



COLORADO
Department of Agriculture
Inspection & Consumer Services Division

A Stakeholder Review of the Feasibility of Industrial Hemp By-Products as Animal Feed Ingredients

December 29, 2017

A report to the Colorado Legislature in Response to SB17-109

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Commissioner of Agriculture Don Brown

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Executive Summary

In 2017, the Colorado hemp industry initiated a legislative effort to establish a group of stakeholders with a wide range of expertise to examine the possibility of including industrial hemp (hemp) as an animal feed ingredient. In response to Senate Bill 17-109, the Colorado Department of Agriculture (CDA) conducted a stakeholder review and prepared this report to summarize expert opinion on the potential of approving hemp and its by-products as animal feed ingredients, as well as limitations and concerns in doing so. For this project, the CDA and stakeholders engaged in a series of discussions to examine the current regulatory status of hemp and hemp by-products as animal feed ingredients and explored a process by which the safety and utility of the hemp products would be fully evaluated. Stakeholders identified points of constraint and obstacles related to regulatory requirements, animal health and nutrition, public safety and economics.

Stakeholders reviewed the feasibility of hemp becoming an animal feed ingredient and identified six conclusions and one legislative recommendation. In general, stakeholders concluded that hemp seeds and hempseed by-products show promising potential as a nutritional source for animals and it is plausible for these products to become approved for use as animal feed ingredients. However, the safety and utility of hemp seeds, as well as the safety of any subsequent processing of the seeds, need to be confirmed before animal feed products with hemp can be approved for distribution in the U.S. market.

The details of the six stakeholder conclusions and legislative recommendation are provided in the body of the report, but are summarized here for convenience:

Conclusion 1: Prioritize federal approval

Since animal feed ingredients are subject to regulation by both the U.S. Food and Drug Administration (FDA) and state governing agencies, stakeholders noted that a submission effort should focus on gaining federal approval, rather than approval by states individually. However, there are resources and general support from private industry and academic institutions in Colorado that can contribute to a submission effort, including conducting additional research that will most likely be needed for a comprehensive submission to the FDA.

Conclusion 2: Focus on whole hemp seed and hempseed by-products

An ingredient submission should focus on parts of the plant that have the best chance of receiving federal approval, namely whole hemp seed and hempseed by-products: i.e., hempseed cake and hempseed oil. Other parts of the plant, such as the stalk, flower, root, and leaf could be the focus of a future ingredient submissions if research supports their safety and utility for livestock production and companion animals.

Conclusion 3: Conduct research on economic viability

Economic research on the viability of any new crop is essential. Stakeholders felt there is a lack of domestic economic data specific to hemp seed and hempseed by-products in animal feed. Additional U.S.-based economic studies on hemp by-products for use in animal feed would help address questions regarding the practicality of producing and manufacturing hempseed products for animal feed as well as provide a competitive analysis of existing feed options currently used.

Conclusion 4: Target submission of a Food Additive Petition (FAP)

While there are multiple pathways for a proposed ingredient to become approved for animal feed, stakeholders felt that any submission effort should focus on submitting a Food Additive Petition (FAP) to the Center of Veterinary Medicine at the FDA (FDA-CVM) due to the safety concerns surrounding hemp.

Conclusion 5: Include an experienced consultant in the collaborative effort

Considering the growing interest in hemp by-products in animal feed for both livestock and companion animals, any submission effort should strive to be a collaborative effort that includes a broad number of participants from private, public and academic organizations. While collaboration is a key conclusion from group discussions, stakeholders recommended that a submission effort is coordinated through a consultant with experience in developing and submitting FAPs to the FDA-CVM.

Conclusion 6: Execute a S.A.F.E petition process

Execution of a submission effort will require a “S.A.F.E.” petition to be successful, where petitioners should:

- **S** - Start early discussions with the FDA-CVM
- **A** - Assemble and assess existing research
- **F** - Fill in any gaps with additional research
- **E** - Execute a targeted petition that identifies specific species and intended uses

Legislative Recommendation

No direct legislative action is required since the submission would originate from petitioners from the hemp industry and other stakeholders with an interest in submitting a petition. However, stakeholders felt the Colorado Legislature could provide general support for additional research needed to determine the safety and nutritional content of hemp by-products. Additional research could be completed by either private industry or through Colorado universities. Any support for the submission of a FAP will help provide clarity to the public on the safety and allowable use of hemp seed and hempseed by-products as an animal feed ingredient.

1 Background Information

Hemp has emerged as an innovative crop and interest in its marketability is growing. Efforts to highlight the diversity of hemp products has led to the interest in its potential use in animal feed for production animals, horses and household pets (companion animals). Existing research, specifically on hemp seeds and hempseed by-products, show hemp has characteristics that make it a promising nutritional source (European Food Safety Authority (EFSA), 2011, p. 8).

