



DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Document Number AMS-NOP-14-0079; NOP-14-05]

RIN 0581 AD60

National Organic Program; Amendments to the National List of Allowed and Prohibited Substances (Crops, Livestock and Handling)

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the National List of Allowed and Prohibited Substances (National List) provisions of the U.S. Department of Agriculture's (USDA's) organic regulations to implement recommendations submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB). This rule proposes to change the use restrictions for seventeen substances allowed for organic production or handling on the National List: micronutrients; chlorhexidine; parasiticides; fenbendazole; moxidectin; xylazine; lidocaine; procaine; methionine; excipients; alginic acid; flavors; carnauba wax; chlorine; cellulose; colors; and, glycerin. This rule also proposes to add sixteen new substances on the National List to be allowed in organic production or handling: hypochlorous acid; magnesium oxide; squid byproducts; activated charcoal; calcium borogluconate; calcium propionate; injectable vitamins, minerals, and electrolytes; kaolin pectin; mineral oil; propylene glycol; acidified sodium chlorite; zinc sulfate; potassium lactate; and, sodium lactate. In addition, this proposed rule would list the botanical pesticide, rotenone, as a prohibited substance in organic crop

production. Finally, this proposed rule would remove ivermectin as an allowed parasiticide for use in organic livestock production.

DATES: Comments must be received by (INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER).

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

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: Robert Pooler, Standards Division, National Organic Program, USDA-AMS-NOP, 1400 Independence Ave., SW, Room 2642-S., Ag Stop 0268, Washington, DC 20250-0268. Telephone: (202) 720-3252.

Instructions: All submissions received must include the docket number AMS-NOP-14-0079; NOP-14-05, and/or Regulatory Information Number (RIN) 0581-AD60 for this rulemaking. When submitting a comment, clearly indicate the proposed rule topic and section number to which your comment refers. In addition, comments should clearly indicate whether you support or oppose the action being proposed and the reason(s) for your position. Your comments can also include information on alternative management practices, where applicable, that support alternatives to the proposed amendments. You should also offer any recommended language change(s) that would be appropriate to your position. Please include relevant information and data to support your position, such as scientific, environmental, manufacturing, industry, or impact information, or similar sources. Only relevant material supporting your position should be submitted. All comments received will be posted without change to <http://www.regulations.gov>.

Document: For access 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, Room 2642-South Building, 1400 Independence Ave., SW., Washington, DC, from 9 a.m. to 12 noon and from 1 p.m. to 4 p.m., Monday through Friday (except official Federal holidays). Persons wanting to visit the USDA South Building to view comments received in response to this proposed rule are requested to make an appointment in advance by calling (202) 720-3252.

FOR FURTHER INFORMATION CONTACT: Robert Pooler, Standards Division, National Organic Program. Telephone: (202) 720-3252.

SUPPLEMENTARY INFORMATION:

I. Background

On December 21, 2000, the Secretary published the National List of Allowed and Prohibited Substances in §§ 205.600 through 205.607 of the USDA organic regulations (7 CFR §§ 205.1 - 205.690). This National List identifies the synthetic substances that may be used and the nonsynthetic (natural) substances that may not be used in organic production. The National List also identifies synthetic, nonsynthetic nonagricultural, and nonorganic agricultural substances that may be used in organic handling. The Organic Foods Production Act of 1990, as amended (7 U.S.C. 6501- 6522) (OFPA), and § 205.105 of the USDA organic regulations specifically prohibit the use of any synthetic substance in organic production and handling unless the synthetic substance is on the National List. Section 205.105 also requires that any nonorganic agricultural and any nonsynthetic nonagricultural substance used in organic handling be on the National List.

Under the authority of OFPA, the National List can be amended by the Secretary based on recommendations presented by the NOSB. Since the final rule establishing the National Organic Program (NOP) became effective on October 21, 2002, AMS has published multiple rules amending the National List.

This proposed rule would amend the National List to implement 29 NOSB recommendations on 35 amendments to the National List that were submitted to the Secretary on November 17, 2000, September 19, 2002, May 6, 2009, November 5, 2009, October 28, 2010, December 2, 2011, March 20, 2012, October 16, 2012, May 2, 2014, April 30, 2015, October 29, 2015, April 26, 2016, and November 18, 2016.

Table 1 summarizes the NOSB recommendations on adding substances to the National List or amending currently listed substances that are included in this proposed rule.

Table 1. Substances being added to the National List or current listings being amended.

Substance	National List Section	Proposed rule action
Hypochlorous acid	§ 205.601	Add to National List
Magnesium oxide	§ 205.601	Add to National List
Micronutrients	§ 205.601(a)	Amend listing
Squid byproducts	§ 205.601	Add to National List
Rotenone	§ 205.602	Add to National List
Activated charcoal	§ 205.603(a)	Add to National List
Calcium borogluconate	§ 205.603(a)	Add to National List
Calcium propionate	§ 205.603(a)	Add to National List
Chlorhexidine	§ 205.603(a)	Amend listing
Hypochlorous acid	§ 205.603(a)	Add to National List
Kaolin pectin	§ 205.603(a)	Add to National List
Mineral oil	§ 205.603(a)	Add to National List
Nutritive supplements - Injectable vitamins, minerals, & electrolytes	§ 205.603(a)	Add to National List
Parasiticides	§ 205.603(a)	Amend listing
Fenbendazole	§ 205.603(a)	Amend listing

Ivermectin	§ 205.603(a)	Remove from National List
Moxidectin	§ 205.603(a)	Amend listing
Propylene glycol	§ 205.603(a)	Add to National List
Sodium chlorite, acidified	§ 205.603(a & b)	Add to National List
Xylazine	§ 205.603(a)	Amend listing
Zinc sulfate	§ 205.603(a)	Add to National List
Lidocaine	§ 205.603(b)	Amend listing
Procaine	§ 205.603(b)	Amend listing
Methionine	§ 205.603(d)	Amend listing
Excipients	§ 205.603(f)	Amend listing
Alginic acid	§ 205.605(a)	Reclassify listing
Flavors	§ 205.605(a)	Amend listing
Carnauba wax	§ 205.605(a)	Reclassify listing
Cellulose	§ 205.605(b)	Amend listing
Chlorine	§ 205.605(b)	Amend listing
Hypochlorous acid	§ 205.605(b)	Add to National List
Potassium lactate	§ 205.605(b)	Add to National List
Sodium lactate	§ 205.605(b)	Add to National List
Glycerin	§ 205.605(a) & § 205.606	Reclassify listing
Colors	§ 205.606	Amend listing

Each substance included in Table 1 is addressed in the Overview of Proposed Amendments. Substances recommended by the NOSB between November 2000 and April 2015 are described in more detail because less petition and technical information is available in NOP's petitioned substance database¹. Less technical and petition information is provided within the overview for substances recommended by the NOSB after its three public meetings between October, 2015, and November, 2016, because such information is available in NOP's petitioned substance database.

II. Overview of Proposed Amendments

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

¹ NOP petitioned substance database, A – Z: <https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned>.

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

This proposed rule would add three new substances, and amend one substance currently on the National List in § 205.601, Synthetic substances allowed for use in organic crop production.

Hypochlorous acid

The proposed rule would amend the National List to add hypochlorous acid as a chlorine material for use as a disinfectant and sanitizer in §§ 205.601, 205.603, and 205.605. Table 2 illustrates the proposed listing.

Table 2. Proposed rule action for hypochlorous acid.

Current rule:	N/A
Proposed rule action:	§§ 205.601(a), 205.603(a), 205.605(b), Hypochlorous acid — generated from electrolyzed water.

On May 29, 2015, AMS received a petition to add hypochlorous acid to the National List in §§ 205.601 and 205.605, for use as an antimicrobial/sanitizer on equipment and raw agricultural products in organic crop production and handling.² In water, chlorine materials such as calcium and sodium hypochlorite are in equilibrium with related chlorine species, including hypochlorous acid (HOCl) and hypochlorite (ClO⁻). These related chlorine species are formed in the generation of electrolyzed water. Chlorine materials (calcium hypochlorite, chlorine dioxide and sodium hypochlorite) are included on the National List in §§205.601, 205.603 and 205.605.

² The hypochlorous acid petition is available in the NOP Petitioned Substances Database: <https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned>

On September 11, 2015, AMS published NOP Policy Memorandum PM 15-4, Electrolyzed Water.³ This memo revised a prior NOP determination about the status of electrolyzed water by stating that hypochlorous acid, generated by electrolyzed water, is an allowable type of chlorine material. The petition review process continued after that memo was issued in order to codify the allowance for hypochlorous acid on the National List.

At its April 25 – 27, 2016, public meeting, the NOSB considered the petition to add hypochlorous acid to the National List for uses in organic production and organic handling and received public comment on these allowances. During its review, the NOSB also considered a technical evaluation report on hypochlorous acid⁴ that described its manufacture, industry uses, regulation, and chemical properties.

In consideration of the petition, technical report, and public comments, the NOSB determined that the use of hypochlorous acid generated from electrolyzed water as a disinfectant and sanitizer satisfies OFPA evaluation criteria for National List substances and recommended adding hypochlorous acid to the existing listings for chlorine materials in § 205.601(a) as an algicide, disinfectant, and sanitizer, including irrigation cleaning systems in organic crop production; § 205.603(a) for use as a disinfectant, sanitizer, and medical treatment in organic livestock production; and §205.605(b) as a disinfectant and sanitizer in organic handling. The NOSB included the annotation “generated from

³ The policy memo is published in the NOP Handbook: <http://www.ams.usda.gov/sites/default/files/NOP-PM-15-4-ElectrolyzedWater.pdf>

⁴ Hypochlorous acid technical report: <https://www.ams.usda.gov/sites/default/files/media/Hypochlorous%20Acid%20TR%2008%2013%2015.pdf>

electrolyzed water” to clarify that the source of hypochlorous acid allowed for use in organic production or handling must be production from electrolyzed water.

AMS has reviewed and proposes to address this NOSB recommendation through this proposed rule. Consistent with the NOSB recommendation, this proposed rule would amend the listings for Chlorine materials in § 205.601(a)(2), § 205.603(a), and § 205.605(b) to add hypochlorous acid—generated from electrolyzed water.

Magnesium oxide

This proposed rule would add magnesium oxide to § 205.601(j) as an allowed substance to control the viscosity of a clay suspension agent for humates. In consideration of the petition, technical report, and public comments, the NOSB determined that this use of magnesium oxide satisfies the OFPA evaluation criteria for National List substances. Table 3 illustrates the proposed listing.

Table 3. Proposed rule action for magnesium oxide.

Current rule:	N/A
Proposed rule action:	§ 205.601(j) Magnesium oxide—for use only to control the viscosity of a clay suspension agent for humates.

Applications

Magnesium oxide (CAS Number 1309-48-4) is a white, free flowing, odorless powder. The technical report for magnesium hydroxide⁵ states that magnesium oxide is considered to be a relatively benign substance with a wide range of applications. There are several manufacturing processes used to produce magnesium oxide. The petition⁶ to add magnesium oxide to the National List describes an efficient and inexpensive process

⁵ 2007 magnesium hydroxide technical report, see: <https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned>

⁶ Petition for magnesium oxide, see: <https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned>.

for producing magnesium oxide by combining sea water or salt brine with dolomitic limestone to precipitate magnesium hydroxide, which is then dehydrated by heating to form magnesium oxide. Since magnesium oxide is physically and chemically stable at high temperatures, it is widely used for agricultural and nonagricultural applications. For food use, magnesium oxide is listed in 21 CFR Part 184 – Direct Food Additives Affirmed as Generally Recognized As Safe (GRAS), in § 184.1431, for the following uses: anticaking and free-flow agent, firming agent, lubricant and release agent, nutrient supplement, and a pH control agent.

Timeline

On January 3, 2013, AMS received a petition to add magnesium oxide to the National List in § 205.601. The petition states that the substance is “intended to be used in combination with other organic inputs applied as a liquid foliar on a wide variety of different agricultural, vegetable, fruit and horticultural crops.” According to the petition, small quantities of magnesium oxide would be used during the processing of attapulgite clay to control its viscosity when the clay is used as a suspension agent for finely ground humates. As stated in the petition, the rate of magnesium oxide use per the manufacturer’s recommended rate would be 0.074 percent of the diluted humate product applied, or approximately 0.0007–0.0014 pounds of magnesium oxide per acre, which is a very low application rate.

At its May 2, 2014, public meeting, the NOSB considered the petition to add magnesium oxide to the National List in § 205.601. At this meeting, the NOSB considered magnesium oxide against the evaluation criteria stipulated in OFPA § 2119(m). After review of the petition, technical report, and public comments, the NOSB

determined that magnesium oxide satisfies the evaluation criteria and recommended magnesium oxide as a soil amendment for use in organic crop production.

AMS has reviewed and proposes to address this NOSB recommendation through this proposed rule. Consistent with the NOSB recommendation, this proposed rule would amend § 205.601(j) by adding: Magnesium oxide—for use only to control the viscosity of a clay suspension agent for humates.

Micronutrients

This proposed rule would amend the current listing on micronutrients in § 205.601(j) as an allowed plant or soil amendment material for use in organic crop production. This proposed rule would change the listing for micronutrients to remove soil testing as the required method for demonstrating a soil micronutrient deficiency.

Table 4 illustrates the proposed listing.

Table 4. Proposed rule action for micronutrients.

Current rule:	§ 205.601(j) 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.
Proposed rule action:	§ 205.601(j) Micronutrients—not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Micronutrient deficiency must be documented by soil or tissue testing, advice from certified crop advisors or professional agronomists, agricultural extension information, or other methods approved by the certifying agent.

In April 2015, the NOSB initiated a change to the existing listing for micronutrients in § 205.601(j) based on public comments⁷ received during the NOSB

⁷ The public comments to the NOSB pertaining to the 2017 sunset review are posted here: <https://www.ams.usda.gov/event/spring-nosb-meeting-2015-ca>, and <https://www.ams.usda.gov/event/nosb-meeting-2015-vt>.

2017 sunset review for micronutrients. The USDA organic regulations permit micronutrients to be used as a soil amendment only when soil deficiency is documented by testing. Commenters suggested that alternative methods to document micronutrient deficiency, including, but not limited to, tissue testing, the incorporation of professional opinions and regional knowledge from agronomists, crop advisors, extension agents and publications, should be permitted in lieu of testing.

During a public meeting on October 26-29, 2015, the NOSB considered an amendment to the micronutrients listing to remove the requirement for testing as the only method for documenting a soil micronutrient deficiency. In consideration of public comments, the NOSB determined that requiring soil testing for micronutrients was outdated and that other means of assessing micronutrient deficiencies in soil are acceptable.⁸

AMS has reviewed and proposes to address this NOSB recommendation through this proposed rule. Consistent with the NOSB recommendation, this proposed rule would amend § 205.601(j) Micronutrients, by removing soil testing as the only way to document a deficiency and stating that a deficiency must be documented.

Squid byproducts

This proposed rule would add squid byproducts to § 205.601(j) as an allowed substance for use in organic crop production. Table 5 illustrates the proposed listing.

Table 5. Proposed rule action for squid byproducts.

Current rule:	N/A
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⁸ <https://www.ams.usda.gov/rules-regulations/organic/nosb/recommendations/fall2015>

Proposed rule action:	§ 205.601(j) squid byproducts—from food waste processing only. 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.
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In April 2015, AMS received a petition to add “squid and squid byproducts” to the National List under the listing for liquid fish products allowed as plant or soil amendments in organic crop production, § 205.601(j)(7). Squid byproducts are used as starting ingredients in the production of enzymatically produced hydrolysates which are used as foliar sprays and soil amendments for propagating crops such as cranberries, cherries and apples. Squid byproduct hydrolysates are similar in composition to fish emulsions and can be used as a fertilizer that provides organic matter to the soil.

At the April 25-27, 2016 NOSB meeting, the Board reviewed the petition, public comments, and information in a technical report on squid and squid byproducts. The NOSB explained that squid byproducts are stabilized with acid to lower the pH, and that this practice is consistent with the existing listing for liquid fish products that are stabilized with synthetic sulfuric, citric, or phosphoric acid. The NOSB also stated that only squid byproducts from the food waste processing stream are acceptable; fertilizer from whole squid would not be acceptable.

