



DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

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

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule amends 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 changes the use restrictions for seventeen substances allowed for organic production or handling on the National List. This rule also adds sixteen new substances on the National List to be allowed in organic production or handling. In addition, this final rule lists the botanical pesticide, rotenone, as a prohibited substance in organic crop production. This final rule removes ivermectin as an allowed parasiticide for use in organic livestock production and amends our regulations to allow the use of parasiticides in fiber bearing animals. Finally, this rule inserts corrections of instructions and regulation text as listed in the proposed rule.

DATES: *Effective date:* This rule is effective [Insert date 30 days after date of publication in the Federal Register].

Implementation Dates: This rule will be fully implemented [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], except that the amendments for the substances ivermectin, flavors, cellulose, and glycerin will be implemented December 27, 2019.

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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 final rule amends the National List to implement 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.

II. Overview of Amendments

The following provides an overview of the final rule additions and amendments to designated sections of the National List regulations. Application and timeline information on the amendments were addressed in the proposed rule (83 FR 2498) and have not been included in the final rule. In addition, the basis for the NOSB recommendations was presented in the proposed rule. In summary, the NOSB evaluated each substance by applying the OFPA substance evaluation criteria to determine if the substance is compatible with organic production or handling. AMS reviewed each NOSB recommendation and accepted each recommendation for rulemaking. Subsequently, AMS submitted the NOSB recommendations through rulemaking in the proposed rule and this final rule. After considering the received comments, AMS has determined that the additions and amendments described in the proposed rule will be included, with a few minor changes based on comments, in the final rule. Section E of this final rule provides an overview of the comments received and AMS's response on all additions and amendments.

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

This final rule amends § 205.601 by adding three new substances, hypochlorous acid, magnesium oxide, and squid byproducts, to this section and amends this section by

changing the annotation of micronutrients as listed in § 205.601 to include other agricultural practices that may be used in maintaining soil fertility.

Hypochlorous acid

This final rule adds hypochlorous acid to § 205.601 as a chlorine material allowed for use as an algicide, disinfectant, and sanitizer. Paragraph (a)(2)(iii) reads as follows: Hypochlorous acid—generated from electrolyzed water. Upon the effective date of this final rule hypochlorous acid is allowed as an algicide, disinfectant, and sanitizer, including irrigation cleaning systems in organic crop production. AMS has reviewed and agrees with the NOSB recommendation that hypochlorous acid be allowed for use in organic crop production. AMS received comments on the proposed rule for amending hypochlorous acid onto § 205.601.

Magnesium oxide

This final rule adds magnesium oxide to the National List in § 205.601(j) for use in controlling the viscosity of a clay suspension agent for humates. Paragraph (j)(5) is added to this section to read as follows: Magnesium oxide (CAS # 1309-48-4)—for use only to control the viscosity of a clay suspension agent for humates. Upon the effective date of this rule, magnesium oxide is allowed in organic crop production as an agent for controlling the viscosity of clay suspension for humates. AMS has reviewed and agrees with the NOSB recommendation that magnesium oxide acid be allowed for use in organic crop production. AMS received comments on the proposed rule for amending magnesium oxide onto § 205.601.

Micronutrients

This final rule amends the annotation of micronutrients as listed in § 205.601(j). Paragraph (j)(7) is modified to read as follows: 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 or other documented and verifiable method as approved by the certifying agent. This change removes the restriction on documenting micronutrient deficiency that was imposed by allowing soil testing as the only method for demonstrating a soil micronutrient deficiency. This rule change allows alternative verifiable methods, such as tissue testing when approved by the certifying agent, to be used to document micronutrient deficiency. AMS has reviewed and agrees with the NOSB recommendation that the annotation for micronutrients be amended to clarify its use in organic crop production. AMS received comments on the proposed rule for amending the micronutrient annotation listed in § 205.601.

Squid byproducts

This final rule adds squid byproducts to § 205.601(j) as an allowed substance for use in organic crop production. Paragraph (j)(10) is added to § 205.601 to read as follows: 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. Only squid byproducts from food waste processing are permitted for use as a soil amendment in organic crop production. AMS has reviewed and agrees with the NOSB recommendation that squid by-products be allowed for use in organic crop production. AMS received comments on the proposed rule for amending squid by-products onto § 205.601.

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

This final rule amends § 205.602 by adding rotenone to this section.

Nonsynthetic substances are allowed in organic crop production except for those specifically listed as prohibited in § 205.602.

Rotenone

This final rule adds rotenone, a nonsynthetic substance, to § 205.602 which prohibits its use in organic crop production. Paragraph (f) is amended in this section to read as: Rotenone (CAS #83-79-4). After the effective date of this rule, rotenone will be a prohibited nonsynthetic substance in organic crop production. AMS has reviewed and agrees with the NOSB recommendation that rotenone be added to the National List as a prohibited non-synthetic and not allowed for use in organic crop production. AMS received comments on the proposed rule for amending rotenone onto § 205.602.

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

This final rule adds 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. This final rule also adds acidified sodium chlorite to § 205.603(b). This final rule also amends the restrictive annotations 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 final rule removes ivermectin, § 205.603(a).

Activated Charcoal

This final rule adds activated charcoal to § 205.603(a) for use in organic livestock production. Paragraph (a)(6) is amended in § 205.603 to read as follows: Activated charcoal (CAS # 7440-44-0)—must be from vegetative sources. After the effective date of this final rule, organic livestock producers may use activated charcoal as a therapeutic treatment on an as-needed basis with mammalian livestock in cases of suspected ingestion of toxic plants and control of diarrhea caused by moldy silage. Synthetic forms of activated charcoal derived from other non-vegetative sources continue to be prohibited in organic livestock production. AMS has reviewed and agrees with the NOSB recommendation that activated charcoal be allowed for use in organic livestock production. AMS received comments on the proposed rule for amending activated charcoal onto § 205.603.

Calcium Borogluconate

This final rule adds calcium borogluconate to § 205.603(a) of the National List for use in organic livestock production. Paragraph (a)(7) is amended in § 205.603 to read as follows: Calcium borogluconate (CAS # 5743-34-0)—for treatment of milk fever only. Organic livestock producers should know that calcium borogluconate cannot be used routinely, but only as an emergency treatment for milk fever. AMS has reviewed and agrees with the NOSB recommendation that calcium borogluconate be allowed for use in organic livestock production. AMS received comments on the proposed rule for amending calcium borogluconate onto § 205.603.

Calcium Propionate

This final rule adds calcium propionate to the National List at § 205.603(a) for use in organic livestock production. Paragraph (a)(8) is amended in § 205.603 to read as follows: Calcium Propionate (CAS # 4075-81-4)—for treatment of milk fever only. Specifically, calcium propionate is allowed only as a treatment for milk fever. Organic livestock producers should know that calcium propionate is not to be used routinely, but only as an emergency treatment for milk fever. AMS has reviewed and agrees with the NOSB recommendation that calcium propionate be allowed for use in organic livestock production. AMS received comments on the proposed rule for amending calcium propionate onto § 205.603.

Chlorhexidine

This final rule amends the annotation for chlorhexidine in § 205.603(a). Paragraph (a)(9) is amended to read as follows: 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. Including this amendment to the annotation of chlorhexidine in the final rule adds to organic livestock producers' ability to establish and maintain preventive livestock health care practices. AMS has reviewed and agrees with the NOSB recommendation that the annotation for chlorhexidine be amended to clarify its use in organic livestock production. AMS received comments on the proposed rule for amending the annotation for chlorhexidine as listed in § 205.603.

Hypochlorous Acid

This final rule adds hypochlorous acid to § 205.603 as a chlorine material allowed for use in disinfecting and sanitizing equipment and facilities in organic livestock

production. Paragraph (a)(10)(iii) is modified to read as follows: Hypochlorous acid—generated from electrolyzed water. As listed in § 205.603, hypochlorous acid is allowed for use as a disinfectant, sanitizer, and medical treatment in organic livestock production. AMS has reviewed and agrees with the NOSB recommendation that hypochlorous acid be allowed for use in organic livestock production. AMS received comments on the proposed rule that supported or opposed amending hypochlorous acid onto § 205.603.

