Western Organic Dairy Producers Alliance

Ms. Michelle Arsenault, Special Assistant
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Avenue, SW
Room 2648-So, Ag Stop 0268
Washington, DC 20250-0268

April 14, 2016

Dear Ms. Arsenault:

The Western Organic Dairy Producers Alliance (WODPA) is a nonprofit Mutual Benefit Corporation. Our purpose is to enable organic dairy farmers, situated across an extensive area in the west, to maintain the sustainability of organic dairy farming. We represent approximately 275 organic dairy farm families throughout the western United States.

We are providing comments on the proposal to amend provisions on the use of parasiticides in organic livestock production. We are also providing comments on the proposal to list "Hypochlorous acid" as an allowed crop, livestock, and handling substance.

Proposal to Amend Use of Parasiticides in Organic Livestock Production

The animals most vulnerable to parasite infestation are the young dairy animals placed on pasture prior to full development of their immune system. For dairy cattle parasiticides are almost exclusively needed from about 4 months to a year in age. Paraciticides are rarely used in breeding aged cattle. In fact, most parasiticide products with **on-label** dairy cattle use provide that the product is not for use in breeding aged dairy cattle.

The information immediately below clearly shows that producers are responsible for minimizing the occurrence of parasite infestation. It also clearly shows that certifiers are responsible for assuring that producers have taken the steps necessary to minimizing the occurrence of parasite infestation. When both, producers and certifiers, are in compliance with the regulations, the emergency use of parasiticides should be uncommon. This does not mean that parasiticides should not be available to producers. To the contrary they are a necessity, when all else fails, for the humane treatment of an animal during an emergency.

All livestock producers are required to have an OSP describing the practices and procedures to be performed and maintained (§ 205.201). For organic livestock producers this includes addressing the preventive livestock health care practices to be followed by the producer (§ 205.238). When addressing their preventive livestock health care practices, they must describe the selection of species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites (§ 205.238(a)(1)). They must describe the practices to be used to minimize the occurrence and spread of disease and parasites (§ 205.238(a)(3)). The plan must describe how they will manage pasture (§ 205.240) to comply with § 205.238(a)(3). The producer's OSP must be submitted to the producer's certifying agent (§ 205.400(b) and § 205.401(a)).

The producer's certifying agent is required to review the producer's application for certification (§ 205.402(a)(1) and (2) and § 205.402(b)(1)) and annual update (§ 205.406(b)). The certifier is also required to verify the information in the producer's OSP (§ 205.403(c)(2)). The certifying agent is charged with determining producer compliance with the regulations (§ 205.402 and § 205.403).

The forgoing clearly shows that producers are responsible for minimizing the occurrence of parasite infestation. It also clearly shows that certifiers are responsible for assuring that producers have taken the steps necessary to minimizing the occurrence of parasite infestation. When both, producers and certifiers, are in compliance with the regulations, the emergency use of parasiticides should be uncommon.

Accordingly, rather than reducing withdrawal periods and expanding use, which weakens the standards and encourages use, NOSB should explore options for ensuring compliance and reducing parasiticide use.

WODPA believes that NOSB has an opportunity to strengthen the standards and improve compliance, while also retaining the parasiticides needed in an emergency. NODPA can do this by recommending changes:

1. Requiring that use be "by or on the lawful written order of a licensed veterinarian."
2. Prohibiting off-label use.
3. Allowing topical, oral and subcutaneous use for dairy and breeder stock, not of breeding age.
4. Allowing topical use only for breeding age dairy and breeder stock; since lice, mites and cattle grubs can infest all ages.
5. Establishing milk withdrawal periods twice the slaughter withhold periods.
6. Creating a definition for "emergency."

WODPA's position is that all parasiticide use must be "by or on the lawful written order of a licensed veterinarian." This is a key piece in assuring that the parasiticides are used only in an emergency situation. It also helps in creating an auditable paper trail of compliance.

WODPA's position is that all parasiticide use must be in compliance with the product label. WODPA vigorously objects to off-label use and strongly advocates for a prohibition on off-label use of parasiticides.

