



406 S. Pennsylvania Ave • Centre Hall, PA 16828  
(814) 364-1344 • fax (814) 364-4431  
pco@paorganic.org [www.paorganic.org](http://www.paorganic.org)

Arthur Neal  
Director of Program Administration  
USDA-AMS-TMP-NOP  
Room 4008-South Building  
1400 Independence Avenue, SW  
Ag Stop 0268  
Washington, DC 20250

September 15, 2006

**Comments on: Docket TM- 03-04**

Dear Mr. Neal,

We submit this comment on behalf of Pennsylvania Certified Organic, a USDA accredited certification agency with more than 300 clients, including approximately 178 livestock producers. We appreciate the opportunity to comment on the proposed amendment to the National Organic Program rule published in *Federal Register* docket TM-03-04 (71 *Federal Register* 40624-40632). Our producers and animal health care providers are pleased that the substances recommended by the NOSB for use in livestock production have been proposed for inclusion in the regulations. Livestock producers have very limited tools for use to provide humane animal health care, and these substances have been carefully reviewed and recommended by the NOSB, with previous public input.

We would like to comment on a number of the substances, and are concerned that the restrictions proposed by NOSB were not adopted in a number of cases. We recognize that the differing regulatory schemes authorized by FDA and NOP offer unique challenges for collaboration, but we hope our suggestions may provide a means to reconcile the differing approaches and provide additions to the National List consistent with organic principles and criteria for substances as described in the Organic Foods Production Act.

In summary, PCO:

- Supports the addition of Atropine, Bismuth subsalicylate, Magnesium hydroxide, peroxyacetic acid, and excipients as proposed
- Requests that certain NOSB recommended restrictions be restored for tolazoline, xylazine and poloxalene
- Request that the Secretary include six very important substances (activated charcoal, calcium borogluconate, calcium propionate, kaolin pectin, mineral oil and propylene glycol) recommended by NOSB as allowed.

- Requests that the Secretary consult further with the NOSB on withdrawal times for Butorphanol, Flunixin, Furosemide, Tolazoline, and Xylazine.
- Remove a material not recommended by NOSB
- Add an omitted material

### **1. Support for the following materials as proposed:**

We support the addition of the following substances as proposed by NOSB and included in the docket:

- 7 CFR §205.603
- (3) Atropine...
- (5) Bismuth subsalicylate...
- (16) Magnesium hydroxide...

**Discussion:** The proposed restrictions related to use only under order of a licensed veterinarian in compliance with AMDUCA and FDA regulations are workable in context of the existing certification process for review of the livestock Organic System Plan. Producers must document the need and use of all medical treatments in their OSP.

(20) Peroxyacetic/peracetic acid (CAS #-79-21-0)--for sanitizing facility and processing equipment

**Discussion:** this substance is useful for sanitation of milk processing equipment, packaging, and provides an environmentally benign alternative to chlorine. State milk ordinances (modeled on the federal Pasteurized Milk Ordinance<sup>1</sup>) require use of labeled rates of chlorine or other sanitizers (some not approved for organic use) without rinsing. Peroxyacetic acid is a welcome addition for protection of food safety in organic products.

### **2. Consult with the NOSB regarding withdrawal times, and restore NOSB annotations on emergency use**

- (6) Butorphanol
- (10) Flunixin
- (11) Furosemide –
- (23) Tolazoline – to counter the effects of xylazine
- (24) Xylazine - for emergency use only

**Discussion:** In the case of these materials, the NOSB recommended that an extended withdrawal period of double the labeled time be required. The NOSB made this recommendation out of concern for drug residues and with an abundance of caution to protect organic consumers. The NOP did not add this proposed restriction; stating that “the recommended restriction to extend the withdrawal period twice beyond what the FDA requires would create an additional label claim for the animal drug beyond that which is permitted by the FDA.” Although we support the addition of these substances to the National List, we are concerned that listing these without the annotations substantially changes the recommendations of the NOSB and would represent addition of synthetic substances to the List without NOSB approval. We urge further consultation with NOSB before these are added.

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<sup>1</sup> 2003 Grade "A" Pasteurized Milk Ordinance, available at <http://www.cfsan.fda.gov/~ear/pmo03toc.html>

The NOSB also recommended that tolazoline and xylazine should be listed only for emergency use. This restriction should be added.

### **3. Include materials recommended by NOSB but not proposed by the Secretary**

We are concerned that the NOSB recommended a number of commonly used substances for health care purposes but the NOP did not propose to add them to the National List:

- activated charcoal – from vegetative sources only
- calcium borogluconate- for treatment of milk fever only
- calcium propionate - for milk fever only
- kaolin pectin – allowed when formulated from either natural or synthetic pectin
- mineral oil – for health care
- propylene glycol – only for treatment of acute ketosis in ruminants

These are considered to be unapproved drug of low regulatory priority by FDA, and most are widely used by conventional dairy producers. 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. The recommended substances 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 with no noted serious impacts on the environment. The substances have been demonstrated to be effective in restoring the health of animals.