Industry and regulators have seen new animal feed products containing hemp by-products enter the feed and pet treat markets without prior approval. In particular, there has been an emerging trend in the United States to incorporate the compound cannabidiol (CBD) in animal feed, particularly for companion animals, despite the fact that CBD oil has been determined by the FDA to be an unapproved drug rather than an animal feed ingredient. As an unapproved drug, CBD products will not be appropriate for the submission effort discussed in this report.

Currently, no hemp products are approved for use as animal feed ingredients in the United States and are not Generally Recognized as Safe (GRAS) (Washington State Department of Agriculture, 2017, p. 8). As with any new animal feed ingredient, the safety and utility of hemp will need to be evaluated before it can be approved for use. For food production animals, additional review may be necessary to ensure that there are no negative consequences that could potentially affect humans consuming the meat, milk or eggs of animals that were raised on animal feeds containing hemp. A safety review of any new animal feed ingredient helps ensure a safe supply of food, both for animals and humans consuming animal products.

1.1 Hemp Regulation

The following is a broad summary of legislation and other regulatory actions that frame the current regulatory environment in which the stakeholders focused their discussion on the feasibility of hemp as an approved ingredient.

Controlled Substance Act (CSA)

Under the Controlled Substance Act (CSA), the definition of marijuana specifically states that it “does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination” [21 U.S. Code, Section 802 (16)]. This definition identifies what is not a controlled substance, and the stakeholders decided to focus this report on the parts of the plant exempted from the definition of marijuana.

Agricultural Act of 2014.

Congress passed the Agricultural Act of 2014, also referred to as the “Farm Bill” (Agricultural Act of 2014). While this omnibus bill addressed a number of agricultural issues, the industrial hemp provision within the bill did two things relevant to the stakeholder discussion. First, the bill allowed state departments of agriculture and institutions of higher education to grow industrial hemp for purposes of

research through a pilot program if regulated under state law. Secondly, the Farm Bill provided a statutory definition for industrial hemp as the plant *Cannabis sativa L.* and any part of such plant, whether growing and not, with a delta-9 tetrahydrocannabinol (THC) concentration of no more than 0.3 percent on a dry weight basis (7 U.S. Code, Section 5940(b)(2)). Thus, providing a statutory distinction between hemp and marijuana. A similar definition for industrial hemp was adopted in Colorado statute in 2014 (Colorado Revised Statute, pp. section 35-61-101(7)).

Statement of Principles on Industrial Hemp

The industrial hemp provisions contained in the Farm Bill left the hemp industry and others with questions of interpretation. As a result, the U.S. Drug Enforcement Administration, U.S. Department of Agriculture, and the U.S. Food and Drug Administration published a *Statement of Principles on Industrial Hemp* in 2016 to address the applicability of federal laws towards activities associated with growing and cultivating industrial hemp (Statement of Principles on Industrial Hemp, 2016). While the statement was nonbinding, it clarified that the Farm Bill did not remove hemp from the controlled substance list, nor did the Farm Bill amend the Federal Food Drug and Cosmetic Act (FD&C). The hemp industry and others felt the Statement of Principles left unresolved issues of interpretation and application of the Farm Bill (Johnson, 2017, pp. 24-25).

Colorado Department of Agriculture Hemp Registry Program

Many states have passed laws and regulations designed to implement programs to regulate the legal cultivation of hemp as an agricultural crop within their jurisdictions. As of 2017, more than 35 states or territories have enacted or introduced legislation favorable to hemp cultivation (Johnson, 2017, p. 15). In Colorado, legislation was adopted in 2013 that established the Industrial Hemp Regulatory Program within the CDA, in which registration and regulations pertaining to the cultivation of hemp were established under Title 35, Article 61 of the Colorado Revised Statutes. Since its inception in 2014, participation in the Industrial Hemp Regulatory Program has grown to 527 active registrations and 11,853 registered acres by the end of 2017.

1.2 Regulation of Animal Feed

The Association of American Feed Control Officials

The Association of American Feed Control Officials (AAFCO) was established in 1909 and the membership is comprised of state and federal feed control officials. AAFCO facilitates the development of uniform regulation of animal feed among the states through the development of a model bill, model regulations, ingredient definitions and laboratory proficiency testing. Although the association does not have any regulatory authority, AAFCO provides a forum for which control officials and industry meet in partnership to address problems in administering and enforcing feed laws, identifying emerging issues, studying problems, developing analytical methods, developing strategies, as well as providing guidance and outreach (AAFCO 2017 Official Publication , 2017). AAFCO has a Memorandum of Understanding with the FDA, under which AAFCO provides an animal feed ingredient definition process that includes FDA scientific and technical review.