Based on the petition, technical report, and public comments, the NOSB determined that squid byproducts meet the OFPA evaluation criteria for National List substances. AMS has reviewed and proposes to address this NOSB recommendation through this proposed rule. Consistent with the NOSB recommendation, this proposed rule would add amend § 205.601(j)(7) of the National List to list squid byproducts as an allowed plant or soil amendment that 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. AMS also accepts the source parameters specified by the NOSB, i.e., only squid byproducts from food waste processing are permitted.

§ 205.602 Nonsynthetic substances prohibited for use in organic crop production.

This proposed rule would add rotenone to paragraph (j) of § 205.602 and prohibit its use in organic crop production. Nonsynthetic substances are allowed in organic crop production except for those specifically listed as prohibited in § 205.602.

Rotenone

This proposed rule would add rotenone to § 205.602 and prohibit its use in organic crop production, as recommended by the NOSB in 2012. Table 6 illustrates the proposed changes to this section.

Table 6. Proposed rule action for rotenone.

Current rule:	N/A
Proposed rule action:	§ 205.602(f) Rotenone (CAS # 83-79-4).

Applications

Rotenone (CAS Number 83-79-4) is a substance that is extracted from various plant species such as Hoary pea (Tephrosia spp.) or Jicama vine (Pachyrhizus erosus) and similar tropical and subtropical plants. Rotenone preparations made from plants are also known as barbasco, derris, and cube root. Naturally occurring rotenone is used as a pesticide, insecticide, and as a piscicide (fish toxin). Pesticide formulations containing rotenone are nonsynthetic (natural) when prepared without synthetic extractions. Nonsynthetic substances are allowed in organic crop production except for those specifically listed as prohibited in § 205.602.

Timeline

The U.S. Environmental Protection Agency (EPA) cancelled the registration of rotenone for use on food commodities within the U.S. on March 23, 2011. Aligning with EPA's regulation of rotenone, AMS is adding rotenone to the list of prohibited nonsynthetic materials in § 205.602, and organic producers both within and outside of the U.S. would be prohibited from using rotenone on crops grown in accordance with USDA organic regulations.

The NOSB considered rotenone and other botanical pesticides at its meeting on October 14, 1994, and determined that rotenone should not be prohibited. The USDA agreed and did not prohibit rotenone or other botanical pesticides to control plant diseases, but did require producers to use management practices to prevent crop pests, weeds, and diseases before using botanical pesticides, as specified in the USDA organic regulations at § 205.206.

In August 2012, the NOSB revisited the allowance for rotenone in organic production. After reviewing technical documents and considering public comment, the NOSB recommended to prohibit rotenone, citing adverse environmental and health impacts, lack of essentiality, and incompatibility with organic principles. AMS has reviewed and proposes to address this NOSB recommendation through this proposed rule. Therefore, this proposed rule would amend § 205.602 of the National List by adding rotenone as a prohibited nonsynthetic substance in organic crop production. § 205.603 Synthetic substances allowed for use in organic livestock production.

The proposed rule would add the following substances to the National List in paragraph § 205.603(a) for use in organic livestock production: activated charcoal, calcium borogluconate, calcium propionate, hypochlorous acid, kaolin pectin, mineral oil,

nutritive supplements - injectable vitamins, trace minerals and electrolytes, propylene glycol, acidified sodium chlorite, and zinc sulfate. The proposed rule would also add acidified sodium chlorite to § 205.603(b). This proposed rule would also amend the allowances for the following substances currently allowed in organic livestock production: chlorhexidine, parasiticides, fenbendazole, moxidectin, and xylazine, § 205.603(a); lidocaine and procaine, § 205.603(b); methionine, § 205.603(d); and excipients, § 205.603(f). In addition, this proposed rule would remove ivermectin, § 205.603(a).

Activated Charcoal

This proposed rule would add activated charcoal to § 205.603(a) for use in organic livestock production. In consideration of the petition and public comments from livestock producers and animal health experts, the NOSB determined that activated charcoal should be allowed for use in organic livestock production. Synthetic forms of activated charcoal would continue to be prohibited. Table 7 illustrates the proposed listing.

Table 7. Proposed rule action for activated charcoal.

Current rule:	N/A
Proposed rule action:	§ 205.603(a) Activated charcoal—must be from vegetative sources.

Applications

Activated charcoal is manufactured from a physical activation process using high temperature and hot gases on raw materials such as coconut shells, various hardwoods, or bone. It can also be derived from coal or petroleum. The resulting product is a carbon based substance with small pore size and large surface area for adsorption or chemical reaction.

While this basic process provides sufficient activation capability, the use of a strong acid or strong base, such as phosphoric acid or potassium hydroxide, enhances the activation process and adsorption properties. Chemical activation with a strong chemical acid or base is the preferred activated charcoal manufacturing process since lower temperatures and less time are needed to create the final product. Activated charcoal is distinguished from elemental carbon by the removal of non-carbon impurities and oxidation of the carbon surface.

Activated charcoal is considered to be an adsorbent. Administered orally, activated charcoal chemically interacts with toxins in the intestines and prevents systemic absorption of the toxin into the blood. These bound toxins pass through the intestine to be excreted in the animal's manure. Under 21 CFR 310.545(a)(8), activated charcoal is approved as an ingredient in digestive aid drug products for humans.

Timeline

This proposed rule would implement a 2002 NOSB recommendation to add activated charcoal (CAS # 7440-44-0) with the annotation "must be from vegetative sources" to § 205.603(a) of the National List.⁹ The NOSB recommended that activated charcoal be added to § 205.603(a) as a medical treatment in organic livestock production.

The petition to add activated charcoal to the National List states that this material is a high-priority livestock medication and is commonly used as a therapeutic treatment on an as-needed basis with mammalian livestock, particularly in cases of suspected ingestion of toxic plants and control of diarrhea caused by moldy silage. This information was also supported in public comments to the NOSB from organic livestock producers

⁹ Recommendation for activated charcoal in livestock processing, see <https://www.ams.usda.gov/sites/default/files/media/Activated%20Charcoal%20Committee%20Rec.pdf>.

and veterinarians. The petition also states that there are no comparable nonsynthetic substances that provide a comparable therapeutic benefit nor practices to prevent the occasional ingestion of toxins that warrant treatment.

The NOSB recommendation to add activated charcoal specifies that only vegetative sources of this material would be permitted. The NOSB determined that activated charcoal derived from bone charcoal or lampblack (a by-product from incomplete burning of oil, tar, natural gas, or fat) is not consistent with organic farming and handling, as described in the OFPA substance evaluation criteria. The NOSB also noted that activated charcoal, when used as a toxin binder, is safe, effective, and difficult to overdose.

AMS has reviewed and proposed to address the NOSB recommendation through this proposed rule. Therefore, AMS is proposing to add activated charcoal to the National List at § 205.603(a) with the following annotation: must be from vegetative sources. Only activated charcoal from vegetative sources would be permitted.

Calcium Borogluconate

This proposed rule would add calcium borogluconate to § 205.603(a) of the National List for use in organic livestock production. Specifically, calcium borogluconate would be allowed only for the treatment of milk fever. Table 8 illustrates the proposed listing.

Table 8. Proposed rule action for calcium borogluconate.

Current rule:	N/A
Proposed rule action:	§ 205.603(a). Calcium Borogluconate— for treatment of milk fever only.

Applications

Calcium borogluconate, a D-gluconic acid, cyclic 4,5-ester with boric acid, is a stable, nonhazardous white powder derived from the reaction of five parts calcium gluconate to one part boric acid in an aqueous solution. Calcium borogluconate has been used for treatment of hypocalcemia (milk fever or parturient paresis) in cattle, sheep, and goats. Hypocalcemia, or milk fever, is a disease—observed mostly in high producing dairy cows—that can be induced by low blood calcium levels occurring just before birth or in early lactation just after birth, when demand for calcium for milk production exceeds the animal’s ability to mobilize calcium reserves. Low blood calcium levels can inhibit muscle function causing general weakness, loss of appetite, and eventually heart failure. The condition is more frequent in high producing dairy cows that are five or more years old in age. Mature animals may have reduced ability to mobilize calcium from bone. Certain breeds, such as Jersey cattle, may be more susceptible to milk fever.

When used to treat milk fever, calcium borogluconate is administered intravenously, intramuscularly, or subcutaneously, and has no established required withdrawal time. The calcium borogluconate technical report¹⁰ developed for the NOSB states that calcium borogluconate is recognized as an electrolyte in the European Union. The NOSB has determined that the use of calcium borogluconate in organic livestock production for the treatment of this condition meets the requirements of the OFPA substance evaluation criteria for organic production.

Timeline

This proposed rule would implement a November 2000 NOSB recommendation to add calcium borogluconate (CAS # 5743-34-0) to § 205.603 of the National List. At

¹⁰ Technical report for calcium borogluconate, see <https://www.ams.usda.gov/sites/default/files/media/Calcium%20Borogluconate%20TR.pdf>.

its public meeting the NOSB determined that calcium borogluconate should be added to § 205.603(a) as a medical treatment in organic livestock production for treatment of milk fever. Comments indicated that organic livestock producers use calcium borogluconate as directed by veterinarians. During the meeting, the NOSB discussed that calcium borogluconate would be used rarely, and only in emergency situations.

In formulating its recommendation, the NOSB determined that calcium borogluconate should be allowed for use in organic ruminants when production practices fail to prevent milk fever. AMS has reviewed and proposes to address the NOSB recommendations through this proposed rule. Therefore, AMS is proposing to add calcium borogluconate to § 205.603(a) with the following annotation: for treatment of milk fever only.

Calcium Propionate

This proposed rule would add calcium propionate to the National List at § 205.603(a) for use in organic livestock production. Specifically, this substance would be allowed only as a treatment for milk fever. Table 9 provides the proposed listing.

Table 9. Proposed rule action for calcium propionate.

Current rule:	N/A
Proposed rule action:	§ 205.603(a). Calcium Propionate—for treatment of milk fever only.

Applications

Calcium propionate, also known as calcium propanoate, is a white crystalline water soluble powder manufactured from combining calcium hydroxide and propionic acid. Calcium propionate is a direct food additive affirmed as generally recognized as safe (GRAS) (21 CFR 184.1221) for human food and is primarily used as a preservative

in bakery products. It is also allowed as a preservative for hay and silage in nonorganic livestock production agriculture (21 CFR 582.3221).

In 2002, AMS received a petition¹¹ to add calcium propionate to the National List for use in organic livestock production as a treatment for milk fever and as a mold inhibitor in dry formulated herbal remedies. According to the petition, calcium propionate can be administered to prevent milk fever or when milk fever symptoms first appear.

Timeline

This proposed rule would implement a September 2002 NOSB recommendation to add calcium propionate (CAS # 4075-81-4) to § 205.603 of the National List. At this meeting, the NOSB recommended that calcium propionate be allowed only for the treatment of milk fever. The NOSB recognized that calcium propionate would not be used routinely, but only as an emergency treatment for milk fever. Public comments informed that organic livestock producers use this substance as directed by veterinarians.

During its 2003 public meeting, the NOSB also considered allowing calcium propionate to also be used as a mold inhibitor for aloe pellets, but the NOSB did not include this use in its final recommendation. The technical report on calcium propionate indicates the substance has been used as a feed preservative in nonorganic hay crops. During deliberation, the NOSB crops subcommittee did not propose to allow the use of calcium propionate as a feed preservative, or propose allowing the general use of calcium propionate as a feed additive. As a result, the final NOSB recommendation included the

¹¹ Petition for calcium propionate, see <https://www.ams.usda.gov/sites/default/files/media/Calcium%20Propionate%20Petition.pdf>.

use of calcium propionate for use in organic livestock for the treatment of milk fever only.

The NOSB also determined that the limited use of calcium propionate in organic livestock production in this manner meets the OFPA substance evaluation criteria for organic production. In formulating its recommendation, the NOSB determined that calcium propionate can be used in organic livestock production when organic practices fail to prevent milk fever. AMS has reviewed and proposes to address the NOSB recommendation through this proposed rule. Therefore, AMS is proposing to add calcium propionate to § 205.603(a) with the following annotation: for treatment of milk fever only.

Chlorhexidine

This proposed rule would amend the allowance for chlorhexidine in § 205.603(a). The amendment—as recommended by the NOSB and public comment—will improve organic livestock producers’ ability to establish and maintain preventive livestock health care practices. Table 10 illustrates the changes between the current rule and the proposed rule.

Table 10. Proposed rule action for chlorhexidine.

Current rule:	§ 205.603(a)(6) 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.
Proposed rule action:	§ 205.603(a) Chlorhexidine—for medical procedures conducted under the supervision of a licensed veterinarian. Allowed for use as a teat dip when alternative germicidal agents and / or physical barriers have lost their effectiveness.

Applications

Chlorhexidine is a white to pale yellow, odorless powder. It is only slightly soluble in water and in most organic solvents. Chlorhexidine is manufactured by a two-step process beginning with sodium dicyanamide reacting with hexamethylene diamine to form hexamethylene-biscyanoguanidine (HMBCG). Subsequently, HMBCG is reacted with p-chloroaniline to yield the chlorhexidine base used in applications. In animals, chlorhexidine is used as a topical disinfectant, for wound healing, and for managing skin infection in dogs. Chlorhexidine is also used as a germicidal compound in teat dips for dairy production and as an umbilical cord treatment, udder and eye wash, and surgical scrub and sterilization material. Chlorhexidine's bactericidal effect is due to its binding with the bacterial cell wall or, when chlorhexidine concentrations are higher, inducing bacterial cell membrane disruption.

Timeline

This proposed rule would implement a 2009 NOSB recommendation to amend the allowance for chlorhexidine as listed in § 205.603(a) of the National List. Chlorhexidine is allowed for use in two applications: 1) for surgical procedures in organic livestock as performed by a licensed veterinarian, and 2) as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.¹² At the 2009 meeting, the NOSB determined that the annotation should reflect the use of chlorhexidine by livestock producers and veterinarians for antiseptic purposes and for hygienic cleansing of wounds encountered during livestock production. The NOSB determined that the current annotation is overly restrictive and that the general use of chlorhexidine for antiseptic purposes and for hygienic cleansing of wounds is compatible

¹² 2009 NOSB Recommendation to amend chlorhexidine, see <https://www.ams.usda.gov/sites/default/files/media/NOP%20Final%20Rec%20Chlorhexidine.pdf>.

with organic standards. This proposed change to broaden the allowance from surgical to medical procedures would improve organic livestock producers' ability to establish and maintain preventive livestock health care practices. The use of chlorhexidine may also minimize pain and stress. Such use could preclude the need to use antibiotics, which are prohibited for use in organic livestock production. This proposed rule to amend the chlorhexidine annotation would not alter the existing restriction on using chlorhexidine as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.

In October 1999, the NOSB originally recommended chlorhexidine for addition to the National List for medical procedures conducted under the supervision of a licensed veterinarian. Chlorhexidine was added to the National List that was published in the final rule establishing the NOP (The allowance for chlorhexidine has been renewed via the sunset process in 2007 (October 21, 2007 (72 FR 58469)) and 2012 (June 21, 2012 (77 FR 33290))).

The 2009 NOSB chlorhexidine recommendation¹³ would allow broader use of chlorhexidine for treating injuries and allow use before and after medical procedures to prevent bacterial infections and potentially avoid the need for antibiotics. The NOSB has determined that the use of chlorhexidine in organic livestock production in this manner meets the evaluation criteria for National List substances. In formulating its recommendation, the NOSB concluded that chlorhexidine is an important substance for treating livestock to cleanse infected areas that need medical attention. AMS has reviewed and proposes to address the NOSB recommendation through this proposed rule.

¹³ NOSB Final recommendation on chlorhexidine, see: <https://www.ams.usda.gov/sites/default/files/media/NOP%20Final%20Rec%20Chlorhexidine.pdf>

Therefore, AMS is proposing to amend the listing for chlorhexidine in § 205.603(a) to: Chlorhexidine—for medical procedures conducted under the supervision of a licensed veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.

Hypochlorous Acid

See discussion above under § 205.601 Synthetic substances allowed for use in organic crop production.

Kaolin Pectin

This proposed rule would add kaolin pectin to § 205.603(a) of the National List for use as an adsorbent, antidiarrheal, and gut protectant in organic livestock production.

Table 11 provides the proposed listing.

Table 11. Proposed rule action for kaolin pectin.

