FORMAL RECOMMENDATION BY THE
NATIONAL ORGANIC STANDARDS BOARD (NOSB)
TO THE NATIONAL ORGANIC PROGRAM (NOP)

Date: **March 18, 2005**

Subject: **Livestock Medications recommended by NOSB**

Chair: **Jim Riddle**
(sign)

Recommendation

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: X
Guidance Statement:
Other: X

Statement of the Recommendation (including Recount of Vote)**:**

In order to place NOSB-recommended substances on section 205.603 of the National List, the NOSB Policy Development and Livestock Committees recommend the following:

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.
NOP should pursue rulemaking to create a National List category in section 205.603 of "production aids" with reference to specific use.

USDA should investigate FDA recognition of "organic livestock production" as a "minor species/minor use" category.

NOP should review all recommended materials to more correctly place them in categories consistent with FDA regulation.

Adopted by the NOSB March 1, 2005 Vote: 14 yes, 0 no, 0 abstain.

Rationale Supporting Recommendation (including consistency with OFPA and NOP)**:**

See rationale below.

Response by the NOP:

Recommendation for Addressing FDA Regulations Affecting NOSB Recommendations Concerning Livestock Medications Adopted by the NOSB March 1, 2005

Introduction

Many livestock medications used by conventional producers have not been formally approved by the Food and Drug Administration, since they are relatively benign substances that have not been evaluated under the New Animal Drug Evaluation (NADE) program, but are considered by the FDA to have a low regulatory priority. Many of these substances are non-proprietary general use materials (eg. calcium borogluconate), and no manufacturer has sought a NADA (new animal drug approval). FDA in effect permits "brand name" products, that have completed formal drug reviews, but no "generic" or "over the counter" list for commonly used materials. The use of such drugs, though unapproved by FDA, is allowed under FDA's regulatory discretion. FDA maintains the authority to take action against any such unapproved products, should it find evidence of adverse reactions.

A number of such medications have been petitioned for use in organic livestock production. The substances have undergone Technical Advisory Panel reviews, and the NOSB has voted to recommend that the substances be placed on the National List of Allowed and Prohibited Substances.

The NOSB has been notified by the National Organic Program that livestock medications which are not formally approved by FDA, cannot be placed on the National List. The NOSB Policy Development and Livestock Committees have developed this briefing paper to explore the opportunities for a framework that will allow the approval for use of livestock medications compatible with organic production and handling practices.

Background

In 2000-2003, the National Organic Standards Board livestock committee conducted extensive work to recommend for approval a series of livestock medications compatible with organic production and handling standards. During this period, the board recommended that several materials be included in §205.603(a) of the Final Rule as allowed disinfectants, sanitizers, and medical treatments.

On June 23, 2003, Sharon Benz, Office of Surveillance and Compliance, Center for Veterinary Medicine, U.S. Food and Drug Administration, notified the NOP that all products to be included on the National List must comply with FDA regulations. Accordingly, on July 31, 2003, the NOP informed the Board that 10 synthetic substances recommended to the Secretary for use in organic livestock production would not be approved as medications in food animals. Those substances were:

- Activated Charcoal
- Bismuth subsalicylate
- Butorphanol
- Calcium borogluconate
- Calcium propionate
- Kaolin pectate
- Magnesium hydroxide
- Magnesium oxide
- Mineral oil
- Potasium sorbate

Subsequently, the Policy Development Committee and the Livestock Committee of the National Organic Standards Board have sought feasible methods to accommodate the use of alternative medications within the organic livestock sector while meeting FDA compliance requirements. FDA representatives were invited to the October 2003 board meeting, at which time they expressed willingness to accommodate the NOSB position. However, NOP staff informed the board at the October 2004 meeting, that they have again been told by FDA compliance division that NOP cannot list unapproved new animal drugs as permitted in a Federal Register notice.

The committees have been presented with the following options:

1. Create a category of "alternative medicines" on the National List.

The existing categories on §205.603 "Synthetic substances allowed for use in organic livestock production" are:

(a) As disinfectants, sanitizer, and medical treatments as applicable;
(b) As topical treatment, external parasiticide or local anesthetic as applicable;
(c) As feed supplements;
(d) As feed additives; and
(e) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or a synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

Under this option, a new category "Alternative medicines" would be created.

