



Response to Comments

Evaluating Allowed Ingredients and Sources of Vitamins and Minerals For Organic Livestock Feed

This document summarizes comments received on the “Evaluating Allowed Ingredients and Sources of Vitamins and Minerals for Organic Livestock Feed, Feed Supplements, and Feed Additives ([NOP 5030](#))”. which was posted on the NOP website for public comment. The public was notified in a Federal Register notice (76 FR 34180) on June 13, 2011.

- ***CHANGES MADE IN RESPONSE TO COMMENTS***

- 1) The Use of Incidental Ingredients and Processing Aids.** The U.S. Food and Drug Administration (FDA) does not require that incidental ingredients or processing aids be listed on ingredient labels, making it difficult for a farmer or certifying agent to determine if such a substance has been used. The draft guidance at section 4.2(d) used language from the FDA regulations to identify those uses for which a substance did not need to be either organic or from the National List of Allowed and Prohibited Substances (National List). The National Organic Program (NOP) agrees with the commenters that use of this language is confusing and conflicting with requirements for organic agricultural carriers, and has removed this language.
- 2) Use of Agricultural Carriers in Feed Additives.** Commenters were concerned that requirements for organic carriers in feed additives would be unfairly applied at the retail level for products purchased by farmers, while organic feed mills might not be required to meet the same standard. Several certifiers and a trade organization noted that the proposed policy would have allowed organic feed mills to use vitamin and mineral premixes with non-organic agricultural carriers, since the non-organic carriers would be considered “incidental” when blended to form a final formulated feed. However, livestock farmers who purchase vitamin and mineral premixes and mix with feed on-farm would have been required to use premixes containing organic carriers since they would appear on the retail label in that case.

The NOP agrees that the same rules should apply to all formulators, either on a farm or in a feed mill. The NOP expects that purchasers and organic certifiers should review carriers and diluents or other additives when included on the label in mixtures of vitamins and minerals used to formulate feed. However, if a farmer or feed mill purchases a generic single ingredient allowed as a vitamin or mineral on the National List at 205.603(d) and meeting a definition provided by the Association of American Feed Control Officials (AAFCO) or FDA, there is no need to review other minor ingredients within the formulation. For example, an individual vitamin E supplement is purchased by a feed manufacturer, and then is directly mixed with other vitamins and minerals in batches of organic feed. In this case, no further review of minor formulation ingredients within the Vitamin E supplement is necessary. In another case, a vitamin and mineral premix containing Vitamins A supplement, riboflavin, calcium chloride, iron sulfate, magnesium phosphate, and wheat middlings is purchased, and then blended with organic feed. In this case, the premix product will be labeled with a list of



ingredients identifying all ingredients according to AAFCO definitions, including the agricultural carrier (wheat middlings), which must be organic.

Commenters also questioned whether the handlers who mix vitamin and mineral premixes containing organic carriers have to be certified organic. While certification of feed additive premixes is permitted for products that have organic agricultural content and meet the feed composition requirements of § 205.301(e) and § 205.306, the NOP does not require certification of all feed additives that may have a small content of agricultural substances. Handlers who create feed additives do not need to be certified organic, but they must use organic agricultural products for multi-ingredient products, and the products must be verified by certifiers in the review of the Organic System Plan.

- 3) **Prohibition on the Use of Excluded Methods in the Production of Yeast, Probiotics and Enzymes.** Commenters noted that the guidance specifically prohibited excluded methods for the production of vitamins and minerals, yet did not note whether this prohibition applied to the production of yeast, probiotics and enzymes. The NOP added language to clarify that excluded methods are prohibited in the production of yeast, probiotics and enzymes.
- 4) **Clarification of 100% organic livestock feeds.** A commenter noted that for the 100% organic label claim to be used, no non-organic products could be used. The NOP agreed and made this change.

- ***CHANGES REQUESTED BUT NOT MADE***

- 1) **Use of the Food and Drug Administration (FDA) or the Association of American Feed Control Officials (AAFCO) References for Approved Vitamins and Minerals.** Several certifying agencies and a feed manufacturer requested that the NOP allow any vitamin or mineral that is approved by the FDA or appears in the current edition of the AAFCO Official Publication (Mineral Products or Vitamins), including those sourced from slaughter by-products and excluded methods. The certifiers stated that the handlers of vitamins and minerals are often several steps removed from the manufacturer of the individual nutrients, and that information is not readily available regarding the manufacturing of specific vitamins and minerals. The commenters stated that most vitamins and minerals are highly refined synthetic substances, and should not be considered agricultural products subject to the restrictions on slaughter by-products used in feed at § 205.237(b)(5).

The NOP recognizes that many manufacturers of vitamins and minerals are not the direct seller to organic farms and feed mills, which can make source verification difficult. The NOP also acknowledges a lack of technical review or specific recommendation from the National Organic Standards Board (NOSB) to clarify this issue regarding sources of livestock mineral and vitamins, and agrees that FDA and AAFCO listed vitamins and minerals meet the specifications of the National List at § 205.603(d)(2) and § 205.603(d)(3).



However, § 205.237(b)(5) applies to crude slaughter by-products in livestock feed such as bone meal, bone charcoal, bone phosphate, proteinated mineral sources and other crude extracts as these substances contain animal by-products in a recognizable form. The USDA organic regulations also prohibit use of excluded methods at § 205.105(e), and thus vitamins used in livestock feed should be reviewed for excluded methods. The NOP may seek technical reviews in the future to address the commenter's concerns and provide more information as it becomes available.