Current rule:	N/A
Proposed rule action:	§ 205.603(a) Kaolin Pectin, for use as an adsorbent, antidiarrheal, and gut protectant.

Applications

Kaolin pectin is a combination of kaolin clay and pectin. Kaolin clay is geologically formed and can be either a white, light yellow, light gray, or light brown powder composed of silica, alumina, and water. Kaolin is listed under 21 CFR 186.1256 as an indirect food substance affirmed as GRAS for human food and is used mostly as a gelling or thickening agent or stabilizer. Pectin is present in plant cell walls and consists of a polymer of galacturonic acid often disrupted by short branches of neutral sugars. Pectin is produced commercially as a white to light brown powder, produced mostly from hot dilute acid extraction of fruit juice production byproducts. Pectin is used in foods as

an emulsifier or as a stabilizer and is listed as GRAS under 21 CFR 184.1588 for human food. Pectin molecules vary in the degree of methoxylation, either high (above 50 percent) or low (less than 50 percent) where the degree of methoxylation determines the gelling properties of the pectin.

Timeline

This proposed rule would implement a September 2002 NOSB recommendation to add kaolin pectin to § 205.603 of the National List for use as an adsorbent, antidiarrheal, and gut protectant in organic livestock production. The NOSB indicated that kaolin pectin should not be used routinely as a preventive practice but only when organic practices fail to treat gastrointestinal irritants or diarrhea. The NOSB determined that synthetic forms of pectin were compatible with organic livestock production and could be used in formulations to produce kaolin pectin.

The NOSB has determined that the use of kaolin pectin in organic livestock production in this manner meets the requirements of the OFPA material evaluation criteria for organic production. AMS has reviewed and proposes to address the NOSB recommendation through this proposed rule. Therefore, AMS is proposing to add kaolin pectin to section § 205.603(a) with the following annotation: for use as an adsorbent, antidiarrheal, and gut protectant.

Mineral Oil

This proposed rule would add mineral oil to the National List for use in organic livestock production for relief of intestinal impaction. The NOSB recommended that this substance be included in paragraph (a) of § 205.603 as a medical treatment in livestock production. Table 12 provides the proposed listing.

Table 12. Proposed rule action for mineral oil.

Current rule:	N/A
Proposed rule action:	§ 205.603(a) Mineral oil, for relief of intestinal impaction, prohibited for use as a dust suppressant.

Applications

Mineral oil, also known as white oil, liquid paraffin, paraffinum liquidum, and liquid petroleum, is colorless, insoluble in water, and odorless. It is a complex mixture of straight and branched chain aromatic hydrocarbons, such as paraffinic, and naphthenic oils, and is derived mostly from petroleum distillate.

Applications for mineral oil include use as a lubricant (both mechanical and biological), in veterinary treatments, cosmetic products, pharmaceutical preparation (processing aids, intestinal lubricants), food preparation (release agents, binders, defoamers, protective coatings), and as an ingredient in animal feed products.

Mineral oil is permitted as described at 21 CFR 172.878 for direct addition to food for human consumption. When administered orally, mineral oil absorption from the intestine is limited¹⁴. Mineral oil is currently on the National List and is allowed in organic production for topical use and as a lubricant (§ 205.603(b)(6)). This proposed action does not affect this current allowance.

Timeline

This proposed rule would implement a September 2002 NOSB recommendation to add mineral oil to section § 205.603 of the National List for use in organic livestock production. During the September 2002 meeting, the NOSB considered allowing mineral oil to be used as a medical treatment for bloat (rumen-reticulum overdistention) and as a

¹⁴ Mineral Oil technical report: <https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned>.

medical treatment of omasal impaction.¹⁵ The NOSB indicated that ruminal bloat or omasal impaction would occur infrequently. The 2002 NOSB recommendation intended to allow mineral oil as an internal treatment for impaction.

The NOSB has determined that the use of mineral oil in organic livestock production for the proposed use meets the requirements of the OFPA material evaluation criteria for organic production. AMS has reviewed and proposes to address the NOSB recommendation through this proposed rule. Therefore, AMS is proposing to add mineral oil to § 205.603(a) with the following annotation: for treatment of intestinal impaction, prohibited for use as a dust suppressant.

Nutritive Supplements - Injectable Vitamins, Minerals, and Electrolytes

This proposed rule would also add injectable vitamins, minerals, and electrolytes to § 205.603(a) of the National List for use in organic livestock production. Currently, these substances are allowed to be provided only orally as feed additives (vitamins and minerals per § 205.603(d)) or medical treatments (electrolytes without antibiotics per § 205.603(a)). Table 13 illustrates the proposed listings.

Table 13. Proposed rule action for Nutritive supplements - injectable minerals, vitamins, and electrolytes.

Current rule:	N/A
Proposed rule action:	§ 205.603(a) Nutritive supplements - Injectable minerals, vitamins, and electrolytes - formulated injectable supplements of trace minerals per 205.603(d)(2), vitamins per 205.603(d)(3), and electrolytes per 205.603(a)(8), with excipients per 205.603(f), in accordance with FDA and restricted to use by or on the order of a licensed veterinarian.

¹⁵ The NOSB also considered allowing mineral oil as a dust suppressant in livestock feed, but deferred consideration of this use to a subsequent meeting and did not include this use in its final 2002 recommendation.

Application

Vitamins and trace minerals were added to the National List as feed additives, and electrolytes were added to the National List as a medical treatment when the NOP final rule became effective on October 21, 2002.¹⁶ Organic livestock producers are required to provide livestock with a total feed ration, including pasture and forage, that is sufficient to meet the nutritional requirements of the animal. To provide a total feed ration, livestock producers may use nonsynthetic feed additives, and synthetic feed additives included on the National List in § 205.603. As currently allowed under the regulations, vitamins, trace minerals, and electrolytes may be consumed only as part of the total feed ration. On occasion animals go off feed when their appetites are suppressed. If suppressed for an extended period, feeding a total ration with the required nutrients may not provide adequate amounts of vitamins, minerals, or electrolytes to alleviate any existing nutrient deficiencies. During its deliberation on their recommendation at the 2009 meeting, the NOSB received comments indicating that in livestock production it is common practice to provide off feed (low appetite) animals with injectable nutrients to help restore animal health. The NOSB concurred with this practice and argued in its justification that injectable formulations of vitamins and minerals (including electrolytes) can deliver increased amounts of these nutrients and can be used to quickly alleviate symptoms and reverse declines in livestock health resulting from nutrient deficiency.

This proposed rule would implement a 2009 NOSB recommendation to add formulated (i.e., multiple ingredient products) injectable vitamins, trace minerals, and

¹⁶ This final rule established the National Organic Program. It became effective on October 21, 2002. Sunset reviews for the listings for vitamins, minerals, and electrolytes were completed in 2007 (72 FR 58469, October 21, 2007) and 2012 (77 FR 33290, June 21, 2012).

electrolytes, with or without excipients, to the National List under § 205.603(a).¹⁷ The NOSB determined that an allowance for injectable vitamins, trace minerals, and electrolytes was necessary to rapidly deliver higher amounts of vitamins and minerals to targeted tissues in situations where an animal has higher vitamin and mineral demands. The NOSB also determined that use of these products would be occasional and as-needed. AMS is requesting comments on whether including electrolytes in the proposed listing for injectable vitamins and minerals is needed since electrolytes are currently listed as an allowed medical treatment in § 205.603(a)(8). AMS would interpret the proposed listing to mean that an operation would be allowed to use these substances individually or in combination.

Timeline

Both vitamins and trace minerals were included in § 205.603(d) in the USDA organic regulations (65 FR 13512, December 21, 2000), which became effective on October 21, 2002. Since this original listing, both vitamins and trace minerals were renewed under the 2007 and 2012 sunset review processes as recommended by the NOSB. These recommendations were accepted by the Secretary and processed through final rulemaking effective October 21, 2007 (72 FR 58469) and June 21, 2012 (77 FR 33290).

Electrolytes were included in § 205.603(a) in the original National List in the final rule (65 FR 13512, December 21, 2000), which became effective on October 21, 2002. Since this original listing, electrolytes have been renewed under the 2007 and 2012 sunset

¹⁷ NOSB Recommendation on injectable vitamins and minerals, see <https://www.ams.usda.gov/sites/default/files/media/Injectable%20Vitamins%20and%20Minerals%20Formal%20Rec.pdf>.

review process as recommended by the NOSB. These recommendations were accepted by the Secretary and processed through final rulemaking effective October 21, 2007 (72 FR 58469) and June 21, 2012 (77 FR 33290).

At its May 6, 2009, meeting, the NOSB issued a recommendation to the Secretary to add injectable vitamins, trace minerals and electrolytes to the National List. In formulating this recommendation, the NOSB determined that allowing injectable forms of these substances would provide organic livestock producers with the use of injectable vitamins, trace minerals, and electrolytes as nutritive supplements, on an as-needed basis.

This proposed rule would require that injectable vitamins, minerals or electrolytes only be administered or ordered by a licensed veterinarian. Livestock producers would need to keep records that document the need for any use of these materials. Further, producers and certifying agents would need to review the specific formulations intended for use on organic livestock to ensure they comply with the USDA organic regulations.

The NOSB stated in its recommendation that this allowance would provide organic producers with more opportunity to enhance the overall welfare of certified organic livestock. AMS has reviewed and proposes to address this NOSB recommendation through this proposed rule. AMS is proposing to add injectable vitamins, minerals and electrolytes to § 205.603(a) of the National List with the following annotation: formulated injectable supplements of trace minerals per 205.603(d)(2), vitamins per 205.603(d)(3), and electrolytes per 205.603(a)(8), with excipients per 205.603(f), in accordance with FDA and restricted to use by or on the order of a licensed veterinarian.

Parasiticides, Fenbendazole, and Moxidectin

This proposed rule would amend the National List to revise the listing for parasiticides (§ 205.603(a)(17)) and the listings for fenbendazole (§ 205.603(a)(17)(i)) and moxidectin (§ 205.603(a)(17)(iii)). This rule also proposes to amend the livestock health care practice standard in § 205.238(b) to allow the use of parasiticides in organic fiber-bearing animals. Table 14 illustrates the proposed listings.

Table 14. Proposed rule action for parasiticides.

<p>Current rule:</p>	<p>§ 205.603(a)(17) Parasiticides—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.</p> <p>§ 205.603(a)(17)(i) Fenbendazole (CAS #43210-67-9)—only for use by or on the lawful written order of a licensed veterinarian.</p> <p>§ 205.603(a)(17)(iii) Moxidectin (CAS #113507-06-5)—for control of internal parasites only.</p>
<p>Proposed rule action:</p>	<p>§ 205.603(a)(23) Parasiticides— Prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. 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. Allowed for fiber-bearing animals when used a minimum of 90 days prior to harvesting of fleece or wool that is to be sold, labeled, or represented as organic.</p> <p>§ 205.603(a)(23)(i) Fenbendazole (CAS #43210-67-9) Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep and other dairy species.</p> <p>§ 205.603(a)(17)(ii). Moxidectin (CAS #113507-06-5) Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep and other dairy species.</p>

The USDA organic regulations specify conditions under which parasiticides may be used in organic livestock production (§ 205.238(b)) and identify which parasiticides are allowed (§ 205.603(a)(17)). These conditions include: 1) emergency treatment for dairy and breeder stock only when preventive measures have failed; 2) a 90-day withdrawal period before milk or milk products from treated animals can be sold as organic; and 3) a prohibition on use in breeder stock during the last third of gestation or during lactation if progeny will be sold as organic. Organic livestock producers are required to use preventive practices as described in § 205.238 before using any parasiticide included on the National List. However, animals in need of medical attention cannot be left untreated in order to retain organic status (§ 205.238(c)(7)).

In April 2016, the NOSB considered amendments to the use restrictions for parasiticides allowed in organic production based on updated information. The NOSB recommended: 1) Removing the 90-day withholding time for milk and milk products and specifying withholding times in the listings for specific parasiticides; and 2) permitting fiber-bearing organic animals to be treated with allowed parasiticides, provided there is a 90-day interval from treatment to harvest of fleece or wool to be sold as organic.¹⁸ The NOSB recommended that the provision for the use of parasiticides in the livestock health care practice standard, § 205.238(b)(2), also be amended to reflect these changes.

The NOSB determined that these modifications would benefit sick animals in emergency situations without impacting the organic integrity of the products. Public comment received by the NOSB requested that the USDA organic regulations allow for animal skin and fleece treated with parasiticides to be sold as organic. The NOSB

¹⁸ The April 2016 NOSB recommendation is available here: <https://www.ams.usda.gov/sites/default/files/media/LS%20Parasiticides%20NOP.pdf>

determined that parasiticide use in fiber-bearing animals should be allowed in organic production if necessary.

In April 2016, the NOSB also considered modifications to the use restrictions for two allowed parasiticides, fenbendazole, and moxidectin. The USDA organic regulations permit the use of fenbendazole only when there is a written order of a licensed veterinarian. The NOSB recommended removing the requirement for the written order of a licensed veterinarian and reducing the 90-day withdrawal period for milk or milk products that will be sold as organic to 2 days for cattle and 36 days for goats, sheep and other dairy species.

The USDA organic regulations permit the use of moxidectin only to control internal parasites and require a 90-day withdrawal period for milk and milk products after use. The NOSB recommended removing that restriction and reducing the 90-day withdrawal time for milk or milk products that will be sold as organic to 2 days for cattle and 36 days for goats, sheep and other dairy species.

In addition, the NOSB recommended allowing the use of parasiticides in organic fiber-bearing animals.

At its April 25 – 27, 2016 meeting, the NOSB received public comment on the proposals to amend the allowances for parasiticides generally in addition to the allowances for fenbendazole and moxidectin. Based on updated technical reports on parasiticides and public comments, the NOSB recommended the above amendments to the use parameters for parasiticides in organic livestock production.¹⁹

¹⁹ The 2015 technical evaluation report on parasiticides is available here: <https://www.ams.usda.gov/sites/default/files/media/Para%20Technical%20Evaluation%20Report%20%282015%29.pdf>

AMS has reviewed and proposes to address these NOSB recommendations on parasiticides as a category, fenbendazole, and moxidectin through this proposed rule. Consistent with the NOSB recommendations, this proposed rule would amend § 205.238(b) and § 205.603(a)(17) as follows:

- § 205.238(b)(2) will be amended by replacing the 90-day withholding time for milk and milk products with a cross-reference to withholding times specified in § 205.603. In addition, the term “stock” will be replaced with “animal.”
- § 205.238(b) will be amended to add an allowance for parasiticide use in fiber-bearing animals.
- The 90-day withholding time described in § 205.603(a)(17) for milk and milk products following treatment with allowed parasiticides will be deleted.
- The listing for parasiticides in § 205.603(a)(17) will be amended to allow for use in fiber bearing animals with a 90-day withdrawal time from treatment to harvest of wool or fleece.
- The annotation for fenbendazole in § 205.603(a)(17)(i) will be amended to delete the requirement for use by or on the lawful written order of a licensed veterinarian, and modified withholding times for milk and milk products will be added.
- The annotation for moxidectin in § 205.603(a)(17)(iii) will be amended to delete the requirement for use by or on the lawful written order of a licensed veterinarian, and modified withholding times for milk and milk products will be added.

Ivermectin

This proposed rule would remove ivermectin from § 205.603(a) as an allowed parasiticide for use in organic livestock production. Table 15 illustrates the proposed listing.

Table 15. Proposed rule action for ivermectin.

Current rule:	§ 205.603(a)(17) (ii) Ivermectin (CAS #70288-86-7).
Proposed rule action:	Remove § 205.603(a)(17) (ii) Ivermectin (CAS #70288-86-7)

Ivermectin has been on the National List since October 21, 2002. On June 26, 2016, AMS received a petition to remove ivermectin²⁰ from the National List. The petition explained that ivermectin does not meet the OFPA criteria for the National List because: 1) the availability of two other synthetic parasiticides which are allowed in organic production as emergency treatment when preventive measures have failed; 2) environmental toxicity, more specifically, that ivermectin residues adversely affect soil organisms and dung beetles that support healthy pastures and rangelands. Further, the petition stated that the NOSB received new information during the 2017 sunset review of ivermectin indicating that this substance is not always effective.