In 2017, AAFCO released a policy statement to address the growing interest in hemp in animal feed. Within the statement, AAFCO encouraged the hemp industry to submit data to address potential safety concerns related to the presence of THC and CBD before approving hempseed products for distribution. A full copy of the AAFCO guidelines can be found in Appendix B.

The Food and Drug Administration-Center for Veterinary Medicine

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). The FD&C Act is the primary federal regulation governing the manufacture and distribution of animal feed products and establishes standards for adulteration and misbranding. Within the FDA, the Center for Veterinary Medicine reviews substances intended for animal food to determine their suitability through the FAP and GRAS notification processes.

In 2015, the FDA-CVM published a guidance document for industry that outlines the FAP process (FDA GFI221, 2015), providing valuable information on how to prepare and submit a FAP to any interested party. General information that should be included in a FAP entails:

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

The United States Department of Agriculture Food Safety Inspection Service

The United States Department of Agriculture Food Safety Inspection Service (USDA-FSIS) is responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged. The USDA-FSIS regulates the sale of meat through the inspection of animals both before and after slaughter, including testing for residues of drugs and other adulterants. The USDA-FSIS also regulates the labeling of these products.

Colorado Department of Agriculture-Division of Inspection and Consumer Services

The CDA regulates commercial animal feed in Colorado. The Colorado feed law and regulations are based on the AAFCO Model Bill and Model Regulations published in the AAFCO Official Publication. The department reviews products for distribution within Colorado and works with animal feed manufacturers to ensure good manufacturing practices are being followed. The department's product review involves determining the acceptability of ingredients for use in animal feed, and that ingredients entering Colorado's marketplace are officially defined by AAFCO and reviewed by FDA-CVM. The CDA samples animal feed and analyzes it for nutrient content as well as testing for the presence of adulterants and contaminants.

Approval options for new animal feed ingredients

There are a number of pathways through which a proposed new animal feed ingredient can be reviewed for safety and utility before it becomes an approved ingredient. Approval for new animal feed ingredients is typically done through the submission of either an animal feed ingredient definition to AAFCO, or directly to the FDA-CVM as a Food Additive Petition. A firm may also conclude that an ingredient is "Generally Recognized as Safe" (GRAS) for a given intended use if sufficient information is available in the public domain to support the safety of that use. This GRAS conclusion can then be

shared with FDA to become a GRAS-notified ingredient. Because of the lack of sharing of detailed safety data, states do not typically recognize GRAS conclusions. AAFCO does publish in the Official Publication a list of GRAS notices that have received “no questions” letters from FDA-CVM.

2 Project Overview

2.1 Project Scope and Objective

The primary scope of the project was for the CDA to assemble a stakeholder group to explore the feasibility of including hemp products in animal feed. For this project, stakeholder discussion of feasibility centered on the regulatory approval processes for new animal feed ingredients, including discussion of the regulatory requirements needed to demonstrate the safety and utility of hemp and hemp by-products. In addition, the scope of the project included discussions of animal nutrition and public health, and economic viability of hemp seed and hempseed by-products as a feeding option for livestock and companion animals.

The primary objective was to evaluate whether hemp seed and hempseed by-products can be properly reviewed and approved for safe use, and to identify obstacles and challenges that will need to be addressed in any submission effort.

2.2 Formation of the Stakeholder Group

The CDA assembled a large stakeholder group in order to gain a wide range of perspectives on the various issues. Considering the broad implications and impact of these issues, it was important to include representatives from across the United States, including other state departments of agriculture and federal agencies. The stakeholder group included:

- Hemp producers and processors
- Animal feed manufacturers
- State and federal regulatory agencies
- Veterinarians
- Toxicologists
- Nutritionists
- Non-Governmental Organizations (NGOs)
- Academic faculty
- Ranchers
- Agricultural economists
- Meat export associations
- Attorneys specializing in hemp law

A complete list of stakeholders is provided in Appendix D.

2.3 Approach to Stakeholder Discussions

The CDA worked with a third party to facilitate stakeholder discussions and assist in identifying areas of consensus among the stakeholders. The project utilized large group discussions, breakout subgroup meetings and one-on-one interviews with stakeholders to formulate key insights and conclusions about the possibility of hemp as an animal feed ingredient. Stakeholders were broken into subgroups to explore three areas of focus.

- **Subgroup 1: Regulatory Requirements**
Focused on the current regulatory environment and what will be required to submit a petition for hemp to be approved as a safe ingredient.
- **Subgroup 2: Animal Nutrition/Safety and Public Health**
Focused on animal nutrition, safety questions and any concerns related to the consumption by the public of animal products.
- **Subgroup 3: Agricultural Economics**
Focused on the economic questions regarding using hemp in animal feed and the implications for agricultural industries, namely ranching and hemp production.

