# NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

**For NOSB Meeting:** **May 2008** | **Substance:** **Fenbendazole**

**Committee:** **Crops** ☐ **Livestock** √ **Handling** ☐ **Petition is for:** **inclusion of Fenbendazole on the National List § 205.603 Parasiticides**

**A. Evaluation Criteria** (Applicability noted for each category; Documentation attached) **Criteria Satisfied? (see B below)**

| | | | | |
|---|---|---|---|---|
| 1. | Impact on Humans and Environment | Yes X | No ☐ | N/A ☐ |
| 2. | Essential & Availability Criteria | Yes X | No ☐ | N/A ☐ |
| 3. | Compatibility & Consistency | Yes X | No ☐ | N/A ☐ |
| 4. | Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606) | Yes ☐ | No ☐ | N/A X |

**B. Substance Fails Criteria Category:** _____ Comments: _____

**C. Proposed Annotation (if any):** Only to be used upon written diagnosis of clinical infestation by a veterinarian; 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.

Basis for annotation: To meet criteria above: ___X___ Other regulatory criteria: _____Citation:_____

**D. Recommended Committee Action & Vote (State Actual Motion)**: inclusion of FENBENDAZOLE on the National List **§** 205.603 Parasiticides (with the annotation as shown in C directly above)

***Motion by: Dan Giacomini Seconded: Jennifer Hall Yes: 5 No: 0 Absent: 2 Abstain: 0***

| | | | | | |
|---|---|---|---|---|---|
| Crops | | Agricultural | | Allowed[1] | √ |
| Livestock | √ | Non-Synthetic | | Prohibited[2] | |
| Handling | | Synthetic | √ | Rejected[3] | |
| No restriction | | Commercially Un-Available as Organic[1] | | Deferred[4] | |

1) Substance voted to be added as "allowed" on National List to § 205. 603 Parasiticides with Annotation (if any): Only to be used upon written diagnosis of clinical infestation by a veterinarian; 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.

2) Substance to be added as "prohibited" on National List to § 205._____with Annotation (if any) _____

Describe why a prohibited substance:_____

3) Substance was rejected by vote for amending National List to § 205. _____Describe why material was rejected:_____

4) Substance was recommended to be deferred because _____

_____ If follow-up needed, who will follow up _____

**E. Approved by Committee Chair to transmit to NOSB:**

**Hubert Karreman** **March 14, 2008**
**Committee Chair** **Date**

## NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

**Category 1. Adverse impacts on humans or the environment? Substance - FENBENDAZOLE**

| Question | Yes | No | N/A [1] | Documentation (TAP; petition; regulatory agency; other) |
|---|---|---|---|---|
| 1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2] | | | X | |
| 2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3] | X | | | Fenbendazole is produced by petrochemicals involving the use of benzene and amines considered to be carcinogenic compounds. |
| 3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i] | X | X | | The product decomposes into fenbendazole sulfone, that is considered to be biologically inactive; but it can accumulate and be persistent, however, it is expected to be used infrequently. |
| 4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2] | | X | | |
| 5. Is there potential for detrimental chemical interaction with other materials used?[§6518 m.1] | X | | | Parasiticides have the potential to chemically interact with other chemicals used in organic farming when excreted by the treated animals. The benzimidizoles exhibit a high degree of chemical stability |
| 6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5] | X | | | The risks associated with chemical treatment of parasites include (1) immediate non-target effects, (2) obligation for repeat treatments, (3) potential risk to domestic animals and human health, (4) target organism resistance to the treatment, (5) potential residue buildup and (6) potential food chain contamination (Rudd, 1985). |
| 7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5] | X | | | Fenbendazole can break into albendazole. However, there is a low likelihood of physiologic effects. (pg 5 TAP) |
| 8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2] | X | X | | See #7 |
| 9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2] | X | X | | See #3 |
| 10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4] | X | | | Fenbendazole has no known teratogenic effects. In adverse drug experiences reported on the FDA's Center for Veterinary Medicine (CVM) website from 1987 to 1997 and considered at least possibly related to the drug by FDA, there were only 6 humans treated for exposure to veterinary fenbendazole with no deaths |
| 11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3] | | | X | |
| 12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5] | | | X | |
| 13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5] | | | X | |

