



DEPARTMENT OF AGRICULTURE

3410-02P

Agricultural Marketing Service

7 CFR Part 205

[Document Number AMS-NOP-09-0074; NOP-09-01PR]

RIN 0581-AC96

National Organic Program (NOP); Sunset Review (2012)

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would address recommendations submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB) on April 29, 2010, October 28, 2010, and April 29, 2011. These recommendations pertain to the 2012 Sunset Review of substances on the U.S. Department of Agriculture's (USDA) National List of Allowed and Prohibited Substances (National List). Consistent with the NOSB recommendations, the proposed rule would continue, without change, the exemptions (use) and prohibitions for multiple listings on the National List for 5 years after their respective sunset dates. This proposed rule would amend the exemptions (use) or prohibition for 7 substances and remove the exemption for 3 substances on the National List.

DATES: Comments must be received by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments.

- Mail: Toni Strother, Agricultural Marketing Specialist, National Organic Program, USDA-AMS-NOP, 1400 Independence Ave., SW., Room 2646-So., Ag Stop 0268, Washington, DC 20250.

Instructions: All submissions received must include the docket number AMS-NOP-09-0074; NOP-09-01, and/or Regulatory Information Number (RIN) 0581-AC96 for this rulemaking. Commenters should identify the topic and section number of this proposed rule to which the comment refers. You should clearly indicate your position to continue, discontinue or further restrict the allowance of any substances as identified in this proposed rule and the reasons for your position. You should include relevant information and data to support your position (e.g., scientific, environmental, manufacturing, industry impact information, etc.). You should also supply information on alternative substances or alternative management practices, where applicable, that support a change from the current exemption for the substance. Only the supporting material relevant to your position will be considered. All comments received will be posted without change to <http://www.regulations.gov>.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>. Comments submitted in response to this proposed rule will also be available for viewing in person at USDA-AMS, National Organic Program, 1400 Independence Ave., SW, Room 2646-South Building, 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, Ph.D., Director, Standards Division, Telephone: (202) 720-3252; Fax: (202) 205-7808.

SUPPLEMENTARY INFORMATION:

I. Background.

The Organic Foods Production Act of 1990 (OFPA), 7 U.S.C. 6501-6522, authorizes the establishment of the National List. The National List identifies synthetic substances that are exempted (allowed) in organic production and nonsynthetic substances that are prohibited in organic crop and livestock production. The National List also identifies nonagricultural nonsynthetic, nonagricultural synthetic and nonorganic agricultural substances that may be used in organic handling. The exemptions and prohibitions granted under the OFPA are required to be reviewed every 5 years by the National Organic Standards Board (NOSB). The Secretary of Agriculture has authority under the OFPA to renew such exemptions and prohibitions. If the substances are not reviewed by the NOSB within 5 years of their inclusion on the National List and addressed by the Secretary, then their authorized use or prohibition expires under OFPA's sunset provision.

In response to the sunset provisions in the OFPA, the Secretary published an Advanced Notice of Proposed Rulemaking (ANPR) in the Federal Register on March 26, 2010 (75 FR 14500), announcing the review of exempted and prohibited substances codified at the National List of the National Organic Program (NOP) regulations and set to expire in 2012. A list of these substances is provided as Table 1 in the Overview of Proposed Actions section.¹ The ANPR explained that, unless reviewed and recommended by the NOSB, a synthetic substance exempted for use on the National List in 2007 and currently allowed for use in organic production would no longer be allowed for use after its respective sunset date in 2012; a nonsynthetic substance prohibited from use on the National List in 2007 and currently prohibited

¹ Table 1 shows a simplified listing for each substance; use categories and any restrictive annotations are not included in this overview.

from use in organic production would be allowed after its respective sunset date in 2012; and a synthetic or nonsynthetic substance exempted for use on the National List in 2007 and currently allowed for use in organic handling would be prohibited after its respective sunset date in 2012. The ANPR announced the upcoming review of these substances by the NOSB and the NOP's intent to complete the sunset process based upon recommendations by the NOSB for all listings added to the National List in 2007. The ANPR notified the public that this rulemaking would be completed by the earliest respective sunset date, June 27, 2012. The ANPR also requested public comment on the continued use or prohibition of these substances. The public comment period lasted 60 days.

The NOP received approximately 100 comments in response to the ANPR. Comments were received from consumers, organic crop producers, academia, accredited certifying agents, trade associations, retailers and organic associations. Most comments voiced support for all substances considered under this sunset review. Some of these commenters provided specific information in support of one or more substances that they promoted, represented, or relied upon in organic production or handling. A few commenters recommended allowing a small number of substances to sunset. Some commenters also expressed the need for the clarification or further restrictions for a limited number of substances on the National List. These commenters recommended amending the listing or adding annotations as a potential approach for providing such clarifications. Some comments opposed the use of any synthetics in organic production, but did not provide documented support against individual substances for this position.

The NOSB reviewed the comments received on the ANPR and developed recommendations regarding the continued use and prohibition of the substances under review. The NOSB received additional public comments concerning the pending sunset of these

substances in response to three Federal Register notices announcing meetings of the NOSB and its planned deliberations for sunset 2012 recommendations. The notices were published in the Federal Register as follows: March 17, 2010 (75 FR 12723), September 20, 2010 (75 FR 57194), and March 4, 2011 (76 FR 12013). The NOSB received further written and oral testimony at all three of these public business meetings which occurred in Woodland, CA on April 26 – 29, 2010, in Madison, WI on October 25 – 28, 2010, and in Seattle, WA on April 26 – 29, 2011. The written comments can be retrieved via <http://www.regulations.gov> by searching for the document ID numbers: AMS-NOP-10-0021 (May 2010 meeting); AMS-NOP-10-0068 (October 2010 meeting); and AMS-NOP-11-05 (April 2011 meeting). The oral comments were recorded in the meeting transcripts available on the NOP Web site, <http://www.ams.usda.gov/nop>.

Prior to the October 2010 meeting, NOSB policy specified that recommendations for substances under sunset review were limited to two options: 1) renewal, or continuation of each exemption or prohibition as codified in the NOP regulations; or 2) removal, allowing the exemption or prohibition to expire. In October 2010, the NOSB changed their sunset policy to allow a third option for issuing a recommendation.² The third option enables the Board to add or change annotations (restrictions) on National List substances under sunset review. This change in policy ensures that the Board can address new use patterns and scientific information on substances allowed or prohibited in organic production. The policy limits such annotation changes under sunset to those which clarify an existing annotation or make the annotation more restrictive. The new policy does not authorize an annotation change during the sunset review process that would result in expanded use of an exempted substance.

² October 28, 2010, NOSB Recommendation on Sunset Review Process. Available at NOP website: <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5088004&acct=nosb>

As a result of their meetings in April and October 2010, and April 2011, the NOSB recommended that the Secretary: 1) renew, as currently codified in the NOP regulations, multiple listings for substances under the 2012 sunset review, 2) remove the exemption for three substances from the National List, and 3) amend the annotations for eight substances (seven exemptions and one prohibition) on the National List. For some annotation amendments, the NOSB recommendation on the amendment occurred concurrent to, rather than after, the institution of the new NOSB sunset policy in October 2010. As a way to streamline the regulatory process and expedite implementation of the NOSB recommendations, the NOP proposes to address all of the annotation changes for substances under sunset review as part of this proposed rule.

The NOSB also recommended renewal of the listing for nutrient vitamins and minerals, as codified, at their April 2011 meeting. During the NOSB's deliberations on this substance, the NOP consulted with the Food and Drug Administration (FDA) about the regulatory citation that is currently incorporated by reference into the annotation for nutrient vitamins and minerals.³ As a result of this consultation, the NOP determined that current listing for nutrient vitamins and minerals was the result of a drafting error and that a correction to this listing is necessary to align the listing with the NOSB's 1995 original recommendation. Therefore, the NOP plans to address the sunset review for nutrient vitamins and minerals and correct the drafting error through a separate proposed rule.

