Re: American Association of Feed Control Officials Erin Bubb, Ingredients Definition Committee Chair

June 25th, 2024

The recent tentative approval of hempseed meal to be fed to laying hens is a historic step for the establishment of Hemp as an American agricultural commodity. Unfortunately, the definition put forth by the FDA-CVM and tentatively approved in January at the American Association of Feed Control Officials (AAFCO) mid-year meeting presents significant barriers to the production of affordable and compliant hemp feed ingredients. It also presents barriers to the regulation of hempseed meal by many state regulatory agencies and Departments of Agriculture. While it is a positive step, the limits for THC and the inclusion of a limit for CBD makes the definition unenforceable for feed labs, charged with monitoring feed ingredient safety, to achieve the detection of THC at the proposed 2ppm (0.0002%) limit. Hemp farmers and animal producers need new domestic and global markets that represent additional offtakes, cost effective feed solutions and provide a stable animal feed supply chain. The proposed definition will prevent their ability to include hemp in that strategy.

Current global limits are based on a number of resources including the US Pharmacopeia, which defines hempseed meal with a limit of: 10 ppm THC, and 75 ppm CBD. Additionally, three Generally Accepted as Safe (GRAS) notices accepted in 2018 by the FDA for hempseed products to be consumed by humans, include a general action limit of 10 ppm (0.001%) for THC in hempseed by-products, that are not dehulled. This limit does not clarify total THC and was approved in 2018 before the current definition of Hemp was mandated to be 0.3% (3000 ppm) $\Delta 9$ THC. There was NO limit adopted for CBD in any of the three GRAS notices and FDA stated in its press release that:

Although hemp is from the same species as cannabis (marijuana), the seeds themselves do not naturally contain tetrahydrocannabinol (THC), the main psychoactive ingredient in cannabis. The hemp seed-derived ingredients that are the subject of these GRAS notices contain only trace amounts of THC and CBD, which the seeds may pick up during harvesting and processing when they are in contact with other parts of the plant. Consumption of these hemp seed-derived ingredients is not capable of making consumers "high".

The FDA agrees with other jurisdictions that cannabinoids found in hemp seed and hempseed products are contaminants and that processing standards and best practices call for proper seed cleaning which in turn limits exposure and contamination of the grain. The tentative definition proposed by the FDA-CVM not only includes a limit on CBD at 20 ppm, but additionally proposes a limit of 2 ppm for $\Delta 9$ THC (0.0002%). This limit would require not only multiple seed cleanings at the farm and processing level but is more likely only achievable by dehulling the hemp seed. This level of processing will not only hurt the offtake markets that

¹ CFSAN. (2018). FDA Responds to Three GRAS Notices for Hemp Seed-Derived Ingredients for Use in Human Food.

farmers need for seed below replanting quality; but would also discourage cracked or partial, and off-sized seeds from entering the feed market, driving cost for hemp seed by-products too high for broad adoption by the feed industry.

The second reason that the proposed limits must be changed is the limitation of labs to reliably detect and report trace amounts of cannabinoids below 10ppm. Acceptable testing methodologies recommended by the USDA include gas or liquid chromatography. The current Limits of Quantification using Gas Chromatography with a Flame Ionization Detector (GC-FID) is 200 ppm, far above the limits proposed by the tentative definition. While there is a detector capable of this low quantification, many labs charged with THC compliance for hemp and feed utilize a GC-FID detector as recommended by the USDA in the Hemp Final rules referenced below. AMS looked at current testing methodologies that would meet the decarboxylation requirement set in the 2018 Farm Bill. In gas chromatography (GC) testing, heat is applied to the sample, which decarboxylates THCA, producing delta-9 THC, so that the final delta-9 THC result is actually a total THC result.²

Liquid Chromatography with a Mass Spectrometer, often called a triple quad (LC/MS/MS), can achieve this very low reporting limit. However, the equipment is expensive and requires specialized training to operate, putting the burden on the regulatory labs to purchase, hire or train lab technicians. Other concerns with this method include the need to calculate total THC. Liquid chromatography (LC) testing does not involve the use of significant heat, so that the THCA in a sample does not generally decarboxylate. When LC is used, the total THC needs to be calculated post-testing in order to report results as a "post decarboxylation" delta-9 THC value.³

Further concerns are raised when considering the proposed definition of THC and CBD quantification falls below many other action limits for contaminants known to cause harm in humans. These include a naturally occurring protein in wheat, well-known for causing celiacs disease. Finished products are allowed to be labeled 'gluten free' when they contain less than 20 ppm of gluten. Another contaminant of concern for humans is Thebaine, this precursor to morphine is a naturally occurring phytochemical in poppyseed allowed in amounts up to 20 ppm.⁵

AAFCO provides published guidance for action limits of heavy metals in feed ingredients in its Official Publication. Only two of these are below our recommended 10 ppm limit for THC; Cadmium at 0.5ppm, and Mercury at 2 ppm. Lead is allowed up to 30 ppm and Arsenic up to 50 ppm, above both the THC and CBD limits in the tentative definition and more than 3 and 5 times the limit of 10 ppm that we propose for total THC.⁶ Hempseed markets for human food continue to grow globally presenting a unique opportunity for domestic production of hemp grain. American farmers and livestock producers would benefit from a new feedstock made from these by-products which contain high amounts of protein and quality omega fatty acids at a price point that they can afford. To accomplish this - regulators and the labs charged with keeping our food and feed safe, must have the appropriate tools and realistic limits. When the labs are given impossible standards; with no validated methods for achieving the limits that are

² 7 CFR Part 990—Domestic Hemp Production Program

³ 7 CFR Part 990—Domestic Hemp Production Program

⁴ FDA. (2018). Gluten and Food Labeling.

⁵ Food Standards Australia New Zealand. (2023). Poppy Seed Safety and Suitability.

⁶ Association of American Feed Control Officials. (2019). AAFCO Official Publication.

lower than the amounts of most other contaminants of concern, are not determined by reported risk or harm and which are cost prohibitive for a robust and stable feed supply chain the feed and farm industry needs a new definition. One that ensures ingredient definitions and compliance can be met.

We understand the amount of work that has been done and want to express our thanks to the FDA-CVM, Departments of Agriculture, AAFCO Investigators and Industry to achieve this milestone. Please adjust the current definition by removing the CBD limit and setting an achievable, reliable and realistic limit on THC in hempseed meal at 10 ppm.

Sincerely,

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