



Washington
State Department of
Agriculture

Preliminary Assessment of Hemp Seed Products as Feed Ingredients for Laying Hens

January 18, 2017

A Report to the Legislature
in response to

HB1268,
Chapter 106, Laws of 2015,
64th Legislature,
2015 Regular Session



Washington State Department of Agriculture
Food Safety & Consumer Services Division

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Washington
State Department of
Agriculture

AGR PUB 517-584 (N/1/17)

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Executive Summary

In response to House Bill 1268, the Washington State Department of Agriculture (WSDA) conducted a study evaluating whether hemp seed products should be an allowable component of commercial feed for laying hens in Washington.

Based on the results of the study, WSDA has determined it is not yet appropriate to move ahead with rulemaking or other administrative actions allowing hemp seed to be included in commercial feed for laying hens, due to lack of research related to public health.

Hemp seed shows good potential as a nutritional source for laying hens. Further studies may help determine if there are any significant effects on hen performance. Although hemp seed does show good potential as feedstuff, it also may contain trace chemical constituents such as the cannabinoid delta-9-tetrahydrocannabinol (THC). Health agencies in the United States have not established an Acceptable Daily Intake (ADI) for THC which is needed to assess the risk to humans consuming eggs from laying hens fed hemp seed products. Although it does not appear the small amount of THC in properly cultivated and processed hemp seed products will pose a safety issue, health agencies in the United States have not verified this observation.

Information is lacking on the transfer rate of cannabinoids to laying hen eggs and tissue, and this data is needed to understand if there is risk to humans. Additional data on cannabinoids in hemp seed products and data on their transfer to animal tissue is needed. Standard analytical methods for determining the low level of cannabinoids in food will be needed to conduct this analysis and evaluate data. Larger and longer feeding studies could provide information on both cannabinoid transfer and impacts on laying hen performance, egg quality and safety.

Most state feed regulations recognize and make reference to the Association of American Feed Control Officials (AAFCO) Official Publication (OP) for feed terms and ingredient definitions. A feed ingredient with an established definition in the OP has gone through a risk assessment process. Hemp seed products are currently not defined in the AAFCO OP.

WSDA is continually involved in discussions with AAFCO on defining hemp seed products in animal feed, not just for Washington State, but also throughout the United States. The regulatory status of hemp appears to be changing rapidly, and it is possible that data needed to determine the safety of hemp seed for laying hens will be available in the near future. If such data becomes available, and if it adequately supports safe use, WSDA will be able to move forward with appropriate administrative actions to allow use of hemp seed products as a laying hen feed ingredient.

1. Introduction and Background

Through House Bill 1268, the 2015 Washington State Legislature directed the Washington State Department of Agriculture (WSDA) to “conduct a study evaluating whether hemp and hemp products should be an allowable component of commercial feed in Washington.”

WSDA was allowed to limit the scope of the study to an area where hemp may have the most benefit on the health of the animal, the welfare of the animal, the resulting human food product and the environment. If WSDA found the use appropriate, it was to move ahead with administrative actions to allow hemp to be included in feed formulations. If it did not find the use to be appropriate, WSDA was required to provide a report to the Legislature explaining the department’s findings and reasons for not taking administrative action.

Because the bill specifically states, “research has shown that when hemp seed meal is included in the feed of laying hens, the omega fatty acid profile in the resulting eggs is favorably influenced” and because published research is available, WSDA limited the scope of its study to hemp seed products for laying hens. WSDA does not find that use to be appropriate at this time and has prepared this report as required.

This first section of the report provides background information on the study, its subject, and the related regulatory framework. This information is provided to support better understanding of WSDA’s findings and decision. The second section identifies those findings, and the third provides the decision and the reasoning behind it. Additional information from the study and references are provide in appendices.

1.1 About the Study – focus and approach

To define and evaluate the suitability of hemp seed products as feed for laying hens, WSDA needed to address four primary areas of concern:

1. Nutritional value for laying hens
2. Risk to laying hens – health and performance
3. Risk to humans/consumers
4. Standardization

This charge required examining the nature and characteristics of hemp seed, including its source, forms, chemical composition and processing, as well as the impacts of feeding hemp seed products to laying hens.

WSDA approached the assignment by conducting an extensive scientific literature review. By reviewing available scientific literature on hemp seed and its use as laying hen feed, the department was able to gather useful information from many credible sources. The department neither

contracted nor conducted its own primary research on the use of hemp seed for animal feed. WSDA staff conducted the literature review under the advisement of Dr. Erin Goldberg, Ph.D., Faculty of Agricultural and Food Sciences, University of Manitoba, Department of Human Nutritional Sciences. Dr. Goldberg's research projects include feeding hemp seed products to laying hens.

WSDA examined several scientific databases for applicable literature. The search was limited to papers available in English and ended in December 2015. See Appendix G for a list of data bases consulted and the more than 50 specific studies/papers reviewed and referenced in this report.

Because more than one type of hemp seed product is available, it is important to define each and understand how these products differ. For example, it would not be expected that whole seed would have the same nutritional benefit as seed meal that has had oil pressed out of it. WSDA reviewed research on the following hemp seed products:

- Whole hemp seed
- De-hulled hemp seed (sometimes called "hemp nut")
- Hemp seed oil
- Hemp seed meal or cake from oil processing
- Hemp seed hulls

Specifically, WSDA examined research identifying:

- Proximate analysis (to include crude protein, crude fat and crude fiber)
- Amino acid composition
- Nutritional values for vitamins and mineral
- Cannabinoids

In an effort to gather sufficient data on hemp seed as a source of nutrition for use in animal feed, WSDA also engaged with industry, consultants, other WSDA programs and other state and federal regulatory officials, including the Washington State Department of Health (DOH) and the American Association of Feed Control Officials (AAFCO). See 1.2 Regulatory Framework and Appendix A.

1.2 Regulatory Framework

Consideration of hemp seed products as a commercial feed ingredient for laying hens in Washington State takes place within a complex environment that includes regulation of food/feed, and cannabis.

FOOD/FEED REGULATION

Commercial animal feeds may not be sold if they include ingredients that are not recognized as acceptable ingredients or if they include ingredients that are seen as an alteration of the feed. Animal feed is regulated at both the state and federal levels. In addition, the Association of American Feed Control Officials (AAFCO) helps to consolidate regulatory efforts and facilitate consistent regulation among states.

- Federal responsibility for the regulation of food is primarily delegated to the Food and Drug Administration (FDA) which enforces the Federal Food, Drug and Cosmetic Act (FD&C Act).** Section [321](f)(1) of the FD&C Act defines *food* as “articles used for food or drink for man or other animal,” and therefore all ingredients and additives used in animal feed are subject to FDA regulation. The FDA carries out its responsibility to regulate animal feed by approving animal food additives and partnering with state and local authorities. One form of partnership is a Memorandum of Understanding (MOU) with AAFCO, under which AAFCO provides a feed ingredient definition process that includes FDA scientific and technical review. See Appendix E.
- AAFCO is a voluntary membership organization of state government agencies that regulate the production, labeling, and distribution of animal feed and feed ingredients.** Although AAFCO has no regulatory authority, it makes recommendations through drafting “model bills, regulations and policies” for state laws and regulations to improve uniformity. Because the production of animal products for foods (such as meat, milk, eggs) depends on the animal’s nutritional status, AAFCO has an Ingredient Definition Committee that reviews safety, utility, nutrient content, nutritional adequacy and intended uses for animal feed ingredients.
- WSDA regulates commercial animal feed in Washington State, including livestock feed, poultry feed, fish feed, pet food, specialty pet food, and feed ingredients.** The department is responsible for deciding which ingredients are acceptable in animal feed, and is required by RCW 15.53.9012 to consider federal regulations and the official definitions and terms adopted by AAFCO (see box at right). Hemp is currently not an allowable component of commercial feed for animals that produce food for humans, and is not defined as a feed ingredient by AAFCO.

RCW 15.53.9012(1)

“...In adopting such rules, the director shall consider

(a) the official definitions of feed ingredients and official feed terms adopted by the association of American feed control officials and published in the official publication of that organization; and

(b) any regulation adopted pursuant to the authority of the federal food, drug, and cosmetic act (21 U.S.C. Sec. 301, et seq.), if the department would have the authority under this chapter to adopt the regulations. ...”

There are several processes available that can lead to a new feed ingredient being recognized as safe for use. The paths are different, but they all require data demonstrating safety.

Most state commercial feed regulations recognize and make reference to the AAFCO Official Publication (OP) for feed terms and ingredient definitions. The AAFCO ingredient definition process is a method to get a new substance recognized as safe for use in feed. New ingredient listings/definitions can be requested by industry, the public or regulatory officials (see box, next page right). When the AAFCO Feed Ingredient Definition Committee finds a requester’s feed ingredient acceptable, the definition is listed in the AAFCO OP, which is updated at least annually.

Food Additives

Under the Section 2 of the FD&C Act, the Food Additives Amendment of 1958 defines a “food additive” as “any substance the intended use of which results, directly or indirectly, in its becoming a component of or otherwise affecting the characteristics of any food.” Food additives must be pre-approved by petition to FDA unless the substance is considered “Generally Recognized as Safe (GRAS)” among qualified experts under the conditions of intended use.

General information that should be included in a Food Additive Petition (FAP) to the FDA:

1. Identity and composition of the additive including manufacturing methods and controls;
2. Intended use, use level, and labeling (cautions, warnings, shelf life, directions for use);
3. Data establishing the intended effect (physical, nutritional, or other technical effect);
4. Analytical methods (for the additive and for animal foods containing the additive);
5. Safety evaluation (target animal and human food)
6. Proposed tolerances for the food additive;
7. Proposed regulation; and
8. Environmental assessment

FDA has agreed to permit the marketing of unapproved food additives in animal feed as long as there are no safety issues and the additive is defined in AAFCO’s OP. If the safety criterion is not met, FDA may require the sponsor or requester of a new animal feed ingredient to submit a food additive petition for approval of the ingredient (Ekelman, 2004, p.8). FDA may also require a food additive petition if a substance is intended to influence the edible tissues of the animals consuming the substance. Hemp seed added to laying hen feed in order to influence the omega-3- fatty acid composition of the eggs for human consumption would seem to qualify as a food additive.