To form the discussion framework, subgroups identified specific questions in their area of focus. In subsequent discussions, key insights were noted by the CDA and the third-party facilitator. These key insights were then summarized into a collective response to the questions and then used to formulate the broad conclusions regarding the feasibility of hemp becoming an animal feed ingredient. A summary of subgroup questions and insights provided by the stakeholders can be found in Appendix C.

Stakeholders reviewed a draft of key insights and conclusions and made additional comments and edits. Stakeholders were provided the opportunity to draft a minority opinion for any areas in which consensus among the groups was not possible, or if any individual stakeholder held an opposing position. However, general consensus was achieved on the conclusions in this report and no minority opinions were submitted.

2.4 Constraints and Limitations of the Project

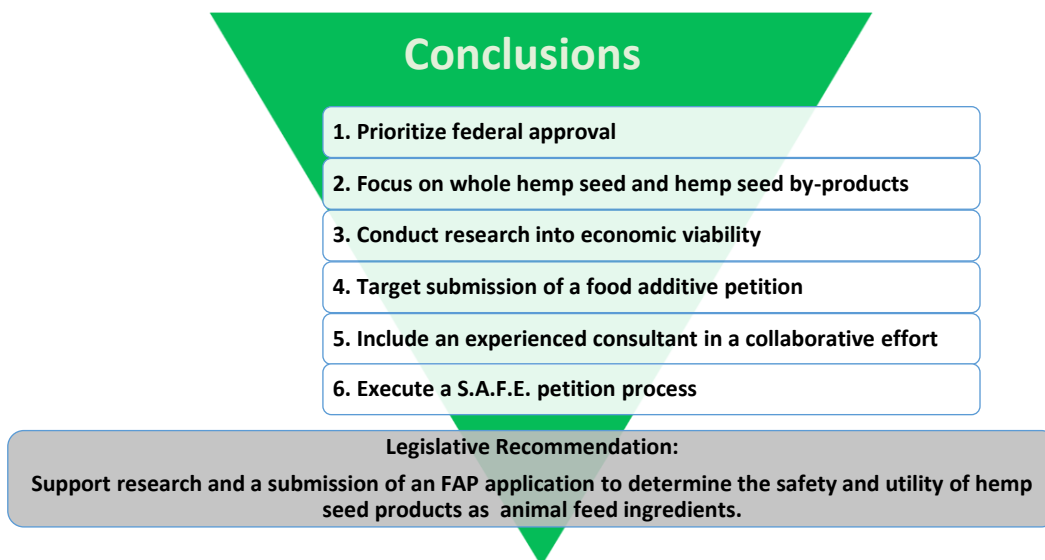
This project was not an academic research project or a scientific study of the use of hemp by-products in animal feed. Rather, the intention of the project was to summarize the discussions among experts on the feasibility of approving hemp products for safe use in animal feed. With limited time for discussion, the project focused on a high-level review of stakeholders' concerns, areas of agreement, and general comments. There is regulatory guidance and a number of published studies publicly available for those interested in a more detailed perspective of the issues involved with hemp by-products in animal feed.

This report is meant to serve as a point of reference for the Colorado Legislature, the public, and for petitioners interested in understanding the submission process.

3 Stakeholder Conclusions and Recommendation

While the demand for industrial hemp is increasing nationally, there is confusion about the status of hemp for use in animal feed. If approved, hemp seeds and hempseed by-products could provide benefits in multiple areas. Preliminary examination of the available data would suggest that hemp seed and other components may provide nutritional benefits for animals. In addition, there appears to be an interest and ongoing effort from the hemp industry to pursue approval from FDA-CVM. If industrial hemp can be approved for use as an animal feed ingredient, hemp production and processing could further contribute to the establishment of hemp as a new agricultural commodity that could help meet increasing animal feeding options and crop choice demands. As the submission process continues to move forward, Colorado is positioned to play a key role in providing clarity on the possible use of hemp in animal feed.

Table 1: Summary of stakeholder conclusions



Conclusion 1: Prioritize federal approval

Stakeholders felt that even though individual states may approve individual animal feed ingredients, a submission effort should focus on federal approval, specifically through the regulatory review process of the FDA-CVM. Hemp brings unique challenges and complexities that are not necessarily found with other animal feed ingredients because of THC and other cannabinoids present in the plant. Stakeholders expressed concern that regulatory action could be taken against animal feed manufacturers and livestock producers if hemp were fed to animals without seeking federal approval.

Federal approval through the FDA-CVM would provide clarity to the public and industries on questions regarding the safety and allowable use. Stakeholders were of the opinion that individual states should exercise caution in unilaterally approving hemp to be used in animal feed. Doing so could create uncertain outcomes for agricultural industries considering that the commercial market for both animal feed and livestock extend beyond Colorado’s borders.

