**National Organic Standards Board**
**Livestock Subcommittee**
**Petitioned Material Discussion Document**
**Fenbendazole**
**August 16, 2019**

**Summary of Petition:**
A petition requesting a revision to the annotation for Fenbendazole to expand the use to poultry. This petition requests an annotation to 7 CFR §205.603(a)(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 of organic materials for use in organic livestock, as specified in 7 CFR §205.603(a):

> *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. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. 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.*

*(i) Fenbendazole (CAS #43210-67-9)—only for use by or on the lawful written order of a licensed veterinarian.*

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 the Spring of 2018 the NOSB recommended clarifying "emergency" for use of synthetic parasiticides in organic livestock production. The following language was recommended for a rule change:

*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.*

This NOSB recommendation is still pending NOP review.

**Summary of Review:**

The Livestock Subcommittee reviewed the petition seeking to add an annotation to fenbendazole to expand its use in laying hens and replacement chickens intended to become laying hens. The Subcommittee did not feel the need to request an update technical report (TR) on Fenbendazole since a TR was conducted in June 2015.

Many organic laying hens have meaningful direct access to the soil, and this is one area where birds that are truly out grazing the land are at a disadvantage compared to birds on concrete porches. With the shifting demand for eggs from hens with humane certifications such as 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. When a chicken has intestinal parasites some of the issues include having lower feed absorption, increased mortality, parasite transmission into the egg, and disease transmission to the hens.

Currently poultry producers sometimes use a diatomaceous earth product to help control intestinal worms. There are several concerns with this product including the amount needed to be ingested in relation to daily feed intake (non-balanced diets), worker and animal health hazards when using diatomaceous earth (respiratory concerns), and lack of efficacy to control severe parasite infestations.

If fenbendazole is added to the national list for laying hens and replacement chickens, it would be allowed only 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. Examples include the discovery of internal parasites during routine posting or autopsy sessions of flocks, and/or observation of parasites in manure droppings. The Subcommittee feels strongly that fenbendazole should be used only in emergency situations and not on a routine basis.

Even though the current listing for fenbendazole for cattle, sheep, goats, and other dairy species specifies withdrawal times, the Subcommittee does not intend to restrict the use of fenbendazole on poultry by specifying a withdrawal time. The FDA reviewed fenbendazole's use as an approved animal drug and determined that it did not require a withdrawal time for poultry. "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 egg 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 could be used 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 this material needed by organic poultry producers? If so, why?

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

3. What are 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://animaldrugsatfda.fda.gov/adafda/app/search/public/document/downloadFoi/3083

**Subcommittee Vote:**
Motion to accept the fenbendazole petitioned-material discussion document
Motion by: Ashley Swaffar
Seconded by: Sue Baird
Yes: 6  No: 0  Abstain: 0  Absent: 0  Recuse: 0