If animal feed intended for use in Washington State influences the edible tissues of the animal consuming the substance, WSDA consults with the Washington State Department of Health. See Appendix A.

NEW INGREDIENT DEFINITION REQUESTS TO AAFCO

Should include:

1. Firm and contact person.
2. Summary of the request; including name of the ingredient, intended use and rationale for the request
3. Proposed definition.
4. Description of the ingredient.
5. Prior Sanctioned use (common use in United States pre 1958) and/or historical regulation of the ingredient
6. General Description of the Manufacturing processes
7. The purpose of the ingredient
8. Use limitations, if any.
9. Data and observations to support intended use. Data may include controlled feeding trials, if necessary.
10. Summary of safety assessment. The safety assessment should include:
 - A. Reports of available safety studies such as: target animal safety, toxicity, carcinogenicity, mutagenicity, and chronic effects.
 - B. For microbial enzymes, information to demonstrate that they are produced from nonpathogenic and nontoxic strains.
 - C. Levels of known impurities and/or potential contaminants and explanation of how to assure the safety of the ingredient.
 - D. Statement of risk for Target Animals
 - E. Statement of risk related to Human Food.
 - F. Statement of environmental safety
11. List of Cited Literature
12. Proposed labeling (can be generic)

--Excerpted From 2016 AAFCO OP

HEMP REGULATION

Hemp is a variety of *Cannabis sativa* which is the same plant species as marijuana (Johnson, 2015, p. 1). The Agricultural Act of 2014 (“Farm Bill”) of the United States has defined industrial hemp as “*Cannabis sativa* L. and any part of such plant whether growing or not, with delta-9-tetrahydrocannabinol (THC) concentration of not more than 0.3 percent on a dry weight basis” and provides states the ability to allow research institutions and the state department of agriculture to grow industrial hemp for research purposes (Section 7606(b)(2)).

The 2016 Washington State Legislature approved the “hemp bill” (ESSB 6202) in accordance with the 2014 federal Farm Bill. Industrial hemp is now defined in Washington by RCW 15.120.010 as “all parts and varieties of the genera *Cannabis* that contain a THC concentration of 0.3 percent or less by dry weight.” Industrial hemp does not include plants of the genera *Cannabis* that meet the definition of “marijuana,” which is defined in RCW 69.50.101 as “all parts of the plant *Cannabis*, whether growing or not, with a THC concentration greater than 0.3 percent on a dry weight basis.”

Although industrial hemp is genetically and chemically different than marijuana and is not cultivated for the psychoactive drug THC, the United States Drug Enforcement Administration (DEA) recognizes *Cannabis* as a controlled substance, Schedule 1 drug, and does not distinguish between industrial hemp and marijuana.

Animal Feed

There is no exemption for industrial hemp in the Controlled Substances Act (CSA), but Congress has provided an exemption for sterilized *Cannabis* seeds if they are used as part of an animal feed mixture 21.CFR1308.35(b)(2). Sterilized seeds are not viable and do not have the potential to germinate and develop into normal mature plants. Importation, sterilization and commercial distribution of hemp seed is regulated by the DEA (Johnson, 2015, p. 18). Animal feed mixtures containing sterilized hemp seed would still be subject to the FD&C Act.

Food

Hemp products have not been reviewed and approved as food ingredients by the FDA. A food ingredient can be determined to be GRAS because of its long history of use in food, but in 2000 FDA rejected industry GRAS notification for hempseed oil, citing that there was not a substantial history of food consumption for a GRAS assessment (Rulis, 2000). At this time, it is believed that hemp has not been recognized as GRAS, but also that FDA has not taken enforcement action on hemp seed products being used as a human food source (Grebow, 2015). FDA has not published any guidance on the Acceptable Daily Intake (ADI) of THC in hemp food products.

In 2003, the DEA interpreted the CSA to mean that hemp with any amount of THC is a controlled substance and issued rules to prohibit *Cannabis* intended for human consumption in the United States. These rules gave retailers of hemp foods a date after which the DEA would seize hemp food products from the shelves. Hemp trade associations, retailers and Canadian exporters responded and were able to get a court order blocking DEA enforcement of the interpretative rule. Industry argued that parts of hemp used for food, seed and oil, contain negligible amounts of THC after processing.

The hemp industry initiated a voluntary program to certify hemp seed products, the Test Pledge Program (Johnson, 2015, p. 15-16). The Test Pledge Program requires that every lot of hemp oil and hemp nut (the inner portion of the seed that remains after the seed shell is removed) must be tested for THC using the protocol set forth in Canada (Hemp Industries Association, n.d.). The Test Pledge covers the most commonly consumed products, hemp nut and oil, but does not cover products that contain the whole hemp seed or hemp flour.

Other Countries

Approximately thirty countries in Europe, Asia, North and South America grow hemp (Johnson, 2015, p.9). Different countries take different approaches to regulation, including the use of hemp seed for human food or animal feed and acceptable levels of THC. Canada has a highly regulated hemp industry, though it has not yet approved hemp as animal feed. Lessons learned from other countries may be helpful for rulemaking in Washington. See Appendix D for more detail.

1.3 Hemp Seed Products

The five basic hemp seed products listed below reflect various levels of hemp seed processing. Hemp seed meal is a by-product from hemp seed oil production.

- Whole Hemp Seed
- De-Hulled Hemp Seed (sometimes called “hemp nut”)
- Hemp Seed Oil
- Hemp Seed Meal or Cake from Oil Processing
- Hemp Seed Hulls

The hemp plant produces cannabinoids, terpenophenolic compounds that are closely associated with the pharmacological activity of *Cannabis* (Upton, Craker, ElSohly, Romm, Russo, Sexton, Marcu, & Swisher, 2014, p. 33). The highest concentration of THC and other cannabinoids in hemp is found in the bract enclosing the seed. (UNODC, 2009, p. 19). If the varieties of hemp seed are not selected, cultivated, processed and handled carefully, cannabinoids can be present in hemp seed products at a significant level. For example, hemp seed oil can absorb cannabinoids during cold pressing. Processing and handling also can transfer cannabinoids from the resin of the flowers or leaves to the seeds.

The United States imports hemp from other countries. Suppliers of hemp to the U.S. include European Countries, China and Canada. China is the largest supplier of raw and processed hemp for fiber in the U.S., while Canada is the largest source of hemp seed and cake (Johnson, 2015, p.7).

1.4 Laying Hens

"Laying hen" is a term used for a female chicken (about 18 weeks of age) that is kept for the primary purpose of producing eggs for human consumption. Evaluating the appropriateness of hemp seed products as a feed ingredient for laying hens requires understanding both hens and eggs, particularly as they relate to human consumption. Key points include:

- A laying hen on average may consume about a quarter of a pound of feed per day containing approximately 16% protein, 3% calcium, among many other nutrients.
- Per capita consumption of eggs in the United States for 2014 was reported to be around 260.5 (USDA, 2014).
- The chicken eggs are made up of two primary components—yolk and albumen. It takes about 10 days for a yolk to develop from the very small to the average size. The egg albumen (egg white), on the other hand, is secreted in about three hours.
- Fatty acid composition of chicken egg yolks has been shown to be altered due to the fatty acid composition of a hen's diet. For example, the color of the egg yolk can be easily altered due to the presence and amounts of fat soluble pigments like xanthophyll, a carotenoid pigment found in legumes like alfalfa.

In commercial egg production in Washington State, when a hen's productive life of about two years is finished, the chickens, called "spent hens," are terminated, and the spent hen does not usually enter the human food chain. Currently, no plant in Washington State processes spent hens for human consumption (based on personal communication and survey of major egg producing firms in Washington). Recent inspections by WSDA showed that a significant number of spent hens were processed as mink feed. However, in small-scale farming, an individual poultry producer may choose to make use of the spent hens for food.

2. Study Findings

The sub-sections below contain a summary of what WSDA found in its review. See appendices for more detailed information. The findings are numbered consecutively and are grouped according to four primary areas of concerns that need to be addressed for WSDA to deem hemp seed products to be appropriate feed ingredients for laying hens:

1. Nutritional value for laying hens
2. Risk to laying hens – health and performance
3. Risk to humans/consumers
4. Standardization

It is important to remember that these findings are WSDA’s assessment of what others’ research indicates, and not the results of primary research by WSDA. Some findings indicate more information is needed.

2.1 Nutritional Value for Laying Hens

FINDING 1. The available research indicates that hemp seed products typically contain nutritional components beneficial to laying hens.

It has been reported that typical seed composition is 30% oil and 25% protein with a considerable amount of fiber (Callaway, 2004, p.65). The composition of hemp seed will vary based on the variety grown (genetics), agronomy, weather conditions and post-harvest processing conditions. Proximate analysis can vary because of crop differences and differences in methodology used for analysis. Different hemp seed products also have different value, due to what portions of the hemp seed they contain. Factors such as processing, storage and age of the samples being tested can contribute to the variability of the fatty acid profile of hemp seed oil (Leizer, Ribnicky, Poulev, Dushenkov, & Raskin, 2000 p. 40).

WSDA averaged analysis data of hemp seed products from reported scientific study results on hemp seed products sourced from different countries, from different cultivars and under different agronomic and post-harvest processing conditions. Analysis shown below is a generalization only, but it illustrates the potential nutritional value for laying hens.

- In general, **whole hemp seed** is a good source of protein (approximately 24%), oil (approximately 30%) and neutral detergent fiber (approximately 35%).
- In general, **de-hulled hemp seed** is a good source of protein (approximately 32%) and oil (approximately 44%).
- In general, **Hemp Seed Meal (HSM)** is a good source of protein (approximately 32%), oil (approximately 11%) and neutral detergent fiber (39%).
- **Hemp seed hulls** are primarily a source of neutral detergent fiber (approximately 65%); however, the hulls are also a source of protein, oil and energy.