While the focus should be on federal approval, Colorado industries can play a key leadership role in any submission effort. There are a number of Colorado organizations, both private and academic, that can contribute to the development of a petition submission to the FDA. These organizations can assist in assembling and reviewing data and other application materials.

Conclusion 2: Focus on whole hemp seed and hempseed by-products

Any initiative to seek approval for hemp as an animal feed ingredient should focus on the parts of the plant that have the best chance of receiving federal approval, namely whole hemp seed and hempseed by-products such as cake and oil from the seed. Other parts of the plant, such as the stalk, flower, root, leaves, and compounds/cannabinoids, could be the focus of future submissions if data supports their utility and safety.

Available research suggests that non-viable hemp seeds have a beneficial nutritional profile. (European Food Safety Authority (EFSA), 2011, pp. 2, 6-9). Alongside the macronutrients (protein, carbohydrate, and fat) and micronutrients, other components may include but not be limited to the omega 6 and 3 fatty acids and tocopherols.

Research indicates that hemp seeds themselves do not contain THC or other cannabinoids. Concern is focused on trace amounts of cross contamination of cannabinoids from the hemp flower during processing (European Food Safety Authority (EFSA), 2011, p. 8). Stakeholders spent time discussing the possibility of including non-seed parts of the industrial hemp plant, e.g., the flower as an animal feed ingredient. However, the FAP process is intended for substances that supply nutrients, add aroma/ flavor, aid stability, or alter a food's characteristics (FDA, Food Additive Petitions for Animal Food, 2017). Petitioners interested in gaining approval for other parts of the plant, for other purposes, should consult with FDA-CVM.

Conclusion 3: Conduct research into economic viability

Generally speaking, hemp is a new and emerging market with significant economic fluctuations year after year. The consensus of the stakeholders was that it may be too early to draw economic conclusions since production practices vary greatly and have yet to be standardized.

The economic viability of hemp by-products in animal feed is important. Stakeholders commented that it is challenging to know the value of hemp seeds and hempseed by-products as animal feed because price discovery has not occurred. In order for hemp by-products to be a viable option for ranchers and animal feed manufactures, they will need to be competitive with existing animal feed ingredients, particularly in regard to their use as protein or possibly hemp fiber sources. If hemp is not a competitive alternative to existing ingredients then the potential scalability of the hemp/animal feed market will be limited to a very small niche market. Colorado has a number of academic and industry resources that could collaborate to provide the necessary research to assist in determining economic feasibility.

Conclusion 4: Target submission of a Food Additive Petition (FAP)

Due to the unresolved safety concerns of hemp seeds containing THC from cross-contamination during processing, stakeholders felt a submission effort should focus on submitting a FAP to the FDA-CVM over other application pathways, such as an application for an ingredient definition from AAFCO. When there are questions about safety, the FDA requires the ingredient to be submitted through the FAP process.

Stakeholders felt that given the complex issues of hemp, particularly with the presence of small amounts of THC, any initiative to seek approval would be required to go through a FAP process. The FAP process could establish appropriate specifications that could alleviate many of the concerns and questions about the safety and allowable use of hemp seed and hempseed by-products. Petitioners interested in a FAP submission should utilize the FDA-CVM's guidance document on the FAP process to better understand the specific requirements that will be needed for a submission.

Conclusion 5: Include an experienced consultant in a collaborative effort

Considering the growing interest in hemp in animal feed and the wide impact on stakeholders, any initiative to seek approval should be collaborative and include a broad number of constituents across diverse disciplines. Through stakeholder discussions, it became evident that the use of hempseed products is of interest to professions and industries beyond just hemp producers and animal feed manufacturers. Ranchers and other livestock producers, veterinarians, nutritional experts, academics, economists, regulatory officials, and other professional experts should be involved in further discussions and offer assistance where appropriate in the development and submission of a FAP. Due to the different perspectives on and depth of this issue, a number of stakeholders felt the dialogue should continue in advance of any preparation and submission of a FAP.

Research and other supporting documentation that will need to be submitted with a FAP will be extensive, particularly if the petition covers multiple species, life stages, and intended uses. The assemblage of the petition material may require the involvement of more than just one organization. Moreover, the submission effort should be overseen by a company or consultant with significant experience with the FAP process and the requirements set forth by FDA-CVM.

Conclusion 6: Execute a S.A.F.E petition process

The stakeholders examined the general requirements in preparing and submitting a FAP application for hempseed products and identified a basic S.A.F.E. petition process which petitioners may use as guidance to submit a FAP to the FDA-CVM:

S - Start early discussions with FDA

The FDA-CVM encourages pre-submission consultations. Consultations can help streamline the process by ensuring that petitioners address required elements efficiently and completely. The FDA-CVM can provide input on the types of data and information that should be included in a petition and will comment on protocols for any planned research.