At its November 16 – 18, 2016, meeting in St. Louis, Missouri, the NOSB reviewed the petition information, parasiticide technical report, and public comments. The NOSB recommended removing ivermectin from § 205.603(a) of the National List

AMS has reviewed and proposes to address this NOSB recommendation through this proposed rule. The removal of ivermectin would leave organic livestock producers with two parasiticides for emergency treatment, fenbendazole and moxidectin. Based on

²⁰ Access to Ivermectin petition: <https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned>.

public comments during the NOSB deliberations on parasiticides, AMS understands that there is support among organic livestock producers to remove ivermectin if AMS concurrently removes the requirement for a veterinarian’s order to administer fenbendazole. As discussed above, this action proposes to remove that requirement and to reduce the withdrawal times following the use of fenbendazole or moxidectin. Consistent with the NOSB recommendation, this proposed rule would amend § 205.603(a)(17) by removing Ivermectin (CAS #70288-86-7).

Propylene Glycol

This proposed rule would add propylene glycol to § 205.603(a) of the National List for use in organic livestock production. The NOSB originally recommended that this substance be included in paragraph (a) of § 205.603 as a medical treatment in livestock production. Table 16 provides the proposed listing.

Table 16. Proposed rule action for propylene glycol.

Current rule:	N/A
Proposed rule action:	§ 205.603(a). Propylene Glycol—only for treatment of ketosis in ruminants.

Applications

Propylene glycol is a viscous, colorless, nearly odorless, substance with a slightly sweet taste, and when mixed with water, it lowers the freezing point of water. Propylene glycol is chemically categorized as a diol (a compound containing two hydroxyl groups) and is miscible with many solvents, including water. It is stable substance under most conditions of use and storage, and it decomposes in water and soil within seven days.

Propylene glycol is noncorrosive, and has a low volatility and low toxicity level, although toxicity varies with animal species as cats show more toxic susceptibility to propylene glycol compared to other animals.

Propylene glycol can be manufactured from a variety of sources and procedures. Food-grade propylene glycol is produced from propylene oxide using either a non-catalytic high temperature process or a lower temperature catalytic process. Propylene glycol can also be manufactured from heating glycerol (biodiesel byproduct) with sodium hydroxide and distillation.

Propylene glycol is considered to be GRAS and is a direct food substance for human food listed at 21 CFR 184.1666. As a food additive, it is used as a humectant (moisture retention), solvent, and preservative. Propylene glycol is also used as a solvent in many pharmaceuticals in oral, topical, or injectable formulations, including those where the active ingredient is insoluble in water.

When present in surface water, propylene glycol can exert a high level of biochemical oxygen demand during degradation. This high demand could adversely affect aquatic species by consuming oxygen needed by aquatic organisms. Similarly, when microbial organisms decompose propylene glycol in surface water, significant amounts of dissolved oxygen are consumed. Low dissolved oxygen levels in surface water may reduce the amount of suitable aquatic habitat.

Timeline

This proposed rule would implement a September 2002 NOSB recommendation to add propylene glycol (CAS # 57-55-6) to section 205.603(a) of the National List. At this public meeting the NOSB determined that propylene glycol should be added to

§ 205.603(a) as a medical treatment in organic livestock production. Propylene glycol was petitioned to the NOSB for addition onto the National List as a medical treatment for ketosis (elevated blood ketones) in ruminants. Primary ketosis (or acetoanaemia) of dairy cows is a metabolic disorder. Ketosis or pregnancy toxemia has been observed in beef cows near parturition. The NOSB recommended restricting the use of propylene glycol to treatment of acute ketosis in ruminants.

During early lactation, the energy intake from feed may be insufficient to meet the energy output in milk, causing the animal to go into negative energy balance. To satisfy the nutrient requirements of milk production, dairy cows may draw on two sources of nutrients, food intake and body reserves. When in negative energy balance, the cow will metabolize fat reserves for energy, producing ketones. When ketone production exceeds ketone use by muscle and other animal tissue, ketosis can occur. Ketosis is an important clinical and sub-clinical disease, as several metabolic disorders and diseases that are common in the periparturient (near calving) and early lactation periods have been linked to ketosis, including milk fever, retained foetal membranes, and displaced abomasums.

The NOSB has determined that the proposed use of propylene glycol in organic livestock production fulfills the OFPA material evaluation criteria. AMS has reviewed and proposes to address the NOSB recommendation through this proposed rule. Therefore, AMS is proposing to add propylene glycol to § 205.603(a).

Sodium Chlorite, Acidified

This proposed rule would add two listings for acidified sodium chlorite for use as a teat dip in organic livestock (dairy) production (§ 205.603(a) and § 205.603(b)). In 2015, the NOSB recommended an allowance for this substance as a pre- and post-milking

teat dip treatment and cited supportive public comments from livestock producers and a lower environmental impact than other substances allowed for this use. Table 17 illustrates the proposed changes to this section.

Table 17. Proposed rule action for acidified sodium chlorite.

Current rule:	N/A
Proposed rule action:	§ 205.603(a) and § 205.603(b) Sodium Chlorite, Acidified—allowed for use on organic livestock as a teat dip treatment.

Applications

Acidified sodium chlorite is produced from mixing an aqueous solution of sodium chlorite with a food grade acid, such as citric acid. Acidified sodium chlorite can also be produced by mixing any FDA GRAS acid with an aqueous solution of sodium chlorite. The FDA has approved acidified sodium chlorite solutions as antimicrobial agents with proscribed sodium chlorite concentrations and pH values for several food product applications.

Acidified sodium chloride is commonly used during livestock production as a standard practice for teat dips in order to prevent mastitis in dairy livestock. Mastitis is the inflammation of udder tissue resulting from bacterial infection. Teat dips are substances used in dairy livestock to control mastitis and reduce contamination of mastitis causing bacteria.

Mastitis can be controlled by practices such as ensuring adequate nutrition, practicing good hygiene pre- and post-milking, and culling chronically mastitis-infected cows. Livestock producers can also use mastitis prevention practices to decrease the incidence of transmission, such as ensuring that cows have clean, dry bedding and carrying out routine sanitation of milking machines between milkings. A mastitis

prevention program usually includes applying a pre-milking and a post-milking teat dip. After milking, the teat canal may remain open for several minutes. A post-milking dip is used as a disinfectant and a barrier between the open teat and the bacteria in the air.

Timeline

This proposed rule would implement an April 2015 NOSB recommendation to add acidified sodium chlorite to sections 205.603(a) and (b) of the National List²¹ for use as a pre- and post-milking teat dip treatment. The NOSB received a petition²² in April 2012 to add acidified sodium chlorite to section 205.603(a) and (b) for use as a teat dip in organic livestock production. At its April 2014 meeting, the NOSB tabled a recommendation not to approve acidified sodium chlorite for use as a teat dip because several substances on the National List were already approved as teat dips. One factor in delaying a recommendation was a lack of public comments from organic livestock producers supporting a need for acidified sodium chlorite for this use.

During the April 2015 public meeting, the NOSB reviewed the 2013 technical report²³ on acidified sodium chlorite that included an assessment on the effectiveness of acidified sodium chlorite as a teat dip indicating that it may be as effective as iodine solution teat dips. The NOSB considered information indicating that alternative practices to teat dipping or udder washing did not prevent mastitis, and may actually increase udder infection. The NOSB also received comments from livestock producers supporting

²¹ Acidified sodium chlorite was originally recommended for addition onto the National List as a microbial control substance for organic handling at the NOSB's May 2009 meeting. On March 15, 2012, acidified sodium chlorite was added onto the National List in § 205.605(b) when final rule 77 FR 8089, published on February 14, 2012, became effective.

²² Petition for acidified sodium chlorite, see <https://www.ams.usda.gov/sites/default/files/media/S%20Chlorite%20Acidified.pdf>.

²³ Technical report on acidified sodium chlorite, see <https://www.ams.usda.gov/sites/default/files/media/S%20Chlorite%20A2%20report.pdf>.

the use of acidified sodium chlorite as a teat dip in organic livestock production. Further, the NOSB determined that acidified sodium chlorite has comparatively lower environmental impacts than other teat dip substances that are currently on the National List. In its recommendation, the NOSB stated that preventive health care is an essential component of organic production and that clean animals and clean milking parlors are paramount for dairy livestock production. Therefore, the NOSB determined that acidified sodium chlorite for pre- and post-milking teat dipping is an important tool in preventing mastitis.

In summary, based on alignment with OFPA evaluation criteria for National List substances, supportive comments from livestock producers on the need for acidified sodium chlorite, and information regarding low environmental impacts, the NOSB recommended allowing acidified sodium chlorite for use as a teat dip. AMS has reviewed and proposes to address the NOSB recommendation through this proposed rule. Therefore, AMS is proposing to add acidified sodium chlorite to sections 205.603(a) and (b) of the National List with the following annotation: allowed for use on organic livestock as a pre and post teat dip treatment.

Xylazine

This proposed rule would amend the current listing for xylazine in § 205.603(a) by removing the limitation on use of this substances to “*The existence of an emergency.*” Xylazine is used by veterinarians as a means for sedation of animals in both emergency and non-emergency procedures. Therefore, the NOSB recommended omitting the emergency condition restriction because it is overly restrictive for a substance that meets all OFPA evaluation criteria for National List substances. This proposed rule would not

affect the provisions for the use of xylazine in the USDA organic regulations that require the written order of a licensed veterinarian and withdrawal periods for slaughter stock and dairy animals. Table 18 illustrates the proposed changes to this section.

Table 18. Proposed rule action for xylazine.

Current rule:	<p>§ 205.603(a)(23) Xylazine—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:</p> <ul style="list-style-type: none"> (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.
Proposed rule action:	<p>§ 205.603(a) Xylazine—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:</p> <ul style="list-style-type: none"> (i) Use by or on the lawful written order of a licensed veterinarian; (ii) 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.

Applications

Xylazine is synthesized by reacting 2,6-dimethylphenylisothiocyanate with 3-amino-1-propanol in a polar solvent (ether) to form a thiourea. Concentrated hydrochloric acid is added after the solvent is removed. Water is added to the cooled mixture which is then filtered, and the filtrate is made basic to form a precipitate that is recrystallized as xylazine.

Xylazine is used as a sedative, analgesic, and muscle relaxant in veterinary medicine. As a medical treatment, it can be administered intravenously, intramuscularly, subcutaneously, or orally, usually as a water based injectable solution. Xylazine can also

be found as a white crystalline powder. Xylazine sedative properties are due to its depressant mode of action on nervous system synaptic receptors. Sedation of animals is necessary for both planned medical procedures and emergency procedures to prevent the pain and suffering of animals as well as injury to the veterinarians performing the procedures.

Timeline

This proposed rule would implement a November 2009 NOSB recommendation to amend the allowance for xylazine as listed in § 205.603(a) of the National List.²⁴ At this meeting, the NOSB determined that the restriction limiting xylazine only to emergency use should be lifted to allow use for sedation of animals when necessary to perform non-emergency health care procedures in organic livestock. The NOSB determined that the proposed change in the xylazine annotation would allow organic livestock producers to improve their ability to establish and maintain preventive livestock health care practices since there are no alternatives to xylazine on the National List or nonsynthetic substances that provide sedative properties.

The NOSB recommended adding xylazine to the National List in September 2002. Xylazine was petitioned for use as a sedative and analgesic during short surgical procedures. Xylazine was added to the National List in 2007, with the use conditions stated in Table 6.²⁵ The allowance for xylazine was renewed via sunset review in 2012 (77 FR 33290, June 6, 2012).

²⁴ 2009 NOSB Final Recommendation on xylazine, see <https://www.ams.usda.gov/sites/default/files/media/NOP%20Final%20Rec%20Xylazine%20Technical%20Correction.pdf>.

²⁵ 2002 Technical Advisory Report on xylazine, see <https://www.ams.usda.gov/sites/default/files/media/Xylazine%20TR.pdf>.

During its initial xylazine deliberation, the NOSB considered limiting xylazine use to “once in a lifetime” applications. The NOSB’s decision to recommend an allowance upon “the existence of an emergency” was the result of a compromise between two objectives, avoiding significant interference with a veterinarian’s judgment and preventing routine use of xylazine. The NOSB described an emergency as an unplanned event requiring immediate medical attention. During its 2009 deliberation, the NOSB received information indicating that xylazine is used more frequently as a sedative for non-emergencies and less often for actual emergencies.

The NOSB has determined that the use of xylazine in organic livestock production for non-emergency medical procedures meets the requirements of the OFPA evaluation criteria for National List substances. AMS has reviewed and proposes to address the NOSB recommendation through this proposed rule. Therefore, AMS is proposing to amend the current listing of xylazine in § 205.603 with the following annotation: 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 8 days after administering to livestock intended for slaughter; and a milk discard period of at least four days after administering to dairy animals.

Zinc Sulfate

This proposed rule would add zinc sulfate to the National List for use in organic livestock production. Table 19 illustrates the changes between the current rule and the proposed rule.

Table 19. Proposed rule action for zinc sulfate.

Current rule:	N/A
Proposed rule action:	§ 205.603(a). Zinc Sulfate— for use in hoof and foot treatments only.

Applications

Zinc sulfate is a white, odorless powder that is soluble in water and alcohol (nonhydrates). The hydrates of zinc sulfate are the primary forms used for commercial applications. Agricultural applications of zinc sulfate include as a zinc supplement in animal feeds since zinc is an essential element in several biological processes. It is also used in fertilizers and agricultural sprays (mold or bacterial inhibitors).

Zinc sulfate is manufactured from mined zinc ore that is crushed and ground. The ground ore is heated to produce a zinc ash that is subsequently mixed with sulfuric acid. The zinc dissolves in the sulfuric acid to yield a zinc sulfate solution that is further processed to yield a zinc sulfate powder.

The 2015 zinc sulfate technical report²⁶ developed for the NOSB states that zinc sulfate can stimulate an immune response to microbes that may cause foot rot to develop. The technical report also indicates that elevated zinc levels are toxic to some bacteria. Research cited in the technical report indicates that zinc sulfate, used alone or in combination with excipients, is effective in controlling foot rot. Zinc sulfate is not

²⁶ <https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned>.

currently FDA approved as a treatment for controlling foot rot or digital dermatitis as described in the zinc sulfate petition submitted to the NOSB²⁷.

Zinc sulfate is allowed as a GRAS food additive for human food under FDA regulation 21 CFR 182.8997. Under the USDA organic regulations, zinc sulfate is on the National List as a synthetic trace mineral in organic livestock feed under § 205.603(d)(2).

As proposed, zinc sulfate would be used in a footbath for control of foot rot in livestock, primarily dairy cattle, sheep and goats. Foot rot, as the name indicates, is a disease that rots away the foot of the animal, specifically the area between the two toes of the affected animal. Foot rot is an infection of anaerobic bacteria that are common in the environments where cattle, sheep, and goats live. Temperature and moisture are factors in the transmission and invasion of these bacteria. More foot rot infections are likely with above average rainfall, elevated temperatures, and lush pasture growth. Infection may occur directly from the soil to the animals, usually through a lesion in the skin. If left untreated, foot rot can cause lameness in sheep, goats, and cattle and an infected animal can infect a whole herd.

Once foot rot is detected, the animal is usually isolated from the herd and treated with antibiotics, or antibacterial treatments such as iodine or zinc sulfate. Foot-bathing solutions with ethanol, copper sulfate, formalin, or zinc sulfate are used when a large number of animals requires treatment. Ethanol, copper sulfate, and iodine are on the National List in § 205.603, each with varying degrees of efficacy (therapeutic effect).

Timeline

²⁷ <https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned>.

This proposed rule would implement an April 2015 NOSB recommendation to add zinc sulfate (CAS # 7733-02-0) to § 205.603 of the National List. At its public meeting, the NOSB determined that zinc sulfate should be allowed as a medical treatment (§ 205.603(a)) and as a topical treatment, local parasiticide, or local anesthetic (§ 205.603(b)) in organic livestock production, specifically for use in hoof and foot treatments only. As proposed, zinc sulfate would be used in a footbath for control of foot rot in livestock, primarily dairy cattle, sheep and goats.

