



Agricultural Marketing Service

7 CFR Part 205

[Doc. No. AMS-NOP-22-0029; NOP-22-02]

RIN 0581-AE25

National Organic Program: National List of Allowed and Prohibited Substances per October 2021, October 2022, and October 2024 Recommendations (Crops and Livestock)

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the U.S. Department of Agriculture's (USDA) organic regulations related to organic crop and livestock production. The proposed rule would provide additional tools to organic producers, allowing carbon dioxide in organic crop production and meloxicam as a pain treatment in organic livestock production. Additionally, this rulemaking would remove overly burdensome restrictions for methionine, an amino acid, in organic poultry feed and would affirm that sodium nitrate may be used as a fertilizer in organic crop production, with certain conditions to protect soil quality.

DATES: Comments must be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may send comments, identified by AMS-NOP-22-0029 and/or RIN 0581-AE25, by any of the following methods:

- Federal eRulemaking Portal: www.regulations.gov. Follow the instructions on the website for sending comments.
- Agency Web Site: www.ams.usda.gov/rules-regulations/proposed-rules. Follow the instructions on the website for sending comments.

- E-mail: Jared.Clark@usda.gov. Include the identifier AMS-NOP-22-0029 and/or RIN 0581-AE25 in the subject line of the message.

- Mail: Jared Clark, Assistant Director, Standards Division, National Organic Program, USDA-AMS-NOP, 1400 Independence Ave. SW, Room 2642-South, Stop 0268, Washington, D.C. 20250-0268.

Instructions: All submissions received should include the agency name and docket number (AMS-NOP-22-0029) or Regulatory Information Number (RIN) 0581-AE25 for this proposed rule. When submitting a comment, clearly indicate the proposed rule topic and section number to which the comment refers. In addition, comments should clearly indicate whether the commenter supports or opposes the action being proposed and clearly indicate the reason(s) for the position. Comments can also include information on alternative management practices, where applicable, that support alternatives to the proposed amendments. Comments may also offer any recommended language change(s) to the regulatory text that would be appropriate to the position. Only relevant material supporting the position should be submitted. All comments and materials received will be posted without change, including any personal identifying information provided, to www.regulations.gov.

Docket: For access to the docket to read background documents or comments received, go to www.regulations.gov (search for Docket ID AMS-NOP-22-0029).

FOR FURTHER INFORMATION CONTACT: Jared Clark, Standards Division, National Organic Program; telephone: (202) 720-3252; email: Jared.Clark@usda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

This proposed rule would amend the USDA organic regulations to implement recommendations from the National Organic Standards Board (“NOSB” or “Board”). If adopted, this proposed rule would allow two additional synthetic substances to be used in

organic crop and livestock production (carbon dioxide and meloxicam, respectively). Additionally, the proposed rule would remove current restrictions on the use of methionine, an amino acid, in organic poultry feed, thus allowing producers additional flexibility and making it unnecessary for organic poultry producers to track the amount of methionine fed to each poultry flock. Finally, the proposed rule would affirm that sodium nitrate, a natural fertilizer, is allowed for limited use in organic crop production by renewing the substance's listing on the National List of Allowed Substances for 5 years.

Authority

The USDA Agricultural Marketing Service's (AMS) National Organic Program (NOP) administers the USDA organic regulations (7 CFR part 205) under the authority granted to it by the Organic Foods Production Act of 1990 ("OFPA") (7 U.S.C. 6501-6524). This proposed rule would amend a portion of the USDA organic regulations known as the National List of Allowed and Prohibited Substances (or "National List"), in accordance with the procedures and criteria set forth in the OFPA (7 U.S.C. 6503, 6517, 6518). OFPA authorizes the Secretary to make amendments to the National List based on recommendations developed by the Board. OFPA authorizes the Board to develop recommendations for submission to the Secretary to amend the National List and to establish a process by which persons may petition the Board for the purpose of having substances evaluated for inclusion on, or deletion from, the National List.

II. General Information

A. Does this Proposed Rule apply to me?

You may be affected by this proposed rule if you are engaged in organic crop and/or livestock production. Potentially affected entities may include, but are not limited to, the following:

- Organic crop and/or livestock producers;
- Individuals or business entities that are considering organic certification for

crop and/or livestock production;

- USDA-accredited certifying agents, inspectors, and certification review personnel;

- Fertilizer, soil amendment, livestock feed supplement, and animal drug manufacturers;

- Material review organizations.

This list is not exhaustive but identifies key entities that this rulemaking may affect. Other types of entities may also be affected. To determine whether you or your business may be affected by this action, you should carefully examine the regulatory text and discussion below.

B. What should I consider as I prepare my comments for AMS?

AMS seeks comment from the public and organic stakeholders regarding the proposed amendments. While all comments submitted are taken into consideration, the most effective comments:

- Clearly state a position (support, opposition, and/or requested modifications) on the proposed rule or specific parts of the proposed rule;

- Clearly identify which specific parts of the proposed rule a comment refers to;

- Explain why the commenter supports or opposes the proposed change;

- Describe the potential effects of the proposed rule using examples, data, or personal experience;

- If applicable, offer suggested alternatives to the proposed changes and/or regulatory text, and explain the reasoning for those suggested changes.

Comments are invited on the entire proposed rule; however, AMS is especially interested in public input on the following questions:

1) Is the proposed regulatory language and accompanying discussion in this document clear enough to allow operations and certifying agents to comply with the proposed requirements?

2) Do the proposed amendments create any conflict with current USDA organic regulations or other Federal regulatory requirements?

3) Carbon dioxide:

a) Why is synthetic carbon dioxide necessary for the uses described in this proposed rule? What are the various sources of synthetic carbon dioxide that operations would be able to obtain? Which of these are sourced as a byproduct? Is there adequate supply of byproduct-sourced synthetic carbon dioxide in the market to meet the needs of the organic industry for either or both uses of described in this proposed rule?

b) Why is natural carbon dioxide insufficient or not available for the uses described in this proposed rule? Are other allowed natural or synthetic substances suitable as alternatives? Why or why not?

c) Should both listings of carbon dioxide at 7 CFR 205.601(a) and/or 205.601(j) be annotated to only allow carbon dioxide sourced as a byproduct? Do producers and certifying agents have enough information to verify compliance with the proposed annotation?

4) Meloxicam:

a) Is the proposed annotation clear? Do veterinarians, producers, and certifying agents have the information they need to establish, document, and verify the proposed withdrawal period? If not, what additional information is necessary?

b) Should the annotation further restrict the use of meloxicam, such as by specifying a minimum withdrawal period for bovine species, and/or restricting non-bovine uses to disbudding and dehorning only?

c) AMS welcomes comments on the NOSB Livestock Subcommittee's technical analysis appendix published as part of the NOSB final recommendation.

