

May 17, 2002

William Bookout, President  
National Animal Supplement Council  
4093 Oceanside Boulevard, Suite B  
Oceanside, California 92056

Dear Mr. Bookout:

The AAFCO Enforcement Strategy for Marketed Ingredients (ESMI) Working Group has received and discussed the NASC proposal for **Compliance PLUS**. In general, the ESMI Working Group commends NASC's efforts for developing such a plan; however, we would like to offer comments relating to specific aspects of the proposal. Our comments are presented for each section of the Compliance PLUS proposal:

1. **Objective**

Your proposal to bring unapproved ingredients into compliance with existing federal and state laws is a good first step to achieving compliance and enhancing food safety.

In your proposal, AAFCO is requested to "recommend to its members a 'low enforcement priority' for products" that are involved in the Compliance Plus program but for which an ingredient definition has not been obtained. A federal or state regulatory authority must make the decision to use their powers of regulatory discretion based on the authority granted under federal or state law.

2. **Near Term Implementation**

We agree with your assessment of unacceptable animal products and ingredients in the marketplace. The situation you describe is the reason why the ESMI Working Group was formed and why an enforcement event is being planned.

3. **Protecting Animal Safety and Welfare**

- A. AAFCO encourages your proposal for Adverse Event Reporting that includes a notification procedure to state control officials. We would suggest that FDA-CVM be the primary contact of any adverse event reported to your members.
- B. While we do not wish to impede the Adverse Event Reporting aspect of your plan, it is important that the corrective procedures also be shared with the appropriate federal/state regulatory officials so that appropriate follow-up actions can be taken.

4. **Best Manufacturing Practices**

- A. We encourage the steps proposed in Compliance PLUS. It is important to note that best manufacturing practices should be a part of every feed manufacturing process.
- B. Again, only a federal or state regulatory agency under the authority of their respective feed law and regulations may grant a “status of lower regulatory priority” to NASC members.

5. **Compliance with Labeling Regulations**

We agree with your assessment that unsupported and exaggerated label claims harm the industry and consumer confidence and may induce potential harm to animal health. All label and product claims must be true and not misleading. Guidelines are already established for claims related to animal feed, feed ingredients, and animal drugs. Unsupported claims, regardless of the impact to the consumer, are not allowed.

6. **NASC Labeling Compliance Procedure**

- A. As stated in item “b” of this section, we would encourage your members, as well as all of the feed industry, to work closely with the regulatory agencies to determine appropriate labeling claims. As you have stated, drug claims and unsubstantiated claims are not acceptable for the labeling of animal feed and feed ingredients.
- B. It is important for NASC members to understand that feed control officials may request information to substantiate that the use of the NASC seal is valid and used appropriately on feed labels.
- C. Although NASC will conduct a label review of their members’ product labels, additional reviews, questions and comments may be required by federal and/or state regulatory officials. It is important for NASC members to understand that they, as well as non-member feed manufacturers, may be asked by regulatory officials to substantiate claims even though their labels have already been approved under the NASC review process.

7. **Long Term Implementation**

AAFCO commends the cooperative nature of this proposal for ingredient review by feed supplement manufacturers. This is especially important given the fact that one company performing the required ingredient testing cannot be granted exclusive marketing rights once their ingredient is defined, accepted or approved.

The process that you propose provides for a cost sharing by all participants in NASC who distribute a particular ingredient.

8. **Mandatory participation in MIRC (Manufacturer Ingredient Research Committee) by NASC Members.**

In item number “3” of this section, you state that “MIRC” membership will include all NASC manufacturers presently marketing or contemplating marketing a product containing that ingredient. The committee shall elect a board that will hire a qualified consultant to serve as project manager.” We would encourage you to include animal nutritionists and veterinarians on the MIRC so that this group has a strong nutrition background.

9. **Options Available for Acceptance of Proposed Ingredients**

AAFCO ingredient investigators and the Ingredient Definitions Committee (IDC) will work with NASC ingredient sponsors for those ingredients utilizing the IDC process to establish an AAFCO definition.

10. **Funding Commitments for NASC Membership**

Thank you for sharing this information. You have a monumental task before you, and we commend your efforts to share the financial burden of the NASC Compliance Plus program.

11. **Scientific Advisory Board**

We would recommend that animal nutritionists be included as members of the Scientific Advisory Board.

12. **Manufacturers Ingredient Research Committee (MIRC) Operating Guidelines and Structure**

As previously stated, the appropriate AAFCO ingredient investigators will work with the MIRC Project Leader through the AAFCO ingredient definition process.

13. **Closing Summary**

AAFCO is encouraged by your proposal to bring unrecognized ingredients into compliance with existing federal and state laws and will provide whatever assistance we can to help ensure the success of this endeavor.

We hope that the comments we have provided will be helpful as the NASC Compliance PLUS program is implemented. AAFCO will work with NASC members, as well as any industry manufacturer, supplier or distributor, to ensure that ingredients are acceptable for use in animal feed. By utilizing the AAFCO IDC process, or any of the

other established processes for achieving recognition as a feed ingredient, feed manufacturers and their customers are assured that their ingredients are safe and effective for their intended use.

Thank you for allowing the opportunity for the AAFCO ESMI Working Group to comment on the NASC Compliance Plus proposal.

Sincerely,

Teresa A. Crenshaw, Chair  
ESMI Working Group