WESTERN ORGANIC DAIRY PRODUCERS ALLIANCE

Mr. Robert Pooler
Standards Division
National Organic Program
USDA-AMS-NOP
1400 Independence Avenue, SW
Room 2642-So, Ag Stop 0268
Washington, DC 20250-0268

March 19, 2018

Docket: AMS-NOP-14-0079; NOP-14-05
Regulatory Information Number (RIN) 0581-AD60

Dear Mr. Pooler:

The Western Organic Dairy Producers Alliance (WODPA) thanks you for the opportunity to comment on proposed rule "National Organic Program; Amendments to the National List of Allowed and Prohibited Substances (Crops, Livestock and Handling)."

Our comment consists of 9 PARTS as follows:

PART 1—Materials On Which WODPA Has No Comment

WODPA has no comments regarding:

Hypochlorous acid for addition to §205.601(a) at subparagraph (2)(iii).
Magnesium oxide for addition to §205.601(a) at subparagraph (5).
Micronutrients at §205.601(a) or the proposed annotation amendment.
Squid byproducts for addition to §205.601(a) at subparagraph (10).

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Rotenone for addition to §205.602 at paragraph (f).

Alginic acid at §205.605(a) being reclassified as an allowed synthetic at §205.605(b).
Flavors at §205.605(a) or the proposed annotation amendment.
Carnauba Wax at §205.605(a) being reclassified as an allowed nonorganically produced agricultural product at §205.606(a).
Cellulose at §205.605(b) or the proposed annotation amendment.
Chlorine at §205.605(b) or the proposed annotation amendment.
Hypochlorous acid for addition to §205.605(b) at subparagraph (3).
Glycerin at §205.605(a) being reclassified as an allowed nonorganically produced agricultural product at §205.606(h) with an amended annotation.

Colors at §205.606(b) or the proposed annotation amendments.

PART 2—Materials WODPA Supports But Questions

WODPA supports but questions the addition of **Activated charcoal, Calcium borogluconate, Calcium propionate, Kaolin pectin, Mineral oil,** and **Propylene glycol** to §205.603(a) at subparagraphs (6), (7), (8), (17), (20), and (27) respectively.

Activated charcoal, Calcium borogluconate, Calcium propionate, Kaolin pectin, Mineral oil, and Propylene glycol were addressed in rulemaking back in 2006 and 2007. On Monday, July 17, 2006, the Agricultural Marketing Service published "National Organic Program (NOP); Proposed Amendments to the National List of Allowed and Prohibited Substances (Livestock); Proposed Rule" (71 FR 40624-40632). On Wednesday, December 12, 2007, the Agricultural Marketing Service published "National Organic Program (NOP); Amendments to the National List of Allowed and Prohibited Substances (Livestock)" (72 FR 70479-70486).

The following is a quote from 71 FR 40630:

"Activated charcoal, Calcium borogluconate, Calcium propionate, Kaolin pectin, Mineral oil, and Propylene glycol. The NOSB made six recommendations to the Secretary regarding the inclusion of activated charcoal, calcium borogluconate, calcium propionate, kaolin pectin, mineral oil, and propylene glycol as substances that should be allowed for use as veterinary treatments in organic livestock production. Based on consultations with the FDA, the NOP was informed that those substances were not approved by the FDA for use in cattle and would not qualify for extralabel use by a licensed veterinarian under the AMDUCA. The EPA deferred to FDA as the appropriate regulatory body for the use of the substances. As a result, the Secretary,

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at this time, cannot accept the recommendations to allow the use of those six substances under § 205.603, as livestock medications. The Secretary remains in consultation concerning the use of these six substances in organic livestock production. However, until otherwise notified by the Secretary, **synthetic activated charcoal, calcium borogluconate, calcium propionate, kaolin pectin, mineral oil, and propylene glycol will remain prohibited for use in organic livestock production**." *Emphasis added.*

The following is a quote from 72 FR 70484:

"Six non-accepted substances. Several comments, including a number from organic dairy farmers, supported adding Activated charcoal, Calcium borogluconate, Calcium propionate (as a medical treatment for milk fever), Kaolin pectin, Mineral oil, and Propylene glycol onto § 205.603(a) as substances that should be allowed for use as medical treatments in organic livestock production. These substances were not included as amendments to the National List in the proposed rule. The NOSB recommended that the Secretary include these substances onto the National List, in § 205.603, as veterinary treatments in organic livestock production. Comments in support of including these substances onto the National List argued that these substances were essential tools for dairy farmers, effective in restoring animal health, and widely available and commonly used by livestock producers and veterinarians, with no significant environmental impacts. Additionally, a few of these commenters argued that FDA considers these drugs to be a low regulatory priority or ''allowed by regulatory discretion.''

As stated in the proposed rule, consultation with the FDA revealed that Activated charcoal, Calcium borogluconate, Calcium propionate, Kaolin pectin, Mineral oil, and Propylene glycol have *not* received approval through the FDA drug approval process to be authorized as medical treatments for livestock. Consultation also revealed that the proposed substances could not qualify for extra-label use by a licensed veterinarian under AMDUCA. **As a result, the synthetic forms of these substances remain prohibited for use in organic livestock production.** *Emphasis added.*

One commenter asserted that USDA should have not stated that the six substances could not be used in organic livestock production, because some of the substances could be sourced and used in nonsynthetic form. USDA agrees that nonsynthetic forms of the medication would not be prohibited from use in organic livestock production. The proposed rule did not address the nonsynthetic forms of the medications because the NOSB's recommendations only addressed the synthetic forms. As a result, we reiterate that the prohibited use of the six substances was made in the context of the synthetic form of the substances, not the nonsynthetic form."

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As noted above, WODPA supports the addition of these materials to the National List. **HOWEVER,** WODPA notes that, in this proposed rule, AMS has not addressed its previous position or that of FDA. WODPA seeks answers to the following questions:

1. Has AMS consulted with FDA regarding its proposal to now add these materials?
2. If yes, what was the result of that consultation?
3. Did FDA give its approval?
4. If yes, what is the basis for FDA's reversal in position?

If AMS has not received clearance from FDA, **WODPA strongly urges AMS** to enter into consultation with FDA to receive clearance. If AMS is unable to receive FDA clearance, AMS will have to withdraw its proposal to add Activated charcoal, Calcium borogluconate, Calcium propionate, Kaolin pectin, Mineral oil, and Propylene glycol. The last thing livestock producers need is to run afoul with FDA.

If AMS has received clearance from FDA, **WODPA strongly urges AMS** to amend this proposed rule to inform the public of its previous position and that of FDA. **WODPA urges** AMS to also inform the public as to what has changed that FDA now approves the addition of Activated charcoal, Calcium borogluconate, Calcium propionate, Kaolin pectin, Mineral oil, and Propylene glycol to the National List of Approved and Prohibited Substances.

PART 3—Material WODPA Supports Adding With Amendment

WODPA supports the addition of Hypochlorous acid—generated from electrolyzed water with amendment.

RECOMMENDATION

WODPA recommends that **Hypochlorous acid—generated from electrolyzed water** be removed from the "Chlorine materials" listing and be placed in its own subparagraph in §205.603 paragraph (a). We recommend listing between the subparagraphs for Glycerin and Hydrogen peroxide.

JUSTIFICATION FOR AMENDMENT

WODPA supports adding **Hypochlorous acid** to §205.603 of the National List for use as a disinfectant, sanitizer, and medical treatment in organic livestock production. We note, however,

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that the proposed placement within §205.603 is inconsistent with the intended uses described in the preamble and therefore problematic.

