September 9, 2024

Comments - Draft GFI #293: FDA Enforcement Policy for AAFCO-Defined Animal Feed Ingredients

The National Hemp Growers Association (NHGA) is a new National Association of Farmers which exists to promote producer influence of the hemp industry in the United States from seed to sale, develop infrastructure to connect growers to resources and markets, and engage governments and businesses in the promotion of industrial hemp as a valuable resource.

Our Board and members appreciate the opportunity to provide the following comments on Draft GFI #293, “FDA Enforcement Policy for AAFCO-Defined Animal Feed Ingredients”.

1. NHGA supports the FDA guidance and asks that the FDA make public its commitment to not take enforcement action on the ingredients currently listed in the 2024 AAFCO OP. However, we would like to express our concerns about the perception that only FDA approvals will be adequate in the future while the AFIC is only interim and the GRAS/FAP process is under review.

2. NHGA would like to recommend that the organization that had been completing this work since the 1920’s be given the opportunity and recognition to continue this work and present its own process through the Ingredients Definition Committee, for gaining feed ingredient approvals. Most feed industry participants, associations and consumers are familiar and trusting of this process and it is well understood.

3. FDA should continue to recognize the ingredients included in the AAFCO Official Publication on an annual basis. This should begin with the 2024 edition, until all ingredient definitions and feed terms submitted before October 1, 2024, have worked their way through the AAFCO process for publication in the OP.

4. NHGA would like to ask the FDA to acknowledge “tentative” definitions listed in 2024 OP, which may or may not become final until subsequent AAFCO OP’s are published.

5. The role that AAFCO plays in regulating and developing feed ingredients, labeling and feed laws seems to be focused on execution of laws and regulations however this is an inadequate description of AAFCO's role in developing those definitions and terms based on their experiences as state regulators working with their farmers, formulators, feed manufacturers, livestock producers and pet food companies.
    a. AAFCO representatives are more accessible than FDA-CVM staff to industry and producers.
    b. AAFCO is most often the enforcement agency when safety concerns are discovered and which are typically reported to them before the FDA.
    c. Because AAFCO works on model legislation among, within and between states its representatives have a unique understanding of the feed value chains including the livestock producers' need for novel and new ingredients, pressure from stakeholders to provide compliance protocols and testing methods, and the complexity of labeling and compliance in each state.
    d. This is especially important when developing terms in states that do not accept GRAS under the current regulatory framework provided by the FDA.
6. The Draft Guidance #293 significantly under represents the role that AAFCO, its Feed Control Officials and their laboratory staff play in ensuring compliance and safety.
    a. The Departments of Agriculture are typically responsible for safety testing and most are underfunded with access to lab equipment that is more than adequate for identifying safety concerns by testing biological, environmental and processing contaminants that are of concern in the feed supply chain. However, when FDA imposes drug-like limits on naturally occurring phytochemicals the labs are forced to either not test, consider these ingredients unsafe or products containing them to be adulterated according to:

       Section 409(b) of the FD&C Act (21 U.S.C. 348 (b)) and FDA's implementing regulations at title 21 of the Code of Federal Regulations (21 CFR), part 571, which describes a feed ingredient that is legally approved and marketed must be approved, covered by an FDA regulation, and used as described in the FDA regulation.
7. NHGA Recommends that the FDA make publicly available AAFCO definitions in the same place as approved GRAS/FAP products so that manufacturers/states/consumers know where to find the most up-to-date information about the ingredients listed on product labels.

Thank you,

National Hemp Growers Association