacetic/peracetic acid (CAS #—79–21–0)—for sanitizing facility and processing equipment.

(107) Phosphoric acid—allowed as an equipment cleaner, Provided, That, no direct contact with organically managed livestock or land occurs.

(108) Poloxalene (CAS #—9003–11–6)—for use under 7 CFR Part 205, the NOP requires that poloxalene only be used for the emergency treatment of bloat.

(109) Tolazoline (CAS #—59–98–3)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires: (i) Use by or on the lawful written order of a licensed veterinarian; (ii) Use only to reverse the effects of sedation and analgesia caused by Xylazine; and (iii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.

(110) Xylazine (CAS #—7361–61–7)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR Part 205, the NOP requires: (i) Use by or on the lawful written order of a licensed veterinarian; (ii) The existence of an emergency; and (iii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals. As topical treatment, external parasiticide or local anesthetic as applicable.

(111) Copper sulfate.

(112) Iodine.

(113) Lidocaine—as a local anesthetic. Use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals.

(114) Lime, hydrated—as an external pest control, not permitted to cauterize physical alterations or deodorize animal wastes.

(115) Mineral oil—for topical use and as a lubricant.

(116) Procaine—as a local anesthetic, use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals.

(117) Sucrose octanoate esters (CAS #s—42922–74–2; 58064–47–4)—in accordance with approved labeling.

As feed additives.

(118) Trace minerals, used for enrichment or fortification when FDA approved.

(119) Vitamins, used for enrichment or fortification when FDA approved.

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.

(120) EPA List 4—Inerts of Minimal Concern.

(121) Excipients, only for use in the manufacture of drugs used to treat organic livestock when the excipient is: Identified by the FDA as Generally Recognized As Safe; Approved by the FDA as a food additive; or Included in the FDA review and approval of a New Animal Drug Application or New Drug Application.

Nonsynthetic substances prohibited for use in organic livestock production.

(122) Strychnine.

Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

Nonsynthetics allowed:

(123) Alginic acid.

(124) Citric acid—produced by microbial fermentation of carbohydrate substances.

(125) Lactic acid.

(126) Bentonite.

(127) Calcium carbonate.

(128) Calcium chloride.

(129) Dairy cultures.

(130) Diatomaceous earth—food filtering aid only.

(131) Enzymes—must be derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria.

(132) Flavors, nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.

(133) Kaolin.

(134) Magnesium sulfate, nonsynthetic sources only.

(135) Nitrogen—oil-free grades.

(136) Oxygen—oil-free grades.

(137) Perlite—for use only as a filter aid in food processing.

(138) Potassium chloride.

(139) Potassium iodide.

(140) Sodium bicarbonate.

(141) Sodium carbonate.

(142) Carnauba wax—nonsynthetic.

(143) Wood resin wax—nonsynthetic.

Yeast—nonsynthetic, growth on petrochemical substrate and sulfite waste liquor is prohibited.

(144) Autolysate.