USDA is engaging in this proposed rulemaking to reflect the recommendations of the NOSB from April 2010, October 2010 and April 2011, for all listings for substances under sunset review, with the exception of nutrient vitamins and minerals and sodium nitrate which

³ April 14, 2011, Letter from FDA to NOP on the FDA Fortification Policy at 21 CFR 104.20. Available at NOP website: <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5090415>

will be dealt with in separate actions. This rulemaking will solicit public comment on all renewals, removals, and annotation changes that are proposed.

Under the authority of the OFPA, as amended, (7 U.S.C. 6501-6522), the National List can be amended by the Secretary based on recommendations developed by the NOSB. Since established, the NOP has published multiple amendments to the National List: 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), August 24, 2010 (75 FR 51919), and December 13, 2010 (75 FR 77521). Additionally, proposed amendments to the National List were published on November 8, 2010 (75 FR 68505), May 5, 2011 (76 FR 25612) and on November 8, 2011 (76 FR 69141).

II. Overview of Proposed Actions.

From April 26, 2010 through April 29, 2011, the NOSB reviewed the listings for exemptions and prohibitions that are authorized on the National List and set to expire on June 27, 2012, October 21, 2012, December 11, 2012, and December 13, 2012. Using the evaluation criteria specified in the ANPR for sunset review, the NOSB reviewed these exemptions and prohibitions for continued authorization in organic agricultural production and handling. As a result of the NOSB's review of public comment and meeting deliberations, the NOSB recommended that the Secretary renew most of the exemptions and prohibitions, with any restrictive annotations, as codified. In addition, the NOSB recommended that 3 exemptions not be renewed. The NOSB also recommended that exemptions or prohibition for 7 substances continue with amendment to their restrictive annotations. The Secretary is addressing these

NOSB recommendations for sunset 2012 listings through this proposed rule as shown in Table 1.

With respect to the criteria used to make recommendations regarding the continued authorization of exemptions and prohibitions, the NOSB's decisions are based on public comments and applicable supporting evidence that express a continued need for the use or prohibition of the substance(s). In voting to change its sunset policy to allow for amendments to annotations during sunset review, the NOSB agreed that this policy would enable the Board to consider, as part of their decision making, changes in use patterns and scientific information for substances under review. Consistent with decisions on continued authorizations of exemptions and prohibitions, such annotation changes can only be made if public comment and applicable evidence demonstrate that the substance, with any restrictive annotations, continues to meet the overall criteria for listing under the OFPA.

Concerning criteria used to make recommendations regarding the discontinuation of an authorized exempted synthetic substance, the NOSB's decision is based on public comments and applicable supporting evidence that demonstrates the currently authorized exempted substance is: (a) harmful to human health or the environment; (b) no longer necessary for organic production due to the availability of alternative wholly nonsynthetic substitute products or practices; or (c) inconsistent with organic farming and handling practices.

Table 1. Overview of Proposed Actions for Sunset 2012⁴

National List Section	Substance	NOSB Meeting	New Sunset Date	Proposed Action
§ 205.601 Synthetic substances allowed for use in organic crop production.	Alcohols (Ethanol; Isopropanol)	April 2011	October 21, 2017	Renew
	Ammonium carbonate	April 2010*	October 21, 2017	Renew
	Aquatic plant extracts (other than hydrolyzed)	April 2010*	October 21, 2017	Renew
	Boric acid	April 2010*	October 21, 2017	Renew
	Chlorine materials (Calcium hypochlorite; chlorine dioxide; sodium hypochlorite)	April 2011	October 21, 2017	Amend: Chlorine materials – For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label

⁴ Table 1 shows a simplified listing for each substance; use categories and any restrictive annotations are not included in this overview.

National List Section	Substance	NOSB Meeting	New Sunset Date	Proposed Action
				directions.
	Coppers, fixed (Copper hydroxide; copper oxide; copper oxychloride)	April 2011	October 21, 2017	Renew
	Copper sulfate	April 2011	October 21, 2017	Renew
	Elemental sulfur (3 uses)	April 2010*	October 21, 2017	Renew
	EPA List 4-Inerts of Minimal Concern	October 2010	October 21, 2017	Renew
	Ethylene gas	April 2010*	October 21, 2017	Renew
	Herbicides, soap-based	April 2010*	October 21, 2017	Renew
	Humic acids	April 2010*	October 21, 2017	Renew
	Hydrated lime	April 2011	October 21, 2017	Renew
	Hydrogen peroxide (2 uses)	April 2010 *	October 21, 2017	Renew
	Lignin sulfonate on § 205.601(j)(4)	April 2011	October 21, 2017	Amend: Lignin sulfonate – chelating agent, dust suppressant.
	Lignin sulfonate on § 205.601(l)(1)	April 2011	October 21, 2017	Renew

National List Section	Substance	NOSB Meeting	New Sunset Date	Proposed Action
	Lime sulfur (2 uses)	April 2010*	October 21, 2017	Renew
	Liquid fish products	April 2010*	October 21, 2017	Renew
	Magnesium sulfate	April 2011	October 21, 2017	Renew
	Micronutrients (Soluble boron products; Sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt).	April 2010*	October 21, 2017	Renew
	Mulches (Newspapers or other recycled paper, without glossy or colored inks; Plastic mulch and covers)	April 2011	October 21, 2017	Renew
	Newspapers or other recycled paper, without glossy or colored inks	April 2011	October 21, 2017	Renew
	Oils, horticultural-narrow range oils as dormant, suffocating, and summer oils (2 uses)	April 2010*	October 21, 2017	Renew
	Pheromones	April 2011	October 21, 2017	Renew
	Potassium bicarbonate	April 2010*	October 21, 2017	Renew
	Soap-based algicide/demossers	April 2010*	October 21, 2017	Renew

National List Section	Substance	NOSB Meeting	New Sunset Date	Proposed Action
	Soaps, ammonium	April 2010*	October 21, 2017	Renew
	Soaps, insecticidal	April 2010*	October 21, 2017	Renew
	Sodium silicate	April 2011	October 21, 2017	Renew
	Sticky traps/barriers	April 2010*	October 21, 2017	Renew
	Streptomycin	April 2011	--	Amend: Streptomycin, for fire blight control in apples and pears only until October 21, 2014.
	Sucrose octanoate esters (CAS #s—42922-74-7; 58064-47-4)	April 2010*	December 11, 2017	Renew
	Sulfur dioxide	April 2011	--	Remove
	Vitamin B ₁ , C, and E	April 2010*	October 21, 2017	Renew
	Vitamin D ₃	April 2011	October 21, 2017	Renew
§ 205.602 Nonsynthetic substances prohibited for use in organic crop production.	Arsenic	April 2010*	October 21, 2017	Renew
	Ash from manure burning	April 2010*	October 21, 2017	Renew
	Lead salts	April 2010*	October 21, 2017	Renew
	Potassium chloride	April 2010*	October 21, 2017	Renew
	Sodium fluoaluminate (mined)	April 2010*	October 21, 2017	Renew
	Sodium nitrate	April 2011	October 21, 2017	Addressed in separate rulemaking action
	Strychnine	April 2010*	October 21, 2017	Renew