Kaolin Pectin

This final rule adds kaolin pectin to § 205.603(a) of the National List for use as an adsorbent, antidiarrheal, and gut protectant in organic livestock production. Paragraph (a)(17) is modified to read as follows: Kaolin pectin—for use as an adsorbent, antidiarrheal, and gut protectant. Organic livestock producers should know that kaolin pectin is not to be used routinely, but only when an adsorbent, antidiarrheal or gut protectant is needed. AMS has reviewed and agrees with the NOSB recommendation that kaolin pectin be allowed for use in organic livestock production. AMS received comments on the proposed rule for amending kaolin pectin acid onto § 205.603.

Mineral Oil

This final rule adds mineral oil to § 205.603(a) for use in organic livestock production for relief of intestinal impaction. Mineral oil is also on the National List as a topical treatment, external parasiticide, or local anesthetic in § 205.603(b). Paragraph (a)(20) is modified to read as follows: Mineral oil—for relief of intestinal compaction, prohibited for use as a dust suppressant. Organic livestock producers should know that under paragraph (a)(20) mineral oil is only allowed for use to relieve intestinal compaction in livestock. Mineral oil cannot be used as a dust suppressant. AMS has

reviewed and agrees with the NOSB recommendation that mineral oil be allowed for use in organic livestock production. AMS received comments on the proposed rule for amending mineral oil onto § 205.603.

Nutritive Supplements - Injectable Vitamins, Minerals, and Electrolytes

This rule adds injectable vitamins, minerals, and electrolytes to § 205.603(a) of the National List for use in organic livestock production. Prior to this rule these substances were allowed under the USDA organic regulations only as part of the total feed ration, either as feed additives (vitamins and minerals per § 205.603(d)) or as medical treatments (electrolytes without antibiotics per § 205.603(a)). Paragraph (a)(21) is modified to read as follows: Nutritive supplements—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 regulations and restricted to use by or on the order of a licensed veterinarian. Under this rule, an operation is allowed to use these substances individually or in combination. This rule requires that injectable vitamins, minerals, or electrolytes only be administered or ordered by a licensed veterinarian. Organic livestock producers will need to keep records that document the need for any use of these materials. Further, producers and certifying agents need to review the specific formulations intended for use on organic livestock to ensure they comply with the USDA organic regulations. AMS has reviewed and agrees with the NOSB recommendation that injectable vitamins, minerals, or electrolytes be allowed for use in organic livestock production. AMS received comments on the proposed rule for amending injectable minerals, vitamins, and electrolytes onto § 205.603.

Parasiticides, Fenbendazole, and Moxidectin

This rule amends the National List to revise the listing for parasiticides (§ 205.603(a)(23)) and the listings for fenbendazole (§ 205.603(a)(23)(i)) and moxidectin (§ 205.603(a)(23)(iii)). This rule also amends the livestock health care practice standard in

§ 205.238(b) to allow the use of parasiticides in organic fiber-bearing animals. Paragraph (a)(23) reads as follows: 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 36 days prior to harvesting of fleece or wool that is to be sold, labeled, or represented as organic. AMS has reviewed and agrees with the NOSB recommendation that the annotation for parasiticides be amended to clarify its use in organic livestock production.

Paragraph (a)(23)(i) is revised to read as follows: 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. AMS has reviewed and agrees with the NOSB recommendation that the annotation for fenbendazole be amended to clarify its use in organic livestock production.

Paragraph (a)(23)(ii) is also revised to read as follows: 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. AMS has reviewed and agrees with the NOSB recommendation that the annotation for moxidectin be amended to clarify its use in organic livestock production.

In addition, paragraph (b)(2) of § 205.238(b) is revised and paragraph (b)(3) is added to § 205.238(b) as follows: (b)(2) Dairy animals, as allowed under § 205.603; and (b)(3) fiber bearing animals, as allowed under § 205.603. AMS has reviewed and agrees with the NOSB recommendation that § 205.238(b) be amended to clarify its use of parasiticides for dairy animals and for fiber bearing animals.

The USDA organic regulations specify conditions under which parasiticides can be used in organic livestock production (§ 205.238(b)) and identify which parasiticides are allowed (§ 205.603(a)(23)). These conditions include: 1) emergency treatment for dairy and breeder stock only when preventive measures have failed; 2) a parasiticide 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 that is included on the National List. However, animals in need of medical attention cannot be left untreated in order to preserve its organic status.

AMS received comments on the proposed rule for amending the annotation for parasiticides and the annotation for the specific parasiticides fenbendazole and moxidectin listed in § 205.603.

Ivermectin

This rule removes ivermectin from § 205.603(a) as an allowed parasiticide for use in organic livestock production. Ivermectin (CAS #70288-86-7), as listed prior to this final rule in paragraph (a)(17)(ii) has been removed from the National List. The removal of ivermectin from the National List leaves organic livestock producers with two

synthetic parasiticides permitted for emergency treatment, fenbendazole and moxidectin. This final rule removes the requirement for a veterinarian to administer fenbendazole and also reduces the withdrawal times following the use of fenbendazole or moxidectin. AMS has reviewed and agrees with the NOSB recommendation that ivermectin be removed from the National List and prohibited for use in organic livestock production. AMS received comments on the proposed rule for removing ivermectin from § 205.603.

Propylene Glycol

This final rule adds propylene glycol to § 205.603(a) of the National List for use in organic livestock production only as a remedy for ketosis in ruminants. Paragraph (a)(27) reads as follows: Propylene glycol (CAS # 57-55-6)—only for treatment of ketosis in ruminants. Organic livestock producers are required to use preventive practices as described in § 205.238 before using propylene glycol to treat ketosis. However, animals in need of medical attention cannot be left untreated in order to retain organic status. AMS has reviewed and agrees with the NOSB recommendation that propylene glycol be allowed for use in organic livestock production. AMS received comments that either supported or opposed adding propylene glycol to § 205.603(a).

Sodium Chlorite, Acidified

This final rule adds two listings for acidified sodium chlorite for use as a teat dip in organic livestock (dairy) production in § 205.603(a) and in § 205.603(b). Both paragraph (a)(28) and paragraph (b)(8) read as follows: Sodium chlorite, acidified—allowed for use on organic livestock as a teat dip treatment only. Preventive health care is essential for organic production. Preventive care through clean milking parlors and clean animals is essential for reducing mastitis in dairy animals and teat dips are used by

dairy producers as an essential tool for preventing mastitis. This rule adds sodium chlorite, acidified to § 205.603(a) as a teat dip when used as a disinfectant, sanitizer, or medical treatment. This rule also adds sodium chlorite, acidified to § 205.603(b) as a teat dip when used as a topical treatment or external parasiticide. AMS has reviewed and agrees with the NOSB recommendation that calcium sodium chlorite, acidified be allowed for use in organic livestock production. AMS received comments on the proposed rule for amending sodium chlorite, acidified onto § 205.603.

Xylazine

This rule amends the annotation of the listing for xylazine in § 205.603(a) by removing the limitation “*The existence of an emergency*” on use of this substance. Paragraph (a)(30) reads as follows: 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, paragraph (a)(30) also includes the following requirements:

- (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.

This change allows xylazine to be used for sedation of animals when necessary to perform non-emergency health care procedures in organic livestock. This amendment allows organic livestock producers to improve their ability to establish and maintain preventive livestock health care practices because there are no alternatives to xylazine on

the National List or nonsynthetic substances that provide sedative properties. This rule does 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. AMS has reviewed and agrees with the NOSB recommendation that the annotation for xylazine be amended to clarify its use in organic livestock production. AMS received comments on the proposed rule for amending the annotation for xylazine as listed in § 205.603.

Zinc Sulfate

This final rule adds zinc sulfate to § 205.603(b) for use in organic livestock production. Paragraph (b)(10) is amended to read as follows: Zinc sulfate—for use in hoof and foot treatments only. This rule allows zinc sulfate to be used in a footbath for control of foot rot in livestock, primarily dairy cattle, sheep and goats. Adding zinc sulfate to the National List provides organic livestock producers with an additional tool to treat foot disease and aids the welfare of the animals. Based upon comments AMS received on amending zinc sulfate onto § 205.603(a & b), zinc sulfate is added only to § 205.603(b). AMS has reviewed and agrees with the NOSB recommendation that zinc sulfate be allowed for use in organic livestock production.

