September 30, 2024

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP

Docket: AMS-NOP-24-0023

RE: Livestock Subcommittee
Petitioned Material Proposal: Meloxicam

Dear Ms. Arsenault:

Thank you for this opportunity to provide feedback to the Livestock Subcommittee on its petitioned material proposal to add meloxicam to the National List of synthetic substances allowed for use in organic livestock production at 7 CFR § 205.603. The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, brands, retailers, material input providers, and others. OTA's mission is to grow and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

On behalf of our members in the livestock sector, **OTA supports the addition of meloxicam to the National List**. Meloxicam offers an additional and needed treatment for pain management in organic livestock production systems and offers a longer therapeutic effect than existing allowed treatments on the National List. With the addition of meloxicam, organic livestock producers will have access to a treatment that is widely accepted in the organic standards of our trading partners and by animal welfare oversight programs. Further, according to OTA's 2024 consumer survey, 54% of consumers believe organic certification is better for animal welfare, and 45% are willing to pay a premium for organic products that protect animal health and welfare. Organic standards must safeguard the brand equity of the USDA organic seal. Therefore, the Board must ensure that any restrictions on synthetic pain relief substances do not conflict with consumers' expectations around the organic seal and animal welfare. The ability to treat animals with meloxicam will ensure organic livestock management continues to meet consumer expectations regarding animal welfare.

With this support, OTA offers three points of feedback in the review of this petition, one regarding the annotation included in the motion to list, one to bring consistency to National List listings, and one regarding the lack of a Technical Review.

1. Annotation: The listing motion includes the following annotation:
   i) Use by or on the lawful written order of a licensed veterinarian; and
   ii) A meat withdrawal period of at least two-times that required by the FDA

   The petition addresses use beyond only meat animals and notes withdrawal times for meat and milk animals. As the intended use for meloxicam is for both classes of animals, an annotation that mirrors existing listings for pain substances would be preferable. Additionally, the use of

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Meloxicam is authorized under AMDUCA which does not prescribe a specific withdrawal time in duration. Finally, this listing is inconsistent with how other substances and withdrawal times are listed on the National List and could create undue confusion for certifiers, vets, and producers. Of the 9 listings on § 205.603 with withdrawal time annotations, 8 list the withdrawal times in days (See attached appendix). While removing the word "meat" alone would be consistent with the Flunixin annotation, the suggested minor revision below would bring the wording in line with the other 8 listings with withdrawal periods. We suggest this minor revision [1]is within the intent of the original wording and therefore should be accomplishable in the meeting and is not substantive enough to hold progress on this petition.

Revise annotation to; suggested change in *italics*:

(i) Use by or on the lawful written order of a licensed veterinarian *and in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations*; and

(ii) A ~~meat~~ withdrawal period of at least ~~two times that required by the FDA~~ *42 days after administering to livestock intended for slaughter; and a milk discard period of at least 10 days after administering to dairy animals.*

2. The board may want to consider amending the annotation of Flunixin in a separate proposal in the future to bring consistency to withdrawal listings on § 205.603.
3. Technical Review: The Board's proposal notes (1) board expertise, (2) thoroughness of the petition, (3) lack of a conflict of interest between petitioners and the substance, and (4) unmet acute animal welfare needs as reasons for moving forward at this meeting. OTA concurs with this logic noting the petition and review was substantive and complete. However, over time the board expertise may change, and OTA believes in the strength of the Technical Review (TR) process in which an independent third-party expert evaluates a substance. Contracting a TR for the benefit of the NOSB has become standard practice with most petitioned substances and many materials under sunset review. While we agree with the board urgency to address animal welfare concerns now by moving forward with this petition, we also recommend the Board pursue a TR on meloxicam after recommending its listing to ensure future boards have access to sufficient expert analysis on the substance.

On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

[1] https://dairy.extension.wisc.edu/articles/nsaid-use-aro
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10144785/
https://www.dairyherd.com/news/meloxicam-pain-relief-cows-and-calves
https://aabp.org/committees/resources/Pain_Brochure_8-15.pdf
http://www.farad.org/publications/digests/032008ExtralabelNonsteroidal_anti-inflammatory.pdf
https://ec.europa.eu/health/documents/community-register/2018/20180319140321/anx_140321_en.pdf
https://extension.usu.edu/dairy/files/UtahStateDairyVetNewsletterMar2015.pdf

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Respectfully submitted,

Scott Rice
Sr. Director, Regulatory Affairs
Organic Trade Association

cc: Tom Chapman
Co-CEO
Organic Trade Association

Appendix on 205.603 and withdrawal annotations

5 of 9 substances have annotations that reference AMDUCA and 21 CFR part 530
8 of 9 substanves have annotations that reference withdrawal times in days.
1 of 9 substances have an annotation that references withdrawal times in two-times FDA.

§ 205.603 Synthetic substances allowed for use in organic livestock production.
In accordance with restrictions specified in this section the following synthetic substances may be used in organic livestock production:

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

(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.

(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.

(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.

(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.

(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.

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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.

(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) As topical treatment, external parasiticide or local anesthetic as applicable.

(5)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.

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