“Neutral detergent fiber” is fiber measured through the “neutral detergent” method, including lignin, cellulose and hemicellulose, which are not generally or significantly broken down for absorption by hens.

- In general, **hemp seed oil** is a good source of polyunsaturated fatty acids (PUFA), approximately 80%, and more specifically is a good source of omega-6 linoleic acid (approximately 55%) and omega-3 alpha-linolenic acid (approximately 20%).
- Albumin and edestin are the two main proteins in hemp seed, and they are rich in amino acids. In fact, the protein in hemp seed is comparable to the high quality protein available from egg white and soybean (Callaway, 2004 p. 69).

See Appendix B for more detail, including reported nutritional values for vitamins and minerals in the Finola variety of hemp seed.

2.2 Risk to Laying Hens – health and performance

FINDING 2. Although current results for feeding hemp seed products to laying hens are encouraging, more studies are advisable to understand effect on laying hen performance and to rule out risks to laying hens

Feeding studies are important for identifying the appropriate use of ingredient in laying hen’s diet. WSDA found only five recently published feeding studies (one from Germany, four from Canada) that evaluated the use of hemp seed products as feed for laying hens. Each study had its own focus and approach, and results were not duplicated among studies. Some results include data on laying hen health, egg content and quality, and were generally encouraging, but not all aspects of hen health were covered. Some studies had varying results.

In addition, the FDA Center for Veterinary Medicine recommends that studies intended to evaluate the safety of substances for use in the diets of laying hen should be 16 weeks in duration (Conway, 2015). One study met that recommendation. The others ranged from 4 weeks to 12 weeks. Two of the 12-week studies included a 10-14 day adaptation period.

Additional research and follow-up studies may be able to fill the gaps needed to ensure hen performance and safety. Here’s a quick profile of the result of the feeding studies WSDA reviewed:

1. Feeding hemp seed meal up to 20% of the diet to 43-week-old DeKalb Sigma hens for a 4-week period had no significant differences for egg production, feed consumption, feed efficiency, body weight change or egg quality (Silversides & Lefancois, 2005, p. 231). The study was looking for suitable use for the by-product of hemp oil production.
2. In a 6-month study, researchers concluded that compound feed with up to 10% of either hemp seed, rapeseed or linseed cake does not negatively influence the laying performance of hens and provides the possibility for enrichment of yolk fat with omega-3 PUFA (Halle & Schöne, 2013, p. 191).
3. In a 12-week study including up to 12% hemp seed oil or up to 20% hemp seed in the diet did not affect feed intake, final bird weights, and average hen-day egg production in comparison

to a control diet of wheat and barley (Gakhar, Goldberg, Jing, Gibson & House, 2012, p. 701). There was some variability in production data, and hens consuming 4% hemp seed oil did exhibit significant depression in feed intake, but this was not seen in the hens that consumed the diets with a higher percentage of hemp seed oil (p. 708). Researchers concluded that a study with a larger sample size might provide insight as to the variance with hens that consumed 4% hemp seed oil. This 12-week study, which included a 10-day adaptation period, was designed to assess the effect of hemp seed and hemp seed oil in laying hen diets on measures of production, egg quality and fatty acid profile of the egg yolks. Another objective was to examine changes in gene expression of enzymes critical for the desaturation and elongation of longer chain PUFA.

4. A 12-week study published in 2014 aimed to provide both data on the laying hen blood biochemistry as well as data on hen performance and egg quality (Neijat, Gakhar, Neufeld, House, 2014, p.2827). Diets were formulated with 10, 20, or 30% hemp seed by weight or 4.5% or 9.0% hemp seed oil by weight.

Blood biochemistry focused on measuring the effect of hemp seed on the laying hen's liver. The high content of unsaturated lipids in hemp seed makes it susceptible to oxidation and can increase the susceptibility of laying hens to hepatic diseases (p. 2828). Changes in liver function affects the metabolism of minerals which are important for egg shell development. This study found that hemp seed and hemp seed oil were well-tolerated by the laying hens. Because there was a high quantity of readily oxidizable PUFAs in the diets, 150 IU of vitamin E and 125 mg of ethoxyquin per kilogram of diet were included as part of the vitamin premix in the feed formulations (p.2829).

Hen performance was not largely affected by the inclusion of hemp seed or hemp seed oil in the diet. At 30% hemp seed, though, egg weight was significantly lower in the first 8 weeks of the study compared to birds fed lower levels of hemp seed or a control diet based on soybean meal, barley and wheat (Neijat et al., 2014 p. 2830). Since egg weight from the birds fed 30% hemp seed stabilized after 8 weeks, it was suggested by the researchers that laying hens would benefit from a rearing period to adapt to the hemp derived diet (p. 2835). Egg quality measurements were not influenced by including hemp seed or oil to the diet and provided additional support for the use of these products in laying hen diets (p.2835).

Blood samples were taken from the laying hens at week 6 and 12. The blood was submitted to an outside lab for plasma chemistry analysis for creatine kinase (CK) in order to assess if there was damage to muscle membranes (Diaz, as cited by Neijat et al. 2014, p. 2835). AST and GGT were analyzed to assess liver function. There was no significant changes in enzymes when hemp product diets were fed to laying hens as compared to a control group, and this supports the safety of using hemp seed derived products in laying hen diets (p. 2839).

5. In another 12-week study published online in 2015, the focus was the distribution of fatty acid profile in the major triacylglycerol and phospholipid fractions within the egg yolk. (Neijat, Suh, Neufeld, House, 2016, p.601). This study had a 2-week adaptation period and hens were

fed diets including hemp seed (10, 20 and 30%) or hempseed oil (4.5 or 9%). Results indicate that hempseed products improved the nutritional value of the egg, and that overall, hempseed products in laying hen diets results in maximum total omega 3-PUFA enrichment achievable by week 8.

2.3 Risk to Humans/Consumers

FINDING 3. Information is needed on the transfer of THC and other cannabinoids to the eggs and tissue of the laying hen.

FINDING 4. Information is needed on the human Acceptable Daily Intake (ADI) for THC and other cannabinoids.

FINDING 5. Feeding hemp seed products to laying hens has the potential to substantially alter the nutritional profile of the egg, and will likely prompt the FDA to request a food additive petition.

Because laying hens, by definition, are producing eggs for human consumption, risks to humans must be considered. The Washington State Department of Health (DOH) has indicated that it is “unable at this time to determine whether the practice of feeding laying hens hemp seed is safe for the public.” See Appendix A.

It is well known that what a laying hen eats affects the eggs it lays. Feeding studies confirm that fatty acid composition of chicken egg yolks is altered by the fatty acid composition of their diets. However, it is not known whether THC or other cannabinoids present in hemp seed products are passed through to laying hen edible tissue and eggs, and thus can be ingested by consumers. Milk excretion of THC has been documented in human and farm animals (EFSA, 2015, p. 36). There is almost no information on transfer of THC to the edible tissue of animal products and eggs (EFSA, 2015, p. 36). In the absence of residue data on cannabinoids present in hemp transferring to the egg, it should be assumed all cannabinoids present in hemp transfer to the egg (Conway, 2015).

It has been reported, though, that when the hemp seed in laying hen feed has very low levels of THC (0.001%), THC has not been detected in some samples of laying hen tissue (Goldberg, 2015). However, analytical methods and limitations for the non-detected results were not provided. And it is unknown if results for tissue or eggs would vary according to the length of time a hen has been fed a diet that includes hemp seed.

Something else that has not been established in the United States is how much THC or other cannabinoid can be ingested on a daily basis over a lifetime without an appreciable health risk. No known Acceptable Daily Intake (ADI) has been established, and further studies evaluating tolerance determinations will be needed.

Some countries have developed tolerances for THC in hemp-based foods, but the other cannabinoids, such as CBD, have not been studied.

- The European Food Safety Authority Panel on Additives and Products or Substances used in Animal Feed (EFSA FEEDAP) established a provisional maximum tolerable daily intake level (PMTDI) for THC of 0.0004 mg/kg bw, which corresponds to 0.024 mg for a 60 kg adult and 0.0048 for a 12 kg child. The panel considered both acute and pharmacological effects when establishing the PMTDI (EFSA, 2011 p. 16).
- In contrast, the European Industrial Hemp Association proposes that the ADI of THC be 0.035 mg/kg bw (Grotenhermen & Carus, 2011, p. 2).
- Other countries that have established a tolerable daily intake (TDI) for THC include New Zealand at 0.006 mg/kg bw and the Republic of Croatia at 0.5 mg/kg bw (EFSA, 2015, p. 11-12).

Even without the concerns related to THC and other cannabinoids, hemp seed's effect on the nutritional composition of the egg must be considered.

- Research has shown that hemp seed meal in a laying hen diet increases the amount of omega-3 PUFA available in eggs (Silversides & Lefancois, 2005, p. 233).
- Recent studies have further shown that the inclusion of hemp seed products in laying hen feed are effective in manipulating the fatty acid profile of the total lipid, triacylglycerol (TAG) and total phospholipid (PL) fractions of yolks while increasing the omega-3 fatty acids (Neijat, et al 2016, p.601).
- Current research indicates that 12% inclusion of hemp seed oil in the diet of a laying hen could raise total omega-3 content from 1.0 mg to 11.6 mg per gram of yolk (Goldberg, Gakhar, Ryland, Aliani Gibson, House, 2012, p. 156).

In such instances, where a food that people routinely consume is altered to contain more or less of a nutrient than typical, FDA will have human health concerns (Conway, 2015) and request a food additive petition for the feed ingredient.

2.4 Standardization

FINDING 6. Standard, validated analytical methods to determine low-level cannabinoid residue foods need to be developed.

FINDING 7. The definition of industrial hemp provided in RCW 15.120.010 is only a starting point for defining hemp seed products for laying hen feed. Additional parameters are needed to assure standardization and appropriate cannabinoid level in hemp seed products.