The preamble states in part "…NOSB…recommended adding hypochlorous acid to the existing listings for chlorine materials in…§ 205.603(a) for use as a **disinfectant, sanitizer, and medical treatment** in organic livestock production;…." *Emphasis added.* The proposed regulatory text places **Hypochlorous acid** in § 205.603(a)(10)(iii). While paragraph (a) reads "As disinfectants, sanitizer, and medical treatments as applicable" subparagraph (10) reads, in part, "Chlorine materials—disinfecting and sanitizing facilities and equipment." This effectively limits **Hypochlorous acid** use to disinfecting and sanitizing facilities and equipment which is substantially different than the preamble stated use as a **disinfectant, sanitizer, and medical treatment.**"

As stated above, the preamble language reads "for use as a disinfectant, sanitizer, and medical treatment in organic livestock production". This implies that Hypochlorous acid could be used on a dairy farm to disinfect cow's teats, milking cups, and towels as well as the facilities and equipment. Hypochlorous acid use as a disinfectant has been shown to be effective in the prevention and treatment of subclinical mastitis of dairy cows.

Microbial contamination is an important issue on dairy farms. Therefore, an effective disinfectant with high efficiency, harmless, and no pollution is crucial to dairy farms. Hypochlorous acid is an effective disinfectant for microbial contamination control on dairy farms and to prevent mastitis in cows.

PART 4—Material of Concern

WODPA supports the addition of **Zinc sulfate** as another substance option for the control of foot rot in livestock. **HOWEVER,** WODPA has concern regarding the proposed addition of **Zinc sulfate** at §205.603(a) of the National List. WODPA acknowledges that it provided comment to the National Organic Standards Board in support of adding Zinc sulfate to the National List. **HOWEVER,** language in the preamble to this proposed rule gives us pause.

The preamble states at 83 FR 2511:

> "Zinc sulfate is not currently FDA approved as a treatment for controlling foot rot or digital dermatitis as described in the zinc sulfate petition submitted to the NOSB.

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> Zinc sulfate is allowed as a GRAS food additive for human food under FDA regulation 21 CFR 182.8997. Under the USDA organic regulations, zinc sulfate is on the National List as a synthetic trace mineral in organic livestock feed under § 205.603(d)(2).
>
> As proposed, zinc sulfate would be used in a footbath for control of foot rot in livestock, primarily dairy cattle, sheep and goats."

Points of concern:

1. There is no indication in the preamble that AMS has consulted with FDA regarding AMS's intention to allow the use of zinc sulfate for use in hoof and foot treatments.
2. There is no indication in the preamble that FDA now approves the use of zinc sulfate for controlling foot rot or digital dermatitis.
3. AMS places farmers at risk by approving a use not sanctioned by the FDA.

RECOMMENDATION

WODPA recommends that AMS consult with FDA and receive written approval for the use of zinc sulfate for use in hoof and foot treatments before placing zinc sulfate on the National List.

PART 5—Materials WODPA Supports Adding

WODPA supports adding the following materials to the National List:

> **Nutritive supplements—Injectable Minerals, Vitamins, and Electrolytes** at §205.603(a)
> **Zinc sulfate** at §205.603(a)
> **Sodium chlorite, acidified** at §205.603(a) & (b)

PART 6—Material Annotation Amendments WODPA Supports

WODPA supports the proposed annotation amendment for the following:

> **Chlorhexidine** at §205.603(a)
> **Xylazine** at §205.603(a)
> **Lidocaine** at §205.603(b)
> **Procaine** at §205.603(b)

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Excipients at §205.603(f)

PART 7—Material Annotation Amendment, No WODPA Objection

WODPA has no objection to the proposed annotation amendment for the following:

Methionine at §205.603(d)

PART 8—Materials Addressed In Preamble But Not Addressed In Regulatory Language

WODPA notes that in the preamble to the proposed rule, AMS states that "…this proposed rule would amend §205.605(b) by adding **Potassium lactate** and **Sodium lactate** with the same restrictive annotation: for use as an antimicrobial agent and pH regulator only." *Emphasis added.* WODPA further notes that neither material is addressed in the proposed regulatory language for §205.605(b). Accordingly, **WODPA calls on AMS to issue an amended proposed rule to address this omission.**

PART 9—Parasiticides—Ivermectin, Fenbendazole, Moxidectin

Parasiticides

WODPA does **not** support expanding the use of parasiticides to include fiber bearing animals.