Lidocaine

This final rule amends the annotation of lidocaine in § 205.603(b) to reduce the withholding periods for lidocaine from 90 days to 8 days for slaughter stock and from 7 days to 6 days for milk. Paragraph (b)(4) is modified to read as follows: 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. A

reduction in the withholding time was needed to improve animal welfare because a lengthy withholding time for lidocaine could result in animals not being timely treated, or not treated at all. AMS has reviewed and agrees with the NOSB recommendation that the annotation for lidocaine be amended to clarify its use in organic livestock production. AMS received comments on the proposed rule for amending the annotation for lidocaine as listed in § 205.603.

Procaine

This final rule amends the annotation of procaine in § 205.603(b) to reduce the withholding periods for procaine from 90 days to 8 days for slaughter stock and from 7 days to 6 days for milk. Paragraph (b)(7) reads as follows: 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. A reduction in the withholding time was needed to improve animal welfare because a lengthy withholding time for procaine could result in animals not being timely treated, or not treated at all. AMS has reviewed and agrees with the NOSB recommendation that the annotation for procaine be amended to clarify its use in organic livestock production. AMS received comments on the proposed rule for amending the annotation for procaine as listed in § 205.603.

Methionine

This rule amends the annotation for methionine in § 205.603(d) by requiring that maximum methionine levels in feed be calculated as averages over the lifespan of organic poultry rather than as a constant percentage of the feed. Paragraph (d)(1) reads as follows: 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, maximum rates as averaged per ton of feed over the life of the flock: laying chickens—2 pounds; broiler chickens—2.5 pounds; turkeys and all other poultry—3 pounds. Alternatives to synthetic methionine have yet to be developed for commercial use. This rule change provides organic poultry producers with the ability to adjust methionine supplementation based on the nutritional needs of the birds at specific stages of production that would have positive impacts on animal welfare. In addition, this rule change maintains limits on the use of synthetic methionine, which preserves the incentive to develop viable nonsynthetic methionine alternatives. AMS has reviewed and agrees with the NOSB recommendation that the annotation for methionine be amended to clarify its use in organic livestock production. AMS received several comments on the amending the methionine annotation.

Excipients

This final rule amends the § 205.603 annotation for excipients that are used in animal drugs to treat organic livestock. The rule adds a provision that the excipient must be approved by the USDA Animal and Plant Health Inspection Service (APHIS) for use in veterinary biologics. Paragraph (f) of § 205.603 reads as follows: 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. This change should minimize the variation in certifying agents’

interpretations of excipients and enhance consistency of enforcement. AMS has reviewed and agrees with the NOSB recommendation that the annotation for excipients be amended to clarify its use in organic livestock production. AMS received comments on the proposed rule for amending the annotation for excipients as listed in § 205.603. § 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

This final rule adds the following substances to the National List in paragraph § 205.605 for use in organic handling: hypochlorous acid, potassium lactate, and sodium lactate. This rule also amends 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 rule removes glycerin from § 205.605(b) and adds it to § 205.606 as an agricultural product.

Alginic acid

This final rule amends the National List to reclassify alginic acid from a non-synthetic substance included in § 205.605(a) to a synthetic substance included in § 205.605(b), for use in organic handling. The listing for alginic acid in paragraph (b) reads as follows: Alginic acid (CAS # 9005-32-7). This rule change is based upon updated information on the sourcing of alginic acid and the definition of “synthetic” in § 205.2 of the USDA organic regulations. AMS has reviewed and agrees with the NOSB recommendation that the listing of alginic acid be reclassified to clarify its use in organic handling. AMS received comments on the proposed rule for reclassifying alginic acid from § 205.605(a) to § 205.605(b).

Flavors

The final rule amends the National List to revise the annotation of flavors in § 205.605(a) to change the allowance for nonorganic flavors to require the use of organic flavors when they are commercially available. The listing of flavors in paragraph (a) reads as follows: 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. This rule retains 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. This rule applies to products in the “organic” and “made with organic (specified ingredients or food group(s))” categories. This rule change does not apply to nonorganic ingredients that may be used in up to 30 percent of “made with organic” products. Due to the number of distinctly different natural flavors and the pace of new product development in flavors, AMS has determined it would be impractical to list individual flavors on the National List to indicate which are commercially available in organic form. AMS has reviewed and agrees with the NOSB recommendation that the annotation for flavors be amended to clarify its use in organic handling. AMS received comments on the proposed rule for amending the annotation for flavors as listed in § 205.605.

Carnauba wax

This final rule reclassifies carnauba wax from a nonagricultural substance on § 205.605(a) to an agricultural product on § 205.606 that may be used in organic handling when organic carnauba wax is not commercially available. Paragraph (a) under §

205.606 reads as follows: Carnauba wax. The basis for this reclassification is new information on how carnauba wax is extracted from the leaves and buds of palm trees. This information shows that carnauba wax extracted from this process meets the definition of an agricultural product in § 205.2 of the USDA organic regulations. AMS has reviewed and agrees with the NOSB recommendation that the listing of carnauba wax be reclassified to clarify its use in organic handling. AMS received comments on the proposed rule for reclassifying carnauba wax from a nonsynthetic listed under § 205.605 to an agricultural product listed under § 205.606.

Cellulose

This final rule amends the current allowance for the use of cellulose in organic processing in § 205.605 of the National List. The listing of cellulose in paragraph (b) in § 205.605 reads as follows: 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. The change specifies the type of cellulose allowed for certain uses. This rule adds language to prohibit the use of microcrystalline cellulose to avoid ambiguity about its status. In the proposed rule AMS specifically asked for comments on the need for this additional language concerning microcrystalline cellulose. This rule change prohibits some forms of cellulose, such as microcrystalline cellulose, which may have the same functions as powdered cellulose. AMS has reviewed and agrees with the NOSB recommendation that the annotation for cellulose be amended to clarify its use in organic handling. AMS received comments on the proposed rule for amending the annotation for cellulose as listed in § 205.605.

Chlorine Materials

This final rule amends the listing of chlorine materials in § 205.605(b). This rule change clarifies what chlorine levels are permitted for use in water in direct contact with food versus in water used as an ingredient in food. The listing of chlorine materials in paragraph (b) in § 205.605 reads as follows: 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 (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite). AMS has reviewed and agrees with the NOSB recommendation that the annotation for chlorine materials be amended to clarify its use in organic handling. AMS received comments on the proposed rule for amending the annotation for chlorine materials as listed in § 205.605.

Hypochlorous Acid

This final rule adds hypochlorous acid to § 205.605 as a chlorine material allowed for use in disinfecting and sanitizing equipment and facilities in organic handling and processing. The listing of hypochlorous acid in paragraph (b)(iii) in § 205.605 reads as follows: Hypochlorous acid—generated from electrolyzed water. As listed under § 205.605, hypochlorous acid is allowed for use as a disinfectant and sanitizer in organic handling. AMS has reviewed and agrees with the NOSB recommendation that

hypochlorous acid be allowed for use in organic handling. AMS received comments on the proposed rule for amending hypochlorous acid onto § 205.605.

Potassium lactate

This final rule adds potassium lactate to § 205.605(b) as an allowed substance for use in organic handling. The listing of potassium lactate in paragraph (b) in § 205.605 reads as follows: Potassium lactate—for use as an antimicrobial agent and pH regulator only. Including the annotation with this listing limits the use applications of potassium lactate to those uses included in the petition to add potassium lactate to the National List. AMS has reviewed and agrees with the NOSB recommendation that potassium lactate be allowed for use in organic handling. AMS received comments on the proposed rule for amending potassium lactate onto § 205.605.

Sodium lactate

This final rule adds sodium lactate to § 205.605(b) as an allowed substance for use in organic handling. The listing of sodium lactate in paragraph (b) in § 205.605 reads as follows: Sodium lactate—for use as an antimicrobial agent and pH regulator only. Including the annotation with this listing limits the use applications of sodium lactate to those uses included in the petition to add sodium lactate to the National List. AMS has reviewed and agrees with the NOSB recommendation that sodium lactate be allowed for use in organic handling. AMS received comments on the proposed rule for amending sodium lactate onto § 205.605.

Glycerin

This final rule removes glycerin from § 205.605(b) and amends § 205.606 to include this substance with an annotation. Paragraph (h) in § 205.606 reads as follows:

Glycerin (CAS # 56-81-5)—produced from agricultural source materials and processed using biological or mechanical/physical methods as described under § 205.270(a). For organic handling and processing, this action changes the classification of glycerin under the USDA organic regulations from an allowed synthetic substance to an agricultural product that must be an organic product unless such organic products are not commercially available. After preventive measures have been exhausted, synthetic glycerin may still be used for organic livestock practices as described in § 205.603. AMS has reviewed and agrees with the NOSB recommendation that the listing of glycerin be reclassified to clarify its use in organic handling. AMS received comments on the proposed rule for reclassifying glycerin from a synthetic substance listed under § 205.605 to an agricultural product listed under § 205.606.