Ensuring content limits of THC and other cannabinoids requires being able to test for them. However, analytical methods for the determination of cannabinoids in foods are not well established (see Appendix C). Industrial hemp producers in Canada must comply with the IHR Technical Manual and use an authorized sampler and competent lab licensed under Section 9 of the Narcotic Control

Regulation. Work to establish methodology to quantify and regulate cannabinoids in hemp food has been hindered in the United States by the federal classification of *Cannabis* as a Schedule 1 drug. Further research is necessary to develop standard analytical methods to determine cannabinoid residue in foods. Approved, standard analytical methods would be needed to ensure accuracy and consistency when testing for the presence of THC and other cannabinoids.

As the nutritional analysis studies show, different hemp seed products have different characteristics. Definitions need to be developed for each type of product (whole seed, oil, meal, etc.). Also, manufacturing or processing of hemp seeds and hemp seed oil is an important control step. For example, hemp seed products, because of the high level of PUFAs, must be processed and stored appropriately to minimize oxidation. Based on feeding study results, the use of antioxidants in hemp seed products is necessary to prevent oxidation PUFAs and limit the susceptibility of laying hens to hepatic diseases (Squires & Leeson, 1988; Schumann et al., 2003 as cited in Neijat et al., 2014, p. 2828). In addition, it is important that hemp seeds fed to animals are sterilized per DEA regulations. Sterilization will render the seed non-viable and prevent any unattended proliferation of the hemp plant in the United States.

3. Conclusion

Based on its study findings, WSDA has determined that, due to lack of research related to public health, it is not yet appropriate to move forward with administrative actions to allow commercial feed license holders to include hemp in their formulations for laying hen feed.

As Finding 1 shows, hemp seed products are clearly promising as a source of nutrition for laying hens, but as the other findings show, there are gaps in available information. Filling these gaps before moving ahead is necessary for ensuring consumer and animal safety.

For example, if THC passes to the egg, knowing the human tolerance for ingesting THC becomes important to ensuring the safety of the consumer. Controlling the amount of THC that an egg contains may require limiting the percentage of hemp seed in a compound feed and/or the amount of THC in the hemp seed product used. Standard analytical methods would be needed for such testing, and for determining if (and how much) THC passes to the egg.

Other countries are currently conducting research on optimizing hemp production as a food source. Canada already allows highly regulated hemp seed in human food, but not animal feed. Considering nutritional and economic potential, it is reasonable and important to conduct the needed research to utilize hemp seed in animal and human food. THC and other cannabinoids are present at a very low level in properly cultivated and processed hemp seed.

WSDA is continually involved in discussions with AAFCO on defining hemp seed products in animal feed. WSDA plans to continue its efforts with AAFCO and FDA on defining hemp seed products as animal feed ingredients not just for Washington State, but also throughout the United States. The regulatory status of industrial hemp appears to be changing rapidly and it is possible that the data needed to determine the safety of hemp seed for laying hens will be available in the near future. If such data becomes available, and if it adequately supports safe use, WSDA will be able to move forward with appropriate administrative actions to allow use of hemp seed products as a laying hen feed ingredient.

Appendices

Appendix A – Communication from State and Federal Agencies

Appendix B – Nutrients in Hemp Seed Products

Appendix C – Cannabinoids in Hemp Seeds

Appendix D – Regulation of Hemp in Other Countries

Appendix E - FDA/AAFCO Memorandum of Understanding (MOU 2225-07-7001)

Appendix F – Abbreviations

Appendix G – References

Appendix A – Communication from State and Federal Agencies



STATE OF WASHINGTON

DEPARTMENT OF HEALTH

OFFICE OF ENVIRONMENTAL PUBLIC HEALTH SCIENCES
243 Israel Road SE • PO Box 47846 • Olympia, Washington 98504-7846
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February 25, 2016

Derek I. Sandison, Director
Washington State Department of Agriculture
P.O. Box 42560
Olympia, WA 98504-2560

Dear Director Sandison

This letter is in response to your agency's request to evaluate the available information on the use of hemp in commercial feed and to provide an assessment from a public health perspective as to its safety. More specifically, the Department of Health's Office of Environmental Public Health Sciences was asked to review the document provided to us by your department entitled *Hemp Seed Products as Feed Ingredients for Laying Hens, Fall 2015 VM-813* and to provide our scientific opinion on the practice of using hemp-containing feeds from a public health agency perspective.

As your staff are aware, the U.S. Department of Food and Drug Administration (FDA) has not approved of food products containing hemp for either human or animal consumption due to the possibility that these products either contain or may contain low levels of the psychoactive compound tetrahydrocannabinol (THC). While hemp-containing foods for human consumption are currently being sold to consumers in Washington State and federal health agencies have not taken enforcement action against these unapproved products, it does not mean that these products are free of THC or have been determined to be safe for human consumption.

In order to evaluate the safety of THC in food products there are several unknowns that would first need to be addressed. First and foremost, there currently is no known Acceptable Daily Intake (ADI) for ingesting THC. An ADI is defined as the measure of the amount of a specific substance (e.g. THC) in food that can be ingested on a daily basis over a lifetime without an appreciable health risk. Without such criteria, it is not possible to compare estimated exposures of THC in eggs or egg-containing products to determine if they are safe for consumption.

The use of hemp seed products as feed ingredients for laying hens may be beneficial in terms of increasing healthy omega 3 and 6 fatty acids. Yet at the same time, hemp feed may also be

transferring THC into eggs or egg-containing products. I was not able to identify any available research to help determine whether or to what extent THC may be transferred to eggs from chickens consuming hemp feed products. However, there are studies involving cows using hemp feed that have shown that THC can transfer to milk and milk products. Although this is merely an observation, it may indicate the likelihood that THC in hemp feed fed to hens may accumulate in eggs. Without the ability to measure or estimate THC transfer to eggs, calculating potential exposures necessary for comparison with health criteria is not possible.

In addition to specific concerns with THC, there are also numerous other cannabinoids in hemp that may act additively or synergistically. These would need to be evaluated and safe exposure levels determined. Another unresolved issue is the lack of an approved, standard analytical method for testing of cannabinoids in both feed and food products.

While it does not appear that trace amounts of THC pose a significant human health concern, without verification of the amount of THC accumulating in egg and egg products, many parents of children may strongly object to their children being exposed to psychoactive drugs such as THC that have not been deemed safe for children.

In summary, given the available information on exposure, safety, and quantification of THC in eggs and egg products, the Department of Health is unable at this time to determine whether the practice of feeding laying hens hemp feed is safe for the public.

Sincerely,

A handwritten signature in blue ink, appearing to read "David McBride".

David McBride
MS Toxicologist

cc: Ali Kashani, Ph.D., Senior Feed Advisor

From: Conway, Charlotte [<mailto:Charlotte.Conway@fda.hhs.gov>]
Sent: Thursday, October 1, 2015 12:29 PM
To: Bautista, Susie (AGR) <SBautista@agr.wa.gov>
Subject: Hemp follow-up

Ms. Susie Bautista
Washington State Department of Agriculture

Via email to: SBautista@agr.wa.gov

Dear Ms. Bautista,

This email is to follow-up on our September 11, 2015 telephone conversation. At that time, I stated I would follow-up with information about target animal safety studies for laying hens, provide a link to the guidance document that is most helpful in discussing residues in edible tissues, and explain why a food additive petition is required for a substance intended to influence the edible tissues of the animals consuming the substance.

A study intended to evaluate the safety of a substance for use in the diets of laying hens should generally be 16 weeks in duration, evaluate typical production parameters, hematology, and serum biochemistry. In addition, evaluation of pathology and histopathology data may be necessary to assess safety. To evaluate human food safety, the residues of any cannabinoids in the edible tissue should be evaluated. In the absence of residue data, it should be assumed that all cannabinoids present in the hemp seed meal end up in the egg. The following guidance document provides information for residue chemistry studies that may be useful for your understanding:

<http://www.fda.gov/downloads/animalveterinary/guidancecomplianceenforcement/guidanceforindustry/ucm052521.pdf>

We have not explained in guidance why a food additive petition would be required for a substance intended to influence the edible tissues of the animals consuming the substance. However, this policy relates to human food safety. If foods that people routinely consume are altered to contain more or less of a nutrient than is typical, the amount consumed may reach unsafe levels. For example, the FDA has established a limitation on the amount of eicosapentaenoic acid or docosahexaenoic acid that a person may consume per day, not to exceed 3.0 grams/person/day.

You also asked about the method used by FDA for analysis of cannabidiol (CBD) in the products that were issued warning letters. I did not find that this information is publically available at this time. A request for this information may be submitted under the Freedom of Information Act (FOIA).

I hope this information is helpful as you complete your project, please feel free to contact me with any additional questions. I can be reached at telephone (240-402-6768), telefacsimile (240-453-6882) or e-mail (charlotte.conway@fda.hhs.gov) and refer to DAF 15238.

Sincerely,
Charlotte E. Conway, MS
FDA Center for Veterinary Medicine
Division of Animal Feeds
Nutrition and Labeling Team I
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Rockville, MD 20855
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Appendix B - Nutrients in Hemp Seed Products

WSDA examined research identifying:

1. Proximate analysis (to include crude protein, crude fat and crude fiber)
2. Composition of hemp seed oil
3. Amino acid composition
4. Nutritional values for vitamins and mineral

KEY to the research studies identified by number (e.g., Study 1, Study 8) is at the end of this appendix.

1. PROXIMATE ANALYSIS OF HEMP SEED PRODUCTS

The composition of hemp seed will vary based on the variety grown (genetics), agronomy, weather conditions and post-harvest processing conditions. It has been reported that typical seed composition is 30% oil and 25% protein with a considerable amount of fiber (Callaway, 2004, p.65). Proximate analysis can also vary because of differences in methodology used for analysis. For example, the data in the tables 1-3 is from international studies researching potential outlets for hemp by-products and also from studies conducted to select and breed hemp varieties for optimum nutritional benefit. By-products of hemp seed include the seed meal or cake from oil processing and hemp hulls.

NOTE: Proximate analysis of hemp seed products data were averaged from reported scientific study results on hemp seed products sourced from different countries, from different cultivars and under different agronomic and post-harvest processing conditions. Data is a generalization of analyses. Analysis methods, reproducibility and varietal differences need to be investigated further.