In its recommendation, the NOSB indicated that copper sulfate and zinc sulfate are the two most accepted foot rot treatments, with similar efficacy. The NOSB considered that there are alternatives to zinc sulfate for foot rot treatment, but noted concerns about the efficacy of other materials and that some are not permitted for use in organic livestock. The NOSB determined that zinc sulfate provides organic livestock producers with an additional tool to treat foot disease, aids the welfare of the animals, and is preferable to the use of copper sulfate because of the buildup of potentially toxic persistent copper in the soil. The NOSB also noted that zinc has the potential to accumulate in soils, but persistence depends on several factors, and excess zinc can be reduced in soil by planting crops such as sunflower or canola.

At its April 2015 public meeting, the NOSB voted to expand the allowed use of zinc sulfate as a treatment for foot disease in livestock for the purpose of ensuring the welfare of animals. The NOSB determined that the availability of zinc sulfate as a foot treatment would reduce the use of copper sulfate for treatment of foot disease, which may contribute to lower copper build up in soils. The NOSB considers zinc sulfate to be a more benign substance when compared to copper sulfate. The NOSB has determined that

the use of zinc sulfate in organic livestock production as a foot treatment meets the requirements of the OFPA material evaluation criteria for organic production.

In formulating its recommendation, the NOSB determined that use of zinc sulfate in organic livestock production promotes animal welfare and is preferable to the use of copper sulfate.

AMS has reviewed and proposes to address the NOSB recommendation through this proposed rule. Therefore, AMS is proposing to add zinc sulfate to § 205.603(a) with the following annotation: for use in hoof and foot treatments only.

Lidocaine and Procaine

This proposed rule would amend the current listing of lidocaine in § 205.603(b), Synthetic substances allowed for use in organic livestock production. Table 20 illustrates the proposed listing.

Table 20. Proposed rule action for lidocaine and procaine.

<p>Current rule:</p>	<p>§ 205.603(b)(4) 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.</p> <p>§ 205.603(b)(7) 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.</p>
<p>Proposed rule action:</p>	<p>§ 205.603(b)(4) Lidocaine— as a local anesthetic. Use requires a withdrawal period of 8 days after administering to livestock intended for slaughter and 6 days after administering to dairy animals.</p> <p>§ 205.603(b)(7) Procaine— as a local anesthetic. Use requires a withdrawal period of 8 days after administering to livestock intended for slaughter and 6 days after administering to dairy animals.</p>

This proposed rule would amend the allowances for lidocaine and procaine in § 205.603(b).

Lidocaine²⁸ and procaine²⁹ have been on the National List since October, 2002, as local anesthetics to reduce pain after de-budding horns or minor livestock surgery.³⁰ The allowance requires withholding periods for livestock treated with either substance: 90 days for livestock intended for slaughter and 7 days for dairy animals.

Based on new information and public comments received during the 2015 sunset review, the NOSB determined that the withholding times should be reduced. The NOSB explained that lengthy withholding times could result in animals not being timely treated, or not treated at all. The NOSB also noted that in 2007 it agreed that withholding times should be double the U.S. Food and Drug Administration (FDA) withholding times.³¹ For lidocaine, FDA recommended withdrawal intervals for cattle are 1 day for meat and 24 hours for milk following an epidural administration, or 4 days for meat and 72 hours for milk following subcutaneous administration. FDA provides information on procaine only as it relates to procaine with an antibiotic as part of delivery and thus it would not be used in organic production. The NOSB determined that withholding periods following the use of lidocaine or procaine should be revised from 90 days to 8 days for slaughter stock and from 7 days to 6 days for dairy animals.

During a public meeting on October 26-29, 2015, the NOSB reviewed public comments on the proposal to amend lidocaine and procaine on the National List.³² Based on new information received in technical reports and public comments, the NOSB

²⁸ <https://www.ams.usda.gov/rules-regulations/organic/national-list/>

²⁹ <https://www.ams.usda.gov/rules-regulations/organic/national-list/p>

³⁰ https://www.ams.usda.gov/sites/default/files/media/LS%20Lidocaine_Procaine%20NOP.pdf

³¹ https://www.ams.usda.gov/sites/default/files/media/LS%20Lidocaine_Procaine%20NOP.pdf

³² <https://www.ams.usda.gov/rules-regulations/organic/nosb/recommendations/fall2015>

determined that reducing the withdrawal times for lidocaine and procaine supports animal health and is consistent with prior NOSB decisions regarding withdrawal times.

AMS has reviewed and proposes to address the NOSB recommendation on lidocaine and procaine through this proposed rule. Consistent with the NOSB recommendation, AMS proposes to amend section 205.603(b) of the National List to reduce the withholding periods for lidocaine and procaine from 90 days to 8 days for slaughter stock and from 7 days to 6 days for milk.

Methionine

This proposed rule would amend the allowance for methionine in § 205.603(d) by requiring that maximum methionine levels in feed be calculated as averages over the lifespan of the birds rather than a constant percentage of the feed. The NOSB considered reports of methionine deficiency in some organic poultry flocks. Alternatives to synthetic methionine have yet to be developed for commercial use. In consideration of public comments, NOSB input, and technical reports, AMS proposes to continue to allow methionine in restricted amounts. The proposed amendment to the methionine annotation includes limits on the amount that may be used over the life of the flock, as well as breed-specific limits. Table 21 illustrates the changes proposed change for this substance.

Table 21. Proposed rule action for methionine.

Current rule:	§ 205.603(d)(1) DL- Methionine, DL- Methionine - hydroxy analog, and DL- Methionine - hydroxy analog calcium (CAS Numbers 59-51-8, 583-91-5, 4857-44-7, and 922-50-9) —for use only in organic poultry production at the following maximum levels of synthetic methionine per ton of feed: Laying and broiler chickens—2 pounds; turkeys and all other poultry—3 pounds.
Proposed rule action:	§ 205.603(d) DL- Methionine, DL- Methionine - hydroxy analog, and DL- Methionine - hydroxy analog calcium (CAS Numbers 59-51-8, 583-91-5, 4857-44-7, and 922-50-9) —for use only in organic poultry production at the following pounds of synthetic 100 percent methionine per ton of feed in the diet, averaged over the life of the

	flock: Laying chickens—2 pounds; Broiler chickens—2.5 pounds; Turkeys and all other poultry—3 pounds.
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Applications

Methionine is a sulfur containing amino acid that is a white solid or white crystalline powder, or may be in liquid form when produced as a hydroxyl analog. The 2011 methionine technical report developed for the NOSB states that methionine is soluble in water, methanol, alkali solutions, and mineral acids. Methionine is stable under normal temperature and pressure but is susceptible to strong oxidizing agents. Methionine can be produced or extracted from nonsynthetic sources or manufactured through a synthetic process. Nonsynthetic methionine is produced from microbial fermentation and extraction or by hydrolyzing protein. Amino acids can also be produced by bacterial fermentation. However, the technical report prepared for the NOSB in 2011 states that methionine yields from bacterial fermentation are low and not cost effective. According to a 2011 petition submitted to AMS, the most economical chemical method involves combining reagents acrolein, methyl mercaptan, hydrogen cyanide, and ammonia carbonate to yield an intermediary substance that is saponified with potassium carbonate, which results in high yields of methionine.

Methionine can be provided either as part of an intact protein or as an amino acid that is added to a poultry diet. As a single ingredient animal feed supplement, it is regulated by the Food and Drug Administration (21 CFR 582.5475). In the 2011 technical report, methionine is described as the first limiting amino acid for the synthesis of protein in poultry. It is considered to be an essential amino acid for poultry production because it is required for cell tissue growth and metabolism, but it cannot be synthesized by poultry and must be supplied in the diet.

To meet requirements for cell growth and function, poultry must obtain adequate methionine from agricultural feed ingredients or receive methionine to the ration through supplementation (addition). In the 2011 NOSB methionine technical report, poultry rations composed of corn and soybean meal may not provide adequate non-synthetic methionine to prevent deficiency symptoms.

To compensate for low methionine content in corn–soybean meal diets, poultry producers may use various production practices to meet methionine requirements. Such production practices include increasing intake of the existing diet (ration); increasing the protein content of a ration by either increasing soybean meal content or by adding other protein feed ingredients that contain higher concentrations of methionine; or by adding synthetic methionine to the ration. Each of these practices presents challenges in ensuring that sufficient methionine is available to meet requirements for the various stages of poultry production.

Young birds, especially those less than three weeks in age, may be physically unable to ingest the additional ration needed to meet minimum methionine levels required at that production stage. These few weeks can represent a significant portion of the production cycle where bird growth may be restricted, resulting in lower production or even increased bird death. When implemented, this practice may not provide adequate methionine to the birds during the early phase of the production cycle. For example, young broilers physically that are unable to increase feed intake for the initial three weeks out of seven weeks of production may not obtain adequate methionine during their production cycle and will have less growth. This practice may also result in reduced feed efficiency and an increase in feed costs. Conversely, increasing feed intake to meet

methionine needs could also result in overfeeding of other nutrients and lead to subsequent livestock health problems.

An alternative to increasing feed intake is to increase the protein content of the diet by adding more soybean meal to the corn–soybean meal ration. Since animals consume feed to meet their energy requirements, adding additional protein may be more effective in meeting poultry methionine requirements when compared to only increasing feed intake. However, increasing protein content in a feed may result in excessive amino acids—the amino acids remaining after methionine is no longer available for protein synthesis—to be used in energy metabolism. When used as an energy source, amino acids are deaminated and the resulting nitrogen is excreted as uric acid. Continued feeding of a higher protein, low methionine ration may result in excessive nitrogen being excreted as uric acid and, subsequently, higher ammonia levels within the bird house.

Increasing methionine content in the diet can be achieved through the use of alternative protein feed sources that can be added to the standard soybean–corn poultry diet. Protein feed sources known to have a high methionine content include blood meal, meat meal, fish meal, crab meal, and corn gluten meal. Organic producers, however, have limited options to use these because of: (1) a lack of commercially available nonsynthetic or organic sources of methionine, such as organic corn gluten meal, and (2) the prohibition on feeding slaughter by-products derived from mammalian or avian sources (§ 205.237(b)(5)), which prohibits feeding blood meal or meat meal to organic poultry. Further, the use of fish meal and crab meal in poultry diets may be limited by the potential for off flavors in the poultry products, especially eggs. For this and other

reasons, organic producers have petitioned the NOSB to allow the use synthetic sources of methionine for supplementation.

The NOSB has acknowledged that certain production practices support the need for synthetic methionine supplementation, but stated that methionine obtained from outdoor access or pasturing alone may not be adequate to offset the need for methionine supplementation. The NOSB also considered that the breed of bird can affect methionine needs.

Timeline

This proposed rule would implement an April 2015 NOSB recommendation to amend the allowance for methionine as listed in § 205.603(d)(1) of the National List.³³ At this meeting, the NOSB determined that the annotation should be amended to allow organic poultry producers to adjust the concentration of synthetic methionine in poultry feed rations to meet the nutritional requirements of the birds at different life stages, while simultaneously limiting the total amount of synthetic methionine used in a poultry ration that is fed during the lifetime of the flock. Table 21 shows the comparison of the current and proposed allowances for synthetic methionine. At this meeting the NOSB considered information that the current restriction on methionine could result in methionine deficiency in poultry flocks. In its recommendation, the NOSB noted that a methionine deficiency may suppress immune system development and cause poor feathering, feather pecking, cannibalism, and increased bird death.

The NOSB also received comments from poultry producers indicating that the use of synthetic methionine is necessary because alternatives to synthetic methionine are not

³³ <https://www.ams.usda.gov/sites/default/files/media/LS%20MET%20Final%20Rec.pdf>

commercially available or are prohibited by § 205.237(b)(5), which states that the producer of an organic operation must not feed mammalian or poultry slaughter by-products to organic mammalian livestock or poultry.

In 2001, the NOSB recommended adding methionine to the National List as a feed supplement for use in organic poultry production. Methionine was added to § 205.603 of the National List on October 31, 2003, with the annotation “for use in organic poultry production until October 21, 2005 (68 FR 61987).” When the NOSB approved its 2001 recommendation to allow methionine, an expiration date was inserted into the annotation to indicate that synthetic methionine would be phased out when non-synthetic alternatives to synthetic methionine were developed and were commercially available. Based on multiple NOSB recommendations, AMS has amended section 205.603 of the National List to allow methionine as a synthetic substance for use in organic poultry production several times. A full description of the NOSB recommendations and rulemaking related to synthetic methionine for organic poultry through 2012 is available in a Final Rule, September 19, 2012 (77 FR 57985).

Between 2010 and 2012, AMS completed two rules that revised the allowance for synthetic methionine by specifying maximum levels as recommended by the NOSB.³⁴ The NOSB conveyed that the intent of this recommendation was to balance various interests including: (1) providing for the basic maintenance requirements of organic poultry; (2) satisfying consumer preference to reduce the use of synthetic methionine in organic poultry production; and (3) motivating the organic poultry industry to continue

³⁴ A detailed discussion of this part of the NOSB recommendation is available in the proposed rule that was published in the Federal Register on February 6, 2012 (77 FR 5717).

the pursuit of commercially sufficient sources of allowable natural sources of methionine.

The two-part April 2010 NOSB recommendation specified:

- Allow synthetic methionine in organic poultry production until October 1, 2012, at the following maximum levels per ton of feed: laying chickens—4 pounds; broiler chickens—5 pounds; and turkey and all other poultry—6 pounds. This recommendation was implemented through a final rule published on March 14, 2011 (76 FR 13501).
- After October 1, 2012, reduce the maximum levels of synthetic methionine allowed in organic poultry feed to: laying and broiler chickens—2 pounds; turkeys and all other poultry—3 pounds. This recommendation was implemented through a final rule published on September 19, 2012 (77 FR 57985).

In 2011, a group of organic poultry producers resubmitted a petition to revise the maximum rates of synthetic methionine as averages per ton of feed over the life of the bird, rather than as a maximum quantity (pounds) per ton of feed.

At the April 2015 meeting, the NOSB considered how the current restriction on methionine, a constant maximum per ton of feed, was impacting organic poultry and described this in its recommendation. The recommendation explained that organic poultry producers have been feeding additional levels of protein to provide sufficient methionine because the maximum allowance is inadequate for certain growth stages. The excess amino acids from the protein are excreted in urine, which causes ammonia levels to rise indoors during winter. The elevated ammonia levels may cause blisters on birds' feet. The recommendation noted reports from producers of increased feather pecking,

which is a symptom of a methionine deficiency. Feather pecking may lead to cannibalism, agitation, nervousness, and other harmful behaviors.

The NOSB reasoned that providing flexibility for producers to adjust methionine supplementation based on the nutritional needs of the birds at specific stages of production could have positive impacts on animal welfare. In effect, the NOSB predicted that overall methionine rates could be lower as supplementation levels would be matched with an average rate and not added at a maximum rate. Further, the NOSB explained that maintaining limitations on the use of synthetic methionine would preserve the incentive to develop viable nonsynthetic alternatives.

Therefore, AMS is proposing to amend the current listing of methionine in § 205.603 with the following annotation: DL- Methionine, DL- Methionine - hydroxy analog, and DL- Methionine - hydroxy analog calcium (CAS Numbers 59-51-8, 583-91-5, 4857-44-7, and 922-50-9) - for use only in organic poultry production at the following pounds of synthetic 100 percent methionine per ton of feed in the diet, averaged over the life of the flock: Laying chickens - 2 pounds; Broiler chickens - 2.5 pounds; Turkeys and all other poultry - 3 pounds.

Excipients

This proposed rule would further clarify the allowance for excipients in animal drugs to treat organic livestock by adding a provision that the excipient must be approved by the USDA Animal and Plant Health Inspection Service (APHIS) for use in veterinary biologics. The proposed amendment, based on a 2009 NOSB recommendation, would minimize the variation in certifying agents' interpretation of excipients and ensure

consistent enforcement. Table 22 illustrates the changes between the current and proposed rule.

Table 22. Proposed rule action for excipients.

Current rule:	§ 205.603(f) 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.
Proposed rule action:	§ 205.603(f) Excipients—only for use in the manufacture of drugs and biologics used to treat organic livestock when the excipient is: (1) Identified by the FDA as Generally Recognized As Safe; (2) Approved by the FDA as a food additive; (3) Included in the FDA review and approval of a New Animal Drug Application or New Drug Application; or (4) Approved by APHIS for use in veterinary biologics.