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

Colors Derived from Agricultural Products

This final rule amends the USDA organic regulations to replace the Chemical Abstract Services (CAS) numbers included in the annotation of each color listed under National List at § 205.606(d)(1) through (18) with the binomial nomenclature of the agricultural source of the color. Paragraph (d)(1) through(18) in § 205.606 reads as follows:

1. Beet juice extract color—derived from *Beta vulgaris* L., except must not be produced from sugarbeets.
2. Beta-carotene extract color—derived from carrots (*Daucus carota* L.) or algae (*Dunaliella salina*).

3. Black currant juice color—derived from *Ribes nigrum* L.
4. Black/ purple carrot juice color—derived from *Daucus carota* L.
5. Blueberry juice color—derived from blueberries (*Vaccinium spp.*).
6. Carrot juice color—derived from *Daucus carota* L.
7. Cherry juice color—derived from *Prunus avium* (L.) L. or *Prunus cerasus* L.
8. Chokeberry, aronia juice color—derived from *Aronia arbutifolia* (L.) Pers. or *Aronia melanocarpa* (Michx.) Elliott.
9. Elderberry juice color—derived from *Sambucus nigra* L.
10. Grape juice color—derived from *Vitis vinifera* L.
11. Grape skin extract color—derived from *Vitis vinifera* L.
12. Paprika color—derived from dried powder or vegetable oil extract of *Capsicum annuum* L.
13. Pumpkin juice color—derived from *Cucurbita pepo* L. or *Cucurbita maxima* Duchesne.
14. Purple sweet potato juice color—derived from *Ipomoea batatas* L. or *Solanum tuberosum* L.
15. Red cabbage extract color—derived from *Brassica oleracea* L.
16. Red radish extract color—derived from *Raphanus sativus* L.
17. Saffron extract color—derived from *Crocus sativus* L.
18. Turmeric extract color—derived from *Curcuma longa* L.

The use of binomial nomenclature in § 205.606(d) clarifies which agricultural sources may be used to derive the color extract. Varieties or cultivars of the same species may be used as sources for a color extract unless otherwise excluded in the annotation.

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(d). For agricultural products, the application of binomial nomenclature for colors derived from agricultural products is appropriate when classifying colors because it better indicates the agricultural source of the color. The NOSB requested AMS review the use of CAS numbers in annotations of colors derived from agricultural products to determine if there is a better classification for defining colors derived from agricultural products. The NOSB recommended that the use of CAS numbers is not accurate and that the annotations for colors derived from agricultural products be amended to clarify their use in organic handling. AMS has reviewed and agrees with the NOSB recommendation that the annotations of colors derived from agricultural products be amended. AMS received comments on the proposed rule for amending the annotations of colors derived from agricultural products listed in § 205.606.

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.

The proposal to allow the use of 16 substances, to amend the allowed use of 17 National List substances, and to remove one substance, along with allowing the use of parasiticides in fiber bearing animals, was published on January 18, 2018. Additional information on or about the substances in this final rule, including petitions, technical reports, and NOSB recommendations, is available on the AMS website at <https://www.ams.usda.gov/rules-regulations/organic/national-list>.

IV. Statutory and Regulatory Authority

The OFPA (7 U.S.C. 6501 *et seq.*) authorizes the Secretary to make amendments to the National List based on recommendations developed by the NOSB. The OFPA at 7 U.S.C 6518(k) and 6518(n) authorizes 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 rulemaking falls within a category of regulatory actions that the Office of Management and Budget (OMB) has exempted from Executive Order (EO) 12866. Additionally, because this final rule does not meet the definition of a significant regulatory action, it does not trigger the requirements contained in EO 13771. *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 to 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 of the RFA 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.

The Small Business Administration (SBA) sets size criteria for each industry described in the North American Industry Classification System (NAICS), to delineate which operations qualify as small businesses. The SBA has classified small agricultural producers that engage in crop and animal production as those with average annual receipts of less than \$750,000. Handlers are involved in a broad spectrum of food production activities and fall into various categories in the NAICS Food Manufacturing sector. The small business thresholds for food manufacturing operations are based on the number of employees and range from 500 to 1,250 employees, depending on the specific type of manufacturing. Certifying agents fall under the NAICS subsector, "All other professional, scientific and technical services." For this category, the small business threshold is average annual receipts of less than \$15 million.

AMS has considered the economic impact of this rulemaking on small agricultural entities. Data collected by the USDA National Agricultural Statistics Service

(NASS) and the NOP indicate most of the certified organic production operations in the U.S. would be considered small entities. According to the 2016 Certified Organic NASS Survey, 13,954 certified organic farms in the U.S. reported sales of organic products and total farm gate sales in excess of \$7.5 billion. Based on that data, organic sales average \$541,000 per farm. Assuming a normal distribution of producers, we expect that most of these producers would fall under the \$700,000 sales threshold to qualify as a small business.

According to the NOP's Organic Integrity Database there are 9,633 certified handlers in the U.S. The Organic Trade Association's 2017 Organic Industry Survey has information about employment trends among organic manufacturers. The reported data are stratified into three groups by the number of employees per company: less than 5; 5 to 49; and 50 plus. These data are representative of the organic manufacturing sector, and the lower bound (50) of the range for the larger manufacturers is significantly smaller than the SBA's small business thresholds (500 to 1,250). Therefore, AMS expects that most organic handlers would qualify as small businesses.

The USDA has 79 accredited certifying agents who provide organic certification services to producers and handlers. The certifying agent that reports the most certified operations, nearly 3,500, would need to charge approximately \$4,200 in certification fees in order to exceed the SBA's small business threshold of \$15 million. The costs for certification generally range from \$500 to \$3,500, depending on the complexity of the operation. Therefore, AMS expects that most of the accredited certifying agents would qualify as small entities under the SBA criteria. The economic impact on entities affected by this rule would not be significant. The effect of this rule is to allow the use of

additional substances in organic crop or livestock production and organic handling. This action increases regulatory flexibility and gives small entities more tools to use in day-to-day operations. AMS concludes that the economic impact of this rule, if any, would be minimal and beneficial to small agricultural service firms. Accordingly, USDA certifies that this rule would not have a significant economic impact on a substantial number of small entities.

B. Executive Order 12988.

EO 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 final rule is not intended to have a retroactive effect. To prevent duplicative regulation, 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 §§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.

Pursuant to § 6507(b)(2) of the OFPA, a state organic certification program that has been approved by the Secretary may, under certain circumstances, contain additional requirements for the production and handling of agricultural products organically produced in the state and for the certification of organic farm and handling operations located within the state. 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.

In addition, pursuant to § 6519(c)(6) of the OFPA, this final rule does not supersede or 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, respectively, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.), nor the authority of the Administrator of the Environmental Protection Agency 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 final 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 final rule has been reviewed in accordance with the requirements of EO 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. Comments Received on Proposed Rule AMS-NOP-14-0079; NOP-14-05.

During two separate comment periods totaling 90 days, AMS received approximately 130 public comments on proposed rule AMS-NOP-14-0079 from farmers,

handlers, ingredient manufactures, universities, consumers, trade associations, certifying agents, and non-governmental organizations. AMS received two requests to extend the comment period near the close of the initial 60-day comment period. Because the request to extend the comment was received late in the comment period, AMS published a notice to reopen the comment period for an additional 30 days after the initial comment period closed. The received comments can be viewed at <http://www.regulations.gov> by searching for the document AMS-NOP-14-0079.

A majority of comments on the proposed rule indicated support for the new substance additions and amendments to the current listings. Several comments stated opposition to adding any of the proposed new substances to the National List. Such comments argued that the addition of any substances would devalue the organic label and weaken the organic standards. There were comments that only addressed a portion of the new additions or amendments, including a few comments that mentioned a specific addition or amendment but did not indicate support or opposition to the proposed addition or amendment. Some comments proposed changes to the proposed rule, including three comments that requested a twelve-month implementation period before the effective date of the final rule. AMS' response to the received comments on the additions or amendments per National List section is described below.