III. Overview of Proposed Amendments

The following provides an overview of the proposed amendments to the National List, along with the NOSB recommendations and AMS justifications for each proposed amendment. AMS welcomes comments on each proposed amendment. Comments received during the comment period will inform AMS's decisions for the final rule; specifically, whether the proposed amendments align with OFPA criteria and are justified. More information on the NOSB meetings can be found in section IV,

RELATED DOCUMENTS.

A. Carbon Dioxide (Crops)

AMS is proposing to add carbon dioxide to the National List at 7 CFR 205.601(a) and 205.601(j) as a synthetic substance allowed for use in organic crop production to adjust the pH of irrigation water and for atmospheric adjustment in indoor crop production environments. This proposed rule would allow organic crop operations to use synthetic carbon dioxide, which is commonly sourced as a byproduct from various commercial processes. This AMS proposal follows two recommendations from the NOSB following its review of a petition, third-party technical reports, and public comments.

Background

Synthetic carbon dioxide has been allowed for organic handling (7 CFR 205.605(b)(10)) since the USDA organic regulations were first established (65 FR 80548, December 21, 2000). Organic handling operations use synthetic carbon dioxide to carbonate beverages, freeze foods, extract compounds, prevent spoilage in modified atmosphere packaging, and control pests in post-harvest storage of grains and produce. This AMS proposal would expand the current allowance of synthetic carbon dioxide to

allow it in organic crop production for irrigation water treatment and as a plant and soil amendment.

On November 30, 2020, Eco2Mix, Inc., a water treatment company, petitioned the NOSB to add carbon dioxide to the National List as an allowed synthetic substance for use in organic crop production.¹ The petition requests carbon dioxide be allowed to adjust the pH of water used in crop irrigation systems in § 205.601(a), and for use as a plant or soil amendment in § 205.601(j).

Many farming areas have alkaline (high pH) water sources that can hinder the efficiency of irrigation systems, reduce soil nutrient availability, and otherwise impair crop-growing conditions. To address these problems, carbon dioxide can be used to lower the pH of water. Dissolving carbon dioxide in water creates carbonic acid, which dissociates into hydrogen and bicarbonate ions, and the hydrogen ions acidify the water (lower the pH). By reducing the pH of alkaline irrigation water, operations can reduce mineral or algal buildup and prevent the clogging of irrigation system equipment (e.g., drip lines, emitters, sprinklers). Adjusting the pH of irrigation water can also help improve nutrient availability and plant health by establishing an ideal pH value (typically neutral or slightly acidic) for crop nutrient absorption.

The petitioner states that the alternative substances currently allowed, such as natural carbon dioxide or synthetic sulfurous acid, are either not commercially available or are not as safe and effective as synthetic carbon dioxide. Natural carbon dioxide can be produced as a byproduct of fermentation (e.g., from ethanol production). However, the petition states that sources of natural carbon dioxide are not typically available in the market and could have impurities. The petition describes several sources of synthetic

¹ Eco2Mix, Inc. carbon dioxide petition, November 30, 2020, www.ams.usda.gov/sites/default/files/media/PetitionNOBCarbonDioxide2020.pdf.

carbon dioxide and states that most sources reclaim or recapture carbon dioxide from processes that would otherwise release carbon dioxide into the atmosphere.

Byproduct-sourced carbon dioxide is trapped and processed in different ways, depending on the source. Most sources involve the capture of byproduct gas mixture, purification of the gas, and final processing for the market as either liquified gas or as “dry ice” (solid carbon dioxide). Liquified carbon dioxide gas is stored in pressurized refrigeration units or in tanks. Large quantities can be delivered as tanker trucks while small quantities can be obtained in 20–50-pound tanks from distributors. Dry ice is sold as ice blocks or pellets and shipped in insulated boxes.

NOSB Recommendation for § 205.601(a)

In 2022, the NOSB recommended adding synthetic carbon dioxide to the National List at 7 CFR 205.601(a) for water pH adjustment in irrigation systems.² In addition to reviewing the petition, the Board considered a third-party technical report related to synthetic carbon dioxide used in organic handling and public comments received at public NOSB meetings in October 2021, April 2022, and October 2022.^{3, 4, 5, 6} The Board ultimately determined that the petitioned use of carbon dioxide meets the OFPA criteria (7 U.S.C. 6518(m)) for inclusion on the National List.

In its recommendation, the NOSB reasoned that when reclaimed synthetic carbon dioxide is used as petitioned, it is not harmful to the environment or human health. The Board acknowledged that carbon dioxide is a greenhouse gas;⁷ however, the use of

² NOSB recommendation on carbon dioxide, October 2022, www.ams.usda.gov/sites/default/files/media/CSCarbonDioxidePetitionFinalRec.pdf.

³ NOP, carbon dioxide technical report, handling, 2006, www.ams.usda.gov/sites/default/files/media/CarbonDioxideSyntheticTR2006.pdf.

⁴ NOSB virtual meeting, Fall 2021, www.ams.usda.gov/event/national-organic-standards-board-nosb-meeting-sacramento-ca.

⁵ NOSB virtual meeting, Spring 2022, www.ams.usda.gov/event/national-organic-standards-board-nosb-meeting-crystal-city-va-1.

⁶ NOSB Sacramento, CA meeting, Fall 2022, www.ams.usda.gov/event/national-organic-standards-board-nosb-meeting-sacramento-ca-2022.

⁷ Gases that trap heat in the atmosphere are called greenhouse gases. Overview of Greenhouse Gases, U.S. Environmental Protection Agency (EPA), www.epa.gov/ghgemissions/overview-greenhouse-gases.

synthetic carbon dioxide as petitioned would not increase carbon dioxide in the atmosphere. The petitioned form of synthetic carbon dioxide is a byproduct and, if not captured, would be released into the atmosphere. Therefore, the Board concluded that the capture of the byproduct for crop production is akin to recycling.

The NOSB also noted there are no apparent adverse effects on other materials used in organic farming systems and that carbon dioxide has little direct impact on human health. Additionally, carbon dioxide is already permitted on the National List for use in or on processed organic products (7 CFR 205.605(b)), which indicates its acceptance as not harmful to human health.