WODPA does **not** support reducing the withhold period for any of the parasiticides.
The regulations clearly show that producers are responsible for minimizing the occurrence of parasite infestation. They also clearly show that certifiers are responsible for assuring that producers have taken the steps necessary to minimize the occurrence of parasite infestation. When both, producers and certifiers, are in compliance with the regulations, the emergency use of parasiticides should be uncommon. Further, the regulations specifically prohibit a producer from withholding necessary medical treatment to preserve the animal's organic status, WODPA argues that by extension, producers are prohibited from withholding necessary medical treatment allowed by regulation. Thus, any argument that the proposed changes to the withhold period are an animal welfare issue is a specious argument.

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Currently, bovine and nonbovine dairy animals are held to the same 90 day withhold period. AMS provides no explanation for the 2 day withdrawal for bovine dairy animals following parasiticide use verses the 36 day withdrawal for nonbovine dairy animals. AMS also does not provide justification for its requirement that the farmer wait a minimum of 90 days after parasiticide use to harvest fleece or wool for fiber bearing animals.

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. Parasiticides 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.

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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 to two days and expanding use, which weakens the standards and encourages use, AMS should explore options for ensuring compliance and reducing parasiticide use.

WODPA believes AMS should strengthen the standards and improve compliance, while also retaining the parasiticides needed in an emergency. AMS can do this by amending the parasiticide provisions to:

1. Prohibit off-label use.
2. Allow topical, oral and subcutaneous use for dairy and breeder stock, not of breeding age.
3. Allow topical use only for breeding age dairy and breeder stock; since lice, mites and cattle grubs can infest all ages.
4. Establish milk withdrawal periods twice the slaughter withhold periods.
5. Create a definition for "emergency."

Amending the parasiticide provisions as noted above would further limit use and thereby reduce the risk to dung beetles which seems to be the reason for the quest to remove Ivermectin.

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. Parasiticides 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.

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Ivermectin

WODPA STRONGLY OPPOSES THE REMOVAL OF IVERMECTIN FROM THE NATIONAL LIST.

Fenbendazole is useful in treatment of internal parasites only. It is not effective whatsoever in treatment of external parasites. Thus, by removing ivermectin as proposed AMS is creating a situation where there is only one parasiticide (Moxidectin) available to organic dairy livestock producers for the treatment of external parasites.

AMS does not have to remove Ivermectin from the National List to mitigate potential effect on dung beetles. Rather than remove Ivermectin and expand the use of the other two parasiticides AMS can amend the parasiticide provisions, as described above, to further limit the use all three parasiticides.

Neither the NOSB nor AMS have looked at whether Moxidectin and Fenbendazole are effective in treating infestations for all the same parasites as Ivermectin. As stated above Fenbendazole is not effective against external parasites.

WODPA compared NADA Number: 141-220, Moxidectin, Subcutaneous, Liquid, to NADA Number: 128-409, Ivermectin, Subcutaneous, Liquid. We found that, unlike the Ivermectin product, this Moxidectin product did not indicate that it was for the treatment of:

1. ***Ostertagia lyrata:*** A small brown stomach worm common in cattle.

2. ***Nematodirus spathiger:*** Which infects cattle, sheep and goats worldwide.

3. ***Bunostomum phlebotomum:*** Cattle hookworm, a species of nematodes of the small intestine of ruminants. An important species in calves.

4. ***Haematopinus eurysternus:*** A sucking louse of cattle.

5. ***Sarcoptes scabiei var bovis:*** A highly contagious disease spread by direct contact between infested and noninfected animals or by contaminated objects or materials.

We found NADA Number: 141-099, Moxidectin, Topical, Liquid, indicated that it treated for ***Bunostomum phlebotomum,*** and ***Haematopinus eurysternus*** while NADA Numbers: 140-841, 200-272, and 200-299, Ivermectin, Topical, Liquid, indicated that they treated for ***Haematopinus eurysternus*** and ***Sarcoptes scabiei var bovis.***

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This shows us that while Ivermectin and Moxidectin treat a number of different types of parasites, both internal and external, they vary in their coverage from one manufacturer to another.

