

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

Date: April 27, 2016

Subject: Amend Use of Parasiticides in Organic Livestock Production

NOSB Chair: Tracy Favre

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: X

Guidance Statement:

Other:

Statement of the Recommendation:

This recommendation, based on new information, is to clarify and amend the use of parasiticides as follows:

- * That parasiticides continue to be prohibited in slaughter stock.
- * That the milk withholding period after treatment with fenbenzadole or moxidectin be changed from 90 days to 2 days for dairy cows, and 36 days for goats and sheep.
- * That the listing for ivermectin remains as presently listed, with a 90 day withdrawal period.
- * That moxidectin be allowed for both internal and external use.
- * 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 fenbenzadole be allowed without written order of a veterinarian.

Rationale Supporting Recommendation (including consistency with OFPA and Organic Regulations):

The use of parasiticides in organic production is strictly confined to emergencies. Parasiticides cannot be used routinely, but sick animals must be treated. At the present time there are three (3) substances on the National List which are approved for use as parasiticides for organic livestock: ivermectin, moxidectin and fenbenzadole. All three materials have annotations and other language limiting usage. Such language was developed when ivermectin was first added to the National List. Recent data and information indicates that milk withholding and other restrictions could be modified in a manner which would be beneficial to the sick animal in emergency situations without jeopardizing the quality of the organic product. In conventional milk production, there is no withholding period for fenbenzadole or moxidectin. For organic production, there is a 90 day withholding period for organic milk. Synthetic parasiticides are prohibited in organic slaughter stock. Wool and fleece from organic fiber bearing animals, such as sheep, cannot be sold as organic even with a single use of a synthetic parasiticide. Organic regulations allowed moxidectin for internal use only. Fenbenzadole use requires a veterinarian order prior to use in organic production, but ivermectin and moxidectin do not have such a requirement.

As discussed below, in 2007 it was agreed that the NOSB could use double FDA or Food Animal Residue Avoidance Databank (FARAD) withholding periods. This recommendation is based on FDA and FARAD and modern scientific research.

NOSB Vote: 5 Motions

1. That the strikethrough language be removed, and the underlined language be added at:

Section 205.238(b)(2) Dairy ~~animals, 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.~~ as allowed under §205.603.

AND

§205.603(a)(18) ...~~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 .~~

Motion by: Jean Richardson

Seconded by: Francis Thicke

Yes: 15 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Motion passed

2. That the underlined language be added at:

§205.238(b)(3) Fiber bearing animals, as allowed under §205.603.

AND

§205.603(a)(18) ... Allowed for fiber bearing animals when used a minimum of 90 days prior to harvesting of fleece or wool that is to be sold, labeled or represented as organic.

Motion by: Jean Richardson

Seconded by: Francis Thicke

Yes: 15 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Motion passed

3. That the strike through language be removed and the underlined language added at:

§205.603(a)(18)(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.

Motion by: Jean Richardson

Seconded by: Francis Thicke

Yes: 15 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Motion passed

4. That the underlined language be added at:

§205.603(a)(18) (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.

Motion by: Jean Richardson

Seconded by: Francis Thicke

Yes: 15 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Motion passed

5. That the strike through language be removed and the underlined language be added at:

§205.603(a)(18) (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 animals.

Motion by: Jean Richardson

Seconded by: Francis Thicke

Yes: 15 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Motion passed

National Organic Standards Board
Livestock Subcommittee
Proposal to Amend Use of Parasiticides in Organic Livestock Production
January 19, 2016

I. INTRODUCTION:

The use of parasiticides in organic production is strictly confined to emergencies. Parasiticides cannot be used routinely, but sick animals must be treated. Typically farmers bring clean animals into their herds or flocks, select breeds which have high resistance to parasites, and manage their land, especially pastures, in a manner which reduces the likelihood of parasite infection. If an increased parasite load is noted in fecal egg counts, farmers have a broad array of alternative treatments available. But when all else fails and animals are not doing well, the farmer, working with the veterinarian, may need to use one of the synthetic parasiticides on the National List.