The NOSB evaluated the suitability of natural alternatives and determined that natural sources of carbon dioxide are not widely available due to a lack of infrastructure at ethanol manufacturing facilities, where natural sources are produced. The Board acknowledged that some organic farmers have been using sulfurous acid from sulfur burners (§ 205.601(j)(11)) to lower pH levels in irrigation water. Sulfur burners create sulfurous acid by dissolving the fumes of burning sulfur in irrigation water, which can irritate human skin, eyes, and respiratory systems. The Board also considered that carbon dioxide is safer and more stable than alternatives, because using a weak acid such as carbon dioxide in the acidification process does not bring the pH of water below 5.0, well above values considered hazardous to humans.

Overall, the NOSB determined that the use of synthetic carbon dioxide to adjust the pH of irrigation water would pose little risk to the environment or human health and is compatible with a system of sustainable agriculture. The Board's vote was unanimous in recommending the addition of carbon dioxide to § 205.601(a) for use in irrigation systems.

NOSB Recommendation for § 205.601(j)

In 2024, the NOSB submitted a second recommendation to AMS related to the petition's request to add synthetic carbon dioxide to the National List in § 205.601(j) for use as a crop or soil amendment.⁸ The petition did not detail the intended use(s), so the NOSB's Crops Subcommittee requested a new technical report.⁹ The technical report identified the most prevalent use of carbon dioxide as an atmospheric enrichment substance in indoor (e.g., greenhouse) crop production.

The NOSB considered the petition, technical report, and public comments received at its public meetings in April 2024 and October 2024.^{10, 11} The Board ultimately determined that synthetic carbon dioxide, when sourced as a byproduct and used for atmospheric adjustment in indoor crop production, meets the OFPA criteria (7 U.S.C. 6518(m)) for inclusion in the National List.

In its recommendation, the NOSB explained the necessity of carbon dioxide supplementation in indoor crop production. An optimal concentration of atmospheric carbon dioxide for plant growth in a greenhouse environment is 800-1,000 parts per million. Plants consume atmospheric carbon dioxide as they grow, depleting carbon dioxide from the atmosphere inside the greenhouse. Supplemental carbon dioxide sources can be used to replenish the depleted atmospheric carbon dioxide within the greenhouse.

The NOSB discussed alternative practices for adjusting atmospheric carbon dioxide, such as venting (exchanging air between inside and outside the greenhouse); however, venting is not a practical solution in colder climates due to the need for a controlled environment and consistent temperature for crop production.

⁸ NOSB recommendation on carbon dioxide, October 2024, www.ams.usda.gov/sites/default/files/media/CS_NOSBRec_CarbonDioxide.pdf.

⁹ NOP, carbon dioxide technical report, crops, 2023, www.ams.usda.gov/sites/default/files/media/CarbonDioxide_Crops.pdf.

¹⁰ NOSB Milwaukee, WI meeting, Spring 2024, www.ams.usda.gov/event/national-organic-standards-board-nosb-meeting-milwaukee-wi.

¹¹ NOSB Portland, OR meeting, Fall 2024, www.ams.usda.gov/event/national-organic-standards-board-nosb-meeting-portland-or.

The NOSB evaluated the commercial sources of synthetic carbon dioxide and recommended allowing synthetic carbon dioxide only when sourced as a byproduct. The recommendation noted that synthetic carbon dioxide is available as a byproduct of manufacturing processes and propane heaters in greenhouses. The recommendation also noted that all commercial sources of synthetic carbon dioxide on the market are byproducts of other manufacturing processes. Restricting synthetic carbon dioxide to byproduct (recycled) sources only would ensure that the use of carbon dioxide will not have adverse effects on the environment. The Board also reaffirmed its assessment that natural sources are inadequate to meet commercial needs.

AMS Review of NOSB Recommendations

AMS agrees with both NOSB recommendations to add synthetic carbon dioxide to 7 CFR 205.601(a) and 205.601(j), as these uses meet the requirements for adding a synthetic substance to the National List under OFPA at 7 U.S.C. 6517(c)(1)(A). AMS reviewed all documentation that the Board considered as part of their recommendations, including the petition and public comments.

AMS agrees with the NOSB's conclusion that the recommended uses of carbon dioxide in crop production are not harmful to human health or the environment. This assessment is consistent with prior AMS determinations that supported the listing of synthetic carbon dioxide on the National List in 7 CFR 205.605(b) for use in organic processing. Additionally, carbon dioxide is generally recognized as safe by the U.S. Food and Drug Administration (FDA) and permitted for direct addition to food for human consumption (21 CFR 184.1240). The U.S. Environmental Protection Agency (EPA) also allows carbon dioxide for pest control on food commodities in storage (40 CFR 180.1049), and as an inert ingredient in EPA-registered pesticides (40 CFR 180.910) and minimum risk pesticide products (40 CFR 152.25(f)(2)). The EPA

allowance for these uses is based on its assessment that the substance is not hazardous to public health or the environment.

AMS also agrees with the NOSB's conclusions that allowed natural and synthetic alternatives to the specific petitioned uses of synthetic carbon dioxide are not commercially available. AMS invites additional comments on the necessity of synthetic carbon dioxide for the uses described in this proposed rule, including whether synthetic substances already on the National List or natural substances are suitable alternatives.

If finalized, this proposed rule would add two listings for synthetic carbon dioxide to the National List for use in organic crop production. First, the rule proposes adding carbon dioxide to 7 CFR 205.601(a), allowing organic crop producers to use synthetic carbon dioxide as an algicide, disinfectants, and sanitizer, including irrigation system cleaning. This listing would allow carbon dioxide to be used to adjust irrigation water pH to inhibit mineral and algae buildup, preventing the clogging of irrigation system equipment. Second, the rule proposes adding carbon dioxide, when sourced as a byproduct, to § 205.601(j), allowing organic crop producers to use synthetic carbon dioxide as a crop or soil amendment. This listing would allow carbon dioxide to be used to adjust the atmosphere in indoor crop production systems, such as greenhouses. This listing also would allow carbon dioxide to be used to adjust irrigation water pH to establish ideal pH values for crop nutrient availability and protect soil quality from alkaline irrigation water.

This proposed rule would not supersede or conflict with applicable FDA or EPA legal authority regarding the uses of carbon dioxide for irrigation water treatment or greenhouse atmospheric enrichment. For example, producers using substances to treat irrigation water would need to do so in a manner that complies with relevant provisions of the FDA Produce Safety rules for agricultural water (21 CFR part 112, subpart E).

AMS requests comments about whether the proposed listing in 7 CFR 205.601(a) should include the same annotation limiting the sources of carbon dioxide proposed in § 205.601(j). Adding the annotation, “must be sourced as a byproduct,” at § 205.601(a), in addition to § 205.601(j), would support consistency among the listings. AMS welcomes comments on whether adding the restriction, “must be sourced as a byproduct,” to § 205.601(a) would preclude the intended uses of carbon dioxide as described in the petition and recommended by the Board. AMS also welcomes comments on whether any annotation related to the source of carbon dioxide is necessary for either listing.