[1] If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

**Category 2. Is the Substance Essential for Organic Production? Substance - FENBENDAZOLE**

| Question | Yes | No | N/A[1] | Documentation (TAP; petition; regulatory agency; other) |
|---|---|---|---|---|
| 1. Is the substance formulated or manufactured by a chemical process? [6502 (21)] | **X** | | | Fenbendazole is produced by petrochemicals involving the use of benzene and amines considered to be carcinogenic compounds. |
| 2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)] | | X | | Derived from petrochemicals. |
| 3. Is the substance created by naturally occurring biological processes? [6502 (21)] | | X | | See #2 |
| 4. Is there a natural source of the substance? [§205.600 b.1] | | | X | |
| 5. Is there an organic substitute? [§205.600 b.1] | | | X | |
| 6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6] | | | X | |
| 7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)] | | | X | There are claims about natural products but no efficacy studies yet. |
| 8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)] | | | X | |
| 9. Is there any alternative substances? [§6518 m.6] | X | | | Yes, but the current allowed product is more harmful to the environment than the petitioned one. |
| 10. Is there another practice that would make the substance unnecessary? [§6518 m.6] | | X | | While we strongly encourage preventive strategies, at times there may be needed emergency treatment. The most promising alternatives to internal parasiticides require methods that disrupt the life cycle of the target organism outside the host (Waller and Faedo, 1996). Rotational grazing, fecal examination, culling heavily infected animals, selection of resistant breeds, biological control at susceptible (usually free-living) stages in the life-cycle. While some non-synthetic herbal remedies, botanicals, and mined minerals are claimed to have anthelmintic properties, most of these materials have not had their efficacy substantiated in controlled experimental trials. |

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

**Category 3. Is the substance compatible with organic production practices? Substance - <u>FENBENDAZOLE</u>**

| Question | Yes | No | N/A[1] | Documentation (TAP; petition; regulatory agency; other) |
|---|---|---|---|---|
| 1. Is the substance compatible with organic handling? [§205.600 b.2] | | | X | |
| 2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)] | X | | | Yes, if only used in emergencies to relieve animal pain and suffering. NOTE: Routine use of parasiticides should be prohibited. Routine use should be defined as use not specified in an annual Farm Plan, or use not at the direction of a veterinarian, or any use in the same livestock species/production type for the same parasite as detailed in the Farm Plan that exceeds two consecutive years. |
| 3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7] | X | | | Parasiticide use has been tolerated in organic livestock production on a limited basis to alleviate animal suffering. This has almost without exception been part of an integrated system of animal health management and requires documentation of a number of approaches other than intervention, as well as an extended withdrawal period well beyond the minimum allowed by the FDA label. |
| 4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3] | | | X | |
| 5. Is the primary use as a preservative? [§205.600 b.4] | | | X | |
| 6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4] | | | X | |
| 7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:<br>a. copper and sulfur compounds; | | X | | |
| b. toxins derived from bacteria; | | X | | |
| c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals? | | X | | |
| d. livestock parasiticides and medicines? | X | | | Yes |
| e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners? | | X | | |

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

**Category 4. Is the commercial supply of an agricultural substance as organic, fragile or potentially unavailable?** [§6610, 6518, 6519, 205.2, 205.105 (d), 205.600 (c) 205.2, 205.105 (d), 205.600 (c)]

**Substance - FENBENDAZOLE**

| Question | Yes | No | N/A | Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown) |
|---|---|---|---|---|
| 1. Is the comparative description provided as to why the non-organic form of the material /substance is necessary for use in organic handling? | | | X | |
| 2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **form** to fulfill an essential function in a system of organic handling? | | | X | |
| 3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quality** to fulfill an essential function in a system of organic handling? | | | X | |
| 4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quantity** to fulfill an essential function in a system of organic handling? | | | X | |
| 5. Does the industry information provided on material / substance non-availability as organic, include ( but not limited to) the following:<br>a. Regions of production (including factors such as climate and number of regions); | | | X | |
| b. Number of suppliers and amount produced; | | | X | |
| c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies; | | | X | |
| d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or | | | X | |
| e. Are there other issues which may present a challenge to a consistent supply? | | | X | |