1.1 Whole Hemp Seed

Published research which included proximate analysis of whole hemp seed was reviewed and the data are presented in Table 1. In general, whole hemp seed from various cultivars and from different geographical regions is a good source of protein (approximately 24%), oil (approximately 30%) and neutral detergent fiber (approximately 35%).

TABLE 1: Whole Hemp Seed: Proximate Analysis

Study	Country of cultivation	Variety	DM%	MC%	PRO %	Oil%	Ash %	NDF%	GE (MJ/KG)
1	Finland	Finola		6.5	24.8	35.5			22
2	Canada	10 varieties	93.8		25.6	29.2	5.5	35.7	
3	Canada	Unika B	93.4		24.9	33.2	5.8	37.2	24.9
4	Canada	4 cultivars	94.1		24	30.4	4.8	32.1	24.2
5	Romania	5 varieties*				27.8			
6	China	No data	95.1		21.1	31.5	8.8		
MEAN			94.1 (0.6)	6.5	24.1 (1.6)	31.3 (2.5)	6.2 (1.5)	35.0 (2.1)	23.7(1.2)

DM=Dry Matter, MC= Moisture, PRO=Protein, NDF=Neutral Detergent Fiber, GE=Gross energy

*hemp was grown for phytoremediation

1.2 De-hulled Hemp Seed

Published research, which included proximate analysis of de-hulled hemp seed, was reviewed and the data is presented in Table 2. Also included with this data are analytical data from report 12012 on hulled hemp seeds found in release 28 of the USDA nutrient data base (REF). In general, de-hulled hemp seed from various cultivars and from different geographical regions is a good source of protein (approximately 32%) and oil (approximately 44%). Further details on each research study line item are provided in Appendix A.

TABLE 2: De-hulled Hemp Seed: Proximate Analysis

Study	Country of cultivation	Variety	DM%	MC %	PRO%	Oil%	Ash%	NDF%	GE (MJ/KG)
1	Finland	Finola		5	33.0	44	6		20.9
4	Canada	4 cultivars	95.1		35.9	46.7	6.4	7.8	27.7
7	China	8 cultivars		6.3*	28.8*	42.2*	6.0*		
REF				5.0	31.6	48.8			23.2
MEAN			95.1	5.4 (0.6)	32.3 (2.6)	45.4 (2.5)	6.1 (0.2)	7.8	23.9 (2.8)

DM=Dry Matter, MC= Moisture, PRO=Protein, NDF=Neutral Detergent Fiber, GE=Gross energy

REF= USDA nutrient database

* There was a large variance in the samples from China. De-hulled seeds had an oil content ranging from 28.5-50.6%, protein content that varied from 20.49—37.6%, moisture from 4.9-6.85% and ash 4.18-7.08%. Variance can be attributed to the span of varieties of hemp.

1.3 Hemp Seed Meal or Cake from Oil Processing

Published research that included proximate analysis of Hemp Seed Meal (HSM) is presented in Table 3. In general, HSM from various cultivars and from different regions is a good source of protein (approximately 32%), oil (approximately 11%) and neutral detergent fiber (39%).

TABLE 3: Hemp Seed Meal or Cake from cold pressing seed: Proximate Analysis

Study	Country of cultivation	Variety	DM%	MC %	PRO%	Oil%	Ash%	NDF%	GE (MJ/KG)
1	Finland	Finola		5.6	33.5	11.1			17
3	Canada	Unika B	91.4		30.7	16.4	7.2	41.4	21.2
4	Canada	4 cultivars	95.1		40.7	10.2	6.7	30.5	20.4
8	Serbia	Helena		7.9*	27.9*	11.8*	6.7*		
9	No data**	No data			29.4	10.1	7.1	36.9	
10	No data	USO 31	91.2		28.1	11.0	7.2	44.7	9.2
MEAN			92.6 (1.8)	6.8 (1.2)	31.7 (4.4)	11.8 (2.1)	7.0 (0.2)	38.9 (6.1)	17.0 (4.7)

DM=Dry Matter, MC= Moisture, PRO=Protein, NDF=Neutral Detergent Fiber, GE=Gross energy

*Hemp seed meal was prepared in a laboratory for further fractionation

** Work published in Italian Journal refers to hemp flour as a byproduct from the extraction of the oil from the seeds

In comparison to other crops' oil seed meal nutrition, HSM is a good source of protein, oil and energy. Data on soy meal (defatted) and safflower seed meal (partially defatted) was obtained from the USDA National Nutrient Database for Standard Reference Release 28. Table 4 is a comparison of HSM to other seed meal products. Hemp seed oil is a valuable natural organic crop and oil extraction is accomplished through cold pressing which is not as efficient as solvent extraction. Therefore, the oil level in HSM is substantially higher than soymeal and safflower meal.

TABLE 4: Hemp Seed Meal compared to defatted Soy and Safflower meal

	%MC	PRO%	OIL%	GE (MJ/KG)
Soymeal	6.9	49.2	2.4	14.1
Safflower meal	6.4	35.6	2.4	14.3
HSM MEAN	6.8	31.7	11.8	17.0

MC= Moisture Content, PRO=Protein, GE=Gross energy

1.4 Hemp Hulls:

Only one research paper included proximate analysis of hemp seed hulls. Data is presented in Table 5. Hemp seed hulls are primarily a source of neutral detergent fiber (approximately 65%); however, the hulls are also a source of protein, oil and energy.

TABLE 5: Hemp Seed hulls: Proximate Analysis

Study	Country of cultivation	Variety	DM%	MC %	PRO%	Oil%	Ash%	NDF%	GE (MJ/KG)
4	Canada	4 cultivars	94.9		12.7	10.3	3.9	64.9	20.2

DM=Dry Matter, MC= Moisture, PRO=Protein, NDF=Neutral Detergent Fiber, GE=Gross energy

2. COMPOSITION OF HEMP SEED OIL

In addition to its protein and fiber content, hemp seed is valued for the two essential fatty acids alpha-linolenic acid and linoleic acid (Callaway, 2004). Factors such as processing, storage and age of the samples being tested can contribute to the variability of the fatty acid profile (Leizer, Ribnicky, Poulev, Dushenkov, & Raskin, 2000 p. 40). For example, higher concentrations of gamma linolenic acid (GLA) and stearidonic acid (SDA) are found in the highest concentrations in the seeds of hemp varieties that are derived from extreme northern climates (Blade et al., 2005 & Callaway et al., 1997 as cited in Callaway, 2009, p.186)

Published research which includes fatty acid analysis of hemp seed oil was reviewed and the data is presented in Table 5. In general, hemp seed oil from various cultivars and different regions is a good source of polyunsaturated fatty acids (PUFA), approximately 80%, and more specifically is a good source of omega-6 linoleic acid (approximately 55%) and omega-3 alpha-linolenic acid (approximately 20%).

TABLE 6: Hemp Seed Oil: Fatty acid analysis

FATTY ACID	Carbon Chain	Study 1	Study 1	Study 2	Study 6	Study 11	MEAN
		Finola	Fiber Type	10 Canadian Varieties	from China	Fedora 19	
Palmitic	C16:0	5	8	6.8	6.7	6	6.5 (1.0)
Stearic	C18:0	2	3	2.5	2.9	1.5	2.4 (0.6)
Oleic	C18:1	9	11	11.8	11.5	10.5	10.8 (1.0)
Linoleic (LA)	C18:2 (omega 6)	56	55	56.1	52.5	57	55.3 (1.5)
Gamma-linolenic (GLA)	C18:3 (omega 6)	4	1	3.2	Not reported	3.5	3.1 (1.1)
Alpha-linolenic (ALA)	C18:3 (omega 3)	22	21	16	23	17	19.8 (2.8)
Stearidonic Acid (SDA)	C18:4 (omega 3)	2	<1	0.9	Not reported	Not reported	1..4 (0.5)
PUFA%		84	77		87.9		(4.5)

3. AMINO ACID COMPOSITION OF HEMP SEED PRODUCTS

Albumin and edestin are the two main proteins in hemp seed and they are rich in amino acids. In fact, the protein in hemp seed is comparable to the high quality protein available from egg white and soybean (Callaway, 2004 p. 69). Variety, genetics, and agronomy are all aspects that influence the amino acid composition (House, Neufeld, & Leson, 2010, p. 11801-11802). In study 4, the amino acid profile of four varieties of hemp seed products approved in Canada were analyzed and reported. Average values of the amino acid composition of the various varieties are in table 7.

TABLE 7: Hemp seed amino acid composition

	Whole seed %	De-hulled seed %	HSM %	Hemp Hulls %
Asparagine	2.39	3.66	3.66	0.9
Threonine	1.01	1.27	1.35	0.36
Serine	1.19	1.7	1.73	0.42
Glutamate/Glutamine	3.74	6.23	6.03	1.19
Proline	0.9	1.62	1.59	0.69
Glycine	1.06	1.61	1.66	0.41
Alanine	0.96	1.52	1.61	0.40
Cysteine	0.41	0.65	0.7	0.18
Valine	1.14	1.78	1.91	0.6
Methionine	0.56	0.94	0.88	0.18
Isoleucine	0.8	1.29	1.45	0.39
Leucine	1.49	2.14	2.35	0.71
Tyrosine	0.68	1.28	1.15	0.40
Phenylalanine	1.03	1.43	1.62	0.53
Histidine	0.55	0.97	0.93	0.25
Lysine	0.86	1.26	1.32	0.33
Arginine	2.28	4.55	3.91	0.94
Tryptophan	0.23	0.38	0.39	0.06

Using the Food and Agriculture/World Health Organization (FAO/WHO) reference protein for children 2-5 years of age, the following amino acid scores in Table 8 were obtained for the hemp seed products in study 4 (House et al., 2010, p.11804). The amino acid score of a protein establishes if the dietary protein meets the amino acid requirements of an individual. Scores that are 1.0 or greater indicate that the amino acid is not limiting. Lysine is the first limiting amino acid in all hemp protein source tested.