B. Sodium Nitrate (Crops)

This rule proposes renewing the listing for sodium nitrate on the National List at 7 CFR 205.602 as a natural substance allowed for limited use in organic crop production. This AMS proposal follows a recommendation from the NOSB in October 2021 to reinstate the listing for this substance. The listing for sodium nitrate is currently expired for reasons further described in Background below. If finalized, this proposed rule would allow for application of natural sodium nitrate as a nitrogen fertilizer for up to 20 percent of a crop’s total nitrogen requirement,¹² the same as prior to October 21, 2012, when the listing for sodium nitrate expired.

Background

The OFPA “sunset provision” requires that the NOSB reviews, and that AMS renews, each exception (“listing”) on the National List every 5 years (7 U.S.C. 6517(e)) for the listing to remain valid. This recurring re-review process is referred to as “sunset review.” For each substance on the National List, AMS calculates a “sunset date” that

¹² For example, if a producer determines that their corn crop requires 120 pounds of nitrogen per acre, they may apply up to 20 percent, or 24 pounds, of nitrogen from sodium nitrate. A typical sodium nitrate fertilizer contains 16% nitrogen, so a producer could apply such a fertilizer at a maximum rate of 150 pounds per acre to supply 24 pounds of nitrogen per acre to comply with the annotation.

establishes the last date a substance listing is valid, calculated as 5 years after the date that AMS last renewed the listing. AMS publishes a complete list of sunset dates on its website.¹³

Typically, as the sunset date for a substance approaches, AMS either announces in the *Federal Register* that a substance on the National List is renewed (i.e., retained on the National List for another 5 years) or AMS proposes a rule to remove a substance from the National List. The removal of a substance is only complete if AMS publishes a final rule that follows such a proposal, as rulemaking is required to add, remove, or revise listings on the National List.

A substance listing can expire (i.e., become invalid) if AMS does not complete rulemaking actions to either renew or remove a substance from the National List by the sunset date. This is the case with sodium nitrate. Sodium nitrate still appears on the National List at 7 CFR 205.602, but AMS has not renewed its listing through rulemaking since October 21, 2007 (72 FR 58469, October 16, 2007). As announced in 2012, AMS considered possible regulatory action on sodium nitrate, (77 FR 1996, January 12, 2012; 77 FR 33290, June 06, 2012), by either renewing the listing or by prohibiting sodium nitrate—both recommended by the NOSB in April 2011.¹⁴ However, AMS did not complete rulemaking. Therefore, the listing has expired.

The fact that the expired listing of sodium nitrate continues to appear on the National List creates confusion that this proposed rule seeks to remedy. If finalized, this rule would renew the listing and establish a new sunset date of 5 years after the effective date of a final rule. The proposed rule would retain the same limitations for use of sodium nitrate that were in place prior to the October 21, 2012 sunset date and described at

¹³ Sunset dates for substances on the National List are included in the “NOSB Work Agenda,” accessible online at: www.ams.usda.gov/rules-regulations/organic/nosb.

¹⁴ NOSB recommendation on sodium nitrate, April 2011, <https://www.ams.usda.gov/sites/default/files/media/Sodium%20Nitrate%20Final%20Rec.pdf>.

§ 205.602. Specifically, this proposed rule retains the maximum use rate for sodium nitrate of 20 percent of a crop's total nitrogen requirement.

Finally, this proposal would remove obsolete language in the annotation stating that use of sodium nitrate in spirulina production is unrestricted until October 21, 2005. Spirulina producers were restricted in their use of sodium nitrate from October 21, 2005, until October 21, 2012. AMS has no information that spirulina production requires a different limit than other types of crop production.

NOSB Recommendation

In October 2021, the NOSB unanimously recommended that AMS renew the listing for sodium nitrate on the National List.¹⁵ In its recommendation, the Board explained that reinstatement was necessary to resolve the confusion with this listing and to create uniform enforcement among certifying agents. The Board also reasoned that a reinstatement was necessary to resume sunset reviews, as directed by OFPA.

The NOSB evaluated over 60 public comments submitted at the October 2021 public meeting on this topic.⁴ Most organic crop producers and certifying agents supported the reinstatement of sodium nitrate, as the action would provide clarity. Several certifying agents explained that they would have no issues verifying compliance with the restriction, as verification using crop nitrogen calculations was a common practice prior to 2012 when the listing was valid. One certifying agent stated that restricting the allowable amount is unnecessary because operations are using sodium nitrate at rates well below the limit of 20 percent of a crop's total nitrogen requirement. Some comments stated they would prefer a complete prohibition of sodium nitrate out of concern that highly soluble nitrogen sources like sodium nitrate only feed the plant and do not protect soil quality. The Board weighed all comments and finalized their unanimous

¹⁵ NOSB recommendation on sodium nitrate, October 2021, www.ams.usda.gov/sites/default/files/media/CSSodiumNitrateFinalRec.pdf.

recommendation for AMS to reinstate the listing of sodium nitrate on the National List and allow its use for up to 20 percent of a crop's total nitrogen requirement, which protects soil quality.

AMS Review of NOSB Recommendation

AMS agrees with the NOSB's recommendation to reinstate the listing of sodium nitrate on the National List. The fact that sodium nitrate appears on the National List as an expired listing creates confusion. This proposed rule would resolve this confusion by affirming that the use of sodium nitrate as annotated (i.e., comprising less than 20 percent of the crops' nitrogen requirements) is valid for 5 years from the effective date of a final rule. The proposed action, if finalized, would then allow the Board to subsequently review sodium nitrate according to the OFPA sunset provision (7 U.S.C. 6517(e)). The proposed rule would also implement a technical correction to remove obsolete language exempting spirulina production from the use limits that expired on October 21, 2005.

AMS also considered resolving the expired listing by removing sodium nitrate from the National List. However, OFPA requires a recommendation from the NOSB to revise the National List (7 U.S.C. 6517(c)(1)(C) and 6517(d)(1)), and the Board has made no such recommendation. Therefore, AMS believes this proposed action to reinstate the listing is the simplest and most effective approach to resolve the confusion around the sodium nitrate listing. If finalized, the rule would provide a path forward for the Board and AMS to resume a regular sunset review schedule for the sodium nitrate listing, like all other substances on the National List.