Applications

Under the USDA organic regulations, excipients are defined at § 205.2 as “any ingredients that are intentionally added to livestock medications but do not exert therapeutic or diagnostic effects at the intended dosage, although they may act to improve product delivery (e.g., enhancing absorption or controlling release of the drug substance). Examples of such ingredients include fillers, extenders, diluents, wetting agents, solvents, emulsifiers, preservatives, flavors, absorption enhancers, sustained-release matrices, and coloring agents.”

Most animal medications are regulated under the Federal Food Drug and Cosmetic Act, as implemented by FDA. Biologics (e.g., vaccines, bacterins, antisera, diagnostic kits and other products of biological origin) are regulated by APHIS under the Virus-Serum-Toxin Act (21 U.S.C. 151-159).

Timeline

This proposed rule would implement a recommendation approved by the NOSB at its November 5, 2009 meeting to amend the allowance for excipients as listed in § 205.603(f) of the National List.³⁵ At its November 2009 meeting, the NOSB determined that the annotation required amending to clarify the use of excipients in formulated livestock products and to minimize variation in certifying agent interpretation of excipient use.

The allowance for excipients was added to the National List on December 12, 2007 (72 FR 70479). The NOSB renewed excipients under the 2012 Sunset review process (77 FR 33290, June 6, 2012). This listing specified criteria for excipients for use in organic livestock production. These criteria pertained to the regulatory status of the substances under FDA authority, but the existing listing for excipients does not include an allowance for excipients approved by APHIS for use in veterinary biologics.

Based on the consideration of National List petitions to allow the use of certain active ingredients in animal drugs, the NOSB observed that verifying the compliance status of excipients in therapeutic and diagnostic products and other formulated livestock products is burdensome and unclear for organic farmers and certifying agents. For example, federal regulations do not require excipients used in therapeutic and diagnostic products to appear on product ingredient labels. In addition, the identity of excipients may not be disclosed when product formulations are held as confidential business information.

³⁵ NOSB Technical Report on excipients, see <https://www.ams.usda.gov/sites/default/files/media/NOP%20Final%20Rec%20Excipients%20Technical%20Correction.pdf>.

Therefore, AMS is proposing to amend the current listing of excipients in § 205.603 with the following annotation: only for use in the manufacture of drugs and biologics used to treat organic livestock when the excipient is: (1) Identified by the FDA as Generally Recognized As Safe; (2) Approved by the FDA as a food additive; (3) Included in the FDA review and approval of a New Animal Drug Application or New Drug Application; or (4) Approved by APHIS for use in veterinary biologics.

§ 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 proposed rule would add the following substances to the National List in paragraph § 205.605 for use in organic handling: hypochlorous acid, potassium lactate, and sodium lactate. This proposed rule would also amend the allowances for the following substances currently allowed in organic handling: alginic acid, flavors, carnauba wax (§ 205.605(a)), and cellulose and chlorine (§ 205.605(b)). In addition, this proposed rule removes glycerin from § 205.605(b) and adds it to § 205.606 as an agricultural product.

Alginic acid

The proposed rule would amend the National List to reclassify alginic acid from a non-synthetic substance included in § 205.605(a) to a synthetic substance listed included in § 205.605(b), for use in organic handling. Table 23 illustrates the proposed listing.

Table 23. Proposed rule action for alginic acid.

Current rule:	§ 205.605(a) <i>Nonsynthetics allowed:</i> Acids (Alginic; Citric—produced by microbial fermentation of carbohydrate substances; and Lactic).
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Proposed rule action:	Remove alginic acid from § 205.605(a) and reinsert alginic acid under § 205.605(b) <i>synthetics allowed</i>
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Alginic acid is allowed as a nonorganic ingredient in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).” During the 2017 sunset review, the NOSB considered new information in an updated technical report³⁶ on alginic acid. This technical report described how alginic acid is extracted from brown seaweed using alkali treatment and acid precipitation. To isolate alginic acid from its salt forms, several pH adjustments are made during the extraction.

Based upon guidance document NOP 5033, Classification of Materials,³⁷ and the definition of “synthetic” in § 205.2 of the USDA organic regulations, the NOSB determined that alginic acid should be reclassified as synthetic because of the pH adjustments used to extract alginic acid. In conjunction with a recommendation to renew alginic acid for the 2017 sunset review, the NOSB also forwarded a separate recommendation to reclassify alginic acid as a synthetic substance on the National List.³⁸

At its October 26 – 29, 2015, public meeting, the NOSB received public comment and reviewed information in an updated technical report. In order to be consistent with NOP 5033, the NOSB recommended reclassifying alginic acid from a non-synthetic substance under § 205.605(a) to a synthetic substance under § 205.605(b). AMS has reviewed and proposes to address this NOSB recommendation through this proposed rule. Consistent with the NOSB recommendation, this proposed rule would amend §

³⁶ Petitioned substance database: <https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned>. See alginic acid, under the “A” sublink.

³⁷ NOP 5033, Classification of Materials: https://www.ams.usda.gov/sites/default/files/media/Program%20Handbk_TOC.pdf.

³⁸ The NOSB recommendation to reclassify alginic acid is available here: https://www.ams.usda.gov/sites/default/files/media/HS%20Reclassification%20Alginic%20Acid_final%20rec.pdf

205.605 by removing alginic acid from § 205.605(a) and inserting alginic acid in § 205.605(b).

Flavors

The proposed rule would amend the National List to revise the annotation of flavors in § 205.605(a), nonsynthetic, nonagricultural substances allowed in organic handling. Table 24 illustrates the proposed listing.

Table 24. Proposed rule action for flavors.

Current rule:	§ 205.605(a) Flavors, nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.
Proposed rule action:	§ 205.605(a) Flavors, non-synthetic flavors may be used when organic flavors are not commercially available. All flavors must be derived from organic or nonsynthetic sources only, and must not be produced using synthetic solvents and carrier systems or any artificial preservative.

On November 6, 2014, AMS received a petition to change the allowance for nonorganic flavors to require the use of organic flavors when they are commercially available.^{39 40} Flavors are allowed in organic products if they are derived from nonsynthetic sources and are not produced using synthetic solvents and carrier systems or any artificial preservative (§ 205.605(a)). Flavors have been on the National List since October 2002. The allowance for flavors is a broad category that includes many substances derived from different methods.

At its October 26–29, 2015, public meeting, the NOSB received public comment on the proposal to require organic flavors when commercially available. During its

³⁹ The petition for flavors is available here:

<https://www.ams.usda.gov/sites/default/files/media/Flavors%20nonsynthetic%201%20Petition.pdf>

⁴⁰ The USDA organic regulations define “commercial availability” as: “The ability to obtain a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling, as determined the certifying agent in the course of reviewing the organic plan.” (§ 205.2 Terms Defined).

petition review the NOSB determined that organic flavors have become more available, but acknowledged the continued need for nonorganic forms in organic handling because of limited organic availability across the category. Due to the number of distinctly different natural flavors and the pace of new product development in flavors, the NOSB determined it would be impractical to list individual flavors on the National List to indicate which are commercially available in organic form. Based on the petition and public comments, the NOSB recommended revising the allowance for flavors to require the use of organic flavors when commercially available.

The NOSB recommended retaining the existing requirements that all flavors must be derived from organic or nonsynthetic sources only, and must not be produced using synthetic solvents and carrier systems, or any artificial preservative. In addition, the NOSB recommended a revision to convey that the listing for flavors applies to products in the “organic” and “made with organic (specified ingredients or food group(s))” categories.

AMS has reviewed and proposes to address this NOSB recommendation through this proposed rule. Consistent with the NOSB recommendation, this proposed rule would amend § 205.605(a) by revising the listing of flavors to read: flavors, non-synthetic flavors may be used when organic flavors are not commercially available. All flavors must be derived from organic or non-synthetic sources only, and must not be produced using synthetic solvents and carrier systems, or any artificial preservative.

Carnauba wax

This proposed rule would reclassify carnauba wax from a nonagricultural substance on § 205.605(a), to an agricultural substance on § 205.606, that may be used in

organic handling when organic carnauba wax is not commercially available. Table 25 illustrates the proposed listing.

Table 25. Proposed rule action for carnauba wax.

Current rule:	§ 205.605(a), Waxes—nonsynthetic (Carnauba wax; and Wood resin).
Proposed rule action:	Remove carnauba wax from § 205.605(a) and insert carnauba wax under § 205.606.

Carnauba wax is allowed as a nonsynthetic substance for use in organic handling. Carnauba wax has been on the National List since October 2002. During the 2017 sunset review, the NOSB reviewed an updated technical report⁴¹ on carnauba wax. This report described how carnauba wax is extracted from the leaves and buds of palm trees. Based upon NOP 5033,⁴² the NOSB determined that carnauba wax meets the definition of an agricultural product in § 205.2 of the USDA organic regulations.⁴³ While the NOSB recommended renewing carnauba wax as part of the 2017 sunset review, it also forwarded a separate recommendation to reclassify carnauba wax as an agricultural substance.⁴⁴

At its October 26–29, 2015, public meeting, the NOSB reviewed public comment and reviewed information in an updated technical report. To be consistent with NOP

⁴¹ 2014 carnauba technical report: <https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned>. Under “C.”

⁴² NOP 5033, Classification of Materials: https://www.ams.usda.gov/sites/default/files/media/Program%20Handbk_TOC.pdf.

⁴³ The USDA organic regulations define “agricultural product” as: “Any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock, that is marketing in the United States for human or livestock consumption.”

⁴⁴ The NOSB recommendation for the reclassification of carnauba wax is available here: https://www.ams.usda.gov/sites/default/files/media/HS%20Reclassification%20Carnauba_final%20rec.pdf

5033, the NOSB recommended reclassifying carnauba wax as an agricultural substance under § 205.606.

AMS has reviewed and proposes to address this NOSB recommendation through this proposed rule. Consistent with the NOSB recommendation, this proposed rule would amend § 205.605 by removing carnauba wax from § 205.605(a) and inserting carnauba wax in § 205.606.

Cellulose

This proposed rule would amend the current allowance for the use of cellulose in organic processing in section 205.605 of the National List. The revision specifies the type of cellulose allowed for certain uses. Table 26 illustrates the changes between the current rule and the proposed rule.

Table 26. Proposed rule action for cellulose.

Current rule:	§ 205.605(b) Cellulose—for use in regenerative casings, as an anti-caking agent (non-chlorine bleached) and filtering aid.
Proposed rule action:	§ 205.605(b) Cellulose—for use in regenerative casings, powdered cellulose as an anti-caking agent (non-chlorine bleached) and filtering aid. Microcrystalline cellulose is prohibited.

Applications

Cellulose is a major component of plant cell walls and is one of the most abundant compounds in nature. It can be derived from several sources and is available in many forms that provide different functional properties in food products. In addition to the petitioned uses as a processing aid for juice filtration, anti-caking agent, or peelable meat casings, cellulose is also used as a fat substitute, bulking agent, texturizer, emulsifier, and an extender. In 2001, the NOSB considered a petition for the use of three forms of cellulose, powdered cellulose, regenerative casing cellulose, and microcrystalline cellulose.

Powdered cellulose is a purified white, odorless polysaccharide consisting of a linear polymer of D-glucose units joined together by glycosidic linkages. When forming, cellulose molecules develop as long chain fibrous bundles with crystalline and amorphous regions. Cellulose is isolated from several biological sources, but most commercial cellulose is derived from cotton linters and wood pulp. Mechanical and chemical extraction procedures are used to isolate the cellulose. Varying these manufacturing procedures can result in a range of cellulose products differing in molecular weight and fiber length, which yields a range of food or drug processing properties.

The NOSB considered two cellulose derivatives in 2001, microcrystalline cellulose and regenerative casing cellulose. Microcrystalline cellulose, also known as nanocrystalline cellulose, is manufactured from the acid hydrolysis of powdered cellulose. This process reduces the degree of molecular polymerization (number of glucose units that make up the polymer molecule) where the amorphous region of the cellulose molecule is extracted, leaving the shorted fiber crystalline region. Altering cellulose to its microcrystalline form provides different ingredient and processing aid uses in addition to the uses provided by powdered cellulose. Comments submitted by organic food processors during the 2013 sunset review stated that they do not use microcrystalline cellulose and they were not aware of any organic food processor using microcrystalline cellulose.

Powdered cellulose is also used to manufacture regenerative casing cellulose where the cellulose fibers are dissolved into smaller polymers, regenerated into tubular forms, and used as a casing to pack skinless meat products such as hot dogs and sausage.

The regenerative casing cellulose is then removed from the packed meat product since this form of cellulose is considered to be inedible.

Timeline

Cellulose was added to § 205.605(b) of the National List in November 2003 (68 FR 62215) for limited uses: in regenerative casings, as an anti-caking agent (non-chlorine bleached) and filtering aid. For the 2013 sunset review, the NOSB provided two recommendations in May 2012.⁴⁵ AMS addressed one recommendation by renewing the current listing for cellulose in a final rule (78 FR 61154, October 3, 2013). This renewal action established October 3, 2018, as the next sunset date for cellulose. For the second 2013 sunset recommendation issued in May 2012, the NOSB recommended revising the cellulose listing to specify that only powdered cellulose is allowed as an anticaking agent and filtering aid, and specifically prohibiting the use of microcrystalline cellulose. This proposed rule addresses the latter recommendation.

During the 2013 sunset review, the NOSB reviewed its 2001 cellulose recommendation, Technical Advisory Panel reports on this substance from 2001 and 2016, NOSB records from the 2008 cellulose sunset review, other technical documents, and received public comments prior to and during the May 2012 NOSB meeting. Some of the public comments requested that the NOSB specifically prohibit microcrystalline cellulose for use in organic handling, asserting that this was the intent of the NOSB's 2001 cellulose recommendation. However, other comments stated that the 2001 cellulose recommendation did not clearly convey the intent to prohibit microcrystalline cellulose as an ingredient or processing aid in organic handling. During the 2013 sunset review, the

⁴⁵ <https://www.ams.usda.gov/sites/default/files/media/Cellulose%20Rec.pdf>.

NOSB determined that the intent of the current annotation was to allow only powdered cellulose and regenerative casing cellulose. In formulating its recommendation, the NOSB received information indicating that certifying agents were already implementing a prohibition of microcrystalline cellulose, so that a specific prohibition in the annotation was not needed. In preparation of this proposed rule, AMS learned that microcrystalline cellulose is also marketed in powdered form. Consequently, AMS revised the NOSB's recommended annotation for cellulose to specifically prohibit microcrystalline cellulose. The revised annotation is consistent with the NOSB recommendation to allow powdered cellulose as defined by the NOSB. Therefore, we have proposed adding language to prohibit the use of microcrystalline cellulose to avoid ambiguity about its status. AMS specifically seeks comments on the need for this additional language concerning microcrystalline cellulose.

Consistent with the NOSB recommendation, this action would clarify the allowed forms of cellulose and corresponding uses. In effect, it would prohibit other forms of cellulose, such as microcrystalline cellulose, that might be used for the same functions as powdered cellulose. Therefore, AMS is proposing to amend the current listing of cellulose in § 205.605 with the following annotation: for use in regenerative casings, powdered cellulose as an anti-caking agent (non-chlorine bleached) and filtering aid. Microcrystalline cellulose is prohibited.

Chlorine

This proposed rule would implement a December 2011 NOSB recommendation⁴⁶ to amend the current allowance for chlorine in organic processing. The proposed change would be consistent with the NOP guidance, “The Use of Chlorine Materials in Organic Production and Handling,” NOP 5026, which clarifies the use of chlorine materials in organic production and handling. Table 27 illustrates the changes between the current rule and the proposed rule.

Table 27. Proposed rule action for chlorine materials in § 205.605.

Current rule:	§ 205.605(b) Chlorine materials—for disinfecting and sanitizing food contact surfaces, <i>Except</i> , That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite).
Proposed rule action:	§ 205.605(b). Chlorine materials—for disinfecting and sanitizing food contact surfaces, equipment and facilities may be used up to maximum labeled rates. Chlorine materials in water used in direct crop or food contact are permitted at levels approved by the FDA or EPA for such purpose, provided the use is followed by a rinse with potable water at or below the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act. Chlorine in water used as an ingredient in organic food handling must not exceed the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act.” (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite).

