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April, 2016

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Ave. SW.,
Room 2648-S, Mail Stop 0268
Washington, DC 20250-0268

Re. LS: Fenbendazole, Ivermectin, and Moxidectin

These comments to the National Organic Standards Board (NOSB) on its Spring 2016 agenda are submitted on behalf of Beyond Pesticides. Founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers and farmworkers, Beyond Pesticides advances improved protections from pesticides and alternative pest management strategies that reduce or eliminate a reliance on pesticides. Our membership and network span the 50 states and the world.

Beyond Pesticides supports the delisting of ivermectin and moxidectin, which pose ecological hazards not posed by fenbendazole. We support the recommendations of the Livestock Subcommittee (LS) as they apply to fenbendazole. However, the delisting actions cannot be proposed at this meeting. Therefore, we urge the NOSB to send the proposal back to the LS with the instruction to bring forth proposals addressing the full range of options supported by public comment.

Current regulations

§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 stock, when used a minimum of 90 days prior to the production of milk or milk products that are to be sold, labeled, or represented as organic.

§205.603(a)(18) 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.

(ii) Ivermectin (CAS #70288-86-7).

(iii) Moxidectin (CAS #113507-06-5)— for control of internal parasites only.

Livestock Subcommittee proposals

The Livestock Subcommittee (LS) has, as requested by commenters during the sunset consideration of these materials, reconsidered the listing of all three and makes these proposals:

1. Amend §205.238(b)(2) as follows: ~~Dairy stock animals, when used a minimum of 90 days, prior to the production of milk or milk products that are to be sold, labeled, or represented as organic as allowed under §205.603.~~

AND

2. Amend §205.603(a)(18) as follows: (18) 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. Allowed in fiber bearing animals, when used a minimum of 90 days prior to production of fleece or wool that is to be sold, labeled, or represented as organic. ~~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.~~ 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) Ivermectin (CAS #70288-86-7)—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.

(iii) Moxidectin (CAS #113507-06-5)—~~for control of internal parasites only~~ 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.

Relevant public comment

In the spring of 2015, Hubert Karreman, DVM recommended that ivermectin (and possibly moxidectin) be sunsetted. “This was the original intent when we voted to allow fenbendazole while I was Livestock Chair of the NOSB. The transcripts of that meeting clearly reflect that intent. Ivermectin is toxic to dung beetles, which are an integral part of pastureland ecology. Moxidectin is less so but somewhat worse for fish if it gets in the water, if I recall correctly. Moreover, ivermectin and moxidectin are macrocyclic lactones, a type of antibiotic. Since antibiotics as active substances are prohibited in organic livestock use (and fortunately soon,

too, in plant use), the inclusion of ivermectin and moxidectin is questionable. Additionally, while the sunset time is not the time for annotation changes, the 90 day milk withholding period is without any kind of scientific basis and should be reduced to 14-21 days (in order to make it tough to use them but not completely out of the question if really needed in milk cows).”

Environmental and health impacts

The 2015 Technical Review (TR) on parasiticides documents many of the environmental impacts of the parasiticides and confirms that the three allowed for use in organic production do vary in their environmental impacts –ivermectin having the greatest, followed by moxidectin, and then fenbendazole. A brief comparison may be found in the following table, based on the TR.

	Ivermectin	Moxidectin	Fenbendazole
Half-life (days)	127-240*	130	54
Toxic to dung beetle larvae?	Yes	Yes	No
Toxic to other dung insects?	Yes	Yes, but less than ivermectin.	No**
Maximum residue limit in milk	10 ug/L	20 ug/kg (muscle meat)	100 ug/L

*The TR listed two estimated half-lives in soil for ivermectin.

** “The dung from fenbendazole-treated animals has no obvious impact on the coleopteran or dipteran species encountered in this study, and the dung pats from the fenbendazole-treated animals were not consistently different from the pats of untreated animals. Earthworms are not significantly affected by fenbendazole.” TR table 7.

Essentiality of parasiticides and compatibility with organic production

As mentioned above, fenbendazole was added to the National List with the intention of removing at least ivermectin. The main argument for keeping more than one parasiticide on the list appears to be resistance management. However, management of resistance to chemicals that may be harmful to the organic system is not an acceptable reason for allowing a synthetic material on the National List. As the TR says, “Anthelmintic resistance is in part the result of improper use. ... Resistance to synthetic parasiticides is not a problem, if synthetic parasiticides are not used.”¹ As the TR documents, there are many practices and natural materials used by organic farmers to prevent and manage parasites.² Because we believe that there should be an alternative when these fail, we support the continued listing of fenbendazole.

Conclusion and comment on process

While we are pleased that the LS considered all three parasiticides together, we believe that the subcommittee should have also brought forward motions to remove ivermectin and

¹ TR, lines 939-942.

² TR, lines 825-946.

moxidectin. This would have allowed the NOSB to consider the full range of actions that have been supported by public comment. As noted in the quoted comments from former NOSB member Dr. Karreman, the intention of the NOSB in approving fenbendazole was to allow for the removal of ivermectin and possibly moxidectin. Since such an action at this meeting would be prohibited as a substantive action not proposed for public comment, these proposals should be referred back to the subcommittee, to return with proposals that address the full range of actions supported by the available evidence.

Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Terry Shistar". The signature is fluid and cursive, with a prominent initial "T" and a long, sweeping underline.

Terry Shistar, Ph.D.
Board of Directors