March 16, 2022

Dear FDA-CVM Officials:

On behalf of the National Industrial Hemp Council of America (NIHC)—the only Washington, D.C.-based trade association in the hemp industry with a mission to protect consumer safety, the consumer’s right to know and to create a hemp economy that works for everyone—I respectfully write to you today in response to the joint letter sent by the Association of American Feed Control Officials (AAFCO) and similar organizations regarding the use of hemp as an animal feed ingredient dated February 9, 2022. The letter specifically called on policymakers and agricultural leaders to “support further education and research to ensure safe use of hemp as an ingredient” and made many claims that we would like to address, as detailed below.

We would like to first begin by clarifying that a lack of credible science is NOT the main barrier to the approval of hemp as a feed ingredient. We appreciate the position that AAFCO and the other signing associations have taken, and we understand and agree with the position that hemp has to be, above all, safe for livestock and companion animals. However, while the need for additional studies would be advantageous, we believe that the current profile of research from around the world, including small research projects in the U.S., provides sufficient data necessary to prove that hemp seed is a safe and effective feed ingredient.

Solutions and Opportunities

The path forward involves the hemp and animal feed industries, AAFCO, and the U.S. Food and Drug Administration's Center for Veterinary Medicine (FDA-CVM) working together to identify ways to decrease barriers and speed up animal feed approvals by focusing on the ingredient for its intended use and affirming its safety and utility. Without clarification from regulators, the confusion surrounding hemp animal feed versus treats and supplements will continue to discourage consumers and prevent a diversified row crop and feed source from being available to our farmers and ranchers. We believe that the following clarifications and recommendations provide a clear solution for allowing hemp-based animal feed to gain federal approval.

1. **Hemp seed is not used to produce cannabinoids and should not be connected to the regulatory standards of cannabidiol (CBD).** Hemp animal feed includes only nutritional hemp seed products. The intended use of seed products as animal feed is to provide a nutritional source of protein, fat, and energy.

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2. **FDA-CVM should establish reasonable and repeatable action limits for cannabinoids in seed products.** The action limits should not be more stringent than those established for heavy metals in animal feed. Only trace amounts of cannabinoids are found in seed and its by-products, making the FDA-CVM requests to test for cannabinoids to parts per billion or even trillion, unjustified. This level of analysis for contaminants in food safety would require pharmaceutical or research laboratory methods and equipment that are commercially inaccessible to farmers, processors, and most regulatory agencies.

3. **FDA-CVM should prioritize AAFCO ingredient approvals and create an expedited process for feed ingredients that relies on already existing research, even if conducted outside of the U.S. or before the 2014 Farm bill allowed hemp to be cultivated for research in the U.S.** The global feed shortage is creating unprecedented competition for feed sources. The expedited approval of hemp seed as animal feed would safely provide an additional feedstuff for domestic and global livestock production and provide clarity to industry and consumers.

4. **Regulatory agencies should work together to identify ways to expedite validation and approval of already developed analytical methods to quantify cannabinoids in seed and seed by-products for feed ingredients and to test the transference of cannabinoids into animal by-products intended for human consumption.** Recent efforts to engage ASTM International and AAFCO laboratory experts have brought this urgent matter to the attention of researchers and scientists across the world. While many labs can internally validate their methods, for example, the U.S. Department of Agriculture Agricultural Research Service (USDA-ARS) is investigating cannabinoid transference in meat from hemp-fed beef cattle, the lack of approved methods and standards must be addressed.

5. **The hemp industry, led by the NIHC, requests to host a webinar with the regulatory agencies, USDA, AAFCO, and FDA-CVM, where researchers can provide education on safety and cannabinoid transference, address gaps in method validation, and discuss pathways to expedite approval of hemp as animal feed.**

**Discussion of Existing Barriers**

When presenting safety information to the FDA-CVM for the hemp seed meal application, the FDA-CVM requested that only studies using American grown and American processed hemp be included. This parameter negates decades of safety research conducted before the 2014 Farm Bill allowed hemp to be cultivated for research purposes in the U.S., and well before it was recognized as an agricultural commodity in the 2018 Farm Bill. Hemp seed is a row crop grown for food and feed around the world and is an oilseed similar to cotton, sunflower, and canola, which are highly valued for the production of edible oils. Like other oilseeds, hemp produces high concentrations of energy and digestible fats. The by-product left behind from the removal of the oils (seed cake) is a concentration of plant protein that can be fed to all classes of animals and humans.