Comments received on additions or amendments to § 205.601

AMS received comments on the three substance additions to § 205.601. Comments on magnesium oxide indicated either support or opposition to its addition to the National List. Almost all comments opposing the addition of magnesium oxide were generally opposed to the addition of any substance to the National List. AMS received

comments supporting the addition of hypochlorous acid to § 205.601 from farmers, certifying agents, handlers, and commodity associations. Comments opposing the addition of hypochlorous acid § 205.601 were generally opposed to any National List additions. Many comments on squid byproducts supported the addition to the National List in § 205.601. Comments opposing the addition of squid byproducts to the National List were generally opposed to the addition of any new substance to the National List.

AMS also received comments on the amendment of the annotation for micronutrients included in § 205.601. Comments on this amendment either supported the amendment or were opposed to the change. Some comments supported the amendment, but requested that the proposed annotation be changed, stating that it was too long and confusing and needed to be shortened. AMS' response to these comments is included in the section on *Changes Based Upon Comments* described below.

Comments received on additions or amendments to § 205.602

AMS did not receive any comments that opposed the addition of rotenone to § 205.602. All of the comments received on rotenone supported its addition to § 205.602.

Comments received on additions or amendments to § 205.603

AMS received the most comments on the section of the proposed rule dealing with the eight substance additions and nine substance annotation amendments for § 205.603. AMS received several comments, either in support of or opposition to the additions of activated charcoal, calcium borogluconate, calcium propionate, kaolin pectin, mineral oil and propylene glycol to § 205.603. Several comments questioned whether these substances are still needed in organic livestock production, as these additions are based upon NOSB recommendations that were submitted for rulemaking

several years ago. A few comments stated that the additions of calcium borogluconate and calcium propionate are not needed, as these substances are already included on the National List. Other comments on these substances argued that the addition of these substances to § 205.603 violated FDA regulations. Our response to these comments is included in the section on AMS' response to comments.

AMS received comments from livestock farmers, certifying agents, handlers, and livestock associations in support of the addition of hypochlorous acid to § 205.603. AMS also received comments opposing the addition of hypochlorous acid § 205.603. Most of these latter comments were generally opposed to any National List substance additions. The proposed addition of nutritive supplements - injectable vitamins, minerals, and electrolytes - generated several comments from certifying agents, organic advocacy groups, livestock associations, and producers. Many comments supported adding nutritive substances to § 205.603. One comment supporting the addition requested altering the annotation to remove the requirement for a licensed veterinarian. Some comments opposing the addition of nutritive substances stated that injectable forms of vitamins, minerals, and electrolytes are already on the National List. Our response to these comments is included under the section AMS' Response to Comments.

AMS received several comments on the proposed amendments of substance annotations listed under § 205.603. Although fewer comments on chlorhexidine were received, most of the received comments supported this amendment. One comment opposing the amendment argued that "...under the supervision of a licensed veterinarian" is not defined, and there are toxicity concerns when used as a teat dip pre-milking. Many comments on the proposed rule supported amending the category of parasiticides and

each individual parasiticide, fenbendazole and moxidectin. A few comments opposed the reduction in withdrawal time or opposed allowing parasiticides in fiber bearing animals. However, comments received from livestock producers, certifying agents and trade associations supported adding paragraph (b)(3) to § 205.238, to allow parasiticide use in fiber bearing animals. Our response to these comments is included under the section on AMS' Response to Comments.

Most comments received on ivermectin supported the removal of ivermectin from § 205.603. Comments submitted by consumers, certifying agents, public health advocacy and organic advocacy groups (non-government organizations) supported the removal of ivermectin, stating that it is nonessential and has negative impacts on pasture ecosystems. Some comments supporting the removal of ivermectin stated that the use of preventative management practices in organic production should preclude the need for parasiticides. Comments from a few producers, a parasiticide manufacturer and a dairy producers' association opposed the removal of ivermectin. Some of the producer comments stated that ivermectin was needed as a rotation with other parasiticides to prevent the development of pesticide resistance. One comment opposing ivermectin's removal stated that ivermectin is effective against parasites that are not controlled by remaining parasiticides on the National List. Our response to these comments is included under the section on AMS' Response to Comments.

AMS received many comments from livestock producers that supported the addition of sodium chlorite, acidified onto § 205.603(a) and § 205.603(b). A certifying agent, a dairy producers' association, and a trade association also indicated support for this amendment in their comments. Comments from a second certifying agent and an

organic consulting organization supported listing sodium chlorite, acidified in § 205.603(a), but were opposed to its listing in § 205.603(b). Several consumers submitted comments that opposed the addition of sodium chlorite, acidified. These commenters were generally opposed to the addition of any substance to the National List. In the sodium chlorite, acidified recommendation forwarded to the Secretary, the NOSB did not fully clarify its reason for adding sodium chlorite, acidified to both § 205.603(a) and § 205.603(b). However, each of these regulation paragraphs contains substances that are used as teat dips or may be ingredients in teat dip products.

Although AMS received fewer comments on the annotation changes for lidocaine, procaine, and excipients listed in § 205.603, and most of these comments supported the amendments, including comments from certifying agents. Comments opposing these amendments were opposed to any synthetic substance being used in organic production. AMS received many comments from trade association groups, certifying agents, livestock producers and researcher supporting the annotation amendment for methionine. Other comments on methionine opposed the amendment and requested that the use of methionine be phased out of organic production. Our response to comments on methionine is discussed in the section on AMS' Response to Comments.

Comments received on additions or amendments to § 205.605

AMS received few comments on the reclassification of alginic acid, and the received comments supported the change. AMS received comments from industry groups and certifying agents indicating support for the reclassification of carnauba wax, although some received comments expressed opposition to all additions and amendments. Several comments received on the amendment of the allowance for the use of cellulose

expressed support for this amendment. A few comments received stated opposition to the prohibition of microcrystalline cellulose. AMS received few comments regarding the proposed amendments to the listing of chlorine in § 205.605(b), and most comments received supported the changes. Most of the comments received regarding the proposed addition of hypochlorous acid to § 205.605 of the National List supported this addition. AMS received one comment from a certifying agent supporting the addition of potassium lactate and sodium lactate to § 205.605(b), while opposing comments were submitted by groups and individuals that are opposed to any synthetic substance being added to the National List. AMS received several comments that supported the removal of glycerin from § 205.605(b) and its addition to § 205.606 as an agricultural product. Comments from manufacturers or industry representatives expressed concern with limits on the manufacturing process or in sourcing glycerin. AMS received several comments on or about the amendment of the annotation for flavors listed in § 205.605, both in support of and in opposition to this rule change. Comments opposed to the change argued that requiring organic flavors to be used when commercially available may adversely impact product formulations. Our response to these comments is discussed in AMS' Response to Comments section.

Comments received on additions or amendments to § 205.606

Colors derived from agricultural products

Nearly all received comments on the use of binomial nomenclature for colors derived from agricultural products supported this change. Some comments proposed adding additional agricultural product sources from the same genus but different species.

Other comments offered technical corrections to the nomenclature cited in the proposed rule. These and other comments are discussed in our response to comments in section E.

AMS Response to Comments

Changes Based Upon Comments

Micronutrients

Few comments addressed the amendment of the annotation for micronutrients. Three comments recommended that the annotation be shortened to “micronutrient deficiency must be documented” or that the annotation also require site specific data. These comments recommended shortening the annotation to reduce confusion. Upon considering the totality of comments received, AMS determined that shortening the annotation would reduce the potential for confusion and has modified the amendment accordingly. Paragraph § 205.601(j)(7) reads as follows: (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 or other documented and verifiable method as approved by the certifying agent. AMS has determined that the modified amendment includes information sources that producers can use to support their need to use micronutrients to maintain soil fertility while providing more tools to the organic producer. The requirement that certifying agents must approve the method for documenting micronutrient deficiency is retained in the final rule.