C. Meloxicam (Livestock)

AMS is proposing to add meloxicam to the National List at 7 CFR 205.603(a) as a synthetic substance allowed for use in organic livestock production. Meloxicam is a nonsteroidal anti-inflammatory drug (NSAID) used primarily to treat pain and inflammation. Organic livestock producers petitioned for use of meloxicam because they

identified a need in their industry for more tools to improve pain management in their operations, for both dairy and meat animals. This AMS proposal follows a recommendation from the NOSB after their review of the petition as well as public comment.

Background

On February 6, 2024, a group of organic dairy operations submitted a petition to the NOSB to allow synthetic meloxicam as a medical treatment in organic livestock production at 7 CFR 205.603(a).¹⁶ Meloxicam is an NSAID that works by reducing hormones that cause pain and inflammation in the body. Nonorganic dairy operations often use it as an easy and effective treatment of pain related to common veterinary procedures, such as disbudding (the removal of the soft tissue that would otherwise form horns on livestock) and dehorning. It is also used to manage pain related to castration and other surgical procedures and medical conditions. Meloxicam is typically administered to livestock in oral tablet form, though it is also available as an injection. Its therapeutic effect lasts 24–48 hours with a single dose.

While other pain management substances are available for organic livestock producers to use, petitioners explained that they are difficult to administer. The petition argues that meloxicam is easier to administer and/or more effective. For example, flunixin can only be administered by intravenous injection or by transdermal (i.e., pour-on) solution. Using intravenous flunixin requires the producer to have the technical skills necessary to administer the injection. Administering transdermal flunixin requires caution to avoid spills or accidental human absorption while pouring the medicine on the animal. Neither application method of flunixin, the petition argues, is as easy nor as safe as the orally administered meloxicam pill. The petition also describes other alternatives as being

¹⁶ CROPP Cooperative/Organic Valley/Organic Prairie, Horizon Organic Dairy, Lactalis Yogurt US/Stonyfield Farms, and Aurora Organic Dairy petition, February 06, 2024, www.ams.usda.gov/sites/default/files/media/NOPPpetitionMeloxicamV2.pdf.

less effective than meloxicam, e.g., lidocaine has shorter-lived therapeutic effects, and natural remedies or tinctures show inconsistent effects in scientific studies.

FDA Allowance

Meloxicam is FDA-approved for use in humans and in certain companion animals (per approved labeling for dogs and/or cats) but only authorized for use in food-producing livestock under the conditions established by FDA at 21 CFR part 530. This practice, called extralabel use, was established by the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA).¹⁷ Extralabel use is when a drug is used in a manner that is not in accordance with the approved labeling (21 CFR 530.3).

FDA regulations at 21 CFR part 530 establish the conditions under which a licensed veterinarian may prescribe the extralabel use of FDA-approved drugs for treatment of meat- or dairy-producing animals. FDA regulations require veterinarians to use scientific information to establish an appropriate withdrawal period, i.e., the required time between administering the treatment and the marketing of milk, meat, or other edible products from the animal (21 CFR 530.20(a)(2)(ii)). The withdrawal period must assure that no drug residues that could present a risk to public health remain in the animal (21 CFR 530.20(a)(2)(iv); 21 CFR 530.11).

The Food Animal Residue Avoidance Databank (FARAD) is a resource of science-based recommendations regarding safe withdrawal periods of drugs in food-producing animals.¹⁸ Veterinarians use FARAD to determine appropriate withdrawal periods that comply with FDA regulations for extralabel drug use.

NOSB Recommendation

¹⁷ Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA), www.fda.gov/animal-veterinary/guidance-regulations/animal-medicinal-drug-use-clarification-act-1994-amduca.

¹⁸ Food Animal Residue Avoidance Databank, www.farad.org.

In October 2024, the NOSB recommended adding meloxicam to 7 CFR 205.603(a) for use in organic livestock production.¹⁹ The Board concluded that meloxicam is a synthetic substance and that the petitioned use of meloxicam meets the OFPA criteria for allowing a synthetic substance in organic production (7 U.S.C. 6517–6518). The Board voted in favor of adding meloxicam to the National List.

The NOSB’s recommendation involved a thorough evaluation of the petition and public comments received during its October 2024 meeting. The petition included substantial technical information and numerous appendices with scientific literature to support the Board’s review. Comments were provided from a range of stakeholders including farmers, manufacturers, veterinarians, researchers, trade associations, advocacy groups, certifying agents, inspectors, and consumers. There were more than 40 substantive written and oral comments provided to the Board specific to meloxicam, the majority of which supported the NOSB recommendation to allow meloxicam in organic production.

In the recommendation, the NOSB noted that the use of meloxicam has minimal adverse effects on the environment or human health (7 U.S.C. 6517(c)(1)(A)(i); 7 U.S.C. 6518(m)(1)-(5)). Specifically, the Board described that after the drug is administered to livestock, it is metabolized into biologically inactive metabolites, which have no adverse impacts on soil organisms or biodiversity when excreted from livestock through feces and urine. Several licensed veterinarians and university research centers submitted comments to the Board stating that meloxicam has been legally and safely administered to livestock with no observed negative side effects. Regarding human health, the FDA approved meloxicam for human use by prescription, and it is considered safe when taken according to the physician’s recommendation. As noted above, FDA

¹⁹ NOSB recommendation on meloxicam, October 2024, www.ams.usda.gov/sites/default/files/media/LS_MeloxicamFinalRec.pdf.

regulations at 21 CFR part 530 require that the administration of meloxicam to livestock is followed by a sufficient withdrawal period to ensure no residues enter the human food supply that would present a risk to public health.

The NOSB thoroughly discussed and evaluated the process that licensed veterinarians use to comply with AMDUCA and its implementing regulations at 21 CFR part 530. This included evaluating the veterinary procedures for diagnosing a specific condition or illness and obtaining scientific information to determine withdrawal periods for the specific dose, duration, and other confounding factors. The Board also received feedback from organic certifying agents, inspectors, and certified producers about the procedures currently in place for documenting treatments and verifying compliance with withdrawal times. The Board recommended that the withdrawal period for meloxicam in organic livestock should be double that required by the FDA for compliance with AMDUCA.

NOSB evaluated alternatives and determined that meloxicam is necessary for organic livestock production (7 U.S.C. 6517(c)(1)(A)(ii); 7 U.S.C. 6518(m)(6)). The Board recognized that the petition was submitted by a varied cross-section of the organic dairy industry representing a majority of U.S. organic dairy operations. Information in the petition and provided by public comments from livestock operators indicate a need for safe and effective pain management tools in both organic meat- and milk-producing animals. Specifically, the Board cited that meloxicam is easier to administer, provides longer therapeutic effectiveness, and requires fewer treatments in a specified period compared to alternatives.