A - Assemble and assess existing research materials

Petitioners should evaluate existing research on feeding hemp seeds and hempseed by-products for various species to determine the significance of the data in regard to submitting a FAP. While peer-reviewed research is beneficial, it is not necessarily required for a FAP. Engaging with an experienced consultant will help review existing research. Research should address intended use, use level, analytical methods, safety, and any potential tolerances for residues.

F - Fill in gaps with additional research

Additional research may need to be conducted to support the safety and utility of these substances for a given intended use. It was discussed by the stakeholders that one well-prepared study can be effective in addressing the safety and utility of hemp in animal feed;

however, most FAPs have more than one study to compensate for any limitations in the data. Additionally, a FAP that is broad in scope for multiple species will require a wider range of data to address the requirements for each species separately. If any new studies are planned, detailed protocols should be submitted to FDA-CVM before conducting the studies to help ensure that the studies will meet desired objectives.

Additional research or studies can be done through a number of Colorado resources, either through private companies or academic institutions. Nevertheless, additional research should use hemp seeds that are legally imported or grown in compliance with state regulatory guidelines.

E - Execute a targeted petition

Stakeholders discussed that a submission effort may need to include separate petitions for hemp seeds, hempseed cake, and hempseed oil. However, within each petition, petitioners could include multiple animal species, including both production and companion animals. The petition(s) should include all species that are feasible from a nutritional and safety perspective. Each FAP should clarify the species, life stages, durations, and other variables. Studies may not be required in each individual species, but sufficient data and information would need to support the safety and utility of any potential cross-species extrapolation if data is not available in all intended species.

Legislative Recommendation

The specific legislative action was not indicated by the stakeholders since the responsibility for the assemblage and submission of a petition to the FDA-CVM would be completed by the hemp industry. However, stakeholders felt that the Colorado Legislature could provide general support for the submission of a FAP, specifically for any additional research that might be needed to determine the safety and utility of hempseed products. Additional research and study could be completed by either private industry or universities in Colorado.

Conclusion

The steps for approval outlined in the submission effort should bring clarity to agricultural industries and the general public on the safety and nutritional benefits of hemp seeds and hempseed by-products in animal feed. Moreover, completion of a review and subsequent approval will help establish standards in regard to its allowable use. If approved, hemp seeds in animal feed could further highlight the diverse use of hemp as an emerging crop. While additional research into this area of study is required, Colorado has a number of resources and interests within the hemp industry and other disciplines that could contribute to the pursuit of any submission effort.

Appendix A: Abbreviations and Terms

- **AAFCO:** Association of Feed Control Officials
- **By-product:** secondary products produced in addition to the principal product.
- **Companion animals:** animals kept for uses other than the production of food or fiber. Includes dogs, cats, and horses.
- **Cannabinoids:** a class of diverse chemical compounds that acts on cannabinoid receptors in cells that alter neurotransmitter release in the brain.
- **CBD:** Cannabidiol is one of at least 85 active cannabinoids identified in cannabis. It is a major phytocannabinoid, accounting for up to 40% of the plant's extract.
- **CDA:** Colorado Department of Agriculture
- **CofA:** certificate of analysis, a document provided by a testing laboratory certifying the content of a product.
- **CSA:** Controlled Substances Act; the statute establishing federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated.
- **DEA:** Drug Enforcement Agency
- **FAP:** Food Additive Petition
- **FDA-CVM:** United State Food and Drug Administration-Center for Veterinarian Medicine
- **FD&C Act:** Federal Food, Drug, and Cosmetic Act
- **GRAS:** Generally Recognized as Safe; substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use
- **Hempseed by-products:** A component of the whole hemp seed, namely hempseed cake (meal) and hempseed oil.
- **Hempseed cake:** the by-product remaining after the extraction of hempseed oil from the whole hemp seed.
- **Least cost ration formulation:** formulating animal feeds based on the relative costs of ingredients. The composition of the animal feed will change based on changes in ingredient prices.
- **Petitioner:** the entity submitting a Food Additive Petition.
- **Production animals:** livestock animals that are raised to produce fiber or food products for human consumption.
- **THC:** Delta 9 tetrahydrocannabinol, the psychoactive substance found in *cannabis*.
- **USDA-FSIS:** United States Department of Agriculture Food Safety Inspection Service

Appendix B: AAFCO Guidelines on Hemp in Animal Food

AAFCO Guidelines on Hemp in Animal Food March 5, 2017

For more information visit the aafco.org website.

