

Formal Recommendation
From: National Organic Standards Board (NOSB)
To: the National Organic Program (NOP)

Date: October 30, 2020

Subject: Fenbendazole - petitioned for amendment

NOSB Chair: Steve Ela

The NOSB hereby recommends to the NOP the following:

Other: None

Statement of the Recommendation:

The NOSB voted to not approve the petition seeking to amend the listing of fenbendazole to expand its use to include use in laying hens or replacement chickens intended to be laying hens

Rationale Supporting Recommendation

Fenbendazole is an antiparasitic drug that works at the sub-cellular level preventing cell division. Benzimidazoles bind to the β -tubulin, inhibiting the cell's microtubule assembly responsible for intracellular transport and required for mitotic cellular division. The targeted organisms of Fenbendazole for laying hens and replacement laying hens are the parasitic roundworms *Ascaridia galli* and *Heterakis gallinarum*. Chickens infected with *A. galli* and *H. gallinarum* become unthrifty, weak and emaciated and exhibit weight loss proportional to the parasite load. Young birds are more susceptible to the parasites than are mature hens, but mature hens will exhibit significant loss of egg production when infected with *A. galli* and *H. gallinarum*. Histomoniasis, also known as Blackhead Disease, is a disease caused by infection with *Histomonas meleagridis*.

A request was submitted to FDA by Ivervet, Inc. to expand the use of Fenbendazole to chickens. In October 2015, the FDA gave formal approval for the use of fenbendazole in treatment and control of adult *A. galli* in broiler chickens and replacement chickens intended to become breeding chickens and for the treatment and control of adult *A. galli* and *H. gallinarum* in breeding chickens. The FDA allowed a total of 2.4 ppm residual of Fenbendazole in eggs with no withdrawal time from application.

Public Comments:

There were many public comments received for the proposed annotation change to 7 CFR §205.603(a)(23)(i) during the Fall 2019 and Spring 2020 NOSB meetings when the annotation change was presented as a discussion document and during the Fall 2020 NOSB meeting when it was presented as a proposed annotation change.

The public comments were divided into two segments:

- (1) Many producers stated that the presence of worms in their laying hens was becoming more prevalent as cooler and more wet climate conditions have become the "normal" weather pattern. They also said that the worm population was increasing due to granting more outdoor access to the birds, which then scratched in the dirt and picked up the worm oocysts. They stated that the worms were causing health issues in the birds, resulting in pain, suffering, and death. They expressed their fears of erosion of the public's confidence if they cracked an egg and found worms in the eggs.
- (2) Consumers and organic industry leaders expressed concerns about potential health risks associated with the residual of fenbendazole in the eggs at a rate of 2 ppm for eight days after application. They feared that residual fenbendazole could cause health issues in more susceptible populations, especially in children, pregnant women, and the elderly. They

expressed their fears of erosion of the public's confidence if it became public knowledge that organic eggs had residual levels of fenbendazole.

During the NOSB Fall 2020 meeting, an NOSB member stated that among the producers and egg processors that he had inspected, none had expressed the need for the use of fenbendazole for their laying hen operations.

The NOSB proposal to amend the listing for Fenbendazole at 7 CFR §205.603 (23)(1) to include the use of Fenbendazole for use in laying hens or replacement chickens intended to be laying hens failed due to the following OFPA sections of the statute: based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.603(a).

OFPA § 6517(c)(1)(A)(i) - Harmful to human health or the environment - Concern was expressed by NOSB board members that there could be adverse human health impact due to the 2.4 ppm residue of fenbendazole in the eggs after application of the fenbendazole to the active laying hens.

OFPA § 6517(c)(1)(A)(ii) Necessary to the production or handling of the agricultural product because of unavailability of wholly natural substitute products – The NOSB concluded that there were natural products and cultural practices that were available to control the parasitic worm infestations without adding the synthetic fenbendazole to the poultry producers' toolbox.

As such, the NOSB overwhelmingly voted to not amend the proposed annotation at §205.603(23)(1).

NOSB Vote:

Motion to amend the listing for fenbendazole to include: Fenbendazole-for use in laying hens or replacement chickens intended to be laying hens at 7 CFR §205.603(a)(23)(i).

Motion by: Sue Baird

Seconded by: Kimberly Huseman

Yes: 1 No: 14 Abstain: 0 Absent: 0 Recuse: 0

Motion Failed

[\[Fall 2020 Original Subcommittee Proposal - Fenbendazole\]](#)