As previously stated, the animals most vulnerable to parasite infestation are the young dairy animals placed on pasture prior to full development of their immune system. In fact, for dairy cattle, parasiticides are almost exclusively needed from about 4 months to a year in age. Paraciticides are rarely used in breeding aged cattle. Further, most parasiticide products with on-label dairy cattle use provide that the product is not for use in breeding aged dairy cattle. Accordingly, WODPA strongly advocates for limiting the use of topical, oral and subcutaneous parasiticides to use for dairy and breeder stock, not of breeding age.

With proper nutrition and management, breeding age animals should not be placed in an emergency situation where the use of a parasiticide is necessary. However, bad things do happen. Accordingly, WODPA recommends allowing topical use only for breeding age dairy and breeder stock. This would allow for the emergency treatment of breeding age animal infested with lice, mites, cattle grubs and other parasites.

Below is a review of Fenbendazole, Ivermectin and Moxidectin with a recommended milk withdrawal period for each.

Fenbendazole

All of the Fenbendazole products are labeled for oral use. There are no products with **on-label** use for sheep. There is one product with **on-label** use for goats. It is administered orally and the label states "Do not use in lactating goats." There are five products with **on-label** use for dairy cattle of which three have the label statement "Do not use in dairy cattle of breeding age." The other two are medicated feeds which would be prohibited unless the feed portion is organic.

Fenbendazole slaughter withhold ranges from and 8 to 16 days (cattle) depending on the product. The tolerances are muscle 0.4 ppm, and milk 0.6 ppm.

Consumers expect their organic milk to be free of chemicals like parasiticides. Accordingly, milk withdrawal should be at least 2 times the 16 day meat withholding which would be 32 days.

WODPA strongly objects to the NOSB's proposed 2 day milk withdrawal period following use in dairy cattle. This period is too short to assure that residues are not present in organic milk. We also strongly objects to the NOSB's proposed 36 day milk withdrawal period following use in goats. As noted above, there is one product with on-label use for goats. It is administered orally and the label states "Do not use in lactating goats." Accordingly, use in goats must be prohibited.

Ivermectin

There are no Ivermectin products with **on-label** use for sheep or goats. There are 17 products with **on-label** dairy cattle use. Thirteen of the products are not for use in breeding aged dairy cattle. Of the remaining four, three are used subcutaneously and one is used topically for breeding aged dairy cattle. All four can be used for the treatment of grubs, mites and lice. None of them mention a meat or milk withdrawal period.

Of the 17 products with **on-label** dairy cattle use, seven are administered topically. For six of these the label states "Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age." These six also state "Do not treat cattle within 48 days of slaughter." The seventh product does not mention a milk or meat withdrawal period.

Ivermectin slaughter withhold ranges from unstated to 180 days. A third of the products, all topical, have a withhold of 48 days. The tolerances are liver 1.6 ppm and milk 0.65 ppm. Muscle residues are not indicative of the safety of other edible tissues.

Again, consumers expect their organic milk to be free of chemicals like parasiticides. Accordingly, milk withdrawal should be at least 2 times the 48 day meat withholding which would be 96 days. We chose the 48 day withhold period because we are recommending that use on breeding aged dairy cattle be limited to Ivermectin administered topically.

Moxidectin

There are no products with **on-label** use for goats. There is only one **on-label** use for sheep. It is administered orally and the label states "Because a withholding time has not been established for this product, do not use in female sheep providing milk for human consumption." This product is not used for the treatment of lice, mite or grub infestation.

There are two products with **on-label** use for dairy cattle; a topical and a subcutaneous for use in the treatment for lice, mites, cattle grubs and other parasites. The topical has an exclusivity granting a zero-day milk discard time and use on dairy cattle of breeding age. The subcutaneous label states "Because a withholding time for milk has not been established, do not use in female dairy cattle of breeding age."

The Moxidectin subcutaneous slaughter withhold is 21 days. The topical does not mention a withhold period for adult animals. Subcutaneous and topical are prohibited for use on calves to be processed for veal. The tolerances are liver 200 ppb, muscle 50 ppb and milk 40 ppb.

As previously stated, consumers expect their organic milk to be free of chemicals like parasiticides. Accordingly, milk withdrawal should be at least 2 times the 21 day meat withholding which would be 42 days.