Ingredients used in animal food (pet, livestock, and poultry) in the United States undergo a scientific review prior to being allowed for sale or distribution. The most comprehensive list of ingredients defined for animal food use is found in the Association of American Feed Control Officials Official Publication (AAFCO OP). Ingredient definitions and their common name come into the OP through one of three routes. They can be the subject of a Food Additive Petition to the FDA (FAP); receive a letter of no questions from the FDA to a generally recognized as safe (GRAS) notification (new—subject to membership approval); or the most popular route, be requested of AAFCO. Each of these routes has some level of a safety and utility review done by the FDA-CVM. States and others then rely on the AAFCO OP to allow feeds to be made with defined ingredients. The common ingredient name established by AAFCO is reflected in the feed's ingredient statement. The FDA and a few states also recognize self-conclusions by firms of GRAS for an intended use.

Hemp production is increasing in the United States. In 2015, AAFCO asked the hemp industry to come forward and present information for the scientific review to establish definitions for animal foods made from the hemp plant. We expected information on hempseed oil, hempseed meal, and whole hemp seeds. To date, the industry has not provided any data showing that ingredients derived from the hemp plant are safe and useful in animal food. AAFCO is encouraging the industry to submit their data promptly. Regulatory members continue to ask for the information prior to distribution of hempseed products in their state. To allow an entire industry to enter the market without the appropriate safety data is unfair to other ingredient manufacturers that are doing their due diligence. There are some potential safety concerns related to the presence of certain compounds, including THC (tetrahydrocannabinol) and CBD (cannabidiol), in parts of the hemp plant that must be addressed.

One thing has become clear as we have had discussions with the hemp industry, materials and products that are CBD infused need to be treated as drugs. There is no nutritional intended use for this compound. This means that several parts of the hemp plant will not be appropriate for animal feeding.

Quoting from the FDA and Marijuana website: "FDA has therefore concluded that it is a prohibited act to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which cannabidiol has been added."

For further information:

AAFCO Ingredient Definition Process: <http://www.aafco.org/Regulatory/Committees/Ingredient-Definitions>

AAFCO Hemp Seed Oil Investigator: brett.boswell@state.mn.us

AAFCO Hemp Seed Meal, Whole Hemp Seed Investigator: bchurch@mt.gov

FDA Food Additive Petitions:

<http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm056809.htm>

FDA GRAS Notification:

<http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/GenerallyRecognizedasSafeGRASNotifications/default.htm>

FDA and Marijuana: Questions and Answers

<http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421168.htm#dietsuppsexclude>

DEA Announces Actions Related to Marijuana and Industrial Hemp

http://www.oisc.purdue.edu/seed/hemp/dea_cannabis.pdf

DEA Eases Requirements for FDA-Approved Clinical Trials on Cannabidiol

http://www.oisc.purdue.edu/seed/hemp/dea_cbd_research.pdf

Appendix C: Summary of Stakeholder Discussions

Stakeholder subgroups focused the discussion on specific questions related to their areas of focus. The following is a summary of the key insights from stakeholders regarding the questions discussed.

Subgroup 1: Regulatory Requirements

Question 1: How will regulations establish the safety, utility and toxicity limits of products for different target species?

- The regulatory framework provides different pathways that are designed to determine the safety, utility and toxicity. Specifically: GRAS, AAFCO ingredient definition, FDA Food Additive Petition. However, submission through the FAP is preferred and is considered the most appropriate pathway. It was the consensus of the group that this pathway would be the most rapid avenue for review and approval.
- The regulatory review focuses on the safety and utility of the proposed new ingredient. The AAFCO Ingredient Definition process is an option but would not result in an official federal approval by FDA-CVM.
- Additional research may be needed in order to submit a petition.
- It is recommended that petitioners review study protocols prior to submitting a FAP. An initial meeting with FDA-CVM is recommended to clarify the FAP requirements.

Question 2: Is there a specific collective strategy to obtain approval of parts of the hemp plant as allowable ingredients?

- Petitioners should focus on parts of the plant that show good potential for nutritional benefits and are exempt from the CSA, namely sterilized hemp seeds and hempseed by-products. The legality of resin, flower, or any other part or derivative of the hemp plant are being disputed at the federal level should not be considered for a FAP at this time.

Question 3: Beyond the ingredient approval process, what other regulatory concerns need to be addressed?

- Often the biggest hurdle is documenting the chemistry and manufacturing specifications documented. Additional applications could be less of an effort for subsequent species once that hurdle is addressed in the first petition.
- Any additional research should be compliant with state and federal laws related to the legal production and cultivation of hemp under state industrial hemp programs.
- The consequences of interstate commerce and global export of livestock or feed using hemp by-products should be considered. For example, could this result in trade barriers from other countries or impact reciprocity of feed and livestock between states? FDA approval and subsequent adoption by AAFCO as a defined animal feed ingredient typically allow for a national recognition of the allowable use in animal feed.

Question 4: What are the challenges or obstacles that need to be addressed in submitting an application for any part of the hemp plant to become an approved ingredient?