Pros:
The creation of a new category for alternative medicines would make the National List more user friendly for producers, consumers, and certifying agents. Approved alternative medicines would be clearly listed in their own section.

Cons:
Creation of an "Alternative medicines" category on the National List does not resolve the issues concerning the use of medications not formally approved by FDA.

2. Create a "negative over-the-counter" list.

Human drugs are regulated differently than animal drugs, and there is a provision for review of Over the Counter (OTC) human drugs through the FDA's Center for Drug Evaluation (CDER) or the CFSAN Office of Color and Cosmetics. Originally, it was intended that some livestock drugs would also be covered by the OTC program, but this aspect was never developed. FDA does have a "drug listing" program for unapproved animal drugs, this database contained 3160 products as of October 2003[1], and there are likely many animal drugs additionally on the market that are not registered in this database.

There was initial discussion about allowing all over-the-counter medications for use in organic livestock production. However, a number of antibiotics are now allowed as over-the-counter medications for livestock. This led to a discussion about creating a "negative list" of prohibited over-the counter medications.

Pros:
This proposal would allow numerous medications to be used by organic livestock producers.

Cons:
FDA does not have an OTC program for livestock medications, so there is no context to create a negative list of prohibited medications. In addition, evaluation criteria, procedures, and bureaucracy would need to be created to manage such a list.

3. Create a National List category of "production aids" with reference to specific use.

OFPA 6517(c)(1)(B)(i) allows for the consideration of "production aids." A category of "production aids" could be created, whereby substances listed in the category do not have medical use claims.

Pros:
The creation of a "production aid" category for alternative livestock materials is consistent with OFPA and could satisfy FDA's concerns about unapproved animal drugs appearing on a USDA list as medical treatments.

Cons:
While creation of a "production aid" category may be part of the solution, it would require a new rule change, in addition to the rule change necessary for adding the recommended substances to the list. It would not likely resolve all of FDA's concerns, since "unapproved" medications would appear on the USDA's National List.

4. Include "organic" as a "minor species/minor use" category by FDA.

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[1] Dr. V. Vengris, FDA. Transcript, Oct. 22, 2003 NOSB meeting. p.39. http://www.ams.usda.gov/nosb/transcripts/NOSBMeetingOctober2203WashingtonDC.pdf

The Minor Use and Minor Species (MUMS) Animal Health Act, enacted in August 2004, is a mechanism to provide FDA-authorized drugs for those less common species and indications. Specifically, it seeks to provide labeled drugs for needy minor species, as well as major species with needed therapeutics for uncommon indications (minor uses).

FDA's Center for Veterinary Medicine is announcing the establishment of a new Office of Minor Use and Minor Species (MUMS) Animal Drug Development and is requesting comment on the implementation of the newly enacted MUMS Animal Health Act.

The law has two relevant sets of provisions. First, the MUMS Act allows conditional approval of drugs for minor species and uses. Full safety data must l be developed before FDA can conditionally approve a drug, but manufacturers have five years post-approval to develop data on drug efficacy. Second, the MUMS Act allows "indexing" – an expedited non-approval process – for drugs used in early non-food life stages of food-producing minor species or in minor species not consumed by humans.

Several elements of the law became immediately effective on that date including the provisions for designation of MUMS drugs and for conditional approval of MUMS drugs. Implementing regulations for drug designation will be the first to be developed by the new Office, with proposed regulations due by August 2, 2005, as mandated by the MUMS Act. The indexing provisions of the law will only become effective upon publication of final implementing regulations.

Organic usage is not currently defined as a minor usage under the MUMS legislation. Inclusion of organic livestock medications in this Act would ease the approval process for such medications.

Pros:
This option may provide a long-term opportunity to facilitate the FDA approval, or in some cases indexing, of medications used by organic livestock producers.

Cons:

The conditional approval process still requires considerable data development, and the indexing process is not applicable to major species, which includes most organic livestock.