National List Section	Substance	NOSB Meeting	New Sunset Date	Proposed Action
	Tobacco dust (nicotine sulfate)	April 2010*	October 21, 2017	Renew
§ 205.603 Synthetic substances allowed for use in organic livestock production.	Alcohols (Ethanol; Isopropanol)	October 2010	October 21, 2017	Renew
	Aspirin	October 2010	October 21, 2017	Renew
	Atropine (CAS #-51-55-8)	April 2010*	December 13, 2017	Renew
	Biologics - Vaccines	April 2010*	October 21, 2017	Renew
	Butorphanol (CAS #-42408-82-2)	April 2010*	December 13, 2017	Renew
	Chlorhexidine	April 2010*	October 21, 2017	Renew
	Chlorine materials (Calcium hypochlorite; chlorine dioxide; sodium hypochlorite)	October 2010	October 21, 2017	Renew
	Copper sulfate	October 2010	October 21, 2017	Renew
	Electrolytes	April 2010*	October 21, 2017	Renew
	EPA List 4-Inerts of Minimal Concern	October 2010	October 21, 2017	Renew
	Excipients	April 2010*	December 13, 2017	Renew
	Flunixin (CAS #-38677-85-9)	April 2010*	December 13, 2017	Renew
	Furosemide	October 2010	December 13, 2017	Renew
	Glucose	October 2010	October 21, 2017	Renew
	Glycerine	October 2010	October 21, 2017	Renew
Hydrogen peroxide	April 2010*	October 21, 2017	Renew	
Iodine (2 uses)	April 2010*	October 21, 2017	Renew	

National List Section	Substance	NOSB Meeting	New Sunset Date	Proposed Action
	Ivermectin	April 2010*	October 21, 2017	Renew
	Lidocaine	April 2010*	October 21, 2017	Renew
	Lime, hydrated	April 2010*	October 21, 2017	Renew
	Magnesium hydroxide (CAS #-1309-42-8)	April 2010*	December 13, 2017	Renew
	Magnesium sulfate	October 2010	October 21, 2017	Renew
	Mineral oil	April 2010*	October 21, 2017	Renew
	Oxytocin	April 2010*	October 21, 2017	Renew
	Peroxyacetic/peracetic acid (CAS #-79-21-0)	April 2010*	December 13, 2017	Renew
	Phosphoric acid	April 2010*	October 21, 2017	Renew
	Poloxalene (CAS #-9003-11-6)	April 2010*	December 13, 2017	Renew
	Procaine	April 2010*	October 21, 2017	Renew
	Sucrose octanoate esters (CAS #s—42922-74-7; 58064-47-4)	April 2010*	December 11, 2017	Renew
	Tolazoline (CAS #-59-98-3)	April 2010*	December 13, 2017	Renew
	Trace minerals	April 2010*	October 21, 2017	Renew
	Vitamins	April 2010*	October 21, 2017	Renew
	Xylazine (CAS #-7361-61-7)	April 2010*	December 13, 2017	Renew
§ 205.604 Nonsynthetic substances prohibited for use in organic	Strychnine	April 2010*	October 21, 2017	Renew

National List Section	Substance	NOSB Meeting	New Sunset Date	Proposed Action
livestock production.				
§ 205.605(a) Nonsynthetic, nonagricultural substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”	Acids (Alginic; citric; lactic)	April 2010*	October 21, 2017	Renew
	Bentonite	April 2010*	October 21, 2017	Renew
	Calcium carbonate	April 2010*	October 21, 2017	Renew
	Calcium chloride	April 2010*	October 21, 2017	Renew
	Dairy cultures	April 2010*	October 21, 2017	Renew
	Diatomaceous earth	April 2010*	October 21, 2017	Renew
	Enzymes	April 2011	October 21, 2017	Renew
	Flavors	October 2010	October 21, 2017	Renew
	Kaolin	April 2010*	October 21, 2017	Renew
	Magnesium sulfate	October 2010	October 21, 2017	Renew
	Nitrogen	April 2010*	October 21, 2017	Renew
	Oxygen	April 2010*	October 21, 2017	Renew
	Perlite	April 2010*	October 21, 2017	Renew
	Potassium chloride	April 2010*	October 21, 2017	Renew
	Potassium iodide	April 2011	October 21, 2017	Renew
Sodium bicarbonate	April 2010*	October 21, 2017	Renew	
Sodium carbonate	April 2010*	October 21, 2017	Renew	
Waxes (Carnauba wax; Wood resin)	April 2010*	October 21, 2017	Renew	

National List Section	Substance	NOSB Meeting	New Sunset Date	Proposed Action
	Yeast (Autolysate; Bakers; Brewers; Nutritional; Smoked)	October 2010	October 21, 2017	Amend: Yeast – When used as food or a fermentation agent, yeast must be organic if its end use is for human consumption; nonorganic yeast may be used when equivalent organic yeast is not commercially available. Growth on petrochemical substrate and sulfite waste liquor is prohibited. For smoked yeast, nonsynthetic smoke flavoring process must be documented.
§ 205.605(b) Synthetic, nonagricultural substances allowed as ingredients in or on processed products labeled as “organic” or	Alginates	April 2010*	October 21, 2017	Renew
	Ammonium bicarbonate	April 2010*	October 21, 2017	Renew
	Ammonium carbonate	April 2010*	October 21, 2017	Renew
	Ascorbic Acid	April 2010*	October 21, 2017	Renew
	Calcium citrate	April 2010*	October 21, 2017	Renew
	Calcium hydroxide	April 2010*	October 21, 2017	Renew
	Calcium phosphates (monobasic; dibasic; tribasic)	April 2010*	October 21, 2017	Renew

National List Section	Substance	NOSB Meeting	New Sunset Date	Proposed Action
“made with organic (specified ingredients or food group(s)).”	Carbon dioxide	April 2010*	October 21, 2017	Renew
	Chlorine materials (Calcium hypochlorite; chlorine dioxide; sodium hypochlorite)	October 2010	October 21, 2017	Renew
	Ethylene	April 2011	October 21, 2017	Renew
	Ferrous sulfate	October 2010	October 21, 2017	Renew
	Glycerides (mono; di)	April 2010*	October 21, 2017	Renew
	Glycerin	April 2011	October 21, 2017	Renew
	Hydrogen peroxide	April 2010*	October 21, 2017	Renew
	Magnesium carbonate	April 2010*	October 21, 2017	Renew
	Magnesium chloride	April 2010*	October 21, 2017	Renew
	Magnesium stearate	April 2010*	October 21, 2017	Renew
	Nutrient vitamins and minerals	April 2011	--	Addressed in separate rulemaking action
	Ozone	April 2010*	October 21, 2017	Renew
	Pectin (low-methoxy)	October 2010	--	Remove; included in amended § 205.606 listing of Pectin (non-amidated forms only).
	Phosphoric acid	October 2010	October 21, 2017	Renew
	Potassium acid tartrate	April 2010*	October 21, 2017	Renew
	Potassium carbonate	April 2010*	October 21, 2017	Renew
	Potassium citrate	April 2010*	October 21, 2017	Renew
Potassium hydroxide	April 2010*	October 21, 2017	Renew	
Potassium iodide	April 2011	--	Remove	
Potassium phosphate	April 2010*	October 21, 2017	Renew	

National List Section	Substance	NOSB Meeting	New Sunset Date	Proposed Action
	Silicon dioxide	October 2010	October 21, 2017	Renew
	Sodium citrate	October 2010	October 21, 2017	Renew
	Sodium hydroxide	October 2010	October 21, 2017	Renew
	Sodium phosphates	October 2010	October 21, 2017	Renew
	Sulfur dioxide	October 2010	October 21, 2017	Renew
	Tocopherols	April 2011	October 21, 2017	Renew
	Xanthan gum	April 2010*	October 21, 2017	Renew
§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”	Casings, from processed intestines	April 2010*	June 27, 2017	Renew
	Celery powder	April 2010*	June 27, 2017	Renew
	Chia (<u>Salvia hispanica L.</u>)	April 2010*	June 27, 2017	Renew
	Colors (Annatto extract color; Beet juice extract color; Beta-carotene extract color; Black currant juice color, Black/purple carrot juice color; Blueberry juice color; Carrot juice color; Cherry juice color; Chokeberry – Aronia juice color; Elderberry juice color; Grape juice color; Grape skin extract color; Paprika color; Pumpkin juice color; Purple potato	October 2010	June 27, 2017	Amend: Colors derived from agricultural products – Must not be produced using synthetic solvents and carrier systems or any artificial preservative.