The NOSB determined that alternative NSAIDs are insufficient replacements for meloxicam. Flunixin, whether in an injectable or pour-on form, is more difficult to apply than meloxicam, which can be administered by an oral tablet. Aspirin is another NSAID currently on the National List for use in livestock, but the FDA clarified that aspirin

products are not permitted for use in lactating dairy cattle.²⁰ Lidocaine is on the National List for use in livestock as a local numbing relief, typically during disbudding, but its efficacy duration is far shorter than meloxicam (less than 2 hours for lidocaine compared to 24-48 hours for meloxicam). According to the Board's review of studies submitted with the petition and public comments, natural alternatives such as herbal tinctures or willow bark are not effective in managing pain.

The NOSB determined that the petitioned use of meloxicam is consistent with organic farming and compatible with sustainable agriculture (7 U.S.C. 6517(c)(1)(A)(iii); 7 U.S.C. 6518(m)(7)). The Board noted that safe and effective pain management is important for protecting animal welfare. The Board received comments from animal welfare groups supporting the allowance of meloxicam for organic livestock.

The NOSB explained that organic producers need access to appropriate pain management tools for dairy- and meat-producing livestock of all species and stages of life. A few comments suggested that meloxicam should be limited to disbudding bovine calves younger than 1 year of age. Other comments from producers and veterinarians cited the benefits of meloxicam as a pain relief tool for older animals, for non-bovine animals, and for treatments of pain other than disbudding, such as castration. The NOSB recommendation states that all animals need to receive pain management in accordance with veterinarian recommendations.

Board members on the NOSB's Livestock Subcommittee ("Subcommittee") used their expertise in livestock management and relevant disciplines to evaluate technical information during their consideration of the meloxicam petition. The Subcommittee determined that the technical information provided in the petition was thorough, objective, and sufficient to evaluate meloxicam in conjunction with the Subcommittee

²⁰ FDA Dear Veterinarian Letter regarding use of aspirin products in lactating dairy cattle. October 11, 2024, www.fda.gov/animal-veterinary/product-safety-information/dear-veterinarian-letter-regarding-use-aspirin-products-lactating-dairy-cattle.

members' own technical expertise and information-gathering effort. To verify sufficiency of the petition's technical information, the Subcommittee produced a technical appendix document that references how each question typically covered in a third-party technical report is directly addressed in the petition. The technical appendix document is attached to the Board's final recommendation, available on the AMS website, but was not published with the Subcommittee's original proposal prior to its meeting.²¹

During the NOSB deliberation at the public meeting, some Board members stated they would have preferred the Subcommittee to publish its technical analysis appendix for public visibility prior to the meeting. Some commenters also said that more technical information was needed and requested the issue be returned to the Subcommittee for further study. With support from the majority of commenters, the Board determined that there was sufficient technical information to support their recommendation, citing the robustness of the petition and public comments (including technical expertise of veterinarians and producers who authored the petition and submitted comments), in combination with the Subcommittee's own expertise in livestock production. Ultimately, the Board voted in favor of the recommendation. The Subcommittee's technical analysis appendix is publicly available on the AMS website as part of the NOSB final recommendation, and AMS welcomes comments from the public during this comment period.

AMS Review of NOSB Recommendation

AMS agrees with the NOSB recommendation to allow meloxicam as a medical treatment for organic livestock, as meloxicam meets the requirements for adding a substance to the National List under 7 U.S.C. 6517(c)(1)(A). AMS reviewed all documentation that the Board considered as part of its recommendation, including the

²¹ The Livestock Subcommittee's technical analysis appendix begins on page 8 of the final recommendation: www.ams.usda.gov/sites/default/files/media/LS_MeloxicamFinalRec.pdf.

petition and public comments, and consulted with the FDA to inform this determination. AMS also agrees with the Board's recommendation to classify meloxicam as synthetic because it is manufactured through a process that meets the definition of “synthetic” at 7 CFR 205.2.

AMS has reviewed and agrees with the NOSB’s conclusion that the petitioned use of meloxicam is not harmful to human health or the environment (7 U.S.C. 6517(c)(1)(A)(i)). The FDA regulations that implement AMDUCA (21 CFR part 530) are sufficient to ensure that meloxicam is used in a manner that does not pose harm to human health. Scientific information reviewed by the Board and AMS indicates that metabolites of meloxicam excreted by livestock do not pose harm to the environment.

Consistent with the NOSB’s recommendation, AMS proposes that the withdrawal period for meloxicam would be calculated to be twice as long as what a licensed veterinarian determines to be required for compliance with FDA regulations (AMDUCA (21 CFR 530.20(a)(2)(ii))). For example, if a licensed veterinarian determines that a 5-day milk withdrawal period is appropriate for extralabel use of meloxicam under full compliance with AMDUCA, then the withdrawal time would be doubled to 10 days for compliance with the USDA organic regulations for use in organic livestock.

AMS understands that veterinarians determine withdrawal periods for each animal based on the individual animal’s conditions, diagnosis, dosage, and other case-specific factors in full compliance with AMDUCA. This approach may result in some variation in withdrawal times between animals with different conditions. However, it is an approach that relies on well-established FDA legal oversight of the use of animal drugs and the sound expertise of licensed veterinarians to determine appropriate prescriptions of each treated animal.

The extended withdrawal period proposed in this rule is only relevant for use of the substance under USDA organic regulations. Organic livestock producers are prohibited from administering animal drugs in violation of the Federal Food, Drug, and Cosmetic Act (7 CFR 205.238(c)(6)). This proposed rule would not supersede or conflict with the FDA's authority to approve drugs and determine the withdrawal periods for animal drugs.

AMS agrees with the NOSB determination that the use of meloxicam is necessary to the production or handling of the agricultural product because of the unavailability of natural substitutes (7 U.S.C. 6517(c)(1)(A)(ii)). Meloxicam is easy to administer as an oral pill compared to alternatives that require an intravenous or transdermal (pour-on) application. Meloxicam also has longer efficacy duration and requires fewer treatments in a given period than any alternatives. The majority of public comments and the Board vote indicate a broad range of support across the organic industry for the allowance of meloxicam in organic livestock production.

AMS further agrees with the NOSB determination that the use of meloxicam is consistent with organic farming (7 U.S.C. 6517(c)(1)(A)(iii)). USDA organic regulations require producers to establish and maintain preventive health care practices. Physical alterations and surgical procedures must be performed in a manner that minimizes pain, stress, and suffering, and with the use of allowed anesthetics, analgesics, and sedatives, as appropriate (7 CFR 205.238(a)(5) and 205.238(a)(7)). USDA organic regulations provide for the allowance of medications to alleviate pain or suffering and when preventive practices are inadequate to prevent sickness (7 CFR 205.238(b)). The use of meloxicam for pain management is consistent with the USDA organic regulations for minimizing pain and stress in organic livestock.