At the present time there are three (3) substances on the National List which are approved for use as parasiticides for organic livestock: ivermectin, moxidectin and fenbenzadole. All three of these materials were reviewed in 2015 as part of the regular five-year Sunset process. At the October 2015 meeting in Stowe, Vermont, after considerable discussion and extensive public comment, it was recommended that all three parasiticides continue to be listed. Ivermectin was renewed with great reluctance owing to the recent research indicating serious negative impact of ivermectin on dung beetles in pastures. A Discussion Document was also presented at the October 2015 meeting seeking public comment on possible changes in use of the parasiticides. Extensive public comment indicates broad support to propose amendments on parasiticide use.

All three materials have annotations and other language limiting usage. Such language was developed when ivermectin was first added to the National List. Recent data and information indicates that milk withholding and other restrictions could be modified in a manner which would be beneficial to the sick animal in emergency situations without jeopardizing the quality of the organic product. In conventional milk production, there is no withholding period for fenbenzadole or moxidectin. For organic production, there is a 90 day withholding period for organic milk. Synthetic parasiticides are prohibited in organic slaughter stock. Wool and fleece from organic fiber bearing animals, such as sheep, cannot be sold as organic even with a single use of a synthetic parasiticide. Organic regulations allowed moxidectin for internal use only. Fenbenzadole use requires a veterinarian order prior to use in organic production, but ivermectin and moxidectin do not have such a requirement.

As discussed below, in 2007 it was agreed that the NOSB could use double FDA or Food Animal Residue Avoidance Databank (FARAD) withholding periods.

This proposal recommends:

- * That parasiticides continue to be prohibited in slaughter stock.
- * That the milk withholding period after treatment with fenbenzadole or moxidectin be changed from 90 days to 2 days for dairy cows, and 36 days for goats and sheep.
- * That the listing for ivermectin remains as presently listed, with a 90 day withdrawal period.
- * That moxidectin be allowed for both internal and external use.
- * 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 fenbenzadole be allowed without written order of a veterinarian.

Acronyms used herewith:

FDA – Food and Drug Administration

FARAD – Food Animal Residue Avoidance Databank

CVM – Center for Veterinary Medicine

NADA – New Animal Drugs Application – under the FDA

AMDUCA – Animal Medical Drug Use Clarification Act

NOEL – No Observable Effect Level is used by the FDA, CODEX etc.

NRP – National Residue Program

ADI – Adult Daily Intake

MRL – Maximum Residue Limit

TR – Technical Report

Trade names—examples:

Fenbendazole: Panacur, Safeguard

Ivermectin: Ivomec, Primatectin

Moxidectin: Cydectin

II BACKGROUND:

In October 1999, the NOSB voted on three parasiticides for inclusion on the National List. Only ivermectin had sufficient votes to be added to the List. The votes were: Ivermectin 8-3-0, Fenbendazole 5-6-0, and Levamisole 0-11-0.

In April 2004, the NOSB voted to add moxidectin to the National List by a vote of 11-1-1-1. The annotation, “for control of internal parasites only,” was included for moxidectin for the given reason that, “There is much less chance of any kind of contamination if it is used for internal parasites versus external”. Moxidectin was added to the National List in 2012 (77 FR 28472).

In December 2007, after much public comment and consultation, the NOP agreed that the NOSB could require double FDA withdrawal times, or double Food Animal Residue Avoidance Databank (FARAD) times (when appropriate), on a number of livestock materials:

As a proposed compromise to satisfy the intent of the NOSB, many commenters suggested that USDA should consider amending the annotations of Atropine, Butorphanol, Flunixin, Furosemide, Tolazoline, and Xylazine by establishing extended withdrawal periods, calculated using withdrawal times from the Food Animal Residue Avoidance Databank (FARAD). The FARAD is a National Food Safety Project administered through the USDA Cooperative State Research, Education, and Extension Service. It is a system designed to provide livestock producers, extension specialists, and veterinarians with practical information on how to avoid drug, pesticide and environmental contaminant residue problems. FARAD is a repository of comprehensive residue avoidance information. It is also sanctioned to provide “withholding period” (also known as withdrawal period) estimates to the U.S. Pharmacopeia-Drug Information (USP-DI) Veterinary Medicine Advisory Committee. Commenters suggested that USDA account for an extra margin of at least double the withdrawal times of FARAD to safely capture the intent of the NOSB. USDA agrees with the position stated in the comments...