While offering some promise in the long run, no work is being done to define organic livestock production as a minor use category. The NOSB exists to "advise the Secretary." The NOSB has no authority to directly advise FDA on creation of an organic usage category under MUMS legislation. NOSB could recommend to the Secretary, however, that this action be taken.

5. **Review all recommended materials to more correctly place them in categories consistent with FDA regulation.**

Some materials that NOSB has recommended for use in health care products do not fall into FDA's definition of a new animal drug. For example, NOSB recommended the listing of two preservatives used in herbal products (Herbal products themselves are considered unapproved animal drugs, but as natural substances do not have to appear on the National List). Potassium sorbate was approved for use as preservative in aloe vera. Calcium propionate was approved as preservative in dried herbal remedies. The NOSB has recommended that the broad category of "excipients" be added to the National List for use in animal medications. Depending on the language in the Federal Register notice concerning "excipients," the individual listing of potassium sorbate for aloe vera and calcium propionate for dry herbal remedies may be unnecessary.

Some of the problematic substances may fall into broad categories already on the National List. For example, §205.603(a)(6) allows the use of electrolytes. The use of calcium borogluconate is considered an electrolyte,when the substance is used in an IV solution.

A number of the recommended substances such as activated charcoal, kaolin pectate, calcium propionate for use as a calcium supplement to treat milk fever, and mineral oil cannot be reclassified as another permitted category, unless some are available in natural form.

Pros:
This option would address a few of the problematic substances without additional rule change, and without formally listing substances not approved by FDA.

Cons:
This option does not allow use of all substances recommended by the NOSB, and does not address the structural problem of allowing organic livestock producers to officially use the same substances currently used by conventional producers.

6. Pursue further clarification at higher levels of USDA and FDA to facilitate co-existence of NOP and FDA regulatory processes for these substances.

On October 22, 2003, Drs. Steve Vaughn and Vitolis Vengris of the FDA's Center for Veterinary Medicine made a presentation to the NOSB on how the FDA determines regulatory discretion or low regulatory priority for unapproved animal drugs. Drs. Vaughn and Vengris explained to the board why FDA would have no problem with the use of certain drugs.

Dr. Vaughn clarified that NOP has the authority to set organic standards, and that NOSB should be aware that both approved and unapproved drugs exist in the marketplace, including those unapproved drugs permitted to be marketed under FDA regulatory discretion.[2] He noted that since NOSB is deciding whether animal drugs "meet the qualifications of an organic product" he saw no conflict with FDA authority over

[2] Transcript, Oct.22, 2003 NOSB meeting. p.61. Note: Dr. Vaughn is incorrectly identified as Mr. Mathews. http://www.ams.usda.gov/nosb/transcripts/NOSBMeetingOctober2203WashingtonDC.pdf

marketability.[3] Linda Tollefson, Deputy Director of FDA's Center for Veterinary Medicine, has expressed support for statements made by Drs. Vaughn and Vengris, but has also indicated that FDA is exploring other options to allow the use of certain substances in organic production – such as considering these substances to be GRAS.[4]

NOSB could recommend that USDA explore the situation with FDA further, perhaps by revisiting the issue with Dr. Vaughn, Director of the New Animal Drug Evaluation program, to facilitate the approval process for livestock medications to be used in organic agriculture.

Some of the FDA objections to NOSB action have been specifically related to the terminology contained in the NOSB recommendations. For example, FDA specifically objected to annotations specifying "double FDA withhold time." According to the agency, only FDA has the authority to establish withhold periods. FDA and USDA could establish a framework for defining acceptable terminology to be used in future NOSB recommendations.

Pros:
This option allows for the current list of substance recommended by the NOSB to be added to the National List. It also addresses the structural issues so that future substances can be added to the National List with the full approval and cooperation of USDA and FDA.

Cons:
While the NOSB can lay the groundwork and urge cooperation between USDA and FDA, communication and effective action must occur at between officials within the two agencies.

Recommendation –

In order to place NOSB-recommended substances on section 205.603 of the National List, the NOSB Policy Development and Livestock Committees recommend the following:

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 of "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.

[3] Ibid. p.68
[4] emails to Becky Goldburg, 12-22-05 and 1-17-05

Board vote –

14 yes, 0 no, 0 abstain.

Minority opinion –

None.