Parasiticides for fiber bearing animals

AMS received many comments supporting the use of parasiticides in fiber bearing animals and the proposed changes to § 205.603(a)(23). Many comments indicated the changes would benefit domestic producers by aligning with international organic

production standards for fiber bearing animals. Some of these comments, however, argued for a reduction in the parasiticide withdrawal period required prior to harvesting fleece or wool of treated animals, and stated that a 90-day withdrawal period for fiber bearing animals is not based upon withholding times established by the FDA or the Food Animal Residue Avoidance Databank (FARAD), a university-based national program. Comments received from a trade association, a consulting firm, and a sheep producer stated that a 90-day withdrawal period for fiber bearing animals is excessive and problematic for sheep production cycles and requested a 36-day withdrawal period instead. Upon review of the 2016 NOSB recommendation on parasiticides and the FARAD withdrawal interval recommendations, AMS determined that the FARAD-recommended withholding time for milk when goats are treated orally with moxidectin is up to 18 days. No recommendations for withholding times for sheep following treatment with parasiticides were available. The recommendation that was forwarded to the Secretary indicated that for organic production, animal withholding periods following treatment with parasiticides should double those recommended by FARAD. AMS has determined that the 36-day withdrawal period for milk or milk products from goats, sheep and other dairy species treated with fenbendazole or moxidectin (§§ 205.603(a)(23)(i) - (ii)) is consistent with a doubling of FARAD recommendations and aligns with the production criteria established by the OFPA. AMS has considered the totality of comments received, the NOSB recommendations and the withholding periods established by FARAD, and determined that a 36-day withdrawal period for fiber-bearing animals treated with parasiticides aligns with the production criteria established by the OFPA. Therefore, this final rule reduces from 90 days to 36 days the withholding period required

before harvesting fleece or wool from fiber-bearing animals treated with parasiticides. Producers are reminded that the use of any individual substance in § 205.603 in a formulated product that is intended or used as a medical treatment is under the authority of FDA and must comply with all FDA regulations.

Methionine

A few of the many comments on methionine that AMS received requested that the term “maximum” be added to the amended annotation to illustrate that the intent of the recommendation submitted to the Secretary is to have maximum rates of synthetic methionine supplementation as averages per ton of feed over the life of the bird, rather than as a maximum quantity per ton of feed. Upon review of both the NOSB recommendation, the comments received, and the technical report on methionine, AMS determined that adding the term “maximum” is appropriate. Thus, AMS amended the methionine annotation in the final rule to read, “maximum rates as averaged per ton of feed over the life of the flock.” This change in the methionine annotation recognizes that methionine requirements change over a bird’s life. This change also ensures that a bird’s changing nutritional requirements are met which, in turn, should reduce the overfeeding of dietary crude protein.

Zinc sulfate

AMS received several comments supporting the addition of zinc sulfate to the national List in § 205.603. A few of these comments stated that the NOSB recommended that zinc sulfate should be added only to § 205.603(b) and not added to § 205.603(a). Based upon a review of the NOSB recommendation, AMS determined that zinc sulfate was only recommended for addition to § 205.603(b), and, therefore, that adding zinc

sulfate to § 205.603(a) would not comply with OFPA requirements. Based upon this finding, zinc sulfate is added only to § 205.603(b) in this final rule.

Colors derived from agricultural products

Nearly all comments received supported the change to remove chemical abstract (CAS) numbers and replace them with binomial nomenclature to identify colors that are derived from agricultural sources. A few comments stated that using binomial nomenclature to identify colors derived from agricultural products is more accurate than using CAS numbers. Based upon analysis developed for this rulemaking, AMS agrees with these comments. AMS reviewed comments on colors submitted during the 2012 Sunset review. Some of the comments stated that the CAS numbers included in the annotations actually refer to pigments in the color and not the color itself. AMS has determined that CAS numbers are applied to chemical substances and not to agricultural products. As a result, AMS agrees with these comments and has replaced all CAS numbers included within each color product annotation with the appropriate binomial or other taxonomic nomenclature to identify the color derived from agricultural product. Other comments on colors offered technical corrections to some of the binomial nomenclatures cited in the proposed rule. AMS agrees with these comments and has corrected the binomial nomenclatures of all color listings in this final rule using binomial nomenclatures currently listed as accepted by both the Integrated Taxonomic Information System¹ and the USDA Natural Resources Conservation Service Plants Database².

⁴U.S. Integrated Taxonomic Information System: <https://www.itis.gov/>. Accessed August 2, 2018.

⁵U.S. Department of Agriculture, Natural Resources Conservation Service Plants Database: <https://plants.usda.gov/java/>. Accessed August 2, 2018.

Two comments received from food coloring manufacturers noted that some colors are derived from more than one agricultural source and requested that these additional color sources be added to the National List at § 205.606. AMS considered these comments and determined that adding these additional agricultural sources complies with OFPA. Thus, in this final rule, additional agricultural sources have been added to the color listings for blueberry juice color, cherry juice color, chokeberry— aronia juice color, pumpkin juice color, and purple potato juice color. Three comments received by AMS noted a technical correction to the beet juice extract color listed in the proposed rule. These comments stated that sugarbeet is not the appropriate cultivar of *Beta vulgaris* for use as a source of food coloring, because it is not used by the organic industry. The comments further indicated it would be difficult for the organic industry to source sugarbeet that is not genetically modified. These comments suggested listing as beet root or redbeet instead of sugarbeet. AMS agrees and has modified this listing to indicate any variety of *Beta vulgaris* may be used except for sugarbeet. AMS has received information which indicates sugarbeet varieties are mostly derived from excluded methods as listed in § 205.2 and use of any of these varieties in organic production or handling is prohibited.

Twelve-month implementation period

AMS received a few comments supporting the inclusion of an implementation period for this final rule. These comments argued that an implementation period would allow organic producers and handlers time to comply with the changes in the USDA organic regulations. One comment recommended a twelve-month implementation

period. AMS only partially agrees with these comments. Based upon other comments that supported the additions of new substances or amendments to substance annotations, many organic producers and handlers want to use these additional substances as soon as allowed. As such, AMS determined that a twelve-month implementation period would not benefit operations seeking to include any of the new National List substances in their organic system plan. Therefore, AMS has determined that all of the additions to the National List and most of the amendments to the List will be effective 30 days after publication of the final rule, per the Federal Register requirements.

AMS does agree that some of the amendments in the final rule will require an implementation period. AMS has determined that changes to the following substances will require a twelve-month implementation before taking effect: Ivermectin, Flavors, Carnauba Wax, Glycerin, and Cellulose. AMS determined a twelve-month implementation period is warranted to permit organic livestock producers to use existing stocks of ivermectin and for organic handlers using flavors, glycerin, or carnauba wax to adjust to the requirement to use organic sources of these substances when organic sources are commercially available. AMS determined that a twelve-month implementation period is also appropriate for the prohibition of microcrystalline cellulose, in order to provide time for industry to modify production practices.

Changes Requested But Not Made

Additions to the National List

AMS received several comments requesting that all of the synthetic substance additions to the National List cited in the proposed rule not be added to the list in the final rule. Because the commenters did not provide any justification for their view, AMS did

not have a basis for evaluating their objections. The OFPA at 7 U.S.C. 6517 authorizes the Secretary to add synthetic substances to the National List provided the Secretary determines that the substance meets the criteria in 7 U.S.C. 6517 (c)(1). Section 6517(d)(1) further authorizes the Secretary to propose amendments to the National List based upon recommendations developed by the NOSB. The NOSB recommended adding these 16 synthetic substances to the National List, based upon their review against the OFPA substance evaluation criteria (7 U.S.C. 6518(m)). AMS reviewed the recommendations and agrees the substances meet the OFPA criteria for addition to the National List. Therefore, this rule adds the 16 synthetic substances to the National List. *Activated charcoal, calcium borogluconate, calcium propionate, kaolin pectin, mineral oil, and propylene glycol.*

AMS received fewer comments on these substances, however a few comments questioned whether these substances are still needed. These comments recommended that the substances be sent back to the NOSB for the purpose of reviewing new information, because the original NOSB recommendations are now considered dated. A few comments opposing the addition of these substances stated that the associated annotations do not comply with U.S. Food and Drug Administration (FDA) regulations. AMS stated in previous rulemaking (proposed rule, July 17, 2006, 71 FR 40624) that these six substances could not be added to § 205.603(a) as medical treatments because they were not FDA-approved and did not qualify for extra-label use by veterinarians under the Animal Medical Drug Use Clarification Act (AMDUCA) provisions. This proposed rule indicated that AMS would continue consultation with the FDA regarding the use of these six substances in organic livestock production. Subsequently, prior to

publication of the proposed rule, AMS conferred with the FDA on the proposed additions and amendments to § 205.603. During this conference, the FDA indicated that their process involves reviewing formulated products for medical treatment approval. FDA indicated they do not review for medical treatment approval of generic materials, as included in this rule. Therefore, individual substances cited in this rule would not be reviewed as medical treatments under the FDA process. Based upon this consultation, AMS believes these substances are not in conflict with FDA regulations. Thus, this final rule adds these six substances to § 205.603.

