

April 3, 2020

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

Docket: AMS-NOP-19-0095

RE: Livestock Subcommittee – Fenbendazole (Discussion Document)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Livestock Subcommittee's Discussion Document on Fenbendazole, which has been petitioned for use in organic poultry production.

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, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

Fenbendazole is a parasiticide currently allowed in organic production for emergency treatment for dairy and breeder stock and fiber-bearing animals under the restrictions at §205.603(a)(23). A petition has been submitted to expand its use in laying hens and replacement chickens intended to become laying hens. A discussion document was presented at the fall 2019 NOSB meeting to solicit feedback on questions regarding the necessity of the material, effectiveness of alternatives, and whether a withdrawal time is needed. A second discussion document is being presented for the spring 2020 NOSB meeting with the same discussion questions. NOSB has also requested a Technical Report that is currently under development and will be limited in scope on the use of fenbendazole in poultry production.

OTA submitted comments last fall responding to the NOSB's discussion questions (Attachment A). OTA does not have any new comments to provide during this comment period. We look forward to reviewing the findings of the forthcoming Technical Report, and will continue to engage throughout the NOSB's evaluation of the petitioned material.

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.

Respectfully submitted,

Manne Muenda

Johanna Mirenda

Farm Policy Director

Organic Trade Association

cc: Laura Batcha

Executive Director/CEO

Organic Trade Association



ATTACHMENT A

October 3, 2019

Ms. Michelle Arsenault National Organic Standards Board USDA-AMS-NOP 1400 Independence Avenue, SW Room 2642-So., Ag Stop 0268 Washington, DC 20250-0268

Docket: AMS-NOP-19-0038

RE: Livestock Subcommittee – Fenbendazole (Petitioned Material Discussion Document)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Livestock Subcommittee's Petitioned Material Discussion Document on Fenbendazole. The subcommittee is inviting discussion on a petition requesting a revision to the annotation for fenbendazole to expand the use to poultry.

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, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

NOSB is considering a petition requesting a revision to the annotation for fenbendazole at §205.603(a)(23)(i) to include an allowance for use in laying hens and replacement chickens intended to become laying hens. The petition does not request changes to the current restrictions on fenbendazole, which limit its use only for emergency treatment when organic system plan-approved preventive management does not prevent infestation.

Fenbendazole is currently allowed in the NOP regulations under the following restrictive conditions at §205.238(b) and §205.603(a)(23)(i) for use in breeder stock, dairy animals, and fiberbearing animals.

§205.238(b) When preventive practices and veterinary biologics are inadequate to prevent sickness, a producer may administer synthetic medications: Provided, That such medications are allowed under §205.603. Parasiticides allowed under §205.603 may be used on:

- (1) Breeder stock, when used prior to the last third of gestation but not during lactation for progeny that are to be sold, labeled, or represented as organically produced; and
- (2) Dairy animals, as allowed under §205.603.
- (3) Fiber-bearing animals, as allowed under §205.603.



§205.603(a)(23) Parasiticides—prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock. Allowed for fiber-bearing animals when used a minimum of 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.

At this point, OTA does not have concerns with the petitioned allowance of fenbendazole for these reasons:

- Fenbendazole is <u>already permitted</u> under restricted conditions for other livestock species, hence it has already satisfied criteria for the National List in terms of not being harmful to the environment or human health, and being compatible with organic farming principles. In terms of essentiality for production of organic laying hens, we will continue to conduct member outreach and encourage organic egg producers to submit comments regarding the need for this input.
- The petitioned use would still be subject to the existing restrictions for fenbendazole, which limit its use only for <u>emergency treatment</u> when organic system plan-approved <u>preventive management</u> does not prevent infestation. Under these highly restricted conditions, poultry operation would still be required to establish preventive health care conditions as required by the NOP regulations and fundamental to organic production principles. Fenbendazole would be a new tool for emergency situations to control internal parasites. Organic livestock producers need adequate tools in their restricted toolbox to control infestations, and ensure animal safety and wellbeing.

Discussion Questions

The NOSB Livestock Subcommittee has requested feedback on the following discussion questions.

1. Is this material needed by organic poultry producers? If so, why?

OTA members in the organic egg sector have expressed a need for this material. Organic poultry producers identify a need for additional effective internal parasite treatment tools to address emergency situations when preventive practices have failed. Roundworm is a specific internal parasite for which organic poultry producers need better treatment tools, particularly for flocks exposed to outdoor access.

2. Do currently allowed alternatives work to control internal parasites? And at what level of effectiveness?

Alternative substances such as diatomaceous earth, essential oils, and apple cider vinegar have limited efficacy for preventing parasites or decreasing worm levels. There are no allowed alternative tools that have been identified that are effective in treating and eliminating parasites once they have infected flocks.



3. What are some of the "emergency" events that would trigger use of this product? And how would producers determine those events?

Poultry producers regularly monitor flock health and could establish an action threshold based on health deterioration, mortality, decreased egg production, lethargy, stool analysis, measurement of confirmed parasite presence, or other factors that could be described in an operation's Organic System Plan.

For guidance on determining whether an event qualifies as an "emergency," producers and certifiers can refer to the Spring 2018 NOSB Recommendation that includes the following definition of emergency treatment for parasite control in organic livestock, "An urgent, non-routine situation in which the organic system plan's preventive measures and veterinary biologics are proven, by laboratory analysis or visual inspection, to be inadequate to prevent life-threatening illness or to alleviate pain and suffering."

Furthermore, as OTA commented in fall 2017 and spring 2018, we see value in developing guidance on "routine use of parasiticide" which is currently defined in §205.2 as "the regular, planned, or periodic use of parasiticides," so that certifiers can consistently identify and take corrective actions against noncompliant routine uses of parasiticides. Tying the justification for use of a synthetic parasiticide to actions taken by producers (i.e. routine use of parasiticides) rather than an occurrence (i.e. an emergency) better matches how organic system plans are reviewed and verified, and would give certifiers better ability to ensure that synthetic parasiticides are not misused. Records and inspections can be used to justify a conclusion that parasiticides were "routinely used" much more easily than they were used in the absence of a legitimate "emergency." Guidance that addresses both how producers can justify the "emergency" use of parasiticides as well as how certifiers can consistently identify "routine use of parasiticide" will ensure a level playing field for organic producers.

4. Is there a concern with the 2.4 ppm residue of fenbendazole in eggs? Please submit information that supports this concern, or lack of concern.

At this point, we have not received indications of concern from our members.

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.

Respectfully submitted,

Johanna Mirenda

Farm Policy Director

Organic Trade Association

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