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USDA-AMS-NOP
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Docket ID # AMS-NOP-19-0095

Re. LS: Fenbendazole petition for use in poultry

These comments to the National Organic Standards Board (NOSB) on its Spring 2020 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.

The Livestock Subcommittee has not received a technical report (TR) to inform its deliberations on the petition to allow use of fenbendazole in organic poultry. Its Fall 2019 discussion document relied instead on the 2015 TR on parasiticides in mammalian livestock. The 2015 TR is not sufficient to support the proposed action to list fenbendazole for use in poultry, particularly with no discard period for eggs. We are glad to see that the LS requested a TR after the Fall 2019 meeting, but without the information from that TR, there is little point in issuing a new discussion document. The new discussion document did not summarize public input (including ours) in response to the Fall 2019 discussion document, but instead poses the same questions again.

The definition of "emergency" has not been put into regulation.

As stated in the LS's discussion document:

> 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)
[(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.]
(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.

The definition of "livestock emergency" has not been adopted into regulation and therefore the NOSB cannot rely upon it to prevent misuse of parasiticides. Furthermore, §205.238(b) applies only to breeder stock, dairy animals, and fiber bearing animals, and thus does not allow administration of parasiticides to poultry.

The LS says, "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." To allow the definition to be established for each producer as proposed by the LS is an invitation for abuse. The use of a parasiticide must depend on a definition of "livestock emergency" in the NOP regulations.

Residues of fenbendazole will be present in eggs.

Typically, medications allowed in organic livestock production require a longer period when products cannot be consumed than is allowed in non-organic products. This is because organic consumers expect that there will be no chemical residue in organic products. The LS states, "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.'"

The "safe" concentration in eggs is calculated by partitioning the acceptable daily intake (ADI) among meat (50%), milk (40%), and eggs (10%). This calculation depends on assumptions about food consumption that may or may not be valid. The 2015 TR, upon which the LS relies, gives scant attention to the potential health effects of chronic exposure to low levels of fenbendazole. Other research has indicated that fenbendazole may cause or contribute to immune system effects, liver tumors, and birth defects.[1]

A European study finds "Oxfendazole sulfone [major metabolite of fenbendazole] residues were detected in eggs from 1 day after the first treatment up to 8 days after the last treatment. The highest residues were determined 1 to 2 days after the last treatment in a concentration range between 559 and 850 µg/kg. No oxfendazole sulfone residues above the limit of quantification were detected 9 days after the last treatment and at later time points."[2] This suggests that if fenbendazole is permitted for use in organic poultry, eggs should be discarded for 14 days (five days of treatment plus nine days of withdrawal).

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[1] Villar, D., Cray, C., Zaias, J. and Altman, N.H., 2007. Biologic effects of fenbendazole in rats and mice: a review. *Journal of the American Association for Laboratory Animal Science*, *46*(6), pp.8-15. https://www.ingentaconnect.com/content/aalas/jaalas/2007/00000046/00000006/art00001?crawler=true; Shoda, T., Onodera, H., Takeda, M., Uneyama, C., Imazawa, T., Takegawa, K., Yasuhara, K., Watanabe, T., Hirose, M. and Mitsumori, K., 1999. Liver tumor promoting effects of fenbendazole in rats. *Toxicologic pathology*, *27*(5), pp.553-562. https://journals.sagepub.com/doi/pdf/10.1177/019262339902700509; Horvat, A.J., Babić, S., Pavlović, D.M., Ašperger, D., Pelko, S., Kaštelan-Macan, M., Petrović, M. and Mance, A.D., 2012. Analysis, occurrence and fate of anthelmintics and their transformation products in the environment. *TrAC Trends in Analytical Chemistry*, *31*, pp.61-84. https://s3.amazonaws.com/academia.edu.documents/45919927/Analysis_Occurrence_and_Fate_of_Anthelmi20160524-7292-2nmj77.pdf?response-content-disposition=inline%3B%20filename%3DAnalysis_occurrence_and_fate_of_anthelmi.pdf&X-Amz-Algorithm=AWS4-HMAC-SHA256&X-Amz-Credential=AKIAIWOWYYGZ2Y53UL3A%2F20190904%2Fus-east-1%2Fs3%2Faws4_request&X-Amz-Date=20190904T190020Z&X-Amz-Expires=3600&X-Amz-SignedHeaders=host&X-Amz-Signature=5be261f405c1e1bd8c8b00136232a443d1d0301e15386ba2e2ac1f749a3f7073.