Ivermectin

A majority of comments on ivermectin received by AMS supported its removal from the National List. A few producers submitting comments on ivermectin opposed its removal, arguing that ivermectin is needed for parasiticide rotation to prevent the development of parasite resistance. A comment from a dairy association opposed the ivermectin removal, arguing that ivermectin is used to control a different set of parasites that are not controlled by either moxidectin or fenbendazole. AMS does not agree with these comments. The USDA regulations stipulate that producers must establish and maintain preventive livestock health care practices before using available healthcare treatments that are on the National List. Only when preventive practices and veterinary biologics are inadequate to prevent sickness can synthetic treatments be administered to livestock, and then only when such treatments are on the National List in § 205.603. AMS review has determined that ivermectin and moxidectin are part of the same chemical class (macrocyclic lactones) with broad spectrum efficacy against both internal parasites and external parasites (e.g., cattle lice). Fenbendazole is a broad spectrum

external parasiticide in a different chemical class (i.e., benzimidazoles). Ivermectin and moxidectin appear to have a similar mode of action and may be less effective when used in a two parasiticide rotation to manage the prevention of parasiticide resistance. AMS review of the 2015 Technical Report on Ivermectin developed for the National List petition process identified several livestock management practices that can control parasite infestation and the report also cited multiple alternative non-synthetic substances that are effective as parasiticides. The technical report also highlighted new research that indicated that when excreted in cattle dung, ivermectin is toxic to dung beetle larvae and causes negative effects to pasture ecosystems. Based on the similar efficacies between ivermectin and moxidectin, and a review of information provided in the technical report, AMS has determined that ivermectin is not essential for organic production.

Subsequently, this final rule removes ivermectin from the National List.

Sodium chlorite, acidified

AMS received several comments, including a signed petition with several signatures, supporting the addition of sodium chlorite, acidified to the National List. Some of these comments cited its effectiveness in controlling mastitis in dairy animals and its environment compatibility. Other comments grouped sodium chlorite, acidified into opposition to any new additions to the National List. Comments opposing the listing of sodium chlorite, acidified did not provide any justification for their opposition. Consequently, AMS did not have for consideration a basis for their opposition to sodium chlorite, acidified.

AMS also received comments supporting the addition of sodium chlorite, acidified only to § 205.603(a) of the National List. Comments seeking to limit the

addition of sodium chlorite, acidified to only § 205.603(a) stated that the intent of the NOSB's recommendation was not for use as a topical treatment. Based upon a review of the NOSB recommendation on sodium chlorite, acidified forwarded to the Secretary, AMS determined that the original recommendation was to add the substance to both § 205.603(a) and § 205.603(b). The recommendation on sodium chlorite, acidified provided for pre-milking and post-milking teat dip treatment, which allows sodium chlorite, acidified to be used as a sanitizer, a use application provided under § 205.603(a), and as a topical treatment, a use application provided under § 205.603(b). AMS determined that dairy producers use teat dips as a sanitizer and as a topical treatment. AMS also reviewed all substances listed in §§ 205.603(a) and 205.603(b) and determined that substances that may be used in teat dips or as ingredients in teat dip products are listed in both §§ 205.603(a) and 205.603(b). Therefore, this rule adds sodium chlorite, acidified to the National List in §§ 205.603(a) and 205.603(b).

Methionine

AMS received many comments supporting the amendment of the annotation of methionine under § 205.603. A few comments in opposition to this change requested that AMS implement a phase-out of methionine. These comments argued the substance is no longer essential for organic poultry production. One opposing comment recommended that the final rule add an expiration date to the annotation. AMS has considered the totality of comments received and reviewed the historical use and effectiveness of expiration dates for this substance. In previous rulemaking, AMS amended section 205.603 of the National List to allow methionine in organic poultry production with established expiration dates included in the annotation for the substance (October 31,

2003, 68 FR 61987; October 21, 2005, 70 FR 61217; August 24, 2010, 73 FR 54057; March 14, 2011, 75 FR 51919). Expiration dates were included in previous rulemaking in order to emphasize the need to develop alternatives to synthetic methionine that are more compatible with organic production practice standards. AMS subsequently published additional rulemaking that removed the previously established expiration dates from the methionine annotation on September 19, 2012 (77 FR 57985). AMS has determined that the use of expiration dates did not result in the development of effective alternatives to synthetic methionine for use by organic poultry producers. Furthermore, establishing a phase-out in the absence of an effective alternative to methionine would result in a significant reduction in organic poultry and egg production. AMS has determined that the use of synthetic methionine is still essential for organic poultry production. Consequently, this final rule does not include a phase-out of methionine.

Microcrystalline cellulose

Some comments opposed amending the cellulose annotation in § 205.605(b) that would prohibit microcrystalline cellulose. Upon review of the technical report on cellulose, AMS determined that microcrystalline cellulose is derived from cellulose through additional chemical processing that has not been subjected to the evaluation criteria stipulated in the OFPA § 6581(m). Therefore, AMS has determined that microcrystalline cellulose is not the same substance as cellulose. Furthermore, based on a review of public comments provided during the 2012 National List sunset reviews, AMS determined that some public comments raised concern that microcrystalline cellulose was being interpreted as being an allowed form of cellulose when these

commenters indicated microcrystalline cellulose is a prohibited substance. Subsequently, this final rule retains the prohibition of microcrystalline cellulose in § 205.605(b).

Clarifications

U.S. Food and Drug Administration, AMS

Comments from an animal feed association, a dairy association, and an animal health association opposed the additions of several substances to § 205.603. These comments inferred that some of the proposed substance additions are not compliant with FDA regulations or other federal regulations. During the development of the proposed rule, AMS staff conferred with the FDA Center for Veterinary Medicine (CVM) staff regarding the additions and amendments that would be included in § 205.603. Copies of all of the proposed § 205.603 additions and amendments were transmitted to CVM staff before the proposed rule was published. AMS and CVM discussed the proposed changes to § 205.603. Based upon this conference, AMS believes adding these substances to the National List is not inconsistent with FDA or other federal regulations. CVM reviews and approves formulated products as medical treatments. The National List contains individual substances that may be used in organic production. The use of any individual substance in § 205.603 in a formulated product that is intended or used as a medical treatment is under the authority of FDA and must comply with all FDA regulations. The OFPA § 2120(c)(6) stipulates that no provision within the USDA organic regulations supersedes the authority of the FDA regulations.

Comments on substances considered to be already on the National List

Some comments opposed adding substances such as calcium borogluconate, calcium propionate, and nutritive supplements – injectable forms of vitamins, minerals,

or electrolytes, to § 205.603 because they interpret these substances to be currently included on the National List. AMS has considered these comments and determined that calcium borogluconate, calcium propionate, and nutritive supplements – injectable forms of vitamins, minerals, or electrolytes, were individually petitioned for addition to the National List. AMS facilitated the NOSB’s petition review process during which public comments were received on each of these substances. After deliberate consideration, the NOSB forwarded to the Secretary separate recommendations to add these substances to the National List. AMS reviewed these recommendations and determined that the NOSB reviewed each substance against the substance evaluation criteria delineated by the OFPA (§ 6518(m)). AMS agrees that these substances have met the criteria. Therefore, this final rule adds calcium borogluconate, calcium propionate, and nutritive supplements – injectable forms of vitamins, minerals, or electrolytes to § 205.603 of the National List. Organic livestock producers and certifying agents should amend any prior interpretation on the allowance of these substances.

Requirement for Licensed Veterinarian and “Off Label” Use.

AMS received comments on the proposed rule that addressed the requirement for use by a “licensed Veterinarian” or for a substance to be administered under the “supervision of a licensed Veterinarian.” Some of these comments argued that inclusion of these requirements with use of the substances as listed under § 205.603 would be confusing or too restrictive. The requirement for use by a licensed veterinarian or the use of a substance under the supervision of a licensed veterinarian is a condition required by FDA regulations. The USDA organic regulations do not supersede FDA regulations. Other comments questioned the oversight of “off label” use of some of the substances

being added or amended in this rule. As noted above, use of any animal drug in organic production must comply with both the USDA organic regulation requirements and the FDA regulation requirements. Certifying agents should ensure compliance with these regulation requirements during approval of an operation's organic system plan and verification during inspection.