Based on public comment, USDA consulted further with the FDA, concerning the ability to extend the withdrawal period on these approved drugs. Based on our consultations, USDA agreed to clarify the rationale for extending the FDA established withdrawal period. Secondly,

USDA agreed to clarify the language used to authorize the use of the substances by indicating the extended withdrawal periods (at least two-times that required by the FDA) were only relevant for use of the substances under the NOP regulations. Therefore, to clarify our rationale for extending the withdrawal periods established by the FDA, we acknowledge that this determination was not based on scientific research or risk assessments. The decision to extend the FDA withdrawal periods (or any other withdrawal period) for the use of Flunixin and Furosemide (and other substances) was based on consumer preference and the recommendations of the NOSB. FDA exercises full responsibility for determining and enforcing the withdrawal intervals for animal drugs. No food safety arguments are used or implied to support the use of extended withdrawal periods authorized under the NOP regulations. Rather, we determined that extended withdrawal periods are more compatible with consumer expectations of organically raised animals. (72 FR 70479)

In May 2008, Fenbendazole was approved by the NOSB for addition to the National List by a vote of 14-0 and added to the National List in 2012 (77 FR 28472). The Withholding period was the same as for Ivermectin.

Three Technical Reports are relevant for this proposal: A 1999 TAP (fenbendazole, ivermectin); a 2003 TAP for moxidectin; and a June 2015 Technical Report on all three parasiticides (fenbenzadole, ivermectin and moxidectin) requested by the Livestock subcommittee as part of its Sunset Review of these parasiticides.

In 2015, all three parasiticides were reviewed as part of the regular Five Year Sunset Review. At the October 2015 NOSB meeting in Stowe, Vermont:

- Moxidectin was recommended for continued listing on a Motion to Remove: 0 Yes; 12 No ; 2 abstentions.
- Fenbenzadole was recommended for continued listing on a Motion to Remove: 0 Yes ; 12 No ; 2 abstentions.
- Ivermectin was recommended for continued listing on a Motion to Remove: 6 Yes ; 4 No; 4 abstentions.

In addition a Discussion Document on parasiticides was presented at the October 2015 NOSB meeting. This is discussed below in the Discussion section.

III RELEVANT AREAS OF THE RULE:

The USDA organic regulations at 7 CFR part 205 describe required preventive health care practices and regulations for the use of synthetic parasiticides in organic livestock production:

§205.238 Livestock health care practice standard.

- (a) The producer must establish and maintain preventive livestock health care practices, including:
- (1) Selection of species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites;
 - (2) Provision of a feed ration sufficient to meet nutritional requirements, including vitamins, minerals, protein and/or amino acids, fatty acids, energy sources, and fiber (ruminants);

- (3) Establishment of appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of diseases and parasites;
- (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 Synthetic substances allowed for use in organic livestock production.

(a) As disinfectants, sanitizer, and medical treatments as applicable.

(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.

IV DISCUSSION:

Fenbendazole, ivermectin and moxidectin are the only antihelmintics approved for use in organic livestock production. They represent two of five antihelmintic drug classes. Fenbendazole is in the benzimidazole group and Ivermectin and Moxidectin are in the polyene group within the macrocyclic lactone group. In organic livestock production they are never used on a routine basis, only in emergency situations. They are used in doses as indicated on the label, by body weight and species of animal, and, under veterinarian supervision can be used “extra label/off-label” (see detailed discussion below).

Parasiticide Uses:

Fenbendazole:

The US Food and Drug Administration Center for Veterinary Medicine and the US Department of Agriculture National Organic Program permit oral administration of fenbendazole in dairy cattle for the removal and control of lungworm (*Dictyocaulus viviparus*); brown stomach worm (*Ostertagia ostertagi*), barberpole worm (*Haemonchus contortus* and *H. placei*), small stomach worm (*Trichostrongylus axei*), hookworm (*Bunostomum phlebotomum*), threadnecked intestinal worm (*Nematodirus helvetianus*), small intestinal worm (*Cooperia punctata* and *C. oncophora*), bankrupt worm (*Trichostrongylus colubriformis*) and nodular worm (*Oesophagostomum radiatum*); in beef cattle (beef) for the removal and control of stomach worm (*Ostertagia ostertagi*) and tapeworm (*Moniezia benedeni*); in goats for the removal and control of stomach worms (*Haemonchus contortus* and *Teladorsagia circumcincta*); in swine for the removal and control of lungworms (*Metastrongylus apri* and *M. pudendotectus*), roundworms (*Ascaris suum*), nodular worms (*Oesophagostomum dentatum*, *O. quadrispinulatum*), small stomach worms (*Hyostromylus rubidus*), whipworms (*Trichuris suis*) and kidney worms (*Stephanurus dentatus*) and in turkeys for the removal and control of round worms (*Ascaridia dissimilis*) and cecal worms (*Heterakis gallinarum*). Fenbendazole is sold by Merck Animal Health as Panacur® and Safe-Guard®. It is available in liquid suspension, as granules, as a paste and in blocks. Products are dispensed both by veterinarian’s prescription and over the counter, but must be used in organic production only

under veterinary supervision. For swine, turkeys, and wild sheep the NADA (141-144, 140-954, 136-116, 131-675) for fenbendazole is for use in medicated feed only. Other uses for these animals are extralabel. Furthermore, the use of fenbendazole in medicated feed for domestic sheep in food production is not permitted by the FDA. (TR 2015, 284-302).

Ivermectin:

The US Food and Drug Administration Center for Veterinary Medicine and the US Department of Agriculture National Organic Program permit topical, subcutaneous and oral administration of ivermectin in cattle for the treatment and control of gastrointestinal nematodes: *Haemonchus placei*, *Ostertagia ostertagi*, *O. lyrata*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia oncophora*, *C. punctata*, *C. pectinata*, *Oesophagostomum radiatum*, *Nematodirus helvetianus*, *N. spathiger*, *Bunostomum phlebotomum*, lungworms: *Dictyocaulus viviparus*, grubs *Hypoderma bovis*, *H. lineatum*, sucking lice: *Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*, mites: *Psoroptes ovis* (syn. *P. communis* var. *bovis*), *Sarcoptes scabiei* var. *bovis*, in reindeer for treatment and control of warbles (*Oedemagena tarandi*), in swine for treatment and control of gastrointestinal roundworms: *Ascaris suum*; red stomach worm, *Hyostrongylus rubidus*; nodular worm, *Oesophagostomum* species; threadworm, *Strongyloides ransomi*, somatic roundworm larvae-threadworm, *Strongyloides ransomi*, lungworms: *Metastrongylus* species, lice: *Haematopinus suis*, mites: *Sarcoptes scabiei* var. *suis* and ear mites: *Otodectes cynotis*, in american bison for the treatment and control of grubs: *Hypoderma bovis* and in sheep for treatment and control gastrointestinal roundworms: *Haemonchus contortus*, *H. placei*, *Ostertagia circumcincta*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia oncophora*, *C. curticei*, *Oesophagostomum columbianum*, *O. venulosum*, *Nematodirus battus*, *N. spathiger*, *S. papillosus* *Chabertia*, *Trichuris ovis*, lungworms: *Dictyocaulus filaria* and all larval stages of the nasal bot *Oestrus ovis*. Ivermectin is marketed by Merial, Inc. and other companies under a number of pharmaceutical labels. It is available as a drench, in liquid solution, for medicated feed, as a sustained release bolus and as a paste. Products are dispensed both by veterinarian's prescription and over the counter. (TR 2015, 303-321).

Moxidectin:

The US Food and Drug Administration Center for Veterinary Medicine and the US Department of Agriculture National Organic Program permit topical, subcutaneous and oral administration of moxidectin in cattle for treatment and control of internal and external parasites, gastrointestinal roundworms: *Ostertagia ostertagi*, *Haemonchus placei*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia oncophora*, *C. pectinata*, *C. punctata*, *C. spatulata*, *C. surnabada*, *Bunostomum phlebotomum*, *Oesophagostomum radiatum*, *Nematodirus helvetianus*, lungworms: *Dictyocaulus viviparus*, cattle grubs: *Hypoderma bovis*, *H. lineatum*, mites: *Chorioptes bovis*, *Psoroptes ovis*, *P. communis* var. *bovis*, lice: *Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*, *Bovicola* (*Damalinia*) *bovis* and horn flies: *Haematobia irritans* and in sheep for the treatment and control of *Haemonchus contortus*, *Teladorsagia circumcincta*, *T. trifurcata*, *Trichostrongylus axei*, *T. colubriformis*, *T. vitrinus*, *Cooperia curticei*, *C. oncophora*, *Oesophagostomum columbianum*, *O. venulosum*, *Nematodirus battus*, *N. filicollis*, and *N. spathiger*. Moxidectin is sold by Boehringer Ingelheim Vetmedica, Inc. as Cydectin. It is available in liquid solution. Products are dispensed over the counter (TR 2015, 322-332).

