



Federation of International Hemp Organizations

July 9, 2024

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Voice of the global industrial hemp industry

Coordinating research and standards

Supporting sustainability

Advocating for consistent terms of trade

Feed Ingredient Committee

American Association of Feed Control Officials (AAFCO)

Erin Bubb, Ingredients Definition Committee Chair

100-1800 S. Oak Street

Champaign, IL 61820-6974

USA

Delivered by email

ebubb@pa.gov

Dear Ms. Bubb:

Re: International request to delay approval of the FDA-CVM hempseed meal definition

The Federation of International Hemp Organizations (FIHO) began in 2019 when international hemp organizations joined together to review and integrate policy and research initiatives of mutual benefit. This group combines experts and resources to address the needs of the industrial hemp sector to benefit global farmers, manufacturers, consumers and the environment. FIHO builds on existing expertise with over 100 qualified industrial hemp and subject matter experts available for assessing and coordinating research and standards related to hemp farming and agronomy, hemp food (protein, fat, and fibre), hemp fibre (soil amendments, textiles, and building materials), hemp livestock feed ingredients (all species and production stages), biocomposites (polymers, epoxies, building materials, and nanocarbon), and bioactives (e.g. ascorbic acid, cannabinoids, carbon, carotenoids, fatty acids, hydroxyls, lignans, phytosterols, polyphenols, tannins, terpenoids, and unsaturated chain hydrocarbons).¹²

Industrial hemp is grown in over 60 countries and the oilseed of this agricultural crop has a high nutritive value for humans and livestock. While the primary market for hempseed and its derivatives are for human food, there are many circumstances where hempseed must be diverted to the livestock feed ingredient market, such as: farmer need to quickly convert inventory to cash; quality degradation under normal storage conditions; small seed size; broken seeds; and, frost damaged seeds (harvested prior to maturity). Alternative feeding to livestock can provide a sustainable re-purposing option for food processors and helps farmers to avoid waste. A secondary livestock feed market can also boost processor and farmer economic positions, serving to underpin the industrial hemp grain value chain and reduce risk for the farmer.

A unique characteristic of the industrial hemp plant is the production of plant-based cannabinoids in the flowers and leaves of the inflorescence (flowering top). These plant phyto-chemicals have potential for human and animal health products at concentrations thousands of times higher than the natural constituent levels present on the outer shell of the seed or in hempseed derivatives (i.e. food and feed). Due to seed contact with the upper flower during harvest, natural residual levels are present on the outer seed shell in trace amounts. The FDA acknowledges that **hemp seed does not produce cannabinoids**:

Foods containing hemp seed and hemp seed-derived ingredients are currently marketed in the US. Hemp seeds are the seeds of the hemp plant, *Cannabis sativa*. 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

¹[https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9841654/#:~:text=Phytochemical%20investigation%20of%20hemp%20roots,%31\)%2C%20and%20an%20unsaturated%20chain](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9841654/#:~:text=Phytochemical%20investigation%20of%20hemp%20roots,%31)%2C%20and%20an%20unsaturated%20chain)

² <https://www.mdpi.com/2624-7402/6/2/75#:~:text=The%20concentrations%20of%20the%20extracted,found%20to%20have%20the%20highest>

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”.³

The only hemp-derived cannabinoid with the potential for intoxication **when concentrated** is tetrahydrocannabinol (THC). However, the majority of natural constituent levels on the outside of hemp seed are in the acidic precursor THC-A form. The acidic form must be heated at high temperatures for a specific time period to be fully converted to the biologically available delta-9 THC. This heating does not generally occur in feed (e.g. pelleting and extrusion) processing.

Interest in other phytocannabinoids – such as cannabidiol (CBD) – has undergone significant research; including potential impacts as animal feed ingredients. This research has shown that the trace amounts of THC and CBD present in hemp seed are not readily available for absorption into animal tissue through feed ingestion. Global research indicates that THC and CBD are naturally less-than trace amounts in hempseed byproducts, and are further reduced when fed up to 20% inclusion rates in any final feed formulation. It is estimated that 88-90% of consumed THC or CBD present at natural constituent levels are excreted by livestock species. The remaining 10-12% of consumed THC or CBD present at natural constituent levels are either metabolized or deposited in various livestock tissues (i.e. meat, fat, organs, milk, or eggs) at non-detectable or extremely low (.01ppm to .05ppm) levels. Research has shown that fed THC and CBD are not transferred to food products at any level of safety concern significant to humans or animals.