AMS finds that meloxicam meets OFPA requirements and proposes adding it to the National List at § 205.603(a) as a synthetic substance allowed in organic livestock

production. If this proposal is finalized, meloxicam would be allowed for use as a medical treatment in organic livestock production. The proposed listing would require that meloxicam be used in full compliance with AMDUCA and 21 CFR part 530 of the FDA regulations. The proposed annotation further requires that meloxicam may only be used in organic production by the lawful written order of a licensed veterinarian, and the withdrawal period must be at least twice that required by FDA. Excipients added to product formulations would need to comply with 7 CFR 205.603(f).²²

To comply with the proposed withdrawal period, AMS expects that veterinarians, organic livestock operations, and certifying agents would follow the same process for determining, documenting, and verifying compliance of withdrawal periods for meloxicam as is done for other synthetic substances on the National List that are used in accordance with AMDUCA. The proposed annotation to double the FDA withdrawal period is consistent with other synthetic livestock medications on the National List for which the FDA-required withdrawal period is doubled (e.g., flunixin).

AMS welcomes comments on whether the proposed annotation is clear enough to allow producers to comply with the proposed requirements. If elements of the annotation are unclear, AMS welcomes suggestions for language to clarify the annotation to achieve the intended outcomes described in this proposed rule.

In developing this proposed rule, AMS considered alternative annotation language that would further restrict the use of meloxicam. For instance, AMS considered proposing a specific minimum withdrawal time for bovine species (i.e., cattle and calves). The minimum withdrawal period could, for example, be calculated by doubling the longest recommended withdrawal times indicated by public comments: a meat withdrawal period of at least 56 days after administering to bovine livestock intended for slaughter, and a

²² Excipients are ingredients that are intentionally added to livestock medications but do not exert therapeutic or diagnostic effects at the intended dosage, although they may act to improve product delivery (7 CFR 205.2).

milk discard period of at least 10 days after administering to bovine dairy animals. AMS welcomes comments on whether a specified minimum withdrawal period is necessary, and if so, what specific duration is appropriate for meat- and milk-producing bovine species. AMS also welcomes comments on whether further restrictions are appropriate, such as whether meloxicam should only be allowed for treating pain resulting from disbudding and dehorning, or whether meloxicam should be limited to certain species (e.g., allowed for cattle but not allowed for goats and sheep).

D. Methionine (Livestock)

This rule proposes amending the current allowance of methionine, an amino acid, in poultry diets by removing the limits on the amount of synthetic methionine a producer can add to poultry feed rations. This AMS proposal follows a unanimous recommendation from the NOSB. If finalized, producers will have greater flexibility in using methionine to meet the health and nutrition requirements of organic poultry flocks.

Background

Methionine is an essential amino acid for poultry. It is a critical building block for proteins that form muscles, tissues, feathers, and support immune response. Without sufficient methionine, poultry are at risk of several significant health and production issues, including growth impairment, compromised immune function, poor feathering, reduced egg production, and behavioral problems like nervousness, feather picking, and cannibalism.

Poultry cannot synthesize methionine on their own, so they must obtain it from protein sources in their diets. Common plant-based feedstuffs typically lack a sufficient supply of methionine. Therefore, synthetic methionine is commonly added to poultry feed rations to meet nutritional needs of poultry.

The USDA organic regulations have allowed synthetic methionine for organic livestock production since 2003 (68 FR 61987, October 31, 2003). Methionine has

undergone several amendments on the National List to restrict its use in various ways, including the use of expiration dates and maximum use limits. The current restriction, which has been effective since 2019, limits its use to no more than 2 to 3 pounds of methionine per ton of feed, depending on the type and species of poultry, calculated as an average over the life of the flock.²³ In this rulemaking, AMS is proposing to remove these limits and to allow the use of methionine as an organic poultry feed additive without restriction beyond the existing general practice standards for livestock feed in § 205.237.

NOSB Recommendation

In October 2024, the NOSB unanimously recommended amending the National List to remove the limit on the amount of methionine that organic producers may feed to poultry.²⁴ The Board recommended removing this limit primarily to give organic producers more flexibility to use methionine to support bird health and to reduce overly burdensome recordkeeping requirements.

In the rationale supporting its recommendation, the NOSB noted the challenges caused by the current annotation. The current limits have prevented some producers from being able to feed their poultry adequate methionine. To address this deficiency, some producers increased the amount of feed ingredients that are high in methionine, like soybean meal. However, these dietary adjustments (e.g., feeding more soybean meal to address methionine deficits) can increase crude protein levels, which can negatively affect bird health, create problems with manure management, and result in increased ammonia concentration in poultry housing. To give producers more flexibility to provide healthy balanced feed rations, without resorting to over-feeding protein and creating secondary problems, the Board recommended removing the limit on methionine.

²³ The full text of the current annotation is, “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.” 7 CFR 205.603(d)(1).

²⁴ NOSB recommendation on methionine, October 2024, www.ams.usda.gov/sites/default/files/media/LS_DLMethionineAnnotChangeFinalRec.pdf.

The NOSB recommendation also noted the ongoing lack of natural alternatives to synthetic methionine. One of the historical justifications for limiting synthetic methionine was preserving the incentive to develop viable natural methionine alternatives. Over the years, the organic industry has explored a number of possible sources of natural methionine, such as insects and fermentation products. However, these products have not achieved widespread adoption or developed the production scale necessary to adequately address the needs of the organic poultry industry. Because the limit on synthetic methionine has not meaningfully accelerated a natural alternative, the Board reasoned that a limit is not effective for this purpose.

The NOSB also explained its recommendation is intended to better align USDA organic regulations with those of our trading partners. For example, neither the European Union (EU) nor Canada limit the amount of methionine in organic feed. EU organic regulations permit a certain percentage of non-organic ingredients in grain-based poultry diets, which allows organic producers in the EU to include high-methionine ingredients (e.g., corn gluten meal) in poultry feed to meet birds' needs. Similarly, Canada permits the addition of synthetic methionine when naturally occurring sources are not adequate to meet a flock's needs.

The NOSB recommendation was informed by public comments at the October 2024 meeting.¹¹ The majority of comments were supportive of removing the limits on methionine, citing benefits such as reduced paperwork burden for producers, inspectors, and certifying agents, as well as better health outcomes for poultry flocks. Comments from organic poultry operations and organic certification agencies indicated the recordkeeping burden was especially difficult for small farms and farms with mixed flocks of multiple poultry species that each required separate calculations. Calculating lifetime averages can also be challenging for flocks that change ownership or locations,

requiring a combination of records from multiple operations. Commenters also continued to note that no viable natural alternatives to methionine have been found.