- (145) Bakers.
- (146) Brewers.
- (147) Nutritional.
- (148) Smoked—nonsynthetic smoke flavoring process must be documented. Synthetics allowed:
- (149) Alginates.
- (150) Ammonium bicarbonate—for use only as a leavening agent.
- (151) Ammonium carbonate—for use only as a leavening agent.
- (152) Ascorbic acid.
- (153) Calcium citrate.
- (154) Calcium hydroxide.
- (155) Calcium phosphates monobasic.
- (156) Calcium phosphates dibasic.
- (157) Calcium phosphates tribasic.
- (158) Carbon dioxide.
- Chlorine materials—disinfecting and sanitizing food contact surfaces, Except, That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.
- (159) Calcium hypochlorite.
- (160) Chlorine dioxide.
- (161) Sodium hypochlorite.
- (162) Ethylene—allowed for postharvest ripening of tropical fruit and degreening of citrus.
- (163) Ferrous sulfate—for iron enrichment or fortification of foods when required by regulation or recommended (independent organization).
- (164) Monoglycerides—for use only in drum drying of food.
- (165) Diglycerides—for use only in drum drying of food.
- (166) Glycerin—produced by hydrolysis of fats and oils.
- (167) Hydrogen peroxide.
- (168) Magnesium carbonate—for use only in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic”.
- (169) Magnesium chloride—derived from sea water.
- (170) Magnesium stearate—for use only in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic”.
- (171) Nutrient vitamins in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods.
- (172) Nutrient minerals in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods.
- (173) Ozone.
- (174) Pectin (low-methoxy).
- (175) Phosphoric acid—cleaning of food-contact surfaces and equipment only.
- (176) Potassium acid tartrate.
- (177) Potassium carbonate.
- (178) Potassium citrate.
- (179) Potassium hydroxide—prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches during the Individually Quick Frozen (IQF) production process.
- (180) Potassium iodide—for use only in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic”.
- (181) Potassium phosphate—for use only in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic”.
- (182) Silicon dioxide.
- (183) Sodium citrate.
- (184) Sodium hydroxide—prohibited for use in lye peeling of fruits and vegetables.
- (185) Sodium phosphates—for use only in dairy foods.
- (186) Sulfur dioxide—for use only in wine labeled “made with organic grapes,” Provided, That, total sulfite concentration does not exceed 100 ppm.
- (187) Tocopherols—derived from vegetable oil when rosemary extracts are not a suitable alternative.
- (188) Xanthan gum.
- Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”
- (189) Casings, from processed intestines.
- (190) Celery powder.
- (191) Chia (*Salvia hispanica L.*). Colors derived from agricultural products—
- (192) Annatto extract color (pigment CAS #1393-63-1)—water and oil soluble.
- (193) Beet juice extract color (pigment CAS #7659-95-2).
- (194) Beta-carotene extract color, derived from carrots (CAS #1393-63-1).
- (195) Black currant juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
- (196) Black/Purple carrot juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
- (197) Blueberry juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
- (198) Carrot juice color (pigment CAS #1393-63-1).
- (199) Cherry juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
- (200) Chokeberry—Aronia juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
- (201) Elderberry juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
- (202) Grape juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
- (203) Grape skin extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
- (204) Paprika color (CAS #68917-78-2)—dried, and oil extracted.
- (205) Pumpkin juice color (pigment CAS #127-40-2).
- (206) Purple potato juice (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
- (207) Red cabbage extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
- (208) Red radish extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
- (209) Saffron extract color (pigment CAS #1393-63-1).
- (210) Turmeric extract color (CAS #458-37-7).
- (211) Dillweed oil (CAS #8006-75-5).
- (212) Fish oil (Fatty acid CAS #'s: 10417-94-4, and 25167-62-8)—stabilized with organic ingredients or only with ingredients on the National List, §§ 205.605 and 205.606.
- (213) Fructooligosaccharides (CAS #308066-66-2).
- (214) Galangal, frozen.
- (215) Gelatin (CAS #9000-70-8). Gums—water extracted only.
- (216) Arabic.
- (217) Guar.
- (218) Locust bean.
- (219) Carob bean.
- (220) Hops (*Humulus lupulus*).
- (221) Inulin-oligofructose enriched (CAS #9005-80-5).
- (222) Kelp—for use only as a thickener and dietary supplement.
- (223) Konjac flour (CAS #7220-17-0).
- (224) Lemongrass—frozen.
- (225) Orange shellac-unbleached (CAS #9000-59-3).
- (226) Pectin (high-methoxy).
- (227) Peppers (Chipotle chile). Starches.
- (228) Cornstarch (native).
- (229) Sweet potato starch—for bean thread production only.
- (230) Turkish bay leaves.
- (231) Wakame seaweed (*Undaria pinnatifida*).
- (232) Whey protein concentrate.



Dated: March 22, 2010.

**Rayne Pegg,**

*Administrator, Agricultural Marketing Service.*

### Appendix

This Appendix contains worksheets to assist you in gathering relevant

information concerning the compatibility of substances with evaluation criteria of the OFPA. These worksheets are not required to submit a comment. These worksheets are used by the NOSB to develop their recommendations to the Secretary to

include an exempted or prohibited substance on the National List. You do not have to answer the questions on the worksheets; they are intended only to help you provide substantive comments to the NOSB when you provide comments on the specific substance.