Industrial hempseed and its derivatives do not contain added concentrated, isolated, or synthetic cannabinoids. As stated above, hempseed and its derivatives contain only low natural constituent cannabinoid levels. Intoxicating, toxic, or therapeutic cannabinoid levels can only be generated in hempseed and its derivatives by supplementing or adulterating the hempseed or its derivatives with concentrated, isolated, or synthetic cannabinoids. Any hempseed or derivative product that has been supplemented or adulterated with concentrated, isolated, or synthetic cannabinoids should not be defined as industrial hemp. **Any product containing added concentrated, isolated, or synthetic cannabinoids is not industrial hemp.**

Analysis of livestock feed research in the Canadian Journal of Animal Science summarizes the efficacy of seed byproducts in feed, safety, and potential residual transfer to food products of animal origin. Over 130 peer-reviewed scientific publications in recognized journals were reviewed by Dr. N .Mohamed and J. House for safety and efficacy in feed, those specific to chickens are summarized below:

- Dalhousie University fed hempseed meal to laying hens at 20% inclusion in the feed ration. THC and CBD content was not detected in yolk and breast meat. Source: S.Collins, Dalhousie University, Canada 2024.
- A large USA study feeding up to 30% hempseed meal to commercial laying hens demonstrated that feeding this hempseed byproduct did not contribute to tetrahydrocannabinol (THC) or cannabidiol (CBD) residues in eggs. Kasula 2021
- Research in broiler chickens (meat production) fed hempseed meal at 8 to 24% of the ration resulted in no determinant levels. THC and its metabolites were measured in broiler breast, thigh, liver and kidney and occurred at less than the limit of detection of 10ng. Rasool 2018

³<https://www.fda.gov/food/cfsan-constituent-updates/fda-responds-three-gras-notices-hemp-seed-derived-ingredients-use-human-food>

Industrial hemp has been bred for centuries to contain extremely low trace amounts of THC. Furthermore, plant breeders regularly monitor hemp globally to meet THC standards established by regulators having jurisdiction. Different maximum THC levels are defined by regulation for the definition of the hemp plant around the world, which results in different maximum allowable levels of natural constituent THC in food derived from hempseed.

Additionally, the European Food Safety Authority in 2015 concluded:

- Tetrahydrocannabinol, more precisely delta-9-tetrahydrocannabinol ($\Delta 9$ -THC) is the most relevant constituent of the hemp plant.
- In fresh plant material up to 90% of the 'total' $\Delta 9$ -THC is present as the non-psychoactive precursor $\Delta 9$ -THCA-A.
- As high temperatures are not generated during dehulling and oil extraction, these processes are not expected to result in increased levels of $\Delta 9$ -THC in the oil or meal resulting from decarboxylation of precursor acids.
- In humans after oral exposure, $\Delta 9$ -THC is slowly and incompletely absorbed from the gastrointestinal tract. The oral bioavailability is lower compared to inhalation. Studies in both rats and humans indicate that the in vivo conversion of $\Delta 9$ -THCA-A to $\Delta 9$ -THC does not occur.

Table 2. THC and CBD Threshold Levels in Food Products

| Jurisdiction | Maximum THC Limit | | | Maximum CBD Limit |
|----------------|----------------------------|-------------------------------|-----------------------|----------------------|
| | Hemp Plant | Hempseed for Food | Hempseed Oil for Food | Hempseed for Food |
| Switzerland | 1.0% | 10 ppm | 20 ppm | No maximum threshold |
| Australia | 1.0% | 5 ppm | 10 ppm | 75 ppm |
| New Zealand | 1.0% | 5 ppm 0.2 ppm: (beverages) | 10 ppm | 75 ppm |
| European Union | 0.3% | 10-20 ppm | 10 ppm | No maximum threshold |
| Canada | 0.3% (0.5% compliance) | 10 ppm | 10 ppm | No maximum threshold |
| United States | 0.3 % (0.5% compliance) | 10 ppm | 10 ppm | No maximum threshold |