TABLE 8: Hemp seed protein products amino acid scores

	Whole seed	De-hulled HS	HSM	Hemp Hulls
Histidine	1.20	1.42	1.25	1.30
Isoleucine	1.20	1.27	1.33	0.96
Leucine	0.94	0.90	0.91	0.89
Lysine	0.62	0.61	0.58	0.50
Methionine +Cysteine	1.63	1.77	1.60	0.90
Phenylalanine + Tyrosine	1.13	1.20	1.13	1.02
Threonine	1.23	1.04	1.02	0.85
Tryptophan	0.87	0.96	0.91	0.52
Valine	1.36	1.42	1.40	1.59

Because the digestibility of proteins can be affected by protein structure, the presence of anti-nutritional compounds and high temperature processing, protein digestibility-corrected amino acid score determination (PDCAAS) by rate bioassay were also reported in study 4. Average results of PDCAAS in study 4 are reported in table 9 (House, et al. 2010, p.11805)

TABLE 9: Hemp seed protein products protein digestibility corrected amino acid scores compared to other protein sources

	PDCAAS%
Egg White	100
De-Hulled Hemp Seed	61
Hemp Seed	51
Rolled oats	57
HSM	48
Whole wheat	40

Results indicate that the protein in hemp seed products is very digestible and removing the hull improves the digestibility of the protein.

4. NUTRITIONAL VALUES FOR VITAMINS AND MINERALS IN HEMP SEED

Nutritional values for vitamins and minerals in the Finola variety of hemp seed were also reported in Study 1, and shown in Table 10 below.

TABLE 10

Typical Nutritional Values for Vitamins and Minerals in the Finola variety of Hemp seed

Vitamins and minerals	Nutritional values (mg/100gm)
Vitamin E (total)	90.0
Thiamine (B1)	0.4
Riboflavin (B2)	0.1
Phosphorous (P)	1160
Potassium (K)	859
Magnesium (Mg)	483
Calcium (Ca)	145
Iron (Fe)	14
Sodium (Na)	12
Manganese (Mn)	7
Zinc (Zn)	7
Copper (Cu)	2

KEY TO STUDIES REFERENCED IN TABLES 1-10

Study 1 refers to *Hemp Seed Oil*, written by J.C. Callaway and David Pate in 2009. This research was conducted to understand the nutrient benefit of the Finola variety of industrial hemp.

Study 2 refers to *Seed composition of ten industrial hemp cultivars approved for production in Canada* (2015) researched by Eliana Vonapartis, Marie-Pier Aubin, Phillippe Seguin, Arif F. Mustafa and Jean-Benoit Charron. The objective of their study was to determine composition of ten industrial hemp cultivars grown in Quebec. This study was comprehensive and did not just focus on one variety. Dual varieties used for fiber and seed were analyzed: Alyssa, Anka, Delores, Jutta and Yvonne and high yielding hemp seed varieties were also analyzed: CanMa, CFX-2, CFX-1, CRS-1 and Finola. Results are consistent with the fact that hemp seed contains a large amount of oil and protein. Seed oil composition varied between 26.9-30.6% and the crude protein ranged from 23.8-28.0%.

Study 3 refers to research conducted in 2005 by Silversides and Lefrancois on feeding hemp to poultry, *The effect of feeding hemp seed meal to laying hens*. This study was conducted because HSM became available for use in animal feed as a by-product from oil production. Hemp seed and HSM came from a cultivar normally grown for fiber (Unika-b). The seed was obtained from a farm in Nova Scotia, Canada.

Study 4 refers to research conducted in 2010 by James House, Jason Neufeld and Gero Leson, *Evaluating the Quality of Protein from Hemp Seed (Cannabis Sativa L.) Product Through the use of the Protein Digestibility-Corrected Amino Acid Score Method*. Hemp seed was grown in Western Canada from one of

four varieties: Finola, USO-14, USO-31 and Crag. USO-14 & USO-31 are dual-purpose crops (fiber and seed) while Crag and Finola are grown for seed.

Study 5 refers to *Nutritive quality of Romanian hemp varieties (Cannabis sativa L.) with special focus on oil and metal contents of seed* (2012) by Marcela Mihoc, Georgeta Pop, Ersilia Alexa and Isidora Radulov which reviewed five Romania hemp varieties grown under drought conditions in 2011. The varieties included Diana monoecious variety, Zenit, Armanca, Silvana and Denise. The conclusion of the study indicated that hemp used for phytoremediation can easily contain metals, such as Cadmium, from the soil and there may need to be heavy metal limits for these seeds if used in food. The average content of the oil in the whole seed of the Romanian hemp varieties is 27.81 and the relative weight of 1000 seed varied between 17-23 grams.

Study 6 refers to *Effect of Hempseed (Cannabis sativa sp.) Inclusion to the Diet on Performance, Carcass and Antioxidative Activity in Japanese Quail* authored by Yusuf Konca, Behzat Cimen, Hasan Yalcin, Mahmut Kaliber and Selma Buyukkilic Beyzi . The researchers analyzed a commercial hemp seed for bird food sourced from China.

Study 7 refers *Analytical Characterization of Hempseed (Seed of Cannabis sativa L.) Oil from Eight Regions in China* (2010) by Tianpeng Chen, Jinfeng He, Jianchun Zhang, Hua Zhang, Hua Zhang, Ping Qian, Jianxiong Hao, and Lite Li. The researchers reviewed eight cultivars of hemp grown in China. The varieties analyzed: Yunma No. 1, Bama Huoma, Liuan Hanma, Beian, Qingshui, Dabaipi, Baotou and Yuci. The authors concluded that Yunma No. 1 and Bama Huoma appear to be the best varieties for oilseed and protein based on kernel yield. The relative weight of 1000 seeds varied between 12.9-50.6 grams and the kernel yield varied between 53-66%. There was much variance amongst the different sources of hemp seed.

Study 8 refers to *Characterization of Byproducts Originating from Hemp oil Processing* by Milica Pojić, Aleksandra Mišan, Marijana Sakač, Tamara Dapčević Hadnađev, Bojana Šarić, Ivan Milovanović and Miroslav Hadnađev which studies the hemp variety Helena which was grown in Serbia. This study suggests evaluates HSM processed in the laboratory. It evaluates meal as a whole and as the different fractions. The study suggests that there might be a nutritional benefit from some fractions of the HSM, while other fractions may be less desirable and have anti nutrient value.

Study 9 refers to the abstract of the study *Chemical characterization of the flour obtained after cold pressing of Cannabis sativa L. seed* (2014) by Folegatti, Ravellini, Baglio, De Cesarei, Fusari, Venturini, and Cavalieri and data is reported on the flour after cold pressing hemp seeds.

Study 10 refers to *Influence of rapeseed cake, linseed cake and hemp seed cake on laying performance of hens and fatty acid composition of egg yolk* (2013) by Ingrid Halle and Friedrich Schöne. The variety of hemp used was USO 31 and the seeds were processed with a screw press. Laying intensity, egg quality and fatty acid composition of egg yolk were investigated based on feed source.

Study 11 refers to *The Composition of Hemp Seed Oil and Its Potential as an Important Source of Nutrition* (2000) by Leizer, Ribnicky, Poulev, Dushenkov and Raskin which is a macro analysis of hemp seed oil. The hemp oil used in this study was pressed from Canadian grown seed of the French variety Fedora-19.

Appendix C - Cannabinoids in Hemp Seed

The hemp plant produces cannabinoids, terpenophenolic compounds that are closely associated with the pharmacological activity of *Cannabis* (Upton, Craker, ElSohly, Romm, Russo, Sexton, Marcu, & Swisher, 2014, p. 33). The hemp plant produces cannabinoids, terpenophenolic compounds that are closely associated with the pharmacological activity of *Cannabis* (Upton, Craker, ElSohly, Romm, Russo, Sexton, Marcu, & Swisher, 2014, p. 33). The highest concentration of THC and other cannabinoids in hemp is found in the bract enclosing the seed. (UNODC, 2009, p. 19). If the varieties of hemp seed are not selected, cultivated, processed and handled carefully, cannabinoids can be present in hemp seed products at a significant level. For example, hemp seed oil can absorb cannabinoids during cold pressing. It is important to evaluate hemp seed products for cannabinoid residue for human and animal health reasons. "Cannabinoids are lipophilic, permeate cell membranes, and have the ability to cross the blood-brain barrier both when inhaled and ingested" (Upton et al., 2014, p. 34). Among the sixty other identified cannabinoids, major cannabinoids in hemp include delta-9-tetrahydrocannabinol (THC), cannabidiol (CBD) and cannabigerol (CBG) type phytocannabinoids. However, "THC and CBD are the most commonly researched cannabinoids in the literature" (Sachs, McGlade, Yurgelum-Todd, 2015, p. 735).

Plants naturally produce chemical compounds, often as a defense system. For example, the terpenes menthol and menthone, produced by the peppermint plant (*Mentha piperita*), can protect against fungal and bacterial attack, yet remain relatively harmless for humans. Toxic effects of chemicals are dose dependent. Foxglove (*Digitalis purpurea*), the principal source of the cardiac glycosides digitoxin and digoxin, can be used in small quantities to treat heart disease, but in high quantities can cause heart attacks (Freeman & Beattie, 2008).

Scientific research determines acceptable dose. For example, the cassia cinnamon plant can naturally contain up to 1% coumarin in the bark, a chemical which is prohibited by FDA for direct addition to food or as a constituent of tonka beans (21CFR 189.130). Coumarin was banned because it has been shown to have hepatotoxic properties in laboratory animals. Scientists in Europe have determined that coumarin has a tolerable daily intake (TDI) of 0.1 mg/kg body weight (bw) daily based on a no-observed-adverse-effect level (NOAEL) for animals (Wang, Avula, Dhammika, Nanayakkara, Zhao & Khan, 2013, p. 4470). For these reasons, there is a set maximum level of coumarin permitted in baked goods in European countries of 0.005% by weight.

