



September 9, 2024

## Comments - Draft GFI #294: Animal Food Ingredient Consultation (AFIC)

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, “Animal Food Ingredient Consultation (AFIC)”.

In general we support the development of the Animal Feed Ingredient Consultation (AFIC) Process as the FDA seeks public feedback on the Feed Additive Petition (FAP) and Generally Recognized as Safe (GRAS) Ingredient approval processes. However, we would like the agency to consider the following comments and recommendations below.

1. NHGA supports the FDA’s approach to issuing interim guidance and the AFIC while it evaluates its GRAS/FAP processes.
2. NHGA recommends FDA align the ingredient definition submission requirements for AFIC with the AAFCO submission requirements that industry, regulators and states are already familiar with and which the AFIC process already mimics.
3. We support the current AAFCO process and recommend that AFIC considers the following:
  - a. Rather than recreating a “a baseline of safety information available about such an ingredient, making it easier to compare developments that might occur during marketing.” We recommend using the AAFCO guidance which provides multiple pages explaining it and allows for detailed comparison of ingredients and terminology already in the marketplace.
  - b. Limit the scope of submission requirements to exclude environmental risk assessments by NEPA. (NEPA is NOT intended for purposes of defining feed products nor is it within FDA’s authority to determine whether an ingredient is “environmentally safe” but rather whether it is safe and healthy for the intended animal and/or for human consumption of said animal).
  - i. Additionally the USDA Food Safety and Inspection Service provides guidelines for [Substantiating Animal-Raising or Environment-Related Labeling Claims](#) creating potential for additional over regulation and regulatory confusion.



4. NHGA is concerned about the AFIC needs for public disclosure because the process is already complicated and time consuming. We have the following concerns:
  - a. The additional website inventories and the inclusion of public comment on ingredient submissions invites confusion from the public who do not have adequate knowledge or understanding to provide beneficial feedback.
  - b. While the goal is to “facilitate transparency and support public engagement,” the unintended consequence is to create a political environment instead of one focused on safe and healthy feed ingredients and animals.
5. We strongly recommend that FDA officials who will be responsible for reviewing the ingredient definitions submitted through AFIC participate in the initial consultation meeting with industry to avoid untimely delays during the review process or additional expenses in method validation or feeding trials.
6. NHGA would like clarity on the submission/approval process timelines which are currently 180. But, the timeline allows for 6 months to pass between responses to questions and submission of additional information. This leads to delays which are expensive for the submitter and cause excessive delays in bringing new ingredients and products to market.
  - a. Especially because the 180 day allowance for FDA to respond begins again with each new question from the submitter or submission in response to FDA officials requests.
7. Our farmers and processors would also like to better understand how the AFIC consultation complete letters will be used for enforcement and interstate commerce while the FDA considers updates to its existing pre-market animal feed Feed Additive Petitions (FAP) and Generally Recognized as Safe (GRAS) programs.
  - a. Additionally, what happens with the consultation complete letters if the AFIC process of the current programs change.

Thank you,

National Hemp Growers Association