National List Section	Substance	NOSB Meeting	New Sunset Date	Proposed Action
	juice color; Red cabbage extract color; Red radish extract color; Saffron extract color; Turmeric extract color). CAS numbers are provided in the Renewals with Amendment section.			
	Cornstarch (native)	October 2010	October 21, 2017	Renew
	Dillweed oil (CAS # 8006-75-5)	April 2010*	June 27, 2017	Renew
	Fish oil (Fatty acid CAS #'s 10417-94-4 and 25167-62-8)	April 2010*	June 27, 2017	Renew
	Fructooligosaccharides (CAS#308066-66-2)	October 2010	June 27, 2017	Renew
	Galangal, frozen	April 2010*	June 27, 2017	Renew
	Gelatin (CAS # 9000-70-8)	April 2010*	June 27, 2017	Renew
	Gums (Arabic; Guar; Locust bean; Carob bean)	April 2010*	October 21, 2017	Renew
	Hops (<u>Humulus lupulus</u>)	October 2010	--	Amend: Hops (<u>Humulus lupulus</u>) until January 1, 2013
	Inulin, oligofructose enriched (CAS # 9005-80-5)	October 2010	June 27, 2017	Renew
	Kelp	April 2010*	October 21, 2017	Renew
	Konjac flour (CAS #	April 2010*	June 27, 2017	Renew

National List Section	Substance	NOSB Meeting	New Sunset Date	Proposed Action
	37220-17-0)			
	Lemongrass, frozen	April 2010*	June 27, 2017	Renew
	Orange shellac – unbleached (CAS # 9000-59-3)	April 2010*	June 27, 2017	Renew
	Pectin (high-methoxy)	October 2010	October 21, 2017	Amend: Pectin (non-amidated forms only).
	Peppers (chipotle chile)	April 2010*	June 27, 2017	Renew
	Sweet potato starch	April 2010*	June 27, 2017	Renew
	Turkish bay leaves	April 2010*	June 27, 2017	Renew
	Wakame seaweed (<u>Undaria pinnatifida</u>)	April 2010*	June 27, 2017	Renew
	Whey protein concentrate	October 2010	June 27, 2017	Renew
<p>* The NOSB originally recommended that these substances be relisted during their April 2010 meeting. Since public comments were still being accepted for these substances, the NOSB decided to reaffirm their recommendations on these substances at the October 2010 meeting after analyzing all public comments.</p>				

RENEWALS

After considering all public comments and supporting evidence, the NOSB determined that many listings for exempted and prohibited substances demonstrated a continued need for authorization in organic agricultural production and handling.

AMS has reviewed and accepts the NOSB recommendations for the continued exemption or prohibition of these listings. Accordingly, this proposed rule would renew the exemptions at § 205.601, along with any restrictive annotations, for the synthetic substances allowed for use in organic crop production as shown in Table 1.

This proposed rule would renew the prohibitions at § 205.602, along with any restrictive annotations, for the nonsynthetic substances prohibited for use in organic crop production as shown in Table 1.

This proposed rule would renew the exemptions at § 205.603, along with any restrictive annotations, for the synthetic substances allowed for use in organic livestock production as shown in Table 1.

This proposed rule would renew the prohibition at § 205.604, for the one nonsynthetic substance, strychnine, prohibited for use in organic livestock production as shown in Table 1.

This proposed rule would renew the exemptions at § 205.605, along with any restrictive annotations, for the nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” as shown in Table 1.

This proposed rule would renew the exemptions at § 205.606, along with any restrictive annotations, for the nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic” as shown in Table 1.

NONRENEWALS

After considering all public comments and supporting evidence, the NOSB determined that three exemptions on the National List are no longer necessary for organic agricultural production and handling.

The Agricultural Marketing Service (AMS) has reviewed and accepts the NOSB recommendations for removal of three exemptions from the National List. Based upon recommendations from the NOSB concerning substances identified for review under this sunset review process, this proposed rule would amend the USDA's National List to remove the exemptions as shown in Table 1 for the following substances in organic agricultural production and handling:

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

The NOP regulation currently includes an exemption for sulfur dioxide as a rodenticide for use in crop production at § 205.601(g)(1) as follows:

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

The Environmental Protection Agency (EPA) registers smoke bomb products for underground rodent control with the active ingredients sulfur, charcoal carbon, and sodium nitrate or potassium nitrate (saltpeter). Smoke bombs are placed into rodent burrows and detonated. The detonation process produces sulfur dioxide smoke from the combustion of sulfur in the product. Sulfur dioxide is not listed as the active ingredient on labels for smoke bomb products. According to a Technical Report prepared for the NOSB on this use of sulfur dioxide, the EPA does not register products with the active ingredient listed as sulfur dioxide.⁵

⁵ Technical Report on Sulfur Dioxide. January 14, 2011. Available at the NOP website: <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5089145&acct=nopgeninfo>

The NOSB Crops Committee considered the finding that EPA does not register products with sulfur dioxide as an active ingredient on the label sufficient justification for the removal of the exemption for this substance. The NOP agrees that the substances included on the National List should be named in the same convention that is used by other regulatory agencies that have jurisdiction, such as the EPA, to avoid confusion.

A few public comments indicated that smoke bombs are an important part of rodent control for some organic crop operations. However, comments from one certifying agent indicated that they have not approved any smoke bomb products due to the presence of a detonator chemical in these products that contains a form of phosphorous that is not included on the National List. The NOSB expressed concern that exempting the effective substance, sulfur dioxide, on the National List instead of the EPA-recognized active ingredients can be confusing and may contribute to inconsistency among certifying agents.

The NOSB also discussed the variety of alternative methods and materials are used by organic growers for rodent control above and below ground. The NOSB noted that even though some organic growers may rely on smoke bombs in certain circumstances, other methods (such as trapping or baiting with approved materials from the National List) are available and could be used if sulfur dioxide is removed from the National List and smoke bombs became unavailable for use by organic growers. It was noted that the alternative use of Vitamin D₃ bait-type control is preferred when rodent control is needed in the close proximity to a building.

After considering all input from the public and any applicable evidence, the NOSB concluded that sulfur dioxide should not remain on the National List as an authorized substance for organic crop production, due to the acknowledgement that EPA registered smoke bomb products do not list sulfur dioxide as an active ingredient for smoke bombs, the availability of

alternatives, and the lack of evidence that the substance is essential to organic production.

AMS accepts the NOSB's recommendation and proposes to remove the exemption for the use of sulfur dioxide. This proposed rule would amend § 205.601 of the National List by removing the exemption at paragraph (g)(1) and redesignating current paragraph (g)(2) as (g) to read as follows: (g) As rodenticides. Vitamin D₃.

This amendment would be effective on the substance's current sunset date, October 21, 2012.

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))" only in accordance with any restrictions specified in this section.

The NOP regulation currently includes an exemption for pectin for use in organic handling at § 205.605(b) as follows:

Pectin (low-methoxy).

There are currently two exemptions for pectin on the National List. One exemption at § 205.605(b) is for low-methoxy pectin as a synthetic, nonagricultural (nonorganic) substance allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food groups(s))." The other exemption at § 205.606 is for high-methoxy pectin as a nonorganically produced agricultural product allowed as ingredients in or on processed products labeled as "organic." High-methoxy pectin is only permitted in organic processed products when it is not commercially available in organic form.

Both high-methoxy and low-methoxy pectin are derived from apple pomace or citrus rinds by a similar extraction process. The degree of esterification determines their classification as a high or low-methoxy pectin. Low-methoxy pectin is commonly produced by using acid

solutions to remove methyl groups (CH₃) from the complex polysaccharide chain, and has a lower molecular weight than high-methoxy pectin. In a 1995 NOSB recommendation, the Board considered the longer extraction process and reduction in molecular weight to be a substantive chemical change, and therefore, classified low-methoxy pectin as synthetic. Some forms of low-methoxy pectin may be manufactured by treating with ammonia to de-methylate the pectin, replacing the methyl groups with an amine group, resulting in amidated pectin. The NOSB considered the amidated forms of pectin during their 1995 deliberations on this substance, but issued a final recommendation that low-methoxy pectin be allowed as a synthetic substance, without restricting use of the amidated forms. This recommendation resulted in a listing for low-methoxy pectin at § 205.605(b). In the same recommendation, the NOSB classified high-methoxy pectin as nonsynthetic. Both pectins are used in organic handling according to their different functions; low-methoxy pectin is used for low sugar jams and high-methoxy pectin is used in high sugar jams.