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

Question	Yes	No	N/A <sup>1</sup>	Documentation (TAP; petition; regulatory agency; other)
<b>Category 1. Adverse impacts on humans or the environment?</b>				
1. Are there adverse effects on environment from manufacture, use, or disposal? [§ 205.600 b.2]				
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§ 6518 m.3]				
3. Is the substance harmful to the environment? [§ 6517 c(1)(A)(i); 6517(c)(2)(A)i]				
4. Does the substance contain List 1, 2, or 3 inerts? [§ 6517 c(1)(B)(ii); 205.601(m)2]				
5. Is there potential for detrimental chemical interaction with other materials used? [§ 6518 m.1]				
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§ 6518 m.5]				
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§ 6518 m.5]				
8. Is there a toxic or other adverse action of the material or its breakdown products? [§ 6518 m.2]				
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§ 6518 m.2]				
10. Is there any harmful effect on human health? [§ 6517 c(1)(A)(i); 6517 c(2)(A)i; § 6518 m.4]				
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]				
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§ 205.600 b.5]				
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§ 205.600 b.5]				
<b>Category 2. Is the Substance Essential for Organic Production?</b>				
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]				
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]				
3. Is the substance created by naturally occurring biological processes? [6502 (21)]				
4. Is there a natural source of the substance? [§ 205.600 b.1]				
5. Is there an organic substitute? [§ 205.600 b.1]				
6. Is the substance essential for handling of organically produced agricultural products? [§ 205.600 b.6]				
7. Is there a wholly natural substitute product? [§ 6517 c (1)(A)(ii)]				
8. Is the substance used in handling, not synthetic, but not organically produced? [§ 6517 c(1)(B)(iii)]				
9. Is there any alternative substances? [§ 6518 m.6]				
10. Is there another practice that would make the substance unnecessary? [§ 6518 m.6]				
<b>Category 3. Is the substance compatible with organic production practices?</b>				
1. Is the substance compatible with organic handling? [§ 205.600 b.2]				

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

Question	Yes	No	N/A <sup>1</sup>	Documentation (TAP; petition; regulatory agency; other)
2. Is the substance consistent with organic farming and handling? [§ 6517 c(1)(A)(iii); 6517 c(2)(A)(ii)] 3. Is the substance compatible with a system of sustainable agriculture? [§ 6518 m.7] 4. Is the nutritional quality of the food maintained with the substance? [§ 205.600 b.3] 5. Is the primary use as a preservative? [§ 205.600 b.4] 6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4] 7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: a. copper and sulfur compounds; b. toxins derived from bacteria; c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals? d. livestock parasiticides and medicines? e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?				
Question	Yes	No	N/A	Comments on information provided (sufficient, plausible, reasonable, thorough, complete, unknown)

**Category 4. Is the commercial supply of an agricultural substance as organic, fragile or potentially unavailable? [§ 6610, 6518, 6519, 205.2, 205.105 (d), 205.600 (c), 205.2, 205.105 (d), 205.600 (c)]**

1. <i>Is the comparative description provided</i> as to why the non-organic form of the material/substance is necessary for use in organic handling? 2. Does the current and historical industry information, research, or evidence provided explain how or why the material/substance cannot be obtained organically in the appropriate <i>form</i> to fulfill an essential function in a system of organic handling? 3. Does the current and historical industry information, research, or evidence provided explain how or why the material/substance cannot be obtained organically in the appropriate <i>quality</i> to fulfill an essential function in a system of organic handling? 4. Does the current and historical industry information, research, or evidence provided explain how or why the material/substance cannot be obtained organically in the appropriate <i>quantity</i> to fulfill an essential function in a system of organic handling? 5. Does the industry information provided on material/substance non-availability as organic, include ( but not limited to) the following: a. Regions of production (including factors such as climate and number of regions); b. Number of suppliers and amount produced; c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies; d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or e. Are there other issues which may present a challenge to a consistent supply?				
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<sup>1</sup>If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.