

**National Organic Standards Board
Livestock Subcommittee
Petitioned Material Discussion Document
Fenbendazole**

Summary of Petition:

A petition requesting a revision to the annotation for fenbendazole to expand the use to poultry was submitted to the NOSB in July 2019. The petition requests an annotation to 7 CFR §205.603(23)(i) to include laying hens and replacement chickens intended to become laying hens.

Background of Current Listing:

In May 2012, fenbendazole was added to the National List for use in organic livestock, as specified in 7 CFR 205.603:

(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.

In 2016 the NOSB recommended that the annotation for fenbendazole be amended to include the following:

- *That parasiticides continue to be prohibited in slaughter stock.*
- *That the milk withholding period after treatment with fenbendazole be changed from 90 days to 2 days for dairy cows, and 36 days for goats and sheep.*
- *That fleece and wool from fiber bearing animals be allowed to be certified organic even if use of parasiticides was necessary at some time in the animal's life.*
- *That fenbendazole be allowed without written order of a veterinarian.*

The NOP issued a final rule with an effective date of January 28, 2019, with the following language:

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.

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.

In Spring 2018 the NOSB recommended clarifying “emergency” for use of synthetic parasiticides in organic livestock production. The following language was recommended:

Add this definition to 205.2

Emergency treatment to allow synthetic parasiticide use in livestock: A livestock emergency is 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. In such cases, a producer must administer the emergency treatment (§205.238(c)(7)). Organic certification will be retained, provided that such treatments are allowed under § 205.603 and the organic system plan is changed to prevent a similar livestock emergency in individual animals or the whole herd/flock in future years as required under §205.238(a).

Add this to § 205.238 (b)

(4) Organic livestock as provided in §205.238 (b) (1), (2), and (3) and only in the event of an emergency where management strategies have been proven insufficient to prevent or control parasites within the accepted threshold for specific parasites, age and species of the animal. These management strategies include but are not limited to, grazing systems and living conditions that prevent infestation and re-infestation, forage height diversity, use of allowed non-synthetic botanicals, biologics and minerals to maintain parasite levels below treatment thresholds, and could include monitoring and documentation of parasites through use of methods such as fecal monitoring and FAMACHA.

To date, the NOP has taken no action on this NOSB recommendation.

Summary of Review:

The Livestock Subcommittee reviewed the petition seeking a revision to the annotation of fenbendazole to expand the use of fenbendazole to include use in laying hens and replacement chickens intended to become laying hens. The Subcommittee requested a technical report (TR) after the Fall 2019 NOSB meeting. The TR is currently in development and is expected back in the summer of 2020.

With the shifting demand for eggs from hens with humane certifications of Free Range or Pasture Raised production models requiring 2.0-108.9 square feet per bird of outdoor access, many laying hen flocks are seeing large internal parasite infestations. When birds are out grazing, they are scratching and digging in the dirt for worms and in return picking up intestinal parasites. Intestinal parasites can cause issues such as lower feed absorption, increased mortality, parasite transmission into the egg, and disease transmission to the hens.

Currently poultry producers use a diatomaceous earth product to help control intestinal worms. There are several concerns with this product including amount needed to be ingested in relation to daily feed intake (non-balanced diets), worker and animal health hazards (respiratory concerns) and many producers feel that diatomaceous earth does not control severe parasite infestations.

If fenbendazole is added to the National List for laying hens and replacement chickens, it would only be allowed for emergency treatment when organic system plan-approved preventive management does not prevent infestation. Producers and certifiers would need to work together to define what an emergency is for each producer. The Subcommittee discussed several potential instances such as if internal parasites are seen during routine posting or autopsy sessions of flocks or parasites are observed

in manure droppings. The Subcommittee felt strongly that fenbendazole should only be used in emergency situations and not on a routine basis.

Even though the current listing for fenbendazole for cattle, sheep, goats, and other dairy species lists withdrawal times, the Subcommittee is not suggesting a withdrawal time for the use of fenbendazole on poultry. During the review of fenbendazole's use as an approved animal drug the FDA did not require a withdrawal time on the label for poultry as compared to other animals. "The data in study #S12173-00-DWF-MET-PO show that total residues of fenbendazole in eggs of treated chickens at zero-day withdrawal are well below the safe concentration of 2.4 ppm for residues in eggs."¹

Use of the Substance:

- 200 mg of fenbendazole/ml for oral administration via drinking water
- Safe-Guard® AquaSol must be administered orally to chickens via the drinking water at a daily dose of 1.0 mg/kg BW (0.454 mg/lb.) for 5 consecutive days.

Conventional poultry producers typically administer fenbendazole to pullets (replacement layers age 0-17 weeks of age) or before outdoor access is given to birds to ensure birds have no internal parasites before starting eggs production. When birds receive access to the outdoors they come into contact with soil and in turn come into contact with internal parasites. Many producers find the need to re-treat their flocks after a period of time when birds have access to the soil and come into contact with many internal parasites. Organic producers will need to utilize preventative management practices defined in their Organic System Plan as a first line of defense for internal parasites, and if those preventative practices fail an emergency treatment of fenbendazole may be required to control internal parasites.

Mode of Action:

Fenbendazole binds to β -tubulin, inhibiting assembly of microtubules, resulting in cell and parasite death. According to the Merck Veterinary Manual, "The wide safety margin of benzimidazoles is due to their greater selective affinity for parasitic β -tubulin than for mammalian tissues." (Merck, 2006)

Questions:

1. Is fenbendazole needed by organic poultry producers? If so, why?
2. Do currently allowed alternatives work to control internal parasites? At what level of effectiveness?
3. What would be some of the "emergency" events that would trigger use of this product? And how would producers determine those events?
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.

¹ <https://animaldrugsfda.fda.gov/adafda/app/search/public/document/downloadFoi/3083>

