

September 15, 2006

Arthur Neal
Director of Program Administration
National Organic Program
USDA-AMS-TMP-NOP
1400 Independence Ave., SW, Room 4008 South
Ag Stop 0268
Washington, D.C. 20250

RE; Docket No. TM-03-04
Submitted by email to national.list@usda.gov

Dear Mr. Neal:

The undersigned former members and chairs of the USDA National Organic Standards Board Livestock Committee wish to file the following comments in regard to Docket No. TM-03-04, concerning amendments to the National List of Allowed and Prohibited Substances.

We appreciate the Secretary moving forward to act upon the recommendations that have been submitted by the National Organic Standards Board from November 15, 2000 to March 3, 2005. However, we want to express concern at the Secretary's failure to accept the NOSB recommendations in several cases. In doing so, we point out that the Organic Foods Production Act, at 6517(d)(2), requires that the "Secretary may not include exemptions for the use of specific synthetic substances in the National List other than those contained in the Proposed National List or Proposed Amendments to the National List," developed by the NOSB. By disregarding restrictions recommended by the NOSB, as proposed in this docket, the Secretary would be allowing uses not recommended by the NOSB.

We recommend that the proposed regulation be amended to address the NOSB recommendations, as described in detail in the body of our comments.

1. NOSB Recommended Substances Accepted

First, we endorse the proposed acceptance of the NOSB's recommendations as submitted for:

- Atropine
- Bismuth subsalicylate
- Magnesium hydroxide
- Peroxyacetic/Peracetic acid, and
- Excipients

We urge that these materials be authorized under the provisions in Docket No. TM-03-04. Further, we suggest that a definition of "excipient" be inserted into 205.2 Terms Defined, to read:

“Excipient. An ingredient that is intentionally added to a drug for purposes other than the therapeutic or diagnostic effect at the intended dosage.”

Inclusion of the above definition of “excipients,” along with the proposed text at 205.603(f), will help make it clear to producers, certifiers, inspectors, and consumers that approved excipients include substances added to livestock medications. The term “excipients” does not apply to substances added to feed or feed supplements.

We also suggest that NOP issue a guidance statement or enter a statement in the preamble to the Final Rule explaining that approved excipients may also be used in natural (nonsynthetic) medications allowed for use in organic livestock production.

2. Calcium Propionate and Potassium Sorbate

The NOP has proposed listing calcium propionate as a mold inhibitor in herbal products used as feed additives, at 205.603(d)(1). The NOSB did not propose to add this substance for feed products, and only considered its use in herbal medical treatments. The proposed listing would allow this synthetic substance without limitation in organic feed, which is not what NOSB intended. It should be eliminated in the Final Rule, as the petitioned and intended use as preservative in herbal health care remedies will be permitted by the proposed addition of excipients to 205.603(f).

Similarly, the NOSB recommended to allow the preservative potassium sorbate in aloe vera products and NOP did not mention this substance in the proposed regulation. Potassium sorbate does not need to be listed specifically, as this use also qualifies as an excipient.

3. Withhold Time Annotations

In the proposed amendment to the National List, the Secretary declines to accept the NOSB recommendation for double withhold time for Flunixin, Butorphanol and Furosemide. The Secretary’s reasoning for this refusal is that such an annotation would create an additional—and unacceptable—label claim.

In addition, on page 40627 and twice again on page 40628, the notice states, “USDA does not have the authority to prescribe or restrict uses of animal drugs outside of what is already approved, permitted, or restricted under the FDA regulations.”

This issue was discussed in detail with the NOSB during a presentation to the Board by Drs. Steven Vaughn, Director of New Animal Drug Evaluation, Center for Veterinary Medicine for FDA and Vitolis Vengris, of the Office of Surveillance and Compliance of CVM, FDA. While Drs. Vaughn and Vengris cautioned against wording such as “double withhold time,” (after the NOSB had suggested that annotation in previous recommendations), they did say that FDA would accept wording that specified a set period of withholding as a condition for “organic use.” In addition, Drs. Vaughn and Vengris clearly indicated that the USDA has the authority to regulate substances used in organic livestock production by not allowing, or by placing further restrictions on, substances allowed by FDA for conventional livestock production.

There is ample precedence for withhold annotations in the current regulation. In 2000, NOP agreed to include extended withhold times for Ivermectin, lidocaine, and procaine in the Final Rule. For example, the use of lidocaine as a local anesthetic requires “a withdrawal period of 90 days after administering to animals intended for slaughter and 7 days after administering to dairy animals.” The FDA has not objected to this annotation, or to similar restrictions on procaine and Ivermectin.

These withdrawal requirements for organic use are longer than FDA label use directives, not as label claims, but as certification requirements.

It is important to note that the development of these annotations as stated was critical in several instances to securing formal NOSB approval of the materials. In other words, these materials would not have likely been approved by the NOSB without the withhold and emergency use annotations. Removing the annotation essentially overturns the NOSB action by adding uses not recommended by the NOSB.

Accordingly, we urge that the Secretary accept language consistent with the original formal NOSB recommendations. We recommend that the following annotations be added to the proposed listings for the following substances.

- Flunixin – “For use in organic production, required withhold period of six days for dairy animals, and 42 days for slaughter stock.”
- Butorphanol – “For use in organic production, required withhold period of eight days for dairy animals and 42 days for slaughter stock.”
- Furosemide – “For use in organic production, required withhold of period of four days for both dairy animals and slaughter stock.”

We believe this will meet the intent of the NOSB and follow guidance from FDA without making an additional label claim.