Regulated approvals:

The use of fenbendazole for food animals is approved under six FDA New Animal Drug Applications (NADA) (TR 2015, Table 3). It is dispensed over the counter. The use of ivermectin for food animals is approved under nineteen FDA new animal drug applications. It is dispensed both by veterinary prescription and over the counter (Table 3). The use of moxidectin is approved under three NADAs. It is available over the counter. Moxidectin is in the polyene group and of macrolides and is not antibiotic in its function. (TR 105-113). The approved FDA NADA numbers for the eight additional anthelmintics

approved by the FDA are provided in Table 3 of the TR. (TR 2015, 243-248).

“Off label/ Extra label use”. Once a NADA is approved, the FDA, under the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA), can permit the use of the approved drug under specific conditions outside the designated or intended label use, e.g. use in species not listed in the labeling, use for indications (disease or other conditions) not listed in the labeling, use at dosage levels, frequencies, or routes of administration other than those stated in the labeling, and deviation from the labeled withdrawal time based on these different uses (FDA, 1994).

This “off-label use” is only permitted in the context of a valid veterinarian-client-patient relationship and is limited to treatments when the health of an animal is threatened or suffering or death may result from failure to treat.

A valid veterinarian-client-patient relationship is one in which: (1) A veterinarian has assumed the responsibility for making medical judgments regarding the health of (an) animal(s) and the need for medical treatment, and the client (the owner of the animal or animals or other caretaker) has agreed to follow the instructions of the veterinarian; (2) There is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and (3) The practicing veterinarian is readily available for follow up in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept (FDA, 2015b). (TR 2015, 249-266)

For example, there is not an FDA approved use for fenbendazole in domestic sheep; however, it is used under veterinary supervision for this purpose. (TR 2015, 266-267)

There are some limitations for the AMDUCA including extra label use of an approved new animal or human drug by a lay person (except when supervised by a veterinarian). (TR 2015, 269-270).

The no observable effect level (NOEL) for parasiticides is determined by drug manufacturer and approved by the US Food and Drug Administration, Codex Alimentarius or other national or international standard setting organization. Protocols are provided by these federal agencies that detail testing and evaluation of the drugs. The NOEL is usually determined in an animal model. The NOEL values for fenbendazole, ivermectin and moxidectin are respectively, 0.7 milligram/kilogram body weight per day (mg/kg bd/day), 1.5 mg/kg bd/day and 10 mg/kg bd/day. The NOEL is used to determine the Adult Daily Intake (ADI) or the maximum residue limit (MRL). Withdrawal time is the time that it takes for the concentration in milk, eggs and meat that will be consumed by people to drop from the residue level at administration to the ADI, MRL, or safe level. (TR 2015 807-814)

Withdrawal periods for Milk:

Fenbenzadole: FDA—zero withdrawal; FARAD does not include recommendations.

Moxidectin: FDA—zero withdrawal, although some products state not established; FARAD—Cows: zero withdrawal when administered topically, and not established when administered subcutaneously; FARAD—Goats one day for topical administration and up to 18 days if administered orally (drench) (based on weight of animal and dosage)

International Use and Restrictions (TR 2015, 432-507):

CANADA:

The organic standards of Canada prohibit the use of parasiticides with exceptions: If no alternative treatment exists a parasiticide may be administered under veterinary supervision as directed by the standard and mandated by law. Treated livestock with a withdrawal period equivalent to double the label requirement or 14 days, whichever is longer is still considered organic. Organic status for chronically infected animals is discontinued, but **use in slaughter stock is allowed within limitations.**