[2] European Medicines Agency, 2013. European public MRL assessment report (EPMAR): Fenbendazole (extension to chicken and extrapolation to all food producing species). https://www.ema.europa.eu/en/documents/mrl-report/fenbendazole-european-public-maximum-residue-limit-assessment-report-epmar-cvmp_en.pdf.

The metabolism of fenbendazole in poultry differs from the metabolism in mammals.

Toutain et al. conclude their broad review of species differences in pharmokinetics (PK) and pharmodynamics (PD) of veterinary drugs with, "The main conclusion from this review is that differences between species are numerous and often unpredictable in terms of both drug PK and drug PD. The ass is not a rustic horse; the horse is not a large rat; the sheep is not a small cow; "dog" does not exist as a single, simple entity and the concept of poultry or of non-salmonide fishes as simple entities are not applicable in veterinary pharmacology. No generalisations are possible. Rather, each drug must be investigated on a species-by-species basis to guarantee the effective and safe use of drugs, thus ensuring the wellbeing of animals and safeguarding also the environment and human consumption of animal products."[3] This is particularly important when animals are of a different phylogenetic class—as birds vs. mammals. Toxic effects of fenbendazole on bone marrow has been documented in several animal species, including dogs, cats, humans, porcupines, and especially certain birds.[4] One study found that there is a difference in fenbendazole metabolism between chickens and turkeys.[5] Birds known to be sensitive to fenbendazole include pigeons, vultures, storks, and white pelicans.[6]

In addition, the use of fenbendazole in poultry can increase the likelihood of resistance in mammalian parasites.

With the excretion of fenbendazole into the environment, many parasites may be exposed to the drug. Horvat et al. find, "Parasites' exposure to a range of anthelmintics and even their metabolites may increase the chances of developing parasite-resistant strains. Resistance to the benzimidazoles in nematodes of sheep has become a common, global phenomenon."[7] Thus, the use of fenbendazole in poultry may compromise the drug's effectiveness against parasites in mammalian livestock on organic farms with mixed livestock.

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[3] Toutain, P.L., Ferran, A. and Bousquet-Mélou, A., 2010. Species differences in pharmacokinetics and pharmacodynamics. In *Comparative and veterinary pharmacology* (pp. 19-48). Springer, Berlin, Heidelberg. https://www.researchgate.net/profile/Hafid_Benchaoui/publication/41762071_Population_Medicine_and_Control_of_Epidemics/links/0c96052653093574a6000000.pdf#page=27.

[4] Siroka, Z. and Svobodova, Z., 2013. The toxicity and adverse effects of selected drugs in animals–overview. Polish Journal of Veterinary Sciences, 16(1), pp.181-191.

[5] Patel, T., Marmulak, T., Gehring, R., Pitesky, M., Clapham, M.O. and Tell, L.A., 2018. Drug residues in poultry meat: A literature review of commonly used veterinary antibacterials and anthelmintics used in poultry. *Journal of veterinary pharmacology and therapeutics*, *41*(6), pp.761-789.

[6] Gozalo, A.S., Schwiebert, R.S. and Lawson, G.W., 2006. Mortality associated with fenbendazole administration in pigeons (Columba livia). Journal of the American Association for Laboratory Animal Science, 45(6), pp.63-66; Howard, L.L., Papendick, R., Stalis, I.H., Allen, J.L., Sutherland-Smith, M., Zuba, J.R., Ward, D.L. and Rideout, B.A., 2002. Fenbendazole and albendazole toxicity in pigeons and doves. Journal of Avian Medicine and Surgery, 16(3), pp.203-211; Bonar, C.J., Lewandowski, A.H. and Schaul, J., 2003. Suspected fenbendazole toxicosis in 2 vulture species (Gyps africanus, Torgos tracheliotus) and marabou storks (Leptoptilos crumeniferus). *Journal of avian medicine and surgery*, *17*(1), pp.16-20; Lindemann, D.M., Eshar, D., Nietfeld, J.C. and Kim, I.J., 2016. Suspected fenbendazole toxicity in an american white pelican (pelecanus erythrorhynchos). *Journal of Zoo and Wildlife Medicine*, *47*(2), pp.681-685.

[7] Horvat, A.J., Babić, S., Pavlović, D.M., Ašperger, D., Pelko, S., Kaštelan-Macan, M., Petrović, M. and Mance, A.D., 2012. Analysis, occurrence and fate of anthelmintics and their transformation products in the environment. *TrAC Trends in Analytical Chemistry*, *31*, pp.61-84.