The proposed restrictions represent double the withholding time as referenced in the USDA sponsored Food Animal Residue Avoidance Databank (FARAD, www.farad.org). This database includes information regarding drug residues and withholding times that are derived from NADAs (new animal drug applications), current labels, including the official tolerances for drugs and pesticides in tissues, eggs and milk. It also includes data on the fate of chemicals in food animals that is frequently published in the in the Journal of the American Veterinary Medical Association.

4. Emergency Use Annotations

In recommending approval of Poloxalene, Xylazine, and Tolazoline, the NOSB included annotations respectively to allow only for use as emergency treatments.

Again, FDA has indicated its willingness to allow more stringent use of materials as a condition for organic use. Thus, we recommend that the Secretary re-instate the Board's recommendations for approval of these materials for emergency use only under the supervision of a licensed veterinarian. The Board did not vote to recommend routine use of these substances. By doing so, the Secretary would be allowing uses not recommended by the NOSB.

We therefore recommend that the following annotations be added to the proposed listings for the following substances:

- Poloxalene – “For use in organic production, only for the emergency treatment of bloat.”
- Tolazoline – “For use in organic production as an emergency treatment, required withdrawal of four days for dairy animals and eight days for slaughter stock.”
- Xylazine – “For use in organic production as an emergency treatment, required withdrawal of four days for dairy animals and eight days for slaughter stock.”

Further, epinephrine should be listed at 205.604 as prohibited nonsynthetic with the annotation, “except when used for emergency treatment of anaphylactic shock,” as recommended by the NOSB. NOP has stated that epinephrine is a natural hormone. Since it is a hormone, OFPA 6509 prohibits its use for stimulating growth or production. This annotation will prevent any misuse, and make it clear that it is permitted only for emergency use.

5. Moxidectin

Moxidectin falls into the same classification of medication as Ivermectin, which is already included on the National List as a synthetic substance allowed for use in organic livestock production, but which also carries a strict annotation regarding its usage. Accordingly, the NOSB recommended the addition of Moxidectin to the National List as a synthetic substance allowed for use in organic livestock production, under an identical annotation as that specified for Ivermectin.

The NOSB's rationale for this approval included the fact that Moxidectin generates less toxicity for insects such as dung beetles.

Moxidectin was not petitioned for use as an antibiotic. It is not licensed by FDA for use as an antibiotic. (TAP Review, Moxidectin, 2003 p.3) It was petitioned for use as a parasiticide, is legally registered for such use, and was recommended by the NOSB for such use, with significant restrictions for organic use, identical to those for a substance (Ivermectin) on the National List.

Accordingly, we recommend the addition of Moxidectin to the National List at 205.603((a)(19) Parasitocides. under the reasoning that it is in the same category—but less toxic—than the material already listed. The annotation should be amended to be consistent

with 205.238(c)(5), to read:

- Moxidectin – control of internal parasites only, prohibited for slaughter stock.

6. Unapproved medications

We are concerned with the substances that the NOSB recommended but the NOP did not propose:

- activated charcoal
- calcium borogluconate
- calcium propionate (for milk fever)
- kaolin pectin
- mineral oil, and
- propylene glycol

There was nothing to indicate in the petition, the TAP review, or any additional information submitted to the NOSB to consider that the recommended substances were harmful to human health or the environment. They are simple remedies that quickly pass through an animal's system and do not pose any documented problems with residues in milk or meat. They are widely available and have been commonly used by producers as well as veterinarians. The substances have been demonstrated to be effective in restoring the health of animals. The NOSB clearly considered these substances to be consistent with organic farming and handling.

As explained by Drs. Vaughn and Vengris, the substances are considered materials of low regulatory priority by FDA, subject to regulatory discretion. They are widely used by conventional livestock producers.

In some cases nonsynthetic forms of these substances may be available (activated charcoal, kaolin pectin) and these forms should not be ruled out, as they are allowed nonsynthetics. Calcium borogluconate, a synthetic, is used as an electrolyte, so should not be considered prohibited, as the preamble language suggests.

We suggest that the substances listed above be placed on the National List as recommended by the NOSB, with the following restriction placed on each substance: “for use in organic production, unless subject to FDA regulatory discretion.”

7. Additional Discussion

The issue of USDA National Organic Standards and FDA regulatory standards will be a source of continuing potential confusion and conflict. The NOSB on February 28, 2005 made the following recommendation to address the issues such as those listed in this proposed rule.

- 1) USDA and FDA should pursue further clarification at higher levels of USDA and FDA to facilitate co-existence of NOP and FDA regulatory processes for the listing of unapproved medications and other substances recommended by the NOSB.

- 2) NOP should pursue rulemaking to create a National List category in section 205.603 of “production aids” with reference to specific use.
- 3) USDA should investigate FDA recognition or “organic livestock production” as a “minor species/minor use” category.
- 4) NOP should review all recommended materials to more correctly place them in categories consistent with FDA regulation.

We encourage the National Organic Program to act upon these recommendations in a timely manner to reduce potential confusion and contradiction in the approval of livestock materials. We hope in the future that NOP will consult more directly with NOSB when conflicts with other agencies arise, so that solutions can be crafted that correctly reflect the NOSB’s intent.

Sincerely,

David E. Carter
Westminster, CO

Rebecca Goldberg
New York, NY

Fred Kirschenmann
Ames, IA

Willie Lockeretz
Boston, MA

Jim Riddle
Winona, MN

Eric Sideman
Greene, ME

George Siemon
LaFarge, WI

Michael Sligh
Chapel Hill, NC