The Canadian Organic Standard requires organic livestock operations to have a comprehensive plan to minimize parasite problems in livestock, including monitoring and emergency measures. Normally, parasiticides cannot be administered to meat, dairy or laying animals, but in emergencies, production operations can use them: (1) if parasites are detected, (2) under veterinary instructions, (3) with double the label withdrawal time or 14 days whichever is longer, (4) with one treatment for slaughter animals under one year and two treatments for older animals (requiring more treatments will lose organic status), (5) but dairy animals requiring more than two treatments lose organic status and require a 12 month transition, (6) but dairy animals cannot be organic for slaughter, (7) and a dam may be treated during gestation, (8) and poultry flocks can be treated, but laying hens with more than one treatment per 12 months lose organic status and (9) the operator must provide a written action plan with amendments to the parasite control plan.

CODEX:

The organic standards of CODEX Alimentarius, do not allow routine use of parasiticides, but they allow some provisions for emergency uses of parasiticides if preventive animal husbandry practices and natural remedies have been used and not found to be effective. Withdrawal periods should be double that required by legislation, with a minimum of 2 days.

IFOAM:

Like the Canadian standards, IFOAM organic standards require that use of antihelmintics will cause animal to lose its organic status – But an exception is allowed when livestock are treated with synthetic parasiticides the required withdrawal time is not less than double the withdrawal period required by legislation, or a minimum of 14 days, whichever is longer. And **use in slaughter stock is allowed within limitations.**

The International Federation of Organic Agricultural Movements (IFOAM) Exception states that an animal can retain its organic status if the operator can demonstrate treatment is in compliance with IFOAM preventive animal husbandry practices, and natural and alternative medicines and treatments are unlikely to be effective to cure sickness or are not available to the operator, and the chemically synthesized allopathic veterinary medical products or antimicrobials are used under the supervision of a veterinarian, withdrawal periods are not less than double the withdrawal period required by legislation, or a minimum of 14 days, whichever is longer. The exception is granted for a maximum of three courses of remedial treatments within 12 months, or one course of treatment if the productive lifecycle of the animal is less than one year. (TR 2015 486-494)

EEC:

The European Economic Community states that preventive, routine use of parasiticides is not allowed but in the case of a sick animal needing immediate treatment the withholding period is double the withdrawal. And **use is allowed in slaughter stock.**

JAS:

The organic standards of Japan do not specify which parasiticides may be used. The withdrawal period is 2 days prior to slaughter for foods, milk or egg collection or twice the period of drug withdrawal. **Use in slaughter stock is allowed.**

NOP: Does not allow for use in slaughter stock, and this proposal does not recommend any changes to this prohibition.

Alternatives:

There are many natural alternative parasiticides being used in organic livestock production today. Natural parasiticides include homeopathic remedies, diatomaceous earth and many herbs with antihelminthic properties. Table 10 of the 2015 TR lists over 50 botanical and alternative de-wormers. The efficacy of most of these natural alternatives is not well documented, and more research is needed. However, there does seem to be a lot of potential for the development of effective natural parasite control systems in the future.

Livestock develop an immune response to nematodes and becomes resistant or tolerates them without signs of disease. Because young livestock do not have a mature immune system, they may not be able to mount an immune response upon infection. The same is also true for older and immuno-compromised animals. Worming with homeopathic and botanical remedies should begin strategically during the first autumn of life to accommodate the low body reserves expected with calves (Karreman, 2004).

Homeopathic wormers are available commercially that satisfy the organic rule. These are available as veterinary preparations with valid labeling systems so that their use may easily be audited (Brunetti and Karreman, 2006). Users of these remedies should be sure that the material has an appropriate potency and the source from which it was extracted is verified and correct. A list of natural wormers is provided in Table 11 of the TR. Herbal remedies with anthelmintic properties were commonly adopted and used as a part of traditional animal husbandry. Some have not been evaluated with modern techniques, but may cause toxic side effects, however in most cases they represent a good alternative to the use of synthetic drugs (Duval, 1997) (TR 2015, 828-840).

Brunetti and Karreman found that with proper pasture management, a good diet with plenty of forage for livestock and knowledgeable coaches to provide appropriate strategies for husbandry and treatment healthy animals can be sustainably raised without synthetic parasiticides (TR 2015 943-946).

