

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

Date: May 6, 2009

Subject: Injectable trace minerals, vitamins and electrolytes

Chair: Jeff Moyer

Recommendation

The NOSB hereby recommends to the NOP the following:

Rulemaking Action:	X
Guidance Statement:	_____
Other:	_____

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

Recommendation

PROPOSED RECOMMENDATION TO ADD NEW SECTION TO 7 CFR 205.603:

(g) As nutritive supplements, formulated injectable supplements of trace minerals per 205.603 (d) (2), vitamins per 205.603 (d) (3), and electrolytes per 205.603 (a) (8), with excipients per 205.603 (f), in accordance with FDA and restricted to use by or on the order of a licensed veterinarian.

NOSB Vote: Yes to Recommend to NOP Motion: Hubert Karreman Second: Bea James

Board vote: Yes - 14 No- 0 Abstain- 0 Absent - 1

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

Currently there are categories of substances for livestock health care already on the list - 205.603 (a)(8), 205.603 (electrolytes) (d)(2) (trace minerals) and (d)(3) (vitamins) and (f) (excipients). However, it is not specific that these materials can be used via injection – in fact, the trace minerals and vitamins are explicitly to be used as feed additives only. This recommendation will allow the injectable formulated versions of (a)(8), (d)(2), and (d)(3). Section (f) because there are no pure vitamins, trace minerals or electrolytes available without excipients. These injectable forms of trace minerals, vitamins and electrolytes are being viewed as nutritive supplements (as many of the labels state) rather than as medicines. See the Livestock Committee's full rationale that is attached.

Response by the NOP:

Attach Committee Recommendation here along that includes committee votes and any attachments

National Organic Standards Board (NOSB)

March 15, 2009

Recommendation

PROPOSED RECOMMENDATION TO ADD NEW SECTION TO 205.603:

(g) As nutritive supplements, formulated injectable supplements of trace minerals per 205.603 (d) (2), vitamins per 205.603 (d) (3), and electrolytes per 205.603 (a) (8), with excipients per 205.603 (f), in accordance with FDA and restricted to use by or on the order of a licensed veterinarian.

I. Introduction:

By law, organic livestock rations need to provide a total feed ration composed of agricultural products, including pasture and forage, that are organically produced and, if applicable organically handled, *Except* that nonsynthetic substances and synthetic substances allowed under 205.603 may be used as feed additives and supplements (7CFR205.237). The goal of livestock producers should be to provide a balanced ration to the animals under their care. Rations, by definition, are fed to animals and consumed in an oral manner. They can have synthetic vitamins and minerals added [205.603 (d) (2) and 205.603(d) (3)]. A balanced ration delivers what the average animal in a herd needs on a daily basis. However, there can be times of stress when certain individual animals need high amounts of vitamins and minerals delivered to target tissues in a rapid manner. Also, animals that are not eating, for whatever reason, are not taking in the oral forms of vitamins and minerals and may need nutritive supplementation best delivered by injection. With the prohibition of the use of antibiotics in certified organic livestock, farmers and veterinarians need as many tools as possible remaining to prioritize animal health. Currently, the prohibition of injectable vitamin and mineral formulations effectively eliminates a common method that works to assist livestock health and well-being. Injectable forms of vitamins and minerals provide valuable support to an animal's immune system, and the recommendation is brought forth to allow, strictly on an as needed basis, the use of formulations of injectable vitamins, minerals and electrolytes as nutritive supplements for organic livestock. The allowance use of injectable formulations of vitamins and minerals will enhance the overall health and welfare of certified organic livestock.

II. Background:

Rations that deliver the daily needs of vitamins and minerals via feedstuffs for animal health are the goal of livestock farmers. However, due to biochemical and physical limitations,

certain areas of the country can be naturally deficient in soil fertility. For example, the northeastern part of the United States is well known to be deficient in soil selenium. Even when feed rations are supplemented with the maximum allowable selenium as per FDA, peri-parturient animals can lack the right balance of vitamin E and selenium, which can then impact the capabilities of the reproductive tract.

When animals are not eating, they do not consume the right balance of vitamins and minerals, whether natural or synthetic (as allowed by 205.603), and these individual animals may benefit from nutritive supplementation via injection. Some examples will help describe and justify the need for an occasional injectable vitamin and/or mineral. In dairy cows that have low blood calcium levels immediately after calving, intravenous delivery of ionic calcium as an electrolyte can be of tremendous benefit. To prevent low blood calcium is the goal of course. However, in areas where high potassium forages are common (due to decades of manure application to land which also receives regular NPK applications) it can be difficult to keep the correct calcium balance in the expectant mother cow. In this case, a one time injection of vitamin D3 may help the animal to assimilate dietary calcium better from the intestine and positively affect the calcium to phosphorus ratio in the blood stream. Also, an animal that has a sluggish appetite or is anorexic may benefit from a dose of vitamin B complex given in the muscle or under the skin. Individual animals also may need vitamin C, sometimes in high doses, for its anti-oxidant effects. Vitamin E, while found in fresh growing pastures, can be critically depleted in stored feeds by the end of winter. Vitamin E in combination with selenium is synergistic for cattle reproductive health and is a commonly used vitamin-mineral formulation used in the conventional industry.