The NOSB considered these substances to be consistent with organic farming and handling. In some cases nonsynthetic forms of these substances may be available (activated charcoal, kaolin pectin) and these forms should not be ruled out. Calcium borogluconate is used as an electrolyte<sup>2</sup>, and permitted at 205.603(a)(6) so should not be considered prohibited as the preamble language suggests on page 40630. This preamble language is also contradictory, because it says calcium propionate is prohibited for use in organic livestock production but recommends adding it to the National List as a feed additive. 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, subject to FDA regulatory discretion.”

### **4. Include NOSB annotations on use for poloxalene**

(22) Poloxalene (CAS #-9003-11-6)—for emergency treatment of bloat

#### **Discussion:**

The NOSB recommended this substance be restricted for emergency treatment only. Otherwise the substance could be fed routinely, contrary to NOSB intentions to limit to emergency situations when other preventive or natural remedies are insufficient.

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<sup>2</sup> Price and Martini, 1994. Memo to Michael Hankin – Organic Food Review. “1994 FDA memo to NOP “Oral electrolytes are considered to be new animal drugs. However, CVM is currently exercising regulatory discretion with regard to these products, provided the only claim is as a source or supplemental source of nutrients contained in the product”. See also FDA Enforcement Policies at [http://www.fda.gov/cvm/Policy\\_Procedures/3150.pdf](http://www.fda.gov/cvm/Policy_Procedures/3150.pdf)

## 5. Excipients

We appreciate the explicit allowance of excipients in health care products and agree that there should be some limits on what excipients are allowed—in order prevent the inclusion of possibly toxic or inappropriate materials for organic production. The proposed candidates for use –either as approved food additives, GRAS substances, or substances included in FDA drug reviews (NADA or NDAs)--provide a reasonable basis for consideration of common additives found in livestock medications.

However, to assist producers and certifying agents understand what is and is not an excipient, we propose the addition of a new definition in 7 CFR Section 205.2, based on the FDA guidance cited at FR 40629.

Excipient. Any ingredient that is intentionally added to therapeutic or diagnostic products but that are not intended to have therapeutic affects at the intended dosage although they may act to improve product delivery.

Inclusion of the above definition 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.

## 4. Remove material not recommended by NOSB – calcium propionate as a feed additive

(d) As feed additives.

(1) Calcium propionate (CAS #--4075-81-4)--for use only as a mold inhibitor in dry herbal products.

The Secretary 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 (7 CFR Section 205. 603). The proposed listing would allow this synthetic substance without limitation in organic feed, which is not what NOSB recommended.<sup>3</sup> 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 allowing the preservative potassium sorbate in aloe vera products, however this substance is not mentioned in the proposed regulation. Potassium sorbate does not need to be listed specifically, as this use also qualifies as an excipient.

## 5. Epinephrine

The NOSB recommended that epinephrine should be listed at 205.604 as prohibited nonsynthetic with the annotation, “except when used for emergency treatment of anaphylactic shock,” as recommended. The NOP has stated that they believe this listing would be confusing to producers, and that epinephrine is a natural hormone and already restricted by FDA to this type of use. Since it is a hormone, OFPA 6509 prohibits its use for stimulating growth or production. We believe it would be more clear to producers to specifically list it at 205.604, with the restriction: “except when used for emergency treatment of anaphylactic shock” to make it clear that it is permitted, and can be formulated with synthetic excipients, as per the proposed 205.603(f).

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<sup>3</sup> NOSB Meeting Summary, May13-15 2003 (also see p. 198 of transcript, 5-14-03) “The committee was concern that if they didn’t annotate it, it would be used for feed purposes – it’s a general feed preservative. The committee wanted to make sure that it’s only used as a therapeutic tool.”

## 6. Omitted material

Finally, the NOSB did recommend adding pheromones to the National List for livestock use in October 2002, with a restriction similar to that currently provided in the crop section at 205.601(f) with allowance for List 3 inerts when used in traps. We believe this would be useful non-toxic tool for use in livestock facilities to control flies and other pests, and a number of commercial products are in fact available. We request this material be added to the docket.

205.603 (f) As insect management:- Pheromones

205.603(e) as synthetic inert ingredients...

(2) EPA –list 3 inerts of unknown toxicity, for use only in passive pheromone dispensers.

In closing, we thank the NOP for bringing this docket to publication and look forward to further resolution of these issues, and finalization of regulations to permit the NOSB recommended uses.

We hope this process will help facilitate the future deliberations of the NOSB and public to make effective recommendations regarding FDA regulated materials. We encourage the NOP to continue to consult with FDA and NOSB in order to resolve any conflicts.

Sincerely,

Leslie Zuck, Executive Director  
Emily Brown Rosen, Materials Manager

*Pennsylvania Certified Organic*