Public comment included many producers, all species of livestock, who consistently use alternative natural materials and plants, pasture and browse, who never use any synthetic parasiticides. Emergency use of synthetic antihelmintics is not common in organic livestock production. This proposal only relates to milk production, not to slaughter stock, and only in emergency situations.

Confusion in present annotation language:

There are some inherent contradictions and problems in the way the three parasiticides are listed and annotated on the National List:

1. Fenbendazole, which is considered the most environmentally benign, is annotated to require the “written order of a licensed veterinarian”. Ivermectin and moxidectin have no such requirement. That may lead producers to choose a potentially more environmentally detrimental parasiticide for convenience.
2. Moxidectin is annotated “for control of internal parasites only.” However, moxidectin is widely used as a pour-on in conventional livestock production, and when used in that form for control of external parasites it is also a de facto control for internal parasites. Moreover, as mentioned above, the annotation “for control of internal parasites only”: was apparently written based on incorrect information on the half-life of moxidectin in the soil.
3. §205.603(a)(18) requires a 90-day withholding period for organic milk or milk products from a treated animal. There seems to be wide consensus that 90 days is much too long of a withholding period, because 1) it may motivate a producer to withhold needed treatment of an animal because of the severe consequences of a 90-day withdrawal, and 2) fenbendazole and moxidectin have no milk withdrawal time for use in conventional production. There is no scientific rationale for the 90 day withholding for milk. The 90 days reflects a desire to assure consumers that organic standards exceed conventional use of restricted materials.

Based on public comment during the first posting of these materials, in fall 2015 the NOSB posted a Discussion Document for public comment. The Discussion Document included the following questions:

1. Should the milk withholding period be modified for any or all of the parasiticides? If so, how many days for moxidectin, fenbendazole and ivermectin?
2. Should minimal use of parasiticides be allowed in organic slaughter stock such as is permitted under Canadian Organic standards with one treatment for slaughter animals under one year and two treatments for older animals (requiring more treatments will lose organic status)?
3. Should Sheep fleece and wool be allowed to be certified organic even if use of parasiticides was necessary at some time in the animal’s life?
4. Should use of Moxidectin be changed to allow both internal and external use?
5. Should use of parasiticides be allowed only under Veterinarian advice?

Public Comment:

Considerable public comment was received from a broad range of stakeholder groups and producers.

To summarize public comment:

* There was strong support to reduce the withholding period for milk following use of either fenbendazole or moxidectin. Recommendations, based on science and research, suggested adoption of a withdrawal period of between zero days and 14 days as opposed to the present 90 days.

One large dairy stated the following: “We support the NOP’s consistent position of an organic milk withdrawal period of twice what is required by the...FDA and/or...FARAD for substances on the National List. However... Fenbendazole and Moxidectin have no FDA required milk withdrawal interval and therefore organic dairy livestock treated with either of these substances should have milk requirement

withdrawal of zero days. Three other commenters also suggested zero withholding and one researcher commented that science indicates that small ruminants metabolize fenbendazole even more rapidly than large ruminants. Research presented as part of public comment indicates Fenbendazole in blood samples peaks at 7 hours and is gone from the blood in 72 hours.

Veterinarians, consumer organizations, a trade organization, individual producers, certifiers, an inspector association, and dairy groups all supported reduction of the withholding period based on science and the FDA and FARAD.

* There was no support for reducing withholding from 90 days after treatment with ivermectin based on science and FARAD. Some commenters suggested the need to prohibit ivermectin treatment for lactating cows.

* One certifier (Western US) noted that synthetic parasiticides are rarely used in dairy production. Several producers stated that they never use parasiticides.

* There was widespread public comment to remove ivermectin completely from the National list especially in light of recent science indicating the negative impact of ivermectin on dung beetles in pastures. However, some producers, notably small ruminant producers, urged that ivermectin be kept on the list at present for the following reasons: the fact that ivermectin is well known; has been allowed for the longest time; is commonly available without prior veterinarian advice or prescription; lack of experience of use of fenbendazole. Veterinarians and a large dairy producer group recommended that ivermectin be prohibited for use on lactating cows. Since parasiticides, if used, are typically given to young stock, several public commenters requested that NOSB consider an annotation to state – Ivermectin- not for use in dairy animals of breeding age or older. Other commenters noted that because ivermectin is ONLY used in an emergency and not on a regular basis, dung beetle impact on organic pastures will be minimal.