Applications

Chlorine is a highly reactive element that rarely exists in free form in the environment. It readily combines with many other elements, including metals, from which metal salts, or chlorides are formed. The most common chloride is sodium chloride (table salt). This substance and other chloride ions are essential for cellular metabolism of all known

⁴⁶ NOSB Final Recommendation on Chlorine, see: <https://www.ams.usda.gov/sites/default/files/media/NOP%20Handling%20Final%20Rec%20Chlorine%20Materials%20Annotation.pdf>.

species of life. Chlorine can be extracted from chlorides through oxidation induced by electrolysis. In free form, chlorine's high oxidizing property is utilized in bleaching and disinfectant chlorine compound products. These products are the most utilized equipment and food contact sanitizers in food processing and handling.

Timeline

Chlorine materials were added to the National List that was published in the final rule establishing the National Organic Program (65 FR 13512, December 21, 2000). The chlorine materials listings were renewed through the 2007 (72 FR 58469) and 2012 sunset reviews (77 FR 33290).

When the NOSB initially considered chlorine materials in November 1995, the annotation included in the resulting recommendation acknowledged that levels of chlorine permitted in municipal drinking water were acceptable for organic production and handling. The 1995 recommendation stated that chlorine materials should be allowed for use in organic crop production, organic food processing, and organic livestock production with the following annotation: "Allowed for disinfecting and sanitizing food contact surfaces. 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." In 2010, the NOP issued guidance on the use of chlorine materials in organic production and handling in order to provide clarity on chlorine materials.

At its December 2011 public meeting, the NOSB recommended modifying the chlorine materials annotation listed in § 205.605(b) to improve consistency between the USDA organic regulations and the NOP guidance, "The Use of Chlorine Materials in

Organic Production and Handling,” NOP 5026. The proposed amendment would clarify what levels of chlorine are permitted for use in water in direct contact with food versus in water used as an ingredient in food. This aligns with the NOP guidance on this subject, provides clarity on the allowed uses of chlorine, and reflects current industry practice. Therefore, AMS is proposing to amend the current listing of chlorine materials in § 205.605(b) with the following annotation:

For disinfecting and sanitizing food contact surfaces, equipment and facilities may be used up to maximum labeled rates. Chlorine materials in water used in direct crop or food contact are permitted at levels approved by the FDA or EPA for such purpose, provided the use is followed by a rinse with potable water at or below the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act. Chlorine in water used as an ingredient in organic food handling must not exceed the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act.” (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite).

Hypochlorous Acid

See discussion above under § 205.601, Synthetic substances allowed for use in organic crop production.

Potassium lactate and sodium lactate

This proposed rule would add potassium lactate and sodium lactate to § 205.605(b) as an allowed synthetic substance for use in organic handling. Table 28 illustrates the proposed listing.

Table 28. Proposed rule action for potassium lactate and sodium lactate.

Current rule:	N/A
Proposed rule action:	§ 205.605(b) potassium lactate, for use as an antimicrobial agent and pH regulator only. § 205.605(b) sodium lactate, for use as an antimicrobial agent and pH regulator only.

Potassium lactate and sodium lactate were originally petitioned⁴⁷ for addition to the National List on January 5, 2005, for use in organic handling as antimicrobial ingredients. On January 27, 2005, the NOP notified the petitioner that their petition was not necessary because the precursors, lactic acid and potassium hydroxide or sodium hydroxide, which are used to manufacture potassium lactate or sodium lactate, were on the National List. This decision caused confusion in the industry on the use of potassium lactate and sodium lactate, as well as other lactate salts.

To resolve this confusion, the NOP issued a memorandum to the NOSB on June 25, 2014, requesting that the NOSB review the petition to add potassium lactate and sodium lactate to the National List in § 205.605(b).⁴⁸

At its April 25 – 27, 2016, public meeting, the NOSB received public comment and reviewed the petition and technical report.⁴⁹ During this review, the NOSB determined that uses for potassium lactate and sodium lactate had expanded from the original petitioned use as an antimicrobial. As a result, the NOSB determined that adding potassium lactate and sodium lactate to the National List would need the annotation, “for use as an antimicrobial agent and pH regulator only” to maintain use applications in

⁴⁷ Potassium lactate and sodium lactate petition: <https://www.ams.usda.gov/rules-regulations/organic/national-list/s>.

⁴⁸ The June 25, 2014 memorandum is available at: https://www.ams.usda.gov/sites/default/files/media/S%20Lactate%20national%20list%20petitions_0.pdf

⁴⁹ Potassium lactate / Sodium lactate technical report: <https://www.ams.usda.gov/sites/default/files/media/Lactic%20Acid%20and%20Lactates%20TR%2002-17-15%20Final.pdf>.

organic handling. Based on the petition, technical report, and public comments, the NOSB determined that potassium lactate and sodium lactate, as petitioned, meet the OFPA criteria for National List substances.

AMS has reviewed and proposes to address this NOSB recommendation through this proposed rule. Consistent with the NOSB recommendation, this proposed rule would amend § 205.605(b) by adding potassium lactate and sodium lactate with the same restrictive annotation: for use as an antimicrobial agent and pH regulator only.

Glycerin

This proposed rule would remove glycerin from section 205.605(b) and amend section 205.606 to include this substance with annotation. In effect, for organic processing activities, this proposed action would change the classification of glycerin under the USDA organic regulations from an allowed synthetic to an agricultural product which must be in organic form unless an organic version is not commercially available. Table 29 illustrates the changes between the current rule and the proposed rule.

Table 29. Proposed rule action for glycerin.

Current rule:	Remove from § 205.605(b). Glycerin—produced by the hydrolysis of fats and oils.
Proposed rule action:	Add to § 205.606. Glycerin—produced from agricultural source materials and processed using biological or mechanical/physical methods as described under § 205.270(a).

Applications

Glycerin, whether made by fermentation of carbohydrate substrates or by hydrolysis of fats and oils, is listed as GRAS by the FDA and has a long history of safe use in a wide variety of food, cosmetic, and medical applications, including but not limited to use as a solvent, emollient, bodying agent, plasticizer, pharmaceutical agent,

and sweetening agent in a wide range of processed food and cosmetic products. Glycerin is metabolized as a carbohydrate in the body.

Commercial glycerin can be produced in several ways: common methods include hydrogenolysis of carbohydrates or by synthesis from propylene; as a waste byproduct of biodiesel production; and by saponification of natural fats and oils. Glycerin produced from saponification was recommended by the NOSB in 1995 for inclusion on the National List with the annotation “produced by hydrolysis of fats and oils.” It is currently included on the National List as a synthetic nonagricultural substance at § 205.605(b) and also for livestock use as a teat dip at § 205.603(a)(12).

Saponification of natural fats and oils is a process of hydrolyzing agricultural product fat or oil with water (steam) under pressure (or chemically with sodium carbonate, sodium hydroxide, or potassium hydroxide) to produce synthetic glycerin and fatty acids. The steam process is described in the 1995 Technical Advisory Panel Report on glycerin. The alkali process is the traditional process used to saponify fats and oils. The three sources of alkali used in this process, identified above, are included in the National List.

According to a 2013 Technical Report⁵⁰, glycerin can be produced organically by microbial fermentation using only mechanical and biological processes and without the use of allowed synthetics listed in section 205.605(b). Those are acceptable methods for processing organically produced products as provided in section 205.270(a). Glycerin produced organically by fermentation is an agricultural product as defined in § 205.2

⁵⁰ Petition to remove glycerin from § 205.605 to add to § 205.606 and the Glycerin Technical Report, see <https://www.ams.usda.gov/sites/default/files/media/Glycerin%20Petition%20to%20remove%20TR%202013.pdf>.

since it is a processed product produced from an agricultural commodity, e.g. cornstarch. In addition, certified organic glycerin can be produced by hydrolysis of organic fats and oils using either steam splitting or traditional saponification with a catalytic amount of an alkali (sodium carbonate, sodium hydroxide, or potassium hydroxide) on the National List.

The NOSB determined that glycerin produced by hydrolysis of fats and oils using a chemical process is considered to yield synthetic glycerin, which may be used only when certified organic glycerin is not commercially available. In summary, glycerin produced through saponification of fats and oils using steam, and glycerin produced by microbial fermentation of carbohydrate substances, would be agricultural products that may be certified organic. The technical report for glycerin indicates that there are currently 21 USDA certified organic operations supplying glycerin.⁵¹

Timeline

This proposed rule would amend paragraph (b) of § 205.605 of the National List regulations by removing the exemption for the following substance: Glycerin—produced by the hydrolysis of fats and oils. This proposed rule would also amend § 205.606 of the National List regulations by adding Glycerin—produced from agricultural source materials and processed using biological or mechanical/physical methods as described under § 205.270(a), and would require organic glycerin to be used unless not commercially available. Glycerin was included in § 205.605(b) of the National List as originally published on December 21, 2000 (FR 65 80548), as an allowed synthetic

⁵¹ The April 2015 NOSB recommendation for Glycerin is available at the following link: <https://www.ams.usda.gov/sites/default/files/media/HS%20Glycerin%20Final%20Rec.pdf>.

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

In December 2012, a petition was submitted to the NOSB for the removal of glycerin from § 205.605(b). The petition stated that certified organic glycerin had become available and could replace nonorganic glycerin. Specifically, the petition cited that certified organic glycerin is currently available, but there is no “commercial availability” requirement to incentivize processors to use it or certifiers to require it. The petition described how the process of microbial fermentation used to produce organic glycerin is consistent with USDA organic regulation requirements because it relies on mechanical and biological processes as required in § 205.270(a) without the use of allowed synthetics, and stated that the removal of glycerin from § 205.605(b) will encourage organic agricultural production.

Based upon NOP guidance, “Classification of Materials Draft Guidance,” NOP 5033⁵² published in the Federal Register on April 2, 2013 (78 FR 19637), the NOSB determined that some forms of glycerin could be listed as an agricultural product at § 205.606 rather than a nonagricultural product as currently listed at § 205.605. The NOSB determined that agricultural forms of glycerin would include glycerin produced by microbial fermentation of carbohydrate substances as well as glycerin produced from hydrolysis of fats and oils using mechanical/physical methods, as long as the original source material was agricultural.

The petition to remove glycerin from § 205.605(b) was first considered at the 2014 Spring NOSB meeting. At its spring 2015 meeting, the NOSB evaluated glycerin

⁵² NOP 5033 Classification of Materials Draft Guidance, see <https://www.ams.usda.gov/sites/default/files/media/NOP-5033.pdf>.

against the evaluation criteria of 7 U.S.C. §§ 6517 and 6518 of the OFPA and NOP criteria on commercial availability, received public comment, and concluded that agricultural forms of glycerin are consistent with the OFPA evaluation criteria. The NOSB determined that the manufacturing processes used to produce glycerin differentiate how the types of glycerin are classified, e.g., as synthetic or agricultural, and that because of the concerns regarding the commercial availability of organically produced glycerin in appropriate quality and quantity, agricultural glycerin should be listed at § 205.606.

This proposed rule would prohibit the use of nonorganic synthetic glycerin and allow the use of nonorganic agricultural glycerin—produced from agricultural source materials and processed using biological or mechanical/physical methods as described under § 205.270(a)—when an organic version is not commercially available.

Consistent with this NOSB recommendation, AMS proposes to: (1) remove the exemption for synthetic Glycerin—produced by the hydrolysis of fats and oils in paragraph (b) of § 206.605 and (2) amend § 205.606 of the USDA organic regulations to allow the use of agricultural forms of glycerin as a nonorganically produced agricultural substance allowed as an ingredient in or on processed products labeled as “organic” as follows: Glycerin—produced from agricultural source materials and processed using biological or mechanical/physical methods as described under § 205.270(a).

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

This proposed rule would amend the allowance for colors currently allowed in organic handling by replacing color Chemical Abstract Services (CAS) numbers with the binomial name of the agricultural source of the color.

Colors Derived from Agricultural Products

This proposed rule would amend USDA organic regulations to replace Chemical Abstract Services (CAS) numbers included in the annotation of each color listed under National List § 205.606(c) with the binomial name of the agricultural source of the color. The NOSB requested that AMS conduct a review on the accuracy of these CAS numbers and propose any necessary changes.⁵³ During its 2012 sunset review, the NOSB received comments stating that the CAS numbers within annotations for several colors were incorrect. After completing its 2012 sunset review, the NOSB recommended retaining the current color listings without change until either CAS numbers could be verified or until corrections to the USDA organic regulations could be added. Subsequently, the final rule (77 FR 33290) on the 2012 sunset review retained CAS numbers in the annotations for each color derived from agricultural product.

Colors - nonsynthetic sources only, was included in § 205.605(a), in the original National List incorporated into the USDA organic final rule (65 FR 80548) published on December 21, 2000, and became effective on October 21, 2002. Based upon comments received during the 2007 sunset review process, the NOSB recommended not to renew this category of substances in National List § 205.605(a). Comments on listing of colors in § 205.605(a) that were provided during the 2007 sunset review informed the NOSB

⁵³ On October 28, 2010, the NOSB requested the review of CAS numbers in its recommendation on amending the National List to prohibit the use of synthetic solvents and carrier systems or any artificial preservatives in manufacturing colors derived from agricultural product.

that the listing of colors in § 205.605(a) never received a formal NOSB recommendation to be added to the National List. Since OFPA states that the National List shall be based upon recommendations developed by the NOSB, it was determined that colors, as listed in § 205.605(a), were erroneously included in the final rule. Several comments also requested the NOSB to recommend the removal of colors from the National List in § 205.605(a), and to have nonsynthetic colors be evaluated by the NOSB through the National List petition process. Additional comments indicated that the broad category of “nonsynthetic colors” as listed in § 205.605(a) hindered certifying agents in determining and verifying nonsynthetic colors and that this ambiguity could give rise to the use of inappropriate substances in organically handled products.

During the 2007 sunset review, the NOSB deliberated on the fact that colors, as listed under § 205.605(a), had been allowed for use by organic handlers for more than five years. Some commenters expressed concern that removing colors from § 205.605(a) would cause disruption in the manufacture of organic products in the organic handling sector. While considering these comments the NOSB determined that, since there was no formal recommendation from the NOSB to allow nonsynthetic colors as a broad category for use in organic handling, the listing of colors in § 205.605(a) could not continue.

At the completion of the 2007 sunset review, the NOSB voted not to renew the listing of colors on § 205.605(a). Prior to this decision, the NOSB decided that there is a need to provide the organic industry with the opportunity to petition to add nonsynthetic colors to the National List before finalizing its vote. In April 2006 the NOSB announced it would defer its vote not to renew the colors from nonsynthetic sources listing in § 205.605(a) and proposed that organic handling operations using nonsynthetic colors in

organic handling submit petitions to add specific nonsynthetic colors to the National List. Prior to its March 2007 NOSB meeting, the NOSB received several National List petitions to add individual nonsynthetic colors to the National List. At the March 2007 meeting, the NOSB voted to add 19 nonsynthetic colors to National List § 205.606. These nonsynthetic colors, with CAS numbers listed in their annotations, were added to the National List in June 2007 (72 FR 35137).

In May 2013 (78 FR 31815), the listing of annatto extract color in § 205.606 was removed from the National List as recommended by NOSB after considering a petition to remove this color from the National List. The petition to remove annatto extract color was submitted by the same petitioner that submitted the 2007 petition to add annatto extract color to the National List. This petitioner indicated that annatto extract color is no longer needed on the National List in § 205.606 since certified organic annatto extract is available in adequate quantities and in the forms needed to meet demand for organic annatto extract color.

Each color listed under § 205.606(c) includes CAS numbers cited in the annotation. Some listed colors have several CAS numbers within the annotation. The listed CAS numbers actually apply to the pigments contained in the color extract. CAS numbers are unique numerical identifiers assigned by CAS to every known chemical substance. Such numbers are not assigned to chemical compounds or formulations. As requested by the NOSB, AMS reviewed the CAS numbers contained in the color annotations in § 205.606(c). The AMS review determined that CAS numbers are not assigned to the fruit and vegetable raw materials used to make colors. Consequently, CAS numbers may not be appropriate for use when classifying agricultural colors as the

use of CAS numbers would not indicate an agricultural source. The AMS review also determined that the petitions to add nonsynthetic colors to the National List may have cited incorrect CAS numbers or applied multiple CAS numbers to the same material. Some of the written comments received during the 2012 sunset review provided more than one CAS number for the same substance. Other comments stated that CAS numbers are not appropriate for nonorganic agricultural substances listed in § 205.606 and some operations may consider a substance represented by a certain CAS number obtained from any source to be compliant with the USDA organic regulations. Some comments received during the 2012 sunset review suggested that binomial nomenclature (genus and species classifications) is more appropriate for identifying nonorganic agricultural products listed in § 205.606. For colors that are derived from agricultural product, use of binomial name may better define these color extracts. Since CAS numbers may not be appropriate for use with agricultural products, and there is variation in what CAS numbers should be applied to some of the color extracts, AMS agrees with the comments that use of binomial nomenclature may provide better clarification on source of colors that are listed in § 205.606.