In developing their October 2010 recommendation for low-methoxy pectin, the NOSB Handling Committee considered public comments submitted by organic handlers. Organic handlers stated that there was no reason to use any form of amidated pectin in organic products, and that they supported the NOSB Handling Committee recommendation to reclassify non-amidated forms of low-methoxy pectin under § 205.606 as a nonsynthetic substance. During their October 2010 deliberations, the NOSB also considered amidated forms of low-methoxy pectin to be synthetic. Because the NOSB recommended non-amidated, low-methoxy pectin to be nonsynthetic and listed at § 205.606, the NOSB recommended the removal of the exemption for low-methoxy from § 205.605(b), a section limited to synthetic, nonagricultural substances allowed in processed products. By deleting the exemption, the use of amidated, low-methoxy

pectin would be prohibited in organic handling.

During their deliberations, the NOSB clarified that all non-amidated forms of pectin, including low-methoxy, should continue to be allowed under an amended § 205.606 listing for pectin. The NOSB recommended a change in annotation to the current listing for pectin on § 205.606, such that all non-amidated pectins, regardless of the methoxy level, would be available for use in organic products under § 205.606, subject to commercial availability. This change in annotation is proposed as part of this proposed rule and is addressed in an upcoming section of the preamble.

There was no public comment opposing the NOSB's approach for addressing the use of pectin in organic handling. Organic jam makers indicated unanimous support of the Board's recommendation. The NOSB's recommendation was also supported by a petition from an organic jam maker who proposed adding non-amidated, low-methoxy pectin to § 205.606. The petitioner suggested that amidated forms of pectin are unnecessary in organic handling because non-amidated forms are currently available for use in jam and low sugar fruit spreads and preparations.

AMS accepts the NOSB's recommendation. This proposed rule would amend § 205.605(b) of the National List by removing the exemption for pectin (low-methoxy).

This amendment would be effective on the substance's current sunset date, October 21, 2012.

The NOP regulation currently includes an exemption for potassium iodide for use in organic handling at § 205.605(b) as follows:

Potassium iodide – for use only in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic”.

Potassium iodide has two listings on § 205.605 for use in organic handling. It is listed as nonsynthetic on § 205.605(a) and it is listed as synthetic on § 205.605(b) of the National List. Under this sunset review, the NOSB voted unanimously to continue listing the substance on § 205.605(a), as naturally mined potassium iodide is used in some organic products. One commenter supported the continued exemption for potassium iodide at § 205.605(a) because the substance is also used as a sanitizer in some organic handling operations.

The listing as a synthetic on § 205.605(b) restricts its use to products in the “made with organic (specified ingredients or food groups(s))” labeling category. The NOSB concluded that the synthetic listing for potassium iodide at § 205.605(b) is redundant and that its annotation is in conflict with the allowance for potassium iodide as a nutrient additive under a separate listing. Synthetic potassium iodide is the primary form of iodide allowed for fortification of food, and would be permitted under the listing for vitamins and minerals at § 205.605(b). Therefore, the NOSB determined that a separate listing for synthetic potassium iodide was not necessary.

AMS accepts the NOSB’s recommendation. This proposed rule would amend § 205.605(b) of the National List by removing the exemption, along with its restrictive annotation, for potassium iodide.

This amendment would be effective on the substance’s current sunset date, October 21, 2012.

RENEWALS WITH AMENDMENT

After considering all public comments and supporting evidence, the NOSB identified seven exemptions and one prohibition for which renewal is critical to organic agricultural production and handling, but for which amendments are needed to the current listings for these substances to clarify or restrict their use.

AMS has reviewed and accepts the NOSB recommendations to renew, with amendment, seven exemptions and one prohibition on the National List. Based upon these recommendations from the NOSB, this proposed rule would amend the USDA's National List as shown in Table 1 for the following substances in organic agricultural production and handling:

Section 205.601 Synthetic substances allowed for use in organic crop production

The NOP regulation currently includes an exemption for chlorine materials for use in crop production at § 205.601(a)(2) as follows:

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

- (i) Calcium hypochlorite.
- (ii) Chlorine dioxide.
- (iii) Sodium hypochlorite.

The NOSB Crops Committee reviewed comments received on chlorine materials in response to the ANPR published on March 26, 2010 (75 FR 14500), and issued a committee recommendation on March 7, 2011. The Board noted that the current annotation does not accurately represent the 1995 NOSB recommendation for chlorine materials, which stated that chlorine may be used to disinfect and sanitize food contact surfaces and that “residual chlorine levels for wash water in direct crop or food contact and in flush water from cleaning irrigation systems that is applied to crops or fields cannot exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (currently 4mg/L expressed as Cl₂).”⁶ The NOSB Crops Committee also discussed a 2003 NOSB recommendation that suggested modification of the chlorine materials annotation to reflect the NOSB's intention that water in direct crop or soil

⁶ NOSB, 1995. Final Minutes of the NOSB Full Board Meeting, Austin TX, Oct. 31-Nov. 4 1995. Page 18, line 611. Available at the NOP website: <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5057496>.

contact should not have higher levels of chlorine than those permitted for municipal drinking water.⁷ The NOP concurs with the NOSB that the current annotations for chlorine materials do not align precisely with the 1995 or 2003 recommendations of the Board.

At the April 2011 NOSB meeting, the Board received public comments on this issue and recommended the following change to the annotation for chlorine materials: “For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act. For disinfecting or sanitizing equipment or tools or in edible sprout production, chlorine products may be used up to maximum labeled rates.” The NOSB stated that this revised annotation would clarify the allowance for chlorine materials and align with past NOSB recommendations and NOP policy.

The NOP agrees that this language addresses the intent of the NOSB to specify that water in direct contact with crops during production should not contain more chlorine than is permitted in municipal drinking water. The NOP issued final guidance (NOP 5026) on May 6, 2011, that is consistent with the April 2011 NOSB recommendation on chlorine materials for crop use.⁸ This guidance document also clarifies that chlorine products may be used at labeled rates to disinfect or sanitize tools. The NOP also acknowledges that, while chlorine materials also have similar listings under § 205.603(a) for use in livestock operations, and § 205.605(b) for use in handling, the NOSB only voted to change the annotation for the use of chlorine in crops production.

⁷ NOSB, 2003. Summary of Meeting Minutes, NOSB Meeting – May 13–14, 2003, page 4. Available at the NOP website: <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5058538>; NOSB, 2003. Measuring Effluent: Clarification of Chlorine Contact with Organic Food, NOSB Processing Committee April 30, 2003. Available at the NOP website: <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELDEV3104548>.

⁸ NOP 5026. Guidance: The Use of Chlorine Materials in Organic Production and Handling. May 9, 2011. Available at the NOP website: <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5090760>.

The NOSB's recommended annotation change includes a clarification on the use of chlorine in edible sprout production. The NOP proposes to amend the chlorine listing to include the Board's clarification on edible sprouts. However, the NOP consulted the EPA and learned that a number of calcium hypochlorite products are labeled for use in disinfecting seeds used for sprouts. EPA label directions for sprout seed state that seed should be soaked at 20,000 ppm available chlorine followed by a rinse with potable water. The NOP is seeking comments on the appropriateness of this type of chlorine treatment for organic sprout production. The NOP also seeks information regarding other FDA and EPA approved materials or methods that can be used to comply with FDA guidance regarding safety of sprouts⁹. These specific uses and alternatives were not addressed by commenters in detail and may require additional clarification in the final rule.