Flavors and Commercial availability

AMS received a comment from the petitioner of the amendment to the flavors annotation which requires that non-synthetic flavors be used when organic flavors are not commercially available. The petitioner noted that this change should be applied to "organic" products and not be applied to non-organic ingredients that make up the 30 percent or less portion of a "made with organic (specified ingredients)" product. AMS concurs with the petitioner's comments and interprets the rule to not apply to non-organic ingredients that compose 30 percent or less of "made with organic" products. Also, in its comment, the petitioner requested that the National Organic Program develop guidance on commercial availability based upon the NOSB's November 2007 recommendation on commercial availability. Prior to being revised in 2013, the National List petition guidelines included guidance on commercial availability that was based upon a Fall 2006 NOSB recommendation.

Requested changes not addressed in the proposed rule

AMS received comments that requested changes to annotations that were not addressed in the proposed rule. These changes, as such, cannot be included in this final rule because they have not been available for comment.

Corrections to proposed rule 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).

This document corrects the regulation text of the proposed rule published in the Federal Register of January 17, 2018, regarding National Organic Program; Amendments to the National List of Allowed and Prohibited Substances (Crops, Livestock, and Handling). These corrections clarify that the proposed rule applies prospectively to the plans submitted for approval from the effective date of this final rule. AMS has inserted the following corrections in this final rule:

- In the proposed rule (83 FR 2498), beginning on page 2522 in the issue of January 17, 2018, column C, make the following correction, under the List of Subjects in 7 CFR Part 205, 3. Amend § 205.601 as follows: b. Redesignate paragraphs (j)(5) through (j)(8) as (j)(6) through (j)(9), redesignate paragraph (j)(9) as (j)(11), add new paragraphs (j)(5) magnesium oxide and (j)(10) squid byproducts, and revise newly redesignated paragraph (j)(7) micronutrients.
- In the proposed rule (83 FR 2498), beginning on page 2524 in the issue of January 17, 2018, column A, make the following correction, under the List of Subjects in 7 CFR Part 205, 6. Amend § 205.605 as follows: Remove “Alginic” from the listing for “Acids” and remove “Carnauba wax” from the listing for “Waxes” in paragraph (a). Revise the listing for “Flavors” in paragraph (a). Add “alginic acid” to paragraph (b). Add “potassium lactate” and “sodium lactate” to paragraph (b). Revise the substances “cellulose” and “chlorine materials” in paragraph (b). Remove “Glycerin—produced by hydrolysis of fats and oils” from paragraph (b).

- In the proposed rule (83 FR 2498), beginning on page 2524 in the issue of January 17, 2018, column B, make the following correction, under the List of Subjects in 7 CFR Part 205, Amend (b), Add “Potassium lactate—for use as an antimicrobial agent and pH regulator only,” and “Sodium lactate—for use as an antimicrobial agent and pH regulator only,” to paragraph (b). Revise the substances “cellulose” and “chlorine materials” in paragraph (b). Remove “Glycerin—produced by hydrolysis of fats and oils” from paragraph (b).

List of Subjects in 7 CFR Part 205

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

For the reasons set forth in the preamble, 7 CFR part 205 is amended as follows:

PART 205 – NATIONAL ORGANIC PROGRAM

1. The authority citation for 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); and,
- b. Redesignate paragraph (j)(9) as (j)(11), redesignate paragraphs (j)(5) through (j)(8) as (j)(6) through (j)(9), add new paragraphs (j)(5) and (j)(10), and revise newly redesignated paragraph (j)(7).

The additions and revision 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 or other documented and verifiable method as approved by the certifying agent.

(i) Soluble boron products.

(ii) Sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt.

* * * * *

(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 as follows:

- a. Remove reserved paragraphs (j)-(z); and
- b. Redesignate 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 as follows:

- a. Revise paragraph (a);
- b. Revise paragraphs (b)(4) and (7);
- c. Redesignate paragraph (b)(8) as (b)(9) and add new paragraph (b)(8);
- d. Add paragraph (b)(10);
- e. Revise paragraph (d)(1); and
- f. Revise paragraph (f).

The revisions and addition read as follows:

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

* * * * *

(a) As disinfectants, sanitizer, and medical treatments as applicable.

(1) Alcohols.

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

(ii) Isopropanol-disinfectant only.

(2) Aspirin-approved for health care use to reduce inflammation.

(3) Atropine (CAS #-51-55-8)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:

(i) Use by or on the lawful written order of a licensed veterinarian; and

(ii) A meat withdrawal period of at least 56 days after administering to livestock intended for slaughter; and a milk discard period of at least 12 days after administering to dairy animals.

(4) Biologics—Vaccines.

(5) Butorphanol (CAS #-42408-82-2)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:

(i) Use by or on the lawful written order of a licensed veterinarian; and

(ii) A meat withdrawal period of at least 42 days after administering to livestock intended for slaughter; and a milk discard period of at least 8 days after administering to dairy animals.

(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 paragraph (d)(2) of this section, vitamins per paragraph (d)(3), and electrolytes per paragraph (a)(11), with excipients per paragraph (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 36 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)—only for treatment of ketosis in ruminants.

(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.

(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.

* * * * *

(10) Zinc sulfate—for use in hoof and foot treatments 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, maximum rates as averaged per ton of feed 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. Remove “Alginic:” from the listing for “Acids” and remove “Carnauba wax; and” from the listing for “Waxes” in paragraph (a);
- b. Revise the listing for “Flavors” in paragraph (a);
- c. Add a listing for “Alginic acid” to paragraph (b) in alphabetical order;

- d. Revise the listings for “Cellulose” and “Chlorine materials” in paragraph (b);
- e. Remove the listing for “Glycerin” from paragraph (b); and
- f. Add listings for “Potassium lactate” and “Sodium lactate” to paragraph (b) in alphabetical order.

The revisions and additions 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) * * *

* * * * *

Flavors—nonsynthetic 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.

* * * * *

(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.

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

* * * * *

Potassium lactate—for use as an antimicrobial agent and pH regulator only.

* * * * *

Sodium lactate—for use as an antimicrobial agent and pH regulator only.

* * * * *

7. Amend § 205.606 as follows:

- a. Redesignate paragraphs ((g) through (t) as paragraphs (i) through (v); and,
- b. Redesignate paragraphs (d) through (f) as paragraphs (e) through (g);
- c. Redesignate paragraphs (a) through (c) as paragraphs (b) through (d).
- d. Add new paragraph (a).
- e. Revise newly redesignated paragraphs (d)(1) through (d)(18); and
- f. Add new paragraph (h).

The additions and revisions 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 *Beta vulgaris* L., except must not be produced from sugarbeets.
- (2) Beta-carotene extract color—derived from carrots (*Daucus carota* L.) or algae (*Dunaliella salina*).
- (3) Black currant juice color—derived from *Ribes nigrum* L.
- (4) Black/ purple carrot juice color—derived from *Daucus carota* L.
- (5) Blueberry juice color—derived from blueberries (*Vaccinium spp.*).
- (6) Carrot juice color—derived from *Daucus carota* L.
- (7) Cherry juice color—derived from *Prunus avium* (L.) L. or *Prunus cerasus* L.
- (8) Chokeberry, aronia juice color—derived from *Aronia arbutifolia* (L.) Pers. or *Aronia melanocarpa* (Michx.) Elliott.
- (9) Elderberry juice color—derived from *Sambucus nigra* L.
- (10) Grape juice color—derived from *Vitis vinifera* L.
- (11) Grape skin extract color—derived from *Vitis vinifera* L.

(12) Paprika color—derived from dried powder or vegetable oil extract of *Capsicum annuum* L.

(13) Pumpkin juice color—derived from *Cucurbita pepo* L. or *Cucurbita maxima* Duchesne.

(14) Purple sweet potato juice color—derived from *Ipomoea batatas* L. or *Solanum tuberosum* L.

(15) Red cabbage extract color—derived from *Brassica oleracea* L.

(16) Red radish extract color—derived from *Raphanus sativus* L.

(17) Saffron extract color—derived from *Crocus sativus* L.

(18) Turmeric extract color—derived from *Curcuma longa* L.

* * * * *

(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 18, 2018

Bruce Summers, Administrator
Agricultural Marketing Service.

BILLING CODE: 3410-02 P

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