AMS Review of NOSB Recommendation

AMS agrees with the NOSB recommendation to allow methionine as an organic poultry feed additive without limits on the amount of methionine that may be added to organic poultry rations. This deregulatory action will give producers maximum flexibility in using methionine to meet the health and nutrition needs of their flocks. Furthermore, this proposed action will lift a recordkeeping burden from organic producers, who will no longer need to maintain records documenting pounds of methionine fed per ton of feed over the lifetime of each flock.

AMS also agrees with the NOSB's determination that synthetic methionine continues to be necessary for organic poultry production due to the absence of natural alternatives. Although existing limits were intended to incentivize the development of natural alternatives, it does not appear that the limits have been effective for this purpose. Viable natural alternatives have not been developed and are not commercially available to the extent necessary to support the organic poultry industry. Removing the limit on synthetic methionine should not deter future development of natural alternatives.

AMS concludes that all criteria at 7 U.S.C. 6517(c)(1)(A) would continue to be met under this proposed rule, even in the absence of the current limits. This supports the inclusion of synthetic methionine on the National List. Synthetic methionine is not harmful to human health or the environment, is necessary to the organic poultry production because of the unavailability of wholly natural substitute products and is consistent with organic farming and handling practices.

If this proposed amendment is finalized, producers will maintain access to synthetic methionine for use as a feed additive in organic poultry production. Producers would be allowed to use methionine in poultry feed in a way that complies with USDA

organic regulations to meet the nutritional requirements of the animal (7 CFR 205.237 and 205.238(a)(2)).

IV. Related Documents

AMS published 5 notices in the *Federal Register* announcing the public NOSB meetings and inviting public comments on the NOSB recommendations addressed in this proposed rule: Fall 2021 (86 FR 29738, June 3, 2021), Spring 2022 (87 FR 12074, March 3, 2022), Fall 2022 (87 FR 37495, June 23, 2022), Spring 2024 (89 FR 8398, February 7, 2024), and Fall 2024 (89 FR 70591, August 30, 2024). Meeting transcripts and public comments received by the NOSB can be found on the AMS website at: www.ams.usda.gov/rules-regulations/organic/nosb/meetings.

V. Regulatory Analyses

A. Executive Order (E.O.) 12866 and E.O. 13563

USDA is issuing this proposed rule in conformance with Executive Orders (E.O.) 12866, “Regulatory Planning and Review,” and E.O. 13563, “Improving Regulation and Regulatory Review.” This proposed rule has been determined to be not significant for purposes of Executive Order 12866, and, therefore, has not been reviewed by the Office of Management and Budget (OMB).

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose 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 final rule is not expected to have a significant economic impact on a substantial number of small entities.

AMS does not expect the economic impact on entities affected by this rulemaking to be significant. This proposed rule would allow two additional substances in organic crop and livestock production and would remove restrictions on the use of one substance, thus removing paperwork and regulatory burdens. The amendments would provide small entities with more options to use in day-to-day operations. The proposed rule would also affirm the validity of current USDA organic regulations related to the use of sodium nitrate as a nitrogen fertilizer. AMS does not expect any significant economic impact related to this action for small entities, as certified operations are already required to maintain records of all activities (e.g., input applications) and transactions.

C. E.O. 12988

E.O. 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations to avoid unduly burdening the court system. This proposed rule is not intended to have a retroactive effect. Accordingly, to prevent duplicative regulation, states and local jurisdictions are preempted under 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 the USDA to be accredited as a certifying agent, as described in OFPA (7 U.S.C. 6514(b)). States are also preempted 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 OFPA (7 U.S.C. 6501-6524).

Pursuant to OFPA (7 U.S.C. 6507(b)(2)), 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 OFPA, (b) not be inconsistent with OFPA, (c) not be discriminatory towards agricultural commodities organically produced in other states, and (d) not be effective until approved by the Secretary.

In addition, pursuant to 7 U.S.C. 6519(c)(6) of the OFPA, this proposed 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 EPA under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 et seq.).

D. Paperwork Reduction Act

Routine collection, reporting and recordkeeping related to the use of substances on the National List are covered under OMB Number 0581-0191. No additional collection or recordkeeping requirements are imposed on the public by this proposed rule. Accordingly, OMB clearance is not required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, chapter 35.

E. E.O. 13175

E.O. 13175 requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes, the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. AMS has assessed the impact of this proposed rule on Indian Tribes and determined that this rulemaking would not have Tribal implications that require consultation under E.O. 13175.

F. Unfunded Mandates Reform Act

This proposed rule does not contain Federal mandates under the regulatory provisions of title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. chapter 25) (UMRA) for State, local and Tribal governments, or the private sector of \$100 million or more in any one year. Thus, the proposed rule is not subject to the requirements of sections 202 and 205 of the UMRA.

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agriculture, Agricultural commodities, Animals, Archives and records, Crops, Disinfectants, Fees, Imports, Labeling, Livestock, National List, National Organic Standards Board (NOSB), Organically produced products, Plants, Reporting and recordkeeping requirements, Sanitizers, Seals and insignia, Soil conservation, Sunset.

For the reasons stated in the preamble, AMS proposes to amend 7 CFR part 205 as follows:

PART 205—NATIONAL ORGANIC PROGRAM

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

Authority: 7 U.S.C. 6501-6524.

2. Amend § 205.601 by:

a. Redesignating paragraphs (a)(2) through (8) as paragraphs (a)(3) through (9);

b. Adding new paragraph (a)(2);

c. Redesignating paragraphs (j)(2) through (11) as paragraphs (j)(3) through (12);

and

d. Adding new paragraph (j)(2).

The additions read as follows:

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

* * * * *

(a) * * *

(2) Carbon dioxide.

* * * * *

(j) * * *

(2) Carbon dioxide – must be sourced as a byproduct.

* * * * *

3. Amend § 205.602 by revising paragraph (h) to read as follows:

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

* * * * *

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

* * * * *

4. Amend § 205.603 by:

- a. Redesignating paragraphs (a)(20) through (30) as paragraphs (a)(21) through (31);
- b. Adding new paragraph (a)(20); and
- c. Revising paragraph (d)(1).

The addition and revision read as follows:

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

* * * * *

(a) * * *

(20) Meloxicam (CAS # 71125-38-7) – 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 withdrawal period of at least two times that required by the FDA.

* * * * *

(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.

* * * * *

Erin Morris,
Administrator,
Agricultural Marketing Service.

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