* There was strong support to allow both external and internal use of moxidectin from individual dairy producers, larger dairy organizations, certifiers, an inspector organization, a trade group, and veterinarians. One certifier commented that the present annotation for internal and not external use makes verification difficult. A large dairy commented that moxidectin for both internal and external use is particularly critical in the Southern US states.

* There was little support for possible adoption of allowing parasiticide use in slaughter stock as per the Canadian Organic Standards. Consumer groups and dairy producer organizations expressed concern that this would reduce consumer confidence in organic food. Certifiers and veterinarians also did not support this suggestion. There were two individuals who felt that use of limited parasiticides could be allowed for slaughter stock.

* There was strong support for certification of sheep fleece and wool even after use of parasiticides. This support came from farmer producers, certifiers, veterinarians, farm producers in the West, consumer groups, an inspector organization, and trade groups. We were reminded that this is not a new idea, but one that was proposed to the NOSB in 1990 and never taken up by the NOSB.

* There was mixed response to requiring veterinarian advice before use of parasiticides. Certifiers like the idea that veterinarians would be involved as this would make the audit trail far easier to verify. One certifier stated:

Overall we support an annotation update that requires veterinarian advice because it would clarify how producers should document the emergency necessity for treatment and provide for a clear audit. Currently parasiticides are “allowed for emergency treatment,” which requires that organic producers describe and provide documentation about how they determined that it was an emergency (fecal tests, animal condition, etc.)...A vet recommendation requirement would be more straightforward to document and audit than the existing annotation...but...situations also exist when a veterinarian may not be available to assess the situation quickly, such as when animals are in a remote location.

Most, but not all, veterinarians support requiring veterinarian advice prior to use of parasiticides. This would ensure that the right dosage of the most effective parasiticide is given to the various animal species. One large cow dairy organization stated that there was plenty of most of the parasiticides available without veterinarian advice.

To quote one of the public comments:

In preparing this proposal to recommend amendments to use of parasiticides, the NOSB must be very mindful that we need to remember that livestock producers are raising multiple species in diverse geographic regions facing diverse climatic conditions.

V RECOMMENDATION:

§205.238 Livestock health care practice standard.

(a) The producer must establish and maintain preventive livestock health care practices, including:

- (1) Selection of species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites;
- (2) Provision of a feed ration sufficient to meet nutritional requirements, including vitamins, minerals, protein and/or amino acids, fatty acids, energy sources, and fiber (ruminants);
- (3) Establishment of appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of diseases and parasites;

(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 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, as allowed under §205.603.
- (3) Fiber bearing animals, as allowed under §205.603.

§205.603 Synthetic substances allowed for use in organic livestock production.

(a) As disinfectants, sanitizer, and medical treatments as applicable.

(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.

Sub Committee Vote:

1. That the strikethrough language be removed, and the underlined language be added at:

Section 205.238(b)(2) Dairy ~~animals, 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.~~ as allowed under 205.603.

AND

205.603(a)(18) ...~~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 .~~

Motion by: Jean Richardson

Seconded by: Francis Thicke

Yes: 6 No: 0 Abstain: 0 Recuse: 0 Absent: 0

2. That the underlined language be added at:

§205.238(b)(3) Fiber bearing animals, as allowed under §205.603.

AND

§205.603(a)(18) ... Allowed for 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.

Motion by: Jean Richardson

Seconded by: Francis Thicke

Yes: 6 No: 0 Abstain: 0 Recuse: 0 Absent: 0

3. That the strike through language be removed and the underlined language added at:

205.603(a)(18)(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.

Motion by: Jean Richardson

Seconded by: Francis Thicke

Yes: 6 No: 0 Abstain: 0 Recuse: 0 Absent: 0

4. That the underlined language added at:

205.603(a)(18) (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.~~

Motion by: Jean Richardson

Seconded by: Francis Thicke

Yes: 6 No: 0 Abstain: 0 Recuse: 0 Absent: 0

5. That the strike through language be removed and the underlined language added at:

205.603(a)(18) (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 animals.

Motion by: Jean Richardson

Seconded by: Francis Thicke

Yes: 6 No: 0 Abstain: 0 Recuse: 0 Absent: 0