| Table 3. Hempseed product standards – THC and CBD Thresholds | | | | |
|--|---|---------------------------------------|---------------------------------------|---|
| Agency | Comments | THC in hemp food products | THC in hemp seed oil | CBD in hemp food products |
| ASTM International D8440 ⁴ | Consensus Standard | Total delta-9 THC of 20 ppm | Total delta-9 THC of 20 ppm | No maximum threshold |
| USA GRAS 2018 GRN 771, GRN 778, GRN 765 | 10 ppm of total THC did not result in unsafe food for human consumption | No maximum threshold, subject to GRAS | No maximum threshold, subject to GRAS | No maximum threshold |
| USP-Food Chemical Codex , USA ⁵ | N/A | Total delta-9 THC of 10 ppm | Total delta-9 THC of 10 ppm | Total CBD of 75 ppm (hemp protein, hemp seed oil) |
| Source: FIHO members, Ag Policy Solutions (USA), standard setting bodies, and national regulatory agencies | | | | |
| <p>Notes:</p> <p>CBD in industrial hemp grown as an agricultural crop has not been identified at maximum levels in food products except for the USP-FCC in the USA. This is likely because it is viewed to exist at trace levels, not a human safety risk, and not a significant component of food products.</p> <p>The EU defines maximum THC in hemp plants, however each member country may also define levels for the definition of hemp in their own country. This is due to historic production and timeline differences (i.e. varying years where hemp was re-legalized in each region).</p> <p>Total THC and total CBD includes an adjustment of 0.877 of the level of acidic precursor THC-A or CBD-A component. This adjustment accounts for the absorbable amount remaining after decarboxylation which is a significant heating process. This high heat does not occur in animal feed processing</p> | | | | |

The current trend in global human population growth demands an increase in the production of animal protein of about 60% or more by 2050 (FAO 2011), with the task for the animal industry to provide a sustainable supply of meat and eggs (FAO 2010). Generally, animal feed accounts for greater than 70% of the total cost in animal production, of which dietary protein together with energy represents a substantial portion. For example, diets for monogastric (single stomach) animals are usually formulated around a cereal-protein-based diet, mainly contributed by corn and soybean meal. Feedstuff price fluctuation and accessibility of dietary ingredients contributes to hempseed byproducts potential as feed ingredients.⁶

The tentative definition for hempseed meal intended for laying hens has identified threshold levels for THC and CBD that will disqualify the majority of hempseed meal lots produced in the USA, Canada, Europe, and other potential international suppliers. This represents loss of nutritive value opportunity and no risk to food safety. Instead of testing lots, commercial feed mills are likely to avoid sourcing

⁴ D8440 Specification for Food Safety and Quality of Hempseed Protein Products Intended for Human Consumption is available for purchase at www.astm.org The standard identifies thresholds for food safety and quality in hemp seed and its byproducts.

⁵ Food Chemical Codex (USP-USA) 2021 food identity monographs for hemp seed oil and hemp seed protein are available at <https://www.foodchemicalscodex.org/>

⁶ N.Mohamed et al, Cdn J.Animal Science 2024

hempseed meal due to increased cost and the challenge of managing lots over the threshold. A market for safe, efficacious hempseed meal will support expansion of the overall hemp food sector, and reduce risk for farmers. Low thresholds that do not consider the normal constituent total THC and CBD concentrations present in currently available commercial products – and considerable research completed globally – will not result in a commercially viable hempseed feed ingredient market.

In reviewing the global data there is no discernable risk or evidence to support the identified THC (2ppm) and CBD (20ppm) limits. Based on existing livestock feeding safety and efficacy data and tissue residue research that indicates insignificant transfer to food products from livestock, the Federation of Industrial Hemp Organizations respectfully requests that:

1. The current hempseed meal THC limit of 2 ppm be raised to 10 ppm;
2. The current hempseed meal CBD limit of 20 ppm be completely removed;
3. All future hemp feed ingredient (i.e. whole hempseed, hempseed fines, hempseed hulls, hempseed screenings, hempseed oil, and hemp protein) THC limits be based on actual THC levels in each commercially available hemp product;
4. All future hemp feed ingredient (i.e. whole hempseed, hempseed fines, hempseed hulls, hempseed screenings, hempseed oil, and hemp protein) CBD limits not be established; and,
5. The current hemp feed ingredient registration submitted by the Hemp Feed Coalition be set aside until such time that the feed ingredient definition has been revised as recommended.

Sincerely,



Maren Krings
Director General
Federation of International Hemp Organizations
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CC: Falina Hutchinson, AAFCO Feed Investigator (FHutchinson@mt.gov)
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