AMS accepts the NOSB's recommendation, with a slight modification. The NOP clarified the use of chlorine on tools and equipment through guidance and, therefore, finds that including this language in the annotation change is unnecessary. This proposed rule would amend § 205.601(a)(2) to read as follows:

Chlorine materials – For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions.

(i) Calcium hypochlorite.

(ii) Chlorine dioxide.

⁹FDA. Guidance for Industry: Microbial Food Safety Hazards for Sprouted Seeds. October 27, 1999. Available at the FDA website: <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlantProducts/ucm120244.htm>

(iii) Sodium hypochlorite.

This amendment would be effective on the substance's current sunset date, October 21, 2012.

The National List currently includes an exemption for streptomycin for plant disease control in organic crop production at § 205.601(i)(11) as follows:

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

Streptomycin is derived from the soil bacterium Streptomyces griseus and can be used to control bacterial disease in crops.¹⁰ In organic production, streptomycin is currently allowed as a synthetic substance to treat fire blight in apple and pear orchards. Streptomycin is one of two antibiotics (the other substance being tetracycline) on the National List that organic apple and pear growers can use for fire blight control. Fire blight is caused by the bacterium Erwinia amylovora, which is native to North America and lives on alternate hosts such as hawthorne and crabapple. It infects apple and pear blossoms and can spread rapidly through the tree vascular system to kill shoots and destroy trees. The bacterium can be moved from plant to plant by honeybees, other insects, birds, rain, wind, and hail.

As part of their review of the current exemption for streptomycin on the National List, the NOSB considered written comments received in response to the ANPR published on March 26, 2010 (75 FR 14500), and oral comments from their April 2011 public meeting. Some commenters expressed concerns about the potential for antibiotic overuse, potential for development of antibiotic resistance, and the impact of antibiotic use on the environment. Some commenters stated that there are some rootstocks (e.g. the Geneva series) that may provide resistance to fire blight, which, if used by organic growers, could reduce the need for

¹⁰ Technical Report on Streptomycin. March 8, 2011. Available at the NOP website: <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5090468>

streptomycin in organic production systems. The majority of the NOSB Crops Committee stated that selection of fire blight resistant varieties suitable for organic production should be a grower's first choice for disease control, rather than the use of streptomycin.

However, the NOSB also heard from other commenters who stated that research into alternatives to streptomycin for fire blight control is ongoing but has yet to deliver suitable alternatives. Public testimony at the April 2011 NOSB meeting suggested that, while there are apple varieties and rootstocks with differing degrees of resistance to fire blight, there is a lack of varieties that meet commercial demand for both good fruit quality and disease resistance. Other commenters pointed out that resistance is relative and all apple varieties are susceptible to fire blight to some extent. Red Delicious and Macoun are the least susceptible, with all newer commercial varieties being more susceptible. It was also pointed out that the resistance in the rootstock does not translate to resistance in the scion, leaving the tree vulnerable to infection. Varieties are normally replaced every 10-15 years and thus cannot be switched like changing a spray product; the cost of replanting an orchard can exceed \$20,000 per acre. Pears tend to be uniformly more susceptible to fire blight than apples, and resistant germplasm does not appear to be available. Many organic apple and pear growers as well as disease specialists stated that fire blight management is very challenging and additional research is needed to develop effective alternatives to antibiotics. Researchers who commented at the NOSB meeting described one such tool, a new yeast product that may be effective to control fire blight as an alternative to streptomycin; however, this product has only had preliminary field trials, is not commercially available, and has not received registration from the EPA.

Organic growers further explained in their testimony to the NOSB that growers do not routinely apply streptomycin as a preventive every year, but only when conditions indicate risk

of infection is high. Most growers use a predictive model such as Cougarblight or Maryblight to time antibiotic application with potential infection periods. Growers also stated that, while streptomycin has become ineffective in some growing areas due to resistance of the pathogen, it remains a critical tool in other regions of the U.S.

Given that proven effective alternatives are limited, and the impact that failing to renew the allowance for streptomycin would have on the organic apple and pear industry, the NOSB recommended extending the allowance of streptomycin for a limited time period. This limited extension is intended to allow for further development of alternative methods or substances for fire blight control in organic production. While some commenters explained that development of alternatives to streptomycin is 3 to 5 years from commercialization, the NOSB did not agree that the exemption for streptomycin should continue for another 5 years until the next sunset review in 2017. The NOSB opted to support a change in the annotation that would allow the use of streptomycin only until October 21, 2014. The NOSB anticipates that this expiration date will promote industry collaboration on the development of alternatives and prompt growers to use resistant varieties and other management practices for fire blight control on organic pear and apple operations. In response to the requests by the NOSB and the industry for additional resources to support research on alternatives to fire blight, the NOP issued letters to the USDA Agricultural Research Service (ARS) and National Institute of Food and Agriculture (NIFA) in May 2011 to request their assistance in prioritizing research on such alternatives.¹¹

AMS accepts the NOSB's recommendation. This proposed rule would amend § 205.601(i)(11) to read as follows:

Streptomycin, for fire blight control in apples and pears only until October 21, 2014.

¹¹ May 2011 Letters submitted by NOP to USDA ARS and NIFA on fire blight research. Available at the NOP website: <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5091325>

This amendment would be effective on the substance's current sunset date, October 21, 2012.

The National List currently includes an exemption for lignin sulfonate as a plant or soil amendment in organic crop production at § 205.601(j)(4) as follows:

Lignin sulfonate – chelating agent, dust suppressant, floatation agent.

Lignin sulfonate is listed twice on the National List under § 205.601; the first listing is for use as a plant or soil amendment, the second listing is for use as a floatation agent in post-harvest handling. During the sunset review for lignin sulfonate, the NOSB noted that including “floatation agent” as an allowable use under the first listing is incorrect. The substance is not used as a floatation agent for plant or soil amendments. Public comment also stated that lignin sulfonate is used as a floatation agent for post-harvest handling, and this use is currently allowed under the second listing for the substance at § 205.601(l)(1). Therefore, the NOSB recommended the first listing for lignin sulfonate at § 205.601(j)(4) be corrected to remove the language “floatation agent” from the annotation. The change to this annotation has no effect on the allowance of lignin sulfonate as a floatation agent for post-harvest handling under § 205.601(l)(1).

The Secretary accepts the NOSB's recommendation. This proposed rule would amend § 205.601(j)(4) to read as follows:

Lignin sulfonate – chelating agent, dust suppressant.

This amendment would be effective on the substance's current sunset date, October 21, 2012.

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)).”

The National List currently includes a listing for yeast as a nonsynthetic for use in or on processed products at § 205.605(a) as follows:

Yeast – nonsynthetic, growth on petrochemical substrate and sulfite waste liquor is prohibited (Autolysate; Bakers; Brewers; Nutritional; and Smoked – nonsynthetic smoke flavoring process must be documented).

At their October 2010 public meeting, the NOSB issued a recommendation for yeast under sunset review and a recommendation on a petition to change the current listing for yeast. The NOP is responding to both recommendations through a single action in this proposed rule to streamline and efficiently address the regulatory changes requested by the NOSB.

When the NOSB issued their 1995 recommendation for yeast, organic sources of yeast were not available. More recently, manufacturers have developed methods of production and obtained organic certification for yeast products.¹² Manufacturers have since advocated that yeast should be considered an agricultural substance and included on § 205.606, rather than on § 205.605(a). Inclusion of yeast on § 205.606 would require food processors to use organic yeast when it was commercially available. In August 2006, a petition was submitted to the NOSB requesting that yeast be removed from § 205.605(a) and listed on § 205.606.¹³

In their October 2010 deliberations on the status of yeast on the National List, the NOSB Handling Committee favored the potential for expanded use of organic yeast in processed organic products. However, the NOSB also expressed concern that moving yeast to § 205.606

¹² The NOP issued guidance on March 2, 2010, (NOP 5014: Certification of Organic Yeast) to clarify that yeast may be labeled as organic provided certain guidelines are met. Available at the NOP website: <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5087121>.