Also in 2018, the FDA acknowledged the Generally Recognized as Safe (GRAS) status of three hemp seed products for human consumption: hemp oil (from crushing the oilseed), hemp hearts (dehulled hemp seed), and hemp protein powder (milled seed cake), after receipt of a GRAS notice from Fresh Hemp

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Foods, Ltd. In the GRAS notification, FDA states that cannabinoids occur in trace amounts in the hemp seed and accepts a threshold of 10 ppm for tetrahydrocannabinol (THC) in these products, with no action limits requested for other cannabinoids. Utilizing this threshold for cannabinoids reinforces the definition of hemp containing only very small amounts of THC and provides regulatory bodies the ability to immediately test products for compliance, safety, and truth in labeling.

In creating the ingredient profile for the first hemp seed meal application for laying hens (submitted in December 2020 by the Hemp Feed Coalition), cannabinoids were treated as contaminants in hemp seed and its by-products with an action limit of 50 ppm for total cannabinoids, including both THC and CBD and their precursor acids and derivatives (all of the deltas). This threshold was based on observed Certificates of Analysis and the currently available levels of quantification at commercial food safety labs. Many organizations and associations are addressing the need to set cannabinoid thresholds and on March 1st, the U.S. Pharmacopeia published methods for cannabinoid quantification in hemp seed meal and oil which established HPLC limits of 10 ppm of THC (sum of THC + 0.877 THCA) and 75 ppm of CBD. Previous acknowledgement by the FDA of a 10 ppm THC threshold for hemp seed products for human consumption is an appropriate limit, and recently, the U.S. Pharmacopeia and other standard developing bodies have suggested a limit of 75 ppm total CBD.

The testing of cannabinoids is a critical safety matter that the hemp industry needs to address and deserves context. Currently, USDA compliance requires testing the top parts of the plant, focusing on the flower and the highest concentration of cannabinoids. A hemp plant can test up to 3000 ppm, 0.3% ∆9 THC and be compliant. The method used on the dry plant material is to date one of only two AOAC International validated methods to test for cannabinoid concentrations, and no methods have been approved for seed or its by-products. This is not due to lack of research, but instead demonstrates the need for validated methods from agencies and associations.

Across the world, research has and is currently being done to prove the value of hemp as a safe feedstock. In Canada, the Canadian Hemp Trade Alliance has partnered with researchers and private industry members to compile an application to the Canadian Food Inspection Agency for multiple species being fed hemp seed by-products. A similar effort would be an effective way to handle the approval of hemp ingredients for nutritional use. Meanwhile, researchers in the U.S. are conducting feed

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trials including two USDA funded projects at Oregon State and Central State Universities.\textsuperscript{10,11} Other trials are happening at North Dakota State, Colorado State, Virginia Tech, Tarleton, Murray State, Texas A&M, and other institutions where they are investigating hemp seed by-products for inclusion in ruminant, monogastric and aquaculture feeds.

The agriculture sector and the livestock industry have voiced their need for new feedstuffs and climate-smart agriculture, asking for solutions, not additional barriers. This was highlighted during a recent House Agriculture subcommittee meeting on Livestock which also noted concerns that the FDA-CVM process for approval is too expensive, time-consuming, and complex.\textsuperscript{12} It is disconcerting to see the cannabinoid and pet industry with products on store shelves across the country while the livestock industry struggles to find adequate feedstuff.

\textbf{Conclusion}

The hemp industry needs a federal solution to provide the feed and livestock industries with clarity and to assure consumers that hemp is a safe and effective animal feed. This can be accomplished by bringing together FDA, AAFCO, the hemp industry, and researchers. The following actions are needed: the regulation of hemp seed independently from CBD, FDA-CVM establishment of reasonable and repeatable action limits for cannabinoids in seed products, FDA-CVM prioritization of AAFCO ingredient approvals, the creation of an expedited process for feed ingredients that relies on already existing research, and approval by regulatory agencies of analytical methods to quantify cannabinoids. By working together, face-to-face, toward this shared goal, we can achieve federal recognition, appropriate regulatory oversight, and approval of new feed ingredients including hemp seed products more efficiently than through a state-by-state approach.

Sincerely,

\textit{Hunter Buffington}

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