1. Quantity of THC and CBD in Hemp Seed Products:

Canada places a limitation on THC in raw and semi-finished hemp products of 10 ppm (0.001%). In contrast, THC limits in Europe exist for the hemp plant but not for hemp seed products. Some countries in Europe, Germany and Switzerland, however, have placed THC limits on the final foods hemp products are used in (Sarmiento, Carus, Grotenhermen, & Kruse, 2015 pp. 15-17).

Limits for CBD in hemp seed products or human food products are not established in Canada or Europe. There is limited data on quantification of CBD in hemp seed products and it is estimated that

CBD intake from hemp seed is typically 10 times that for THC (Grotenhermen, Leson & Pless, 2001, p. 8). The few results on CBD content of hemp seed products confirm that assessment. For example, in 2000, Leizer reported results on CBD (10ppm) and THC (not detectable) in hemp seed oil (p. 41). Using gas chromatography coupled with mass spectrometry (GC-MS) in 2003, Lachenmeier, Kroeher, Musshoff and Madea analyzed for the THC and CBD content of commercially available hemp seed food products available in Germany. Whole hemp seed had a THC content of approximately 1.0 ppm and CBD content of approximately 0.5-1.0 ppm. Hemp seed oil had a THC content of approximately 1.3 ppm and CBD content of approximately 6.5-7.0 ppm. Shelled hemp seed varied between 0.5-3 ppm THC and CBD between 5.0-33.8 ppm (p. 185). Results varied and CBD was not always ten times higher than THC in hemp seed products; variability of results was attributed to processing.

There are varieties of *Cannabis* developed to contain a high percentage of CBD. In the United States, the farm bill defines industrial hemp as *Cannabis sativa L* with a THC content not more than 0.3%. This broad definition has been described as “fuzzy” (Constance Pure Botanical Extracts, 2015) and allows for high CBD strains of industrial hemp with less than 0.3% THC to be grown for CBD extract for medicinal and purposes. These high CBD strains are marketed as a drug, intended to mitigate or treat a disease and are not marketed as a food. This high CBD variety of *Cannabis* should be considered a drug and not a food.

2. Analytical Methods to Quantify THC and CBD in Hemp Seed Products:

Analytical methods for the determination of cannabinoids in foods are not well established. The European community official method uses gas chromatography with a flame ionization detector (GC-FID) (Lachenmeier et al., 2003, p.184). This method, however, is unable to differentiate between the psychoactive THC and the non-psychoactive precursor acids like delta-9-tetrahydrocannabinolic acid-A (THCA-A). The European Food Safety Authority (EFSA) has determined that GC-MS followed by either liquid-liquid extraction (LLE) or solid phase microextraction (SPME) is the method of choice quantifying THC in hemp containing food products. High temperatures generated by the GC injection port and the FID are not generated during hemp seed processing, de-hulling and oil extraction and influence the accuracy of THC quantification by GC-FID. High Performance Liquid Chromatography (HPLC) with an Ultra Violet (UV) detector or MS detector will not generate as high temperatures and can also be utilized for the analysis of hemp seed foods. The DEA requires hemp seed used in animal feed in the United States to be sterilized and this process will likely decarboxylate THCA to THC, therefore, depending on hemp seed processing and legal parameters, methodology may or may not need scrutiny.

Industrial hemp producers in Canada must comply with the IHR Technical Manual and use an authorized sampler and competent lab licensed under Section 9 of the Narcotic Control Regulation. THC in hemp seed is quantified using a GC-MS. Work to establish methodology to quantify and regulate cannabinoids in hemp food has been hindered in the United States by the federal classification of *Cannabis* as a Schedule 1 drug. Further research is necessary to develop standard analytical methods to determine cannabinoid residue foods.

3. Absorption, Metabolism and Excretion of THC:

THC is psychotropic and has a high affinity for cannabinoid receptors which are found in the neuron terminals of the brain regions involved in motor activity, coordination, short-term memory, executive function, appetite and sedation (Sachs, et al., 2015, p.736). THC, despite its high lipophilicity, is incompletely absorbed by ingestion (EFSA, 2015, p.31). It does, however, bind to plasma proteins and distribute widely to tissues and will accumulate in fat for later redistribution. Studies in both rats and humans indicated that the precursor to THC, THCA-A, is not converted *in vivo* to THC (Jung, Meyer, Maurer, Neusüß, Weinmann & Auwärter, 2009, p.1432). THC exhibits extensive tissue distribution in mammals and readily crosses the placenta. In rats and humans, THC is primarily metabolized by a cytochrome P450 (CYP) oxidative biotransformation to the psychoactive metabolite 11-OH-delta 9-THC. This psychoactive metabolite is then further oxidized with help from microsomal aldehyde oxygenase into the inactive 11-nor-9-carboxy- delta 9 THC (EFSA, 2015, p. 33). THC and its metabolites are slowly eliminated and excreted in feces, and urine. Milk excretion of THC has also been documented in human and farm animals (EFSA, 2015, p. 36). There is almost no information on transfer of THC to the edible tissue of animal products and eggs (EFSA, 2015, p. 36), although breast and thigh tissue from laying hens fed hemp seed products has been analyzed for THC and results were non-detected (Goldberg, 2015). Analytical methods and limitations for the non-detected result were not provided.

CBD is the main non-psychotropic cannabinoid in *Cannabis* and has a low affinity for cannabinoid receptors. Industrial hemp varieties have been shown to produce more CBD than THC (Leizer et al., 2000, p. 37) some of the pharmacological actions of CBD include anticonvulsive, anti-inflammatory, antioxidant, antipsychotic, hypnotic and sedative (Upton et al., 2014, p. 35). CBD may hinder the oxidative metabolism of THC (EFSA, 2015, p. 35).

4. Tolerances for Naturally Occurring THC in Hemp Seed Products:

Tolerances of hemp cannabinoid residue in food have not established in the United States. Tolerances suggest an Acceptable Daily Intake (ADI) as an amount that will not have harmful effects when consumed by a person. Some countries have developed tolerances for THC in hemp-based foods, but the other cannabinoids, such as CBD, have not been studied.

The European Food Safety Authority Panel on Additives and Products or Substances used in Animal Feed (EFSA FEEDAP) established a provisional maximum tolerable daily intake level (PMTI) for THC of 0.0004 mg/kg bw, which corresponds to 0.024 mg for a 60 kg adult and 0.0048 mg for a 12 kg child. The panel considered both acute and pharmacological effects when establishing the PMTDI (EFSA, 2011 p. 16). In contrast, the European Industrial Hemp Association proposes that the ADI of THC be 0.035 mg/kg bw (Grotenhermen & Carus, 2011, p. 2). Other countries that have established a tolerable daily intake (TDI) for THC include New Zealand at 0.006 mg/kg bw and the Republic of Croatia at 0.5 mg/kg bw (EFSA, 2015, p. 11-12). Further risk assessments on the ingestion of THC and other cannabinoids in hemp food need to be conducted to clarify ADI.

Appendix D - Hemp Regulation in Other Countries

Approximately thirty countries in Europe, Asia, North and South America grow hemp (Johnson, 2015, p.9). The United States imports hemp from other countries. Suppliers of hemp to the U.S. include European countries, China and Canada. China is the largest supplier of raw and processed hemp for fiber in the U.S., while Canada is the largest source of hemp seed and cake (Johnson, 2015, p.7).

Canada

Canada also uses 0.3 percent THC as the dividing line between hemp and marijuana. This definition applies to the “plants and plant parts of the genera *Cannabis* the leaves and flowering heads of which do not contain more than 0.3% THC w/w, and includes the derivatives of such plants and plant parts. It also includes the derivatives of non-viable *Cannabis* seed” (IHR, 2015). The United States is Canada’s primary export customer for hemp (Fortenberry, 2014, p.5) and it is possible that Canada would be the initial source of hemp seed products used in commercial animal feed. Currently, hemp has not been approved as animal feed in Canada but is approved for use in human foods.

In Canada, industrial hemp is highly regulated. In most cases, in order to possess, produce, sale, distribute, import or export industrial hemp, one must have an industrial hemp license as set forth in the Industrial Hemp Regulations (IHR), a twenty-seven page document. The IHR require that seed planted for the production of industrial hemp in Canada be of pedigreed status and farmer-saved seed cannot be planted unless it is certified seed. Inspectors collect official seed tags as evidence of compliance. Only varieties approved for commercial cultivation can be grown and imported into Canada. A list of approved cultivars is posted for each growing season. Industrial hemp crops in Canada are required to be sampled and tested for THC by an authorized Crop Sampler, unless the variety is exempted from testing. Three varieties are exempt for all regions of Canada: *Crag*, *USO 14*, and *USO 31*. There are also three other varieties that are exempt for specific provinces in Canada: *Alyssa*, *Anka* and *Zolotonasha 11*.

Canada places further restrictions on hemp seed products by placing a THC limitation of 10 ppm (0.001%) on raw and semi-finished hemp seed products, such as hemp oil. This assures manufacturers will process and handle hemp carefully, such as properly cleaning hemp seeds so they are not contaminated with the THC containing resin of the flowers or leaves. This restriction also allows for further processed foods containing raw hemp products to be produced without the need for THC testing and has prevented any incidents due to consumption of hemp based foods (Sarmiento, Carus, Grotenhermen, & Kruse, 2015, p. 26 & 32).

Europe

In contrast to Canada, THC limits in Europe generally exist for hemp cultivation but not hemp products. However, some countries in Europe, such as Germany and Switzerland, have chosen a stricter model and have placed THC limits on the final foods hemp products are used in. These limitations exist because biologically relevant concentrations of THC were found in Swiss hemp foods

in 1996 (Sarmiento, et al. 2015 pg. 15-17). A salad prepared with hemp oil found to contain 0.15% THC caused gastrointestinal and perception disturbances (as cited by Meier & Vonesch, 1997 in EFSA, 2001, p.30)

The European Union (EU) specifies that the varieties of hemp cultivated and used for feed must be listed in the [EU Official Catalogue of seeds](#). The varieties of hemp must not have a THC level exceeding 0.2 % (EC No. 1124/2008) and each EU Member State establishes a system of verification for THC in hemp.