This rule proposes to make amendments to the color listings in § 205.606(c) by removing the CAS numbers assigned to the color extracts and substituting in the binomial name of the agricultural source that was identified in the color petitions submitted to the NOSB. AMS has inserted this information into Table 30 below describing each binomial name for each color derived from agricultural product listed in § 205.606(c).

Table 30. Colors with CAS numbers changed to binomial names.

Current 205.606 listing: Color - agricultural source / CAS numbers	Proposed 205.606 listing: Color - agricultural source / Binomial nomenclature
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Beet juice extract color (pigment CAS # 7659-95-2)	Beet juice extract color, derived from sugarbeet (<u>Beta vulgaris</u>)
Beta-carotene extract color – derived from carrots and algae (pigment CAS # 1393-63-1)	Beta-carotene extract color derived from carrots (<u>Daucus carota</u>), or algae (<u>Dunaliella salina</u>)
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 currant juice color, derived from <u>Ribes nigrum</u>
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)	Black/ purple carrot juice color, derived from <u>Apiaceae daucus carota</u>
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)	Blueberry juice color, derived from <u>Vaccinium cyanococcus</u>
Carrot juice color (pigment CAS # 1393-63-1)	Carrot juice color, derived from <u>Daucus carota</u>
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)	Cherry juice color, derived from <u>Prunus avium</u>
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)	Chokeberry—Aronia juice color, derived from <u>Aronia prunifolia</u>
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)	Elderberry juice color, derived from <u>Sambucus nigra</u>
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 juice color, derived from <u>Vitis vinifera</u>
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)	Grape skin extract color, derived from <u>Vitis vinifera</u>
Paprika color—dried, and oil extracted (CAS # 68917-78-2)	Paprika color—dried powder and vegetable oil extract, derived from <u>Capsicum annum</u>
Pumpkin juice color (pigment CAS # 127-40-2)	Pumpkin juice color, derived from <u>Cucurbita pepo</u>
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),	Purple potato juice color, derived from <u>Solanum andigenum</u>
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 cabbage extract color, derived from <u>Brassica oleracea</u>
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),	Red radish extract color, derived from <u>Raphanus sativus</u>
Saffron extract color (pigment CAS # 1393-63-1),	Saffron extract color, derived from <u>Crocus sativus</u>

Turmeric extract color (CAS # 458–37–7)	Turmeric extract color, derived from <u>Curcuma longa</u>
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The use of binomial nomenclature in § 205.606 will clarify which agricultural sources may be used to derive the color extract. Varieties or subspecies of the same agricultural product may be used as sources for a particular color extract. Agricultural sources with the same genus but not the same species will not be eligible for use as a source for a color listed in § 205.606(c). For agricultural products, the application of binomial nomenclature for colors derived from agricultural product is appropriate when classifying colors since it better indicates the agricultural source of the color. Therefore, AMS is proposing to amend the current listing of colors in § 205.606 by inserting the binomial nomenclature of the color described in Table 30 into each respective annotation.

III. Related Documents

Thirteen notices were published regarding the meetings of the NOSB and deliberations on recommendations and substances petitioned for amending the National List. Substances and recommendations included in this proposed rule were announced for NOSB deliberation in the following Federal Register notices: 65 FR 64657, October 30, 2000; 67 FR 54784, August 26, 2002; 74 FR 11904, March 20, 2009; 74 FR 46411, September 9, 2009; 75 FR 57194, September 20, 2010; 76 FR 62336, October 7, 2011; 77 FR 21067, April 9, 2012; 77 FR 2679, August 30, 2012; 79 FR 13272, March 10, 2014; 80 FR 12975, March 12, 2015; 80 FR 53759, September 8, 2015; 81 FR 14079 , March 16, 2016; and 81 FR 50460, August 1, 2016.

IV. Statutory and Regulatory Authority

The OFPA, as amended (7 U.S.C. 6501 *et seq.*), authorizes the Secretary to make amendments to the National List based on recommendations developed by the NOSB. Sections 6518(k) and 6518(n) of the OFPA authorize the NOSB to develop recommendations to amend 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 (81 FR 12680, March 10, 2016) can be accessed through the NOP Program Handbook on the NOP Web site at <https://www.ams.usda.gov/rules-regulations/organic/handbook>.

A. Executive Orders 12866 and 13771, and Regulatory Flexibility Act

This proposed rule is not expected to be an EO 13771 regulatory action because this proposed rule is not significant under EO 12866. *See* OMB's Memorandum titled "Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017 titled 'Reducing Regulation and Controlling Regulatory Costs'" (February 2, 2017).

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 rule would not be significant. The effect of this rule, if implemented as final, would be to allow the use of additional substances in organic crop or livestock production and organic handling. This action would increase regulatory flexibility and would give small entities more tools to use in day-to-day operations. AMS concludes that the economic impact of this addition, 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, National Agricultural Statistics Service, certified organic acreage exceeded 5.0 million acres in 2016.⁵⁴ According to NOP's Organic Integrity Database, there are 25,239 certified organic operations in the U.S.⁵⁵ AMS believes that most of these entities would be considered small entities under the criteria established by the SBA. U.S. sales of organic food products and non-food products have grown from \$1

⁵⁴ U.S. Department of Agriculture, National Agricultural Statistics Service. September 2017. Certified Organic Survey, 2016 Summary. <http://usda01.library.cornell.edu/usda/current/OrganicProduction/OrganicProduction-10-04-2012.pdf>.

⁵⁵ Organic Integrity Database: <https://organic.ams.usda.gov/Integrity/>. Accessed on October 13, 2017.

billion in 1990 to more than \$47 billion in 2016.⁵⁶ In addition, the USDA has 83 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 <https://www.ams.usda.gov/services/organic-certification/certifying-agents>. AMS believes that most of these accredited certifying agents would be considered small entities under the criteria established by the SBA. A complete list of NOP certified operations may be found on the AMS NOP web site, at <https://apps.ams.usda.gov/integrity/>.

B. Executive Order 12988.

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

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

⁵⁶ Organic Trade Association, 2017 Organic Industry Survey.

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

Pursuant to section 6519(c)(6) of the OFPA, 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.).

C. 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 the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, Chapter 35.

D. Executive Order 13175

This proposed rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments.

The review reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

E. General Notice of Public Rulemaking.

This proposed rule reflects 29 recommendations submitted by the NOSB to the Secretary to amend the annotation for 17 substances currently on the National List, add 17 substances to the National List, and remove one substance from the National List. A 60-day period for interested persons to comment on this rule is provided and is deemed appropriate.

List of Subjects in 7 CFR Part 205

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

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

PART 205 – NATIONAL ORGANIC PROGRAM

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

Authority: 7 U.S.C. 6501 – 6522.

2. Amend § 205.238 by revising paragraph (b)(2) and adding paragraph (b)(3) to read as follows:

§ 205.238 Livestock health care practice standard

(b) ***

(2) Dairy animals, as allowed under § 205.603.

(3) Fiber bearing animals, as allowed under § 205.603.

3. Amend § 205.601 as follows:

- a. Redesignate paragraph (a)(2)(iii) as (a)(2)(iv) and add new paragraph (a)(2)(iii),
- b. Redesignate paragraphs (j)(5) through (j)(8) as (j)(6) through (j)(9), redesignate paragraph (j)(10) as (j)(11), add new paragraphs (j)(5) and (j)(10), and revise newly redesignated paragraph (j)(7).

The additions and revisions to read as follows:

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

* * * * *

(a) * * *

(2)(iii) Hypochlorous acid—generated from electrolyzed water.

* * * * *

(j) * * *

(5) Magnesium oxide (CAS # 1309-48-4)—for use only to control the viscosity of a clay suspension agent for humates.

* * *

(7) Micronutrients—not to be used as a defoliant, herbicide, or desiccant.

Those made from nitrates or chlorides are not allowed. Micronutrient deficiency must be documented by soil or tissue testing, advice from certified crop advisors or professional agronomists, agricultural extension information, or other methods approved by the certifying agent.

* * *

(10) Squid byproducts—from food waste processing only. 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.

* * * * *

4. Amend § 205.602 by redesignating paragraphs (f) through (i) as (g) through (j), and add new paragraph (f) to read as follows:

§ 205.602 Nonsynthetic substances prohibited for use in organic crop production.

* * * * *

(f) Rotenone (CAS # 83-79-4).

* * * * *

5. Amend § 205.603 by revising paragraphs (a)(6) through (a)(31), paragraphs (b)(4) and (b)(7), redesignating paragraph (b)(8) as (b)(9) adding new paragraph (b)(8); and revising paragraphs (d)(1) and (f) to read as follows:

§ 205.603 Synthetic substances allowed for use in organic livestock production.

* * * * *

(a) * * *

(6) Activated charcoal (CAS # 7440-44-0)—must be from vegetative sources.

(7) Calcium borogluconate (CAS # 5743-34-0)—for treatment of milk fever only.

(8) Calcium propionate (CAS # 4075-81-4)—for treatment of milk fever only.

(9) Chlorhexidine (CAS # 55-56-1)—for medical procedures conducted under the supervision of a licensed veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.

(10) 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.

- (i) Calcium hypochlorite.
- (ii) Chlorine dioxide.
- (iii) Hypochlorous acid—generated from electrolyzed water.
- (iv) Sodium hypochlorite

(11) Electrolytes—without antibiotics.

(12) 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.

(13) Glucose.

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

(15) Hydrogen peroxide.

(16) Iodine.

(17) Kaolin pectin—for use as an adsorbent, antidiarrheal, and gut protectant.

(18) 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.

(19) Magnesium sulfate.

(20) Mineral oil—for treatment of intestinal compaction, prohibited for use as a dust suppressant.

(21) Nutritive supplements—injectable supplements of trace minerals per § 205.603(d)(2), vitamins per § 205.603(d)(3), and electrolytes per § 205.603(a)(11), with excipients per § 205.603(f), in accordance with FDA and restricted to use by or on the order of a licensed veterinarian.

(22) Oxytocin—use in postparturition therapeutic applications.

(23) Parasiticides— Prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. 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. Allowed for fiber bearing animals when used a minimum of 90 days prior to harvesting of fleece or wool that is to be sold, labeled, or represented as organic.

(i) Fenbendazole (CAS #43210-67-9)—milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep, and other dairy species.

(ii) Moxidectin (CAS #113507-06-5)—milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep, and other dairy species.

- (24) Peroxyacetic/peracetic acid (CAS #-79-21-0)—for sanitizing facility and processing equipment.
- (25) Phosphoric acid—allowed as an equipment cleaner, *Provided*, That, no direct contact with organically managed livestock or land occurs.
- (26) 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.
- (27) Propylene glycol (CAS # 57-55-6)—for treatment of ketosis in ruminants only.
- (28) Sodium chlorite, acidified, allowed for use on organic livestock as a teat dip treatment only.
- (29) 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.
- (30) 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; and,
- (ii) 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.

(31) Zinc sulfate—for use in hoof and foot treatments only.

(b) * * *

* * * * *

(4) Lidocaine—as a local anesthetic. Use requires a withdrawal period of 8 days after administering to livestock intended for slaughter and 6 days after administering to dairy animals.

* * * * *

(7) Procaine—as a local anesthetic. Use requires a withdrawal period of 8 days after administering to livestock intended for slaughter and 6 days after administering to dairy animals.

(8) Sodium chlorite, acidified—allowed for use on organic livestock as teat dip treatment only.

* * * * *

(d) * * *

(1) DL- Methionine, DL- Methionine - hydroxy analog, and DL- Methionine - hydroxy analog calcium (CAS #'s 59-51-8, 583-91-5, 4857-44-7, and 922-50-9)—for use only in organic poultry production at the following pounds of synthetic

100 percent methionine per ton of feed in the diet, averaged over the life of the flock: laying chickens - 2 pounds; broiler chickens - 2.5 pounds; turkeys and all other poultry - 3 pounds.

* * * * *

(f) Excipients, only for use in the manufacture of drugs and biologics used to treat organic livestock when the excipient is:

(1) Identified by the FDA as Generally Recognized As Safe;

(2) Approved by the FDA as a food additive;

(3) Included in the FDA review and approval of a New Animal Drug Application or New Drug Application; or

(4) Approved by APHIS for use in veterinary biologics.

* * * * *

6. Amend § 205.605 as follows:

a. In paragraph (a), revise the entry for “Acids,” revise the entries for “Flavors,” and “Waxes;”

b. In paragraph (b) add in alphabetical order an entry for “alginic acid”, revise the entries for “cellulose” and “chlorine materials” and remove the entry for “Glycerin—produced by hydrolysis of fats and oils.”

The revisions and addition to read as follows:

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

* * * * *

(a) * * *

Acids (Citric—produced by microbial fermentation of carbohydrate substances; Lactic).

* * * * *

Flavors, non-synthetic flavors may be used when organic flavors are not commercially available. All flavors must be derived from organic or nonsynthetic sources only, and must not be produced using synthetic solvents and carrier systems or any artificial preservative.

* * * * *

Waxes—nonsynthetic (Wood resin).

* * * * *

(b) * * *

Alginic acid (CAS # 9005-32-7)

* * * * *

Cellulose (CAS # 9004-34-6)—for use in regenerative casings, powdered cellulose as an anti-caking agent (non-chlorine bleached) and filtering aid.

Microcrystalline cellulose is prohibited.

Chlorine materials— disinfecting and sanitizing food contact surfaces, equipment and facilities may be used up to maximum labeled rates. Chlorine materials in water used in direct crop or food contact are permitted at levels approved by the FDA or EPA for such purpose, provided the use is followed by a rinse with potable water at or below the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act. Chlorine in water used as an

ingredient in organic food handling must not exceed the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act.

- (1) Calcium hypochlorite.
- (2) Chlorine dioxide.
- (3) Hypochlorous acid—generated from electrolyzed water.
- (4) Sodium hypochlorite.

* * * * *

7. Amend § 205.606 by

- a. Redesignating paragraphs (g) through (t) as paragraphs (i) through (v);
- b. Redesignating paragraphs (a) through (f) as paragraphs (b) through (g);
- c. Adding new paragraphs (a) and (h) and revising newly redesignated paragraphs (d)(1) through (d)(18).

The additions and revisions to read as follows:

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

* * * * *

(a) Carnauba wax

(d) * * *

- (1) Beet juice extract color, derived from sugarbeet (Beta vulgaris).
- (2) Beta-carotene extract color derived from carrots (Daucus carota), or algae (Dunaliella salina).
- (3) Black currant juice color, derived from Ribes nigrum.

- (4) Black/ purple carrot juice color, derived from Apiaceae daucus carota.
- (5) Blueberry juice color, derived from Vaccinium cyanococcus.
- (6) Carrot juice color, derived from Daucus carota.
- (7) Cherry juice color, derived from Prunus avium.
- (8) Chokeberry—Aronia juice color, derived from Aronia prunifolia.
- (9) Elderberry juice color, derived from Sambucus nigra.
- (10) Grape juice color, derived from Vitis vinifera.
- (11) Grape skin extract color, derived from Vitis vinifera.
- (12) Paprika color—dried powder and vegetable oil extract, derived from Capsicum annum.
- (13) Pumpkin juice color, derived from Cucurbita pepo.
- (14) Purple potato juice color, derived from Solanum andigenum.
- (15) Red cabbage extract color, derived from Brassica oleracea.
- (16) Red radish extract color, derived from Raphanus sativus.
- (17) Saffron extract color, derived from Crocus sativus.
- (18) Turmeric extract color, derived from Curcuma longa.

* * * * *

(h) Glycerin (CAS # 56-81-5)—produced from agricultural source materials and processed using biological or mechanical/physical methods as described under § 205.270(a).

* * * * *

Dated: December 26, 2017

Bruce Summers
Acting Administrator

Agricultural Marketing Service

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