WODPA strongly objects to the NOSB's proposed 2 day milk withdrawal period following use in dairy cattle. This period is too short to assure that residues are not present in organic milk. We also strongly objects to the NOSB's proposed 36 day milk withdrawal period following use in goats, sheep and other animals. As noted above, there are no products with on-label use for goats. There is only one on-label use for sheep. It is administered orally and the label states "Because a withholding time has not been established for this product, do not use in female sheep providing milk for human consumption." This product is not used for the treatment of lice, mite or grub infestation. Accordingly, use in goats, sheep and other animals must be prohibited.

Section 205.238 Livestock health care practice standard

WODPA agrees with amending §205.238(b)(2)to read: (2) Dairy animals as allowed under §205.603.

WODPA opposes the addition of proposed new paragraph §205.238(b)(3) because there are no **on-label** products approved for topical use on sheep. WODPA believes all parasiticide use must be in compliance with the product label. WODPA opposes all **off-label** use of parasiticides.

Recommended Regulatory Text

Based on the above WODPA recommends that §205.603(a)(18) be amended to read as follows:

(18) Parasiticides—

(i) Allowed only for use by or on the lawful written order of a licensed veterinarian.

(ii) Off-label use prohibited.

(iii) Prohibited in slaughter stock.

(iv) Allowed topically, orally and subcutaneously in emergency treatment for dairy and breeder stock, not of breeding age, when organic system plan-approved preventive management does not prevent infestation.

(v) Allowed topically in emergency treatment for breeding age dairy and breeder stock, when organic system plan-approved preventive management does not prevent lice, mite and grub infestation.

(vi) Milk or milk products from an animal treated as allowed under §205.603(18)(v) must not, following treatment, be labeled as provided for in subpart D of this part during the withdrawal period set for the allowed parasiticide.

(vii) 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.

(viii) Parasiticides allowed for use in compliance with this section include:

(A) Fenbendazole (CAS#43210-67-9)—Not for use in sheep. Allowed for dairy cattle and goats not of breeding age. The agricultural products in medicated feed blocks and feed must have been organically produced and handled and are not for use for goats. Medicated feed blocks are not for use for breeding age dairy cattle. Medicated feed, consisting of organic agricultural ingredients may be used to treat breeding age dairy cattle. Milk or milk products from dairy cattle treated with medicated feed cannot be labeled as provided for in subpart D of this part for 32 days following the last treatment.

(B) Ivermectin (CAS#70288-86-7)—Not for use in sheep or goats. Allowed for dairy cattle not of breeding age. Topical use allowed for dairy cattle only when the product label does not contain a limitation on use in female dairy cattle of breeding age. Milk or milk products from dairy cattle treated topically as allowed under §205.603(18)(v) must not be labeled as provided for in subpart D of this part for 96 days following the last treatment.

(C) Moxidectin (CAS #113507-06-5)—Not for use in goats. Not for use in sheep providing milk for human consumption. Topical use allowed for dairy cattle. Subcutaneous use only allowed in non-breeding age dairy cattle. Milk or milk products from dairy cattle treated topically as allowed under §205.603(18)(v) must not be labeled as provided for in subpart D of this part for 42 days following the last treatment.

WODPA recommends that §205.238(b)(2) be amended to read as follows:

§205.238(b)(2)

(2) Dairy animals as allowed under §205.603.

Hypochlorous acid

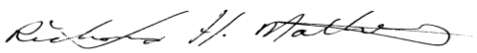
WODPA supports the listing of Hypochlorous acid produced by the electrolysis of sodium chloride and water. However, the listing, as proposed, requires an annotation to limit how the Hypochlorous acid is produced. For example, Hypochlorous acid is formed when chlorine is added to water.

WODPA recommends that the listing be worded as:
(iv) Hypochlorous acid produced by the electrolysis of sodium chloride and water.

Further, WODPA also recommends addition to §205.603 as an approved material for use as a teat dip used pre and post milking. Listing of this product for use as a teat dip would reduce the use of iodine. Benefits include efficient, effective, saves money promotes hygiene, and is safe for the animals, users and the environment.

Thank you for your consideration of our comments.

Sincerely,



Richard H. Mathews
Executive Director
Western Organic Dairy Producers Alliance
717-457-0100