In Europe, hemp seeds are predominately used for animal feed, mostly for non-food producing birds. The European Food Safety Authority Panel on Additives and Products or Substances used in Animal Feed (EFSA FEEDAP) has also concluded that feeding laying poultry 5-7% hemp seed or hemp seed cake is acceptable (EFSA, 2011, p. 9). Additionally, the whole hemp plant can be used as feed materials in EU countries and European Free Trade Association countries (EFSA, 2011, p.6). However, in March of 2005 Switzerland banned feeding hemp products to dairy cows because of concerns for children consuming high amounts of milk from dairy cows (swissinfo.ch, 2005). This prompted an assessment of THC transfer to milk by the European Food Safety Authority (EFSA) Panel on Contaminants in the Food Chain (CONTAM). EFSA CONTAM determined that the use of “hemp seed-derived feed materials at the reported concentrations of use is unlikely to pose a health concern via consumption of milk and dairy products from dairy cows. In contrast, for the hemp plant material, they determined that “A risk assessment resulting from the use of whole hemp plant-derived feed materials is currently not feasible due to a lack of occurrence data” (EFSA, 2015, p.1).

Appendix E – FDA/AAFCO Memorandum of Understanding

The text below was copied from FDA's website, accessed on November 3, 2016.

<http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/default.htm>

225-07-7001 Modification

Memorandum of Understanding between the United States Food and Drug Administration and the Association of American Feed Control Officials

Background

The United States Food and Drug Administration (FDA) is the primary federal agency responsible for enforcing the Federal Food, Drug, and Cosmetic Act (the Act). Included within the FDA's responsibilities under the Act is the responsibility for regulation of animal foods/feeds. The Act provides the authority for FDA to regulate essentially all ingredients and additives used in animal feed. [1] Depending on its intended purpose or use, an ingredient or additive could be classified as a food additive, a generally recognized as safe substance, a new animal drug, or a color additive.

The Association of American Feed Control Officials (AAFCO) is a voluntary membership organization of the states in the United States (US) and Federal government agencies, as well as government agencies from other countries, responsible for the execution of laws and regulations pertaining to the production, labeling, distribution, use, or sale of animal feed and feed ingredients. The purpose of AAFCO is to provide a mechanism for developing and implementing uniform and equitable laws, regulations, standards, definitions, and enforcement policies for the manufacturing, labeling, and sale of animal feeds and ingredients. AAFCO provides "model laws" and regulations that nearly all states have adopted as the basis for their feed-control program. AAFCO membership consists of all 50 states, Puerto Rico, Costa Rica, Canada, the FDA, US Department of Agriculture, and several universities. It is governed by officers and a board of directors (known collectively as the Board) elected by the membership at the annual meeting of AAFCO. The FDA is a member of AAFCO and serves in a non-voting advisory role on the AAFCO Board.

AAFCO provides a process (herein called the AAFCO Ingredient Definition Request Process) to identify the safety, utility, and identity of ingredients used in animal feed. This process helps to ensure ingredients used in animal feed are suitable for that use and also establishes a common or usual name for the ingredients. This common or usual identity is required on feed labels by both federal law and state regulations. The AAFCO Ingredient Definition Request Process is operated by AAFCO, with the FDA providing scientific and technical assistance. The result of this collaboration has been the establishment of an effective program of benefit to feed regulatory officials, the industry, and the public.

[1] Some articles added to animal feed fall under the purview of other federal agencies. Feed through pesticides are regulated by the Environmental Protection Agency (EPA), and vaccines added to animal feed are the responsibility of the US Department of Agriculture (USDA).

Purpose

The purpose of this memorandum is to facilitate the FDA's collaboration with AAFCO in the AAFCO Ingredient Definition Request Process by clarifying the responsibilities of the FDA and AAFCO during the feed ingredient definition request process and providing mechanisms for resolving disputes that arise and for modifying the definitions when required.

Agreement

The FDA and AAFCO agree to the following:

- A. AAFCO maintains definitions of various feed ingredients, which includes the common ingredient name, description, and any appropriate limitations for its use, and publishes the currently accepted feed ingredient definitions in the AAFCO Official Publication (OP).
- B. Requests for new feed ingredients or requests to modify an existing feed ingredient definition are reviewed by AAFCO investigators chosen by the AAFCO Board and FDA scientists assigned by the agency's division director or team leader in the Division of Animal Feeds (DAF).
- C. AAFCO will seek advice and a letter of concurrence regarding the suitability of the feed ingredient for its proposed use from the FDA prior to adopting new feed ingredient definitions or amending existing ones.
- D. AAFCO will provide to the FDA, upon FDA's request (1) industry-generated requests and (2) requests from AAFCO for new feed ingredients and for modifications of existing definitions within 30 working days of AAFCO's receipt of the complete request. AAFCO's Board-assigned AAFCO feed investigator will make the initial contact with the FDA.
- E. The FDA will allow the AAFCO Board or Board-assigned AAFCO feed investigator to request consultation from the FDA on requests for new feed ingredient definitions and modifications of existing definitions. AAFCO's initial contact will be the director of the DAF, Center for Veterinary Medicine (CVM), FDA. The FDA will provide its decision on whether it will be able to consult with AAFCO and the DAF number assigned to the request within 30 working days.
- F. If the FDA determines it will publish a food additive regulation of a requested ingredient definition under section 409 of the Act and FDA's implementing regulations in 21 CFR 571.1 for a feed ingredient, AAFCO will not include that ingredient in the AAFCO OP until the FDA completes the regulation.
- G. Disagreements on existing feed ingredient definitions, the establishment of new ingredient definitions, or modifications of existing definitions between the FDA and AAFCO will be referred to an arbitration board. The arbitration board will be comprised of two representatives from AAFCO appointed by the Board and two representatives from the FDA that are appointed by the director, FDA CVM Office of Surveillance and Compliance and the director, FDA CVM Division of Animal Feeds.
- H. AAFCO will consider all requests from the FDA to remove an ingredient definition from the AAFCO OP upon the FDA presenting scientific evidence substantiating their conclusion the ingredient is no longer suitable for its stated intended use. The Ingredient Definitions Committee will vote on the FDA request to

remove the ingredient from the Feed Ingredient Definitions section in the AAFCO OP at their next scheduled meeting. Disagreements between AAFCO and the FDA would be handled as stated in G.

I. AAFCO is allowed, on its own initiative and with FDA concurrence, to request that an AAFCO Feed Ingredient Definition be removed upon AAFCO providing scientific evidence substantiating their conclusion that the ingredient is no longer suitable for its stated use. The Ingredient Definitions Committee will vote to remove the ingredient from the Feed Ingredient Definitions section in the AAFCO OP at their next scheduled meeting. Disagreements between AAFCO and FDA would be handled as stated in section G.

This Memorandum of Understanding will be reviewed annually by the AAFCO Board and the FDA and may be modified by mutual consent of both parties. Parties will provide each other with written notice 30 working days in advance regarding the modifications being sought. Any modification will be published in the Federal Register.

Liaisons

For FDA:

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Period of Agreement

This agreement, when accepted by both parties, will have an effective period of performance from date of signature until 10/01/2017 (and may be modified by mutual consent by both parties or may be extended or terminated as agreed upon by FDA and AAFCO). Any notice of termination will be published in the Federal Register.

Approved and Accepted for FDA:

Bernadette Dunham, D.V.M., Ph.D. Director, Center for Veterinary Medicine
U.S. Food and Drug Administration
March 11, 2015

Approved and Accepted for AAFCO: Richard Ten Eyck

President 2015 AAFCO
March 5, 2015

Appendix F - Abbreviations

AAFCO: American Association of Feed Control Officials
ADI: Acceptable Daily Intake
ALA: alpha-linolenic acid
AST: Aspartate transaminase
CBD: Cannabidiol
CBG: Cannabigerol
CK: Creatine Kinase
CONTAM: EFSA Panel on Contaminants in the Food Chain (CONTAM)
CSA: Controlled Substances Act
CYP: cytochrome P450
DEA: Drug Enforcement Agency
EFSA: European Food Safety Authority
EU: European Union
FAO: Food and Agriculture Organization of the United Nations
FDA: Food and Drug Administration
FEEDAP: EFSA Panel on additives and Products or Substances used in Animal Feed
FD&C Act: Federal Food, Drug and Cosmetic Act
FID: Flame Ionization Detector
GC: Gas Chromatography
GGT: gamma glutamyl transferase
GLA: gamma linolenic acid
GRAS: Generally Recognized as Safe
HSM: Hemp Seed Meal
HPLC: High Performance Liquid Chromatography
IHR: Industrial Hemp Regulations
LA: linolenic acid
LLE: Liquid liquid extraction
MOU: Memorandum of Understanding
MS: Mass Spectrometer
NOAEL: No Observed Adverse Effect Level
NRC: National Research Council

OP: Official Publication
PL: Phospholipid
PMTDI: Provisional Maximum Tolerable Daily Intake
ppm: parts per million
PDCAAS: Protein Digestibility Corrected Amino Acid Score
PUFA: Polyunsaturated fatty acids
SDA: Stearidonic acid
SPME: Solid Phase microextraction
TAG: Triacylglycerol
TDI: Tolerable Daily Intake
THC: delta-9-tetrahydrocannabinol
THCA: delta-9-tetrahydrocannabinolic acid
THCA-A: delta-9- tetrahydrocannabinolic acid-A
USDA: United States Department of Agriculture
UV: Ultra Violet
WHO: World Health Organization
WSDA: Washington State Department of Agriculture

Appendix G - References

The following databases were consulted as part of WSDA's study.

- Food Science and Technology Abstracts (FSTA)
- CAB Abstracts (Center for Agriculture and Biosciences International)
- CAB Reviews ((Center for Agriculture and Biosciences International)
- Agricola
- AGRIS (Ovid and FAO version)
- PubMed (Medline)
- SciFinder
- Animal Health and Production Compendium
- Web of Knowledge

The following sources were reviewed as part of WSDA's study and are referenced in this report.

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