Livestock producers should retain the right to choose which parasiticide they want to use. They should have the opportunity to listen to their veterinarian and to shop for an effective product at a competitive price.

RECOMMENDATION

WODPA recommends that Ivermectin remain as currently listed on the National List.

WODPA recommends that AMS amend the parasiticide provisions to:

1. Prohibit off-label use.
2. Allow topical, oral and subcutaneous use for dairy and breeder stock, not of breeding age.
3. Allow topical use only for breeding age dairy and breeder stock; since lice, mites and cattle grubs can infest all ages.
4. Establish milk withdrawal periods twice the slaughter withhold periods.
5. Create a definition for “emergency.”

Fenbendazole

WODPA does not support reducing the 90 day withdrawal period to 2 days. A 2 day withdrawal period for milk or milk products following treatment with Fenbendazole is too short. It takes away the incentive to develop, implement, and maintain an effective parasite prevention program. It will encourage increased use and blur the line between legitimate need and routine use.

Fenbendazole is useful in treatment of internal parasites only. It is not effective whatsoever in treatment of external parasites. Thus, by removing ivermectin as proposed AMS is creating a situation where there is only one parasiticide (Moxidectin) available to organic dairy livestock producers for the treatment of external parasites. **AMS should not deny livestock producers the right to choose which parasiticide they want to use. They should have the opportunity to listen to their veterinarian and to shop for an effective product at a competitive price.**

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RECOMMENDATION

WODPA recommends that Fenbendazole remain as currently listed on the National List.

WODPA recommends that AMS amend the parasiticide provisions to:

1. Prohibit off-label use.
2. Allow topical, oral and subcutaneous use for dairy and breeder stock, not of breeding age.
3. Allow topical use only for breeding age dairy and breeder stock; since lice, mites and cattle grubs can infest all ages.
4. Establish milk withdrawal periods twice the slaughter withhold periods.
5. Create a definition for “emergency.”

Moxidectin

WODPA does not support reducing the 90 day withdrawal period to 2 days. A 2 day withdrawal period for milk or milk products following treatment with Moxidectin is too short. It takes away the incentive to develop, implement, and maintain an effective parasite prevention program. It will encourage increased use and blur the line between legitimate need and routine use.

RECOMMENDATION

WODPA recommends that Moxidectin remain as currently listed on the National List.

WODPA recommends that AMS amend the parasiticide provisions to:

1. Prohibit off-label use.
2. Allow topical, oral and subcutaneous use for dairy and breeder stock, not of breeding age.
3. Allow topical use only for breeding age dairy and breeder stock; since lice, mites and cattle grubs can infest all ages.
4. Establish milk withdrawal periods twice the slaughter withhold periods.
5. Create a definition for “emergency.”

WODPA has clearly stated above that it prefers no change to the withhold periods for the three parasiticides. However, WODPA would support a reduced withdrawal period provided it was long enough to: 1) encourage adherence to an effective parasite prevention program; and 2)

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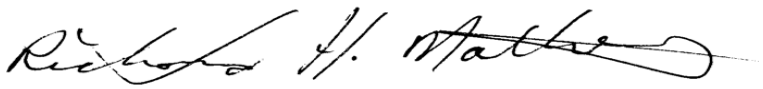
discourage unnecessary, preventive, and routine use. Perhaps a period of not less than 45 days would be effective. It would definitely be less onerous on the producer but at the same time it would be long enough to encourage adherence to an effective parasite prevention program. A shorted period might be possible if AMS were to amend the parasiticide provisions as recommended above.

Should you have questions regarding these comments, please feel free to contact me at rhmathews51@comcast.net or via telephone at 717-257-0100.

Again, thank you for the opportunity to comment.

Sincerely,



Richard H. Mathews
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