In 1995, the NOSB reviewed vitamins and minerals of synthetic sources to be feed additives and recommended their inclusion onto the National List. The NOP codified these feed additives and they have been in use since promulgation of the Rule in October 2002.

III. Regulatory Framework

The National Organic Standards Board was established by the Organic Food Production Act to assist the Secretary of the USDA in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of the title (SEC. 2119. [7 U.S.C. 6518] (a)). The Board is made up of stakeholders representing various segments of the industry. Currently there are three members who are directly involved with the organic dairy industry – a dairy farmer, a nutritionist and a veterinarian. It has come to the attention of the Board that injectable formulations of vitamins and minerals need to be allowed (for the reasons stated in the Background and Introduction), just as the feed additive versions of vitamins and minerals have already been recommended and codified. Direct impact upon animal welfare associated with the allowance or prohibition of formulations of injectable vitamins and minerals forms the basis for the Livestock Committee's recommendation.

Certain sections of the current Rule are germane to the intent and goal of this recommendation. Clearly, vitamins, minerals, electrolytes and excipients are already allowed by the following regulations. While the regulation allows vitamins and minerals only as feed additives, it is not as clear that electrolytes and excipients are restricted to only being used as feed ingredients.

7CFR205.603(d)(2): (d) As feed additives. (2) Trace minerals, used for enrichment or fortification when FDA approved.

7CFR205.603(d)(3): (d) As feed additives. (3) Vitamins, used for enrichment or fortification when FDA approved.

7CFR205.603(f): (f) Excipients, only for use in the manufacture of drugs used to treat organic livestock when the excipient is: Identified by the FDA as Generally Recognized As Safe; Approved by the FDA as a food additive; or Included in the FDA review and approval of a New Animal Drug Application or New Drug Application.

7CFR205.603(a)(8): (8) Electrolytes--without antibiotics.

IV. Discussion:

While the original writers of the Rule had the best intentions, many realities of livestock production were not necessarily analyzed to accommodate the wide range of livestock operations, diverse soil fertility across the country and subsequent feed related issues. While the goal of economically minded livestock producers is always to optimize the feed resources available to their operation, there are times when supplement via injection is necessary. While it is possible that some people would rather say to simply feed the animals the vitamins and minerals they need, this is easier said than done. The fact of the matter is that injectable formulations of vitamins and minerals *as an entire category* will serve to complement what have been already codified by the Program for the feed additives. The Livestock Committee recognizes that there are many injectable formulations of vitamins and minerals that exist in the US market place for livestock. There are probably just as many different manufacturers of said products. To review each and every vitamin and mineral and proprietary formulation is simply not possible due to the following reason - the manufacturer information is not available for disclosure. To the best of our knowledge, no manufacturer of vitamins and minerals has petitioned the NOSB for their product. Owing to the plethora of available injectable vitamin and mineral formulations, conventional farmers and veterinarians simply reach for the most available brand that day. There is no incentive for farmers or veterinarians to go through the formal petition process since they are the end buyer/user and information that is available in the public domain is only for old manufacturing processes. It is important to state that vitamins and minerals as feed additives were recommended and each were placed on the National List *as a category* [205.603 (d)(2) and (d)(3)] and not listed individually.

The Livestock Committee does, however, recognize that the public may, at this point in time, want to have an idea of the vitamin and mineral formulations being discussed in this recommendation. The Livestock Committee will try its best effort to gather as many of the commercial labels as possible *for informational purposes only* but not as a foundation of this recommendation since the recommendation is for a *category* and not individual items within the category [in the exact same manner as .603 (d)(2), .603(d)(3), .603(f), .603(a)(8) are currently codified]

The Livestock Committee looks forward to feedback from different stakeholder groups on this recommendation. Some groups would likely be: farmers and farmer organizations, NGO's that advocate heightened awareness of health and welfare of farm animals, accredited certifying agencies (private and State), pharmacologists, physiologists, nutritionists, veterinarians, and consumers of organic products.

We believe that farmers and organic consumers will be pleased that animals needing an occasional vitamin and/or mineral injection for nutritive supplementation would be allowed to receive such an administration with the proposed recommendation. We believe that nutritionists

will agree that there are times when vitamins and minerals as feed additives may not be adequate to fulfill an animal's need at certain times of life. We believe that persons trained in the animal sciences will concur with the occasional need of an injectable formulation of a vitamin and/or mineral. We look forward to hearing how certifiers have addressed the issue of injectable trace minerals, vitamins, and electrolytes.

V. Recommendation:

It is proposed to amend the National List to add in a new category, 205.603(g) to read:

As nutritive supplements, formulated injectable supplements of trace minerals per 205.603 (d) (2), vitamins per 205.603 (d) (3), and electrolytes per 205.603 (a) (8), with excipients per 205.603 (f), in accordance with FDA and restricted to use by or on the order of a licensed veterinarian.

VI. Committee Vote:

Motion: Hubert Karreman

Seconded: Dan Giacomini

Committee Vote:	Yes: 5
	No: 0
	Abstain: 0
	Absent: 2