Fenbendazole has adverse environmental effects that may be exacerbated by the use pattern in poultry.

Manufacture

According to the TR, "Fenbendazole is manufactured by process that requires petrochemicals such as benzene and various amines. These are considered toxic compounds."[8]

Impacts on soil organisms.

While fenbendazole has less impact on soil invertebrates than some other parasiticides, it is widely accepted to have a fungicidal effect.[9] While impacts on plants have not been widely studied, a study on ribwort plantain (*Plantago lanceolate*) demonstrated oxidative damage from the chemical when under stress.[10] According to the TR, "The impact and effects of prolonged use of anthelmintic parasiticides on terrestrial ecology are not well understood."[11]

Access of treated water to other animals.

Since fenbendazole is administered in drinking water, it is important to note that other animals—other birds, for example—who may consume the water may be detrimentally affected.

Contamination of water from use with waterfowl and disposal of treated drinking water.

Aquatic organisms are very sensitive to fenbendazole. Although fenbendazole is commonly assumed to be adsorbed to soil particles, its disposition from poultry droppings may not be the same as from mammalian feces or urine. Waterfowl may excrete directly into water, and chicken droppings may be disintegrated and washed into streams by rain. Finally, disposal of unconsumed treated water presents an opportunity for fenbendazole to get into water.

Ecological impacts of the use of fenbendazole require further investigation.

The specifics presented above serve to illustrate the need for more research into the ecological impacts of treating poultry with fenbendazole.

The need for fenbendazole has not been established.

Although the 2015 TR was written to address parasiticides used in mammalian livestock, it does address management issues that apply to poultry as well. The TR says, "Naturally, livestock develops an immune response to nematodes and becomes resistant or tolerates them without signs of disease."[12] It continues to say that very young, old, or immunocompromised individuals are more susceptible. Comparable information for poultry is not available.

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[8] 2015 TR, lines 650-651.

[9] Beynon, S.A., 2012. Potential environmental consequences of administration of anthelmintics to sheep. *Veterinary parasitology*, *189*(1), pp.113-124.

[10] Stuchlíková, L.R., Skálová, L., Szotáková, B., Syslová, E., Vokřál, I., Vaněk, T. and Podlipná, R., 2018. Biotransformation of flubendazole and fenbendazole and their effects in the ribwort plantain (Plantago lanceolata). *Ecotoxicology and environmental safety*, *147*, pp.681-687.

[11] 2015 TR, lines 760-761.

[12] 2015 TR, lines 828-829.

Pasture rotation minimizes parasite problems.

The TR states, "Good husbandry and nutrition are vitally important for good parasite control. The level and quality of feed influences how the animal will cope with parasites, and the level of immunity it will develop against them. Forage crops that support mycorrhizial fungi, and contain high levels of tannins are also good for suppressing parasites."[13] With regard to the role of mycorrhizal fungi, it is important to note the fungicidal impact of fenbendazole mentioned above. The TR also cites the importance of rotation and other pasture management.[14] Of particular interest, since excreted fenbendazole can harm soil-dwelling nematodes, is the statement, "Organic farms tend to have a higher diversity of nematodes, since animals are not normally treated with anthelmintic drugs. Helminth diversity has been related to a lower intensity of infection in extensive goat breeding and in meat cattle."[15]

Pastures should include anthelmintic plants.

The TR lists many anthelmintic plants that occur naturally as "weeds" or could be planted in poultry pastures. A number of these are also used in herbal preparations for treating or preventing parasites. Homeopathic remedies are available as well.[16]

Conclusion

The NOSB cannot rely on the 2015 TR covering parasiticides used in mammalian livestock to support a decision to allow the use of fenbendazole in poultry. We have presented research showing that such use does not meet OFPA criteria—that it may harm the environment, allow residues in organic eggs that are not compatible with organic practices, and is not necessary for organic poultry production. The definition of emergency proposed by the LS is inadequate to protect organic consumers from fraudulent use. Therefore, if the LS intends to proceed with this petition, it must depend on a TR that addresses the use of fenbendazole in poultry.

Thank you for your consideration of these comments.

Sincerely,

Terry Shistar, Ph.D.
Board of Directors

[13] 2015 TR, lines 899-901.
[14] 2015 TR, lines 924-946.
[15] 2015 TR, lines 929-931.
[16] 2015 TR, lines 834-895.