¹³ The petition was submitted by Marroquin International Organic Commodity Services, Inc., and is available at the NOP website: <http://www.ams.usda.gov/NOPPetitionedSubstancesDatabase>

would classify it as an agricultural nonsynthetic substance, a classification that would impact the status of yeast used in the livestock feed industry. Under the NOP regulations at § 205.237(a), all agricultural ingredients included in additives and supplements of livestock feed rations must be organic. If the NOSB were to recommend inclusion of yeast on § 205.606, then all yeast used in livestock feed supplements would need to be organic. This action would not serve the interests of livestock producers who feed yeast to livestock as a non-agricultural, non-synthetic feed supplement.

Based upon these considerations, the NOSB recommended an annotation change to the current listing for yeast at § 205.605(a). This annotation change is intended to lead to greater demand for organic products in both the handling and crop categories without elimination of an important source of supplements for organic livestock rations. In the recommendation, yeast would remain on § 205.605(a) with an amended annotation that would require yeast used as food or a fermentation agent to be organic if the end use is for human consumption, but would allow use of nonorganic yeast when equivalent organic yeast is not commercially available. Most comments received on yeast were supportive of this annotation change.

AMS accepts the NOSB's recommendation. This proposed rule would amend § 205.605(a) to read as follows:

Yeast – When used as food or a fermentation agent, yeast must be organic if its end use is for human consumption; nonorganic yeast may be used when equivalent organic yeast is not commercially available. Growth on petrochemical substrate and sulfite waste liquor is prohibited. For smoked yeast, nonsynthetic smoke flavoring process must be documented.

This amendment would be effective on the listing's current sunset date, October 21, 2012.

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

The National List currently includes a listing for colors allowing their use in or on processed products at § 205.606(d) as follows:

Colors derived from agricultural products.

At their October 2010 public meeting, the NOSB issued a recommendation for colors under sunset review and a recommendation for an annotation change to the current listing for colors. The NOP is responding to both recommendations through a single action in this proposed rule to streamline and efficiently address the regulatory changes requested by the NOSB.

In March 2007, the NOSB recommended the addition of colors from agricultural products to § 205.606 of the National List. Their action was the result of several petitions submitted after the colors had been allowed to sunset from § 205.605(a) in 2007.

When the NOSB approved colors for addition to § 205.606, the Board did not consider including a restriction on the use of synthetic solvents in color extraction because the petitions specified colors that were only oil or water extracted using physical processing such as cutting, drying, or grinding. Some NOSB members also felt it was not possible to place restrictions on a nonorganic substance listed as permitted under § 205.606. At that time, some NOSB members emphasized that annotations on nonorganic substances should be limited to those which restrict the use of the listed substance instead of the process of producing it.

Because of the lack in specificity in the colors annotation, stakeholders have advised the NOSB through public comment that there is confusion as to whether synthetic solvents may be used to extract colors and whether use of synthetic solvents in the preparation of the colors listed

on § 205.606 is within the intent of the listing. In response to this concern, the NOSB Handling Committee reviewed transcripts from the March 2007 meeting, petitions, and committee recommendations and concluded that the use of synthetic solvents was not reviewed by the NOSB and is, therefore, clearly outside of the intent of the current listing. In addition, the Handling Committee stated that solvent extraction of these colors is not necessary given that each color was petitioned as being available in the marketplace without synthetic solvent extraction. Public comments received at the October 2010 NOSB meeting also supported the NOSB's recommendation to change the annotation to prohibit solvent extraction and use of synthetic carriers or preservatives.

As part of their October 2010 recommendation, the NOSB also requested that the NOP review the Chemical Abstract Service (CAS) registration numbers for each of these food colors for accuracy and make any technical corrections necessary. The NOP agrees that, in some cases, the CAS numbers are incorrect as they refer to pigments that can be produced from a variety of sources rather than the nonsynthetic colors derived from agricultural sources that the NOSB reviewed. The NOP plans to correct these numbers through a future rulemaking action. This proposed rule would not amend the CAS numbers for colors; all CAS numbers for colors included under § 205.606(d) would continue to be listed as follows: Annatto extract color (pigment CAS # 1393-63-1) – water and oil soluble 107, 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).

AMS accepts the NOSB's recommendation to change the annotation for colors. This proposed rule would amend § 205.606(d) to read as follows:

Colors derived from agricultural products – Must not be produced using synthetic solvents and carrier systems or any artificial preservative.

This amendment would be effective on the listing's current sunset date, June 27, 2012.

The Secretary specifically seeks comments on this proposed amendment with regard to the extent of use of carbon dioxide, a synthetic solvent that is on the National List at § 205.605(b), which may be used in a liquid state (supercritical carbon dioxide) to extract colors.

The National List currently includes a listing for hops allowing its use in or on processed products at § 205.606(l) as follows:

Hops (*Humulus lupulus*).

At their October 2010 public meeting, the NOSB issued a recommendation for hops under sunset review and a recommendation on a petition to add an expiration date to the current listing for hops. The NOP is responding to both recommendations through a single action in this proposed rule to streamline and efficiently address the regulatory changes requested by the NOSB.

Hops are a perennial crop that is customarily grown under contract. Most hops are sold on forward contracts before planting. Hops plantings do not reach optimum production in one season of growth, so growers are unable to switch varieties on an annual basis. The variety of hops used dramatically influences the flavor of different beers, and the different varieties of hops grown distinguish many styles of beers.

Hops was added to the National List at § 205.206 in 2007 to enable brewers to make organic beer with conventionally grown hops in the absence of a commercially available supply of organically grown hops. At that time, industry comments indicated that a sufficient volume of organic hops in the varieties needed did not exist. After the 2007 listing of hops on § 205.606, grower expectations that brewers would begin to seek additional organic hops contracts did not materialize. In December 2009, growers petitioned the NOSB to remove hops from § 205.606 to expedite growth in the organic hops market.¹⁴ This petition was reviewed by the NOSB concurrently with the sunset listing for hops.

The initial recommendation from the NOSB Handling Committee concerning hops was to renew its listing on § 205.606 of the National List without change. When this recommendation was published in the October 2010 NOSB meeting notice with a request for

¹⁴ The petition was submitted by the American Organic Hop Growers Association and is available at the NOP website: <http://www.ams.usda.gov/NOPPitionedSubstancesDatabase>

public comments (FR 75 57194), over 100 comments against the continuation of hops on § 205.606 were submitted by consumers, growers, organic associations, and academics. Hops brokers and growers commented that few brewers actively sought organic hops and voiced dissatisfaction with this situation, as it was commonly described as an effort to maximize profit by the brewers who wanted to produce organic beer at a premium price, but did not seek organic hops for their beer.

At their October 2010 public meeting, the NOSB heard comments from some organic brewers who stated they always used organic hops, and that there was no difficulty in obtaining the specific varieties of hops needed in commercial quantities. These brewers supported the removal of hops from § 205.606, and felt that sourcing all organic hops would not impede the growth and progress of their business. Other comments also indicated that, since organic beer labels are not required to list ingredients, customers and purveyors of beer rarely know whether the hops in their organic beer are organic. A majority of these commenters supported the removal of hops from § 205.606 so that consumers could be assured that organic hops is used in organic beer.

Many commenters also indicated that the availability of organic hops is now sufficient to supply the organic beer market. A few comments were received from brewers who maintained that an adequate organic supply of the varieties of hops needed for their beer varieties could not be sourced by the June 27, 2012, sunset date for hops.

In consideration of the comments received, and in acknowledgement of the time needed to establish a perennial crop and forward contracts, the NOSB determined that the best approach would be to relist hops on the National List at § 205.606 until January 1, 2013. This extension of the listing would allow brewers to source, when organic hops is not commercially available,

from the 2011 and 2012 year supply of conventional hops, while fostering the development of purchasing arrangements for organic varieties from crops in 2013.

AMS accepts the NOSB's recommendation. The NOP also proposes a spelling correction to the binomial name for hops, currently misspelled at § 205.606. This proposed rule would amend § 205.606(l) to read as follows:

Hops (Humulus lupulus) until January 1, 2013.

This amendment would be effective on the current sunset date for hops, June 27, 2012.

The National List currently includes a listing for pectin allowing its use in or on processed products at § 205.606(s) as follows:

Pectin (high-methoxy).

At their October 2010 public meeting, the NOSB issued a recommendation for pectin (high-methoxy) under sunset review and a recommendation on a petition to change the forms of pectin allowed in organic handling. As discussed in the Removals section on low-methoxy pectin, the NOP is responding to both recommendations through a single action in this proposed rule. This is intended to streamline and efficiently address the regulatory changes requested by the NOSB. The result of this proposed rule would list all non-amidated (nonsynthetic) forms of pectin on § 205.606.

During the 2012 sunset review, the NOSB reviewed a petition requesting that the listing at § 205.605(b) for low-methoxy pectin be moved to § 205.606. The petitioner proposed that non-amidated forms of low-methoxy pectin are not synthetic.¹⁵ The petitioner explained that the use of ammonia in the extraction process for producing pectin is limited to amidated forms of pectin and, therefore, only amidated forms should be considered synthetic. In consideration of

¹⁵ The petition was submitted by Crofters Food Ltd. and is available at the NOP website: <http://www.ams.usda.gov/NOPPitionedSubstancesDatabase>

this petition, the NOSB reviewed a Technical Report and a Supplemental Technical Report, both of which supported the petitioner's position.¹⁶ The NOSB determined that amidation is a better indicator of whether the pectin is synthetic. Since all forms of pectin currently on the National List are available in non-amidated (nonsynthetic) form, the NOSB recommended that a single listing for non-amidated forms of pectin on § 205.606 would be more appropriate. If implemented, all amidated forms of pectin would be prohibited. Comments by organic food processors supported the NOSB recommendation and agreed that amidated pectin is not needed for organic processing.

AMS accepts the NOSB's recommendation. This proposed rule would amend § 205.606(s) to read as follows:

Pectin (non-amidated forms only).

This amendment would be effective on the current sunset date for pectin (high-methoxy), October 21, 2012.

III. Related Documents.

An Advanced Notice of Proposed Rulemaking (ANPR) was published in the Federal Register on March 26, 2010, (75 FR 14500) to make the public aware that the exemptions and prohibitions for 232 listings of synthetic and non-synthetic substances in organic production and handling will expire, if not reviewed by the NOSB and renewed by the USDA.

IV. Statutory and Regulatory Authority.

The OFPA, as amended (7 U.S.C. 6501-6522), authorizes the Secretary to make amendments to the National List based on proposed amendments developed by the NOSB.

¹⁶ Technical Report on Non Amidated Low Methoxyl Pectin. August 17, 2009. Available at the NOP website: <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5087206>; Supplemental Report on Non Amidated Low Methoxyl Pectin. July 30, 2010. Available at the NOP website: <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5087205>

Sections 6518(k)(2) and 6518(n) of OFPA authorize the NOSB to develop proposed amendments to the National List for submission to the Secretary and establish a petition process by which persons may petition the NOSB for the purpose of having substances evaluated for inclusion on or deletion from the National List. The National List petition process is implemented under § 205.607 of the NOP regulations. The current petition process (72 FR 2167, January 18, 2007) can be accessed through the NOP website 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. 601-624), the Poultry Products Inspection Act (21 U.S.C. 451-471), or the Egg Products Inspection Act (21 U.S.C. 1031-1056), concerning meat, poultry, and egg products, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.), nor the authority of the Administrator of EPA under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 et seq.).

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

C. Regulatory Flexibility Act.

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601-612) 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, 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). AMS has also considered the economic impact of this action on small entities. The impact on entities affected by this proposed rule would not be significant. The effect of this proposed rule would be to allow the continued use of additional substances in agricultural production and handling. 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 2008.¹⁷ ERS, based upon the list of certified operations maintained by the NOP, estimated the

¹⁷U.S. Department of Agriculture, Economic Research Service. 2009. *Data Sets: U.S. Certified Organic Farmland Acreage, Livestock Numbers and Farm Operations, 1992-2008*. Available at: <http://www.ers.usda.gov/Data/Organic/>

number of certified handling operations was 3,225 in 2007.¹⁸ 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 2008.¹⁹ 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 historically demonstrated a growth rate between 15 to 24 percent each year. In 2010, organic food sales grew 7.7%.²⁰

In addition, USDA has 94 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. 3501-3520, or OMB's implementing regulations at 5 CFR part 1320.

E. General Notice of Public Rulemaking.

This proposed rule reflects recommendations submitted to the Secretary by the NOSB for substances on the National List of Allowed and Prohibited Substances that, under the sunset

¹⁸ U.S. Department of Agriculture, Economic Research Service, 2009. *Data Sets: Procurement and Contracting by Organic Handlers: Documentation*. Available at: <http://www.ers.usda.gov/Data/OrganicHandlers/Documentation.htm>

¹⁹ 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. Available at: <http://www.ers.usda.gov/Publications/EIB58>.

²⁰ Organic Trade Association's *2011 Organic Industry Survey*. Available at: <http://www.ota.com>.

review provisions of OFPA, would otherwise expire in 2012. A 30-day period for interested persons to comment on this rule is provided. Thirty days is deemed appropriate because the review of these listings was widely publicized through three NOSB meetings and an ANPR, the use, prohibition, and amendments to these substances, as applicable, are critical to organic production, and this rulemaking should be completed before the earliest 2012 sunset date, June 27, 2012.

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, is proposed to be amended as follows:

PART 205 – NATIONAL ORGANIC PROGRAM

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

Authority: 7 U.S.C. 6501-6522.

2. Section 205.601 is amended by:

A. Revise paragraph (a)(2);

B. Revise paragraph (g);

C. Revise paragraph (i)(11); and

D. Revise paragraph (j)(4) to read as follows:

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

(a) * * *

(2) Chlorine materials – For pre-harvest use, residual chlorine levels in the water in direct

crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions.

(i) Calcium hypochlorite.

(ii) Chlorine dioxide.

(iii) Sodium hypochlorite.

* * * * *

(g) As rodenticides. Vitamin D₃.

* * * * *

(i) * * *

(11) Streptomycin, for fire blight control in apples and pears only until October 21, 2014.

* * * * *

(j) * * *

(4) Lignin sulfate – chelating agent, dust suppressant.

* * * * *

4. Section 205.605 is amended by:

A. Revise the annotation for “Yeast” under paragraph (a);

B. Remove “Pectin (low-methoxy)” from paragraph (b); and

C. Remove “Potassium iodide” from paragraph (b). The revision reads 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 groups(s)).”

* * * * *

(a) * * *

* * * * *

Yeast – When used as food or a fermentation agent, yeast must be organic if its end use is for human consumption; nonorganic yeast may be used when equivalent organic yeast is not commercially available. Growth on petrochemical substrate and sulfite waste liquor is prohibited. For smoked yeast; nonsynthetic smoke flavoring process must be documented.

* * * * *

5. Section 205.606 is amended by:

A. Revise paragraph (d);

B. Revise paragraph (l); and

C. Revise paragraph (s), the revisions read as follows:

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

* * * * *

(d) Colors derived from agricultural products – Must not be produced using synthetic solvents and carrier systems or any artificial preservative.

* * *

* * * * *

(l) Hops (Humulus lupulus) until January 1, 2013.

* * * * *

(s) Pectin (non-amidated forms only).

* * * * *

Dated: January 6, 2012

David R. Shipman
Acting Administrator
Agricultural Marketing Service

[FR Doc. 2012-362 Filed 01/11/2012 at 8:45 am; Publication Date: 01/12/2012]