- The primary concern of stakeholders was the determination of whether there is enough research to submit a FAP, particularly in regard to questions of safety. If not additional research to fill in any gaps.
- A FAP for hemp should include an expert in the submission of applications for animal feed ingredients. The process should include a number of participants.
- Undertaking research to collect data can be costly and would need financial support.

Question 5: What types of studies should the group consider as first steps?

- Petitioners submitting a FAP should examine existing data on safety and utility, identify gaps in the data that still need to be researched; and begin the conversation with regulators. For food-producing animals, data will be needed on tissue residues and the safety of those products for use as food for humans.
- One comprehensive controlled study may be very helpful in addressing safety and utility, but most cases typically require a few studies or corroboration to support an approval. Incorporation of multiple sources including peer-reviewed and published data is beneficial, though the submission can include well-designed studies that have not been peer-reviewed.

Question 6: What challenges will animal feed regulators find in monitoring these ingredients in the animal feed supply (storage, inspection, recordkeeping, labeling etc.)?

- The focus of the discussion centered on the production chain from the hemp producer to the animal feed manufacturer. The challenge is to ensure that animal feed does not contain hemp with greater than .3% THC, or that has been cross-contaminated with THC during processing. Before taking possession of hemp, processors test loads of hemp products to ensure it is not above .3% THC.
- While not specifically related to regulatory challenges, stakeholders noted that animal feed manufacturers test other commodities before they come into a facility as a control for some hazards, such as mycotoxins in grain. Animal feed manufacturers using hempseed products may need to consider a similar control process.
- State animal feed programs would not have the capacity to test all hemp seed loads. A certified seed program with certificates of analysis (CofAs) would be beneficial to ensure hempseed products meet all standards defined in an approved FAP.
- If approved, proper labeling requirements would need to be addressed through state regulation.

Question 7: Prior to any approval, what has been done or could be done by industry and regulators about the trend of hemp by-products in animal feed?

- Industry and CDA need to educate on the current regulatory environment. At an appropriate time, the hemp industry may wish to craft language for the education of consumers and producers.
- Discussions about public interest in hemp have occurred in recent AAFCO conferences. The AAFCO board put out a policy statement in March 2017 that highlights their request for the

hemp industry to conduct a scientific review prior to the description of hempseed products. To date, there has not been an application request for definitions for hemp seed or hempseed by-product to AAFCO.

Question 8: What other countries have approved hemp ingredients in animal feed and how are they regulating hemp in animal feed?

- Other countries in Europe and Canada have looked into the research, with some countries allowing hemp as animal feed. Those countries could be a good place to look for data. Stakeholders discussed that the laws and regulations from other countries can be different from animal feed regulation in the United States and may not be sufficient. Research from those countries should be carefully reviewed.
- Currently, hemp is not allowed in animal feed in Canada.
- The industry should consolidate and present the best available data.

Question 9: What is the maximum allowable level of cannabinoids in the finished ingredient?

- Stakeholders commented this project cannot make a determination on specific allowable levels. Maximum allowable levels will be determined through the petition process. Available research data can provide a reference point and possibly be used in a submission. Stakeholders pointed to the scientific opinion of the European Food Safety Authority recommendation that recommended the introduction of an upper level of THC for hemp seed-derived animal feed materials of 10mg/kg. (EFSA FFEDAP, 2011 p. 14)
- Life stage of the animal and the duration are important variables to determine the amount consumed.

Question 10: What sort of education requirements will be necessary for both the industry and the public to enable decision-making?

- Once approved for use, it will be important the public and industries are aware of the regulations and any specific requirements or limitations that would arise.
- Limiting the approval to a specific definition of hempseed by-products will provide clarity to the public and industries on what is and is not allowed.
- Education efforts can be done collaboratively through the hemp and animal feed industries working with animal feed regulators and other impacted professions. Educational initiatives should also address the specific intended use and claims would be limited to those acceptable for animal feed (nutritional) products.

Subgroup 2: Animal Nutrition, Safety and Public Health

Question 1: What are potential ingredients that can be used in animal feeds?

- Whole hemp seed and hempseed by-products have a beneficial nutritional distribution of protein, fats, and fiber.
- There are concerns among stakeholders about THC and CBD exposure to the animal and concerns about transmission to the consumer of the animal product. There is not enough data at this point to be conclusive, specifically, on an acceptable average daily intake (ADI) level for THC and other cannabinoids.

Question 2: What health concerns are associated with animals consuming hemp by-products?

- The broad concern is the presence of THC and other cannabinoids in the animal feed products. Cross-contamination during processing from other plant parts into hempseed by-products is a possibility.
- Petitioners may need to consider the possible uptake of contaminants from the environment. Hemp is a bioremediator, which means it can absorb metals and other pollutants from the soil. Studies have shown hemp to be effective at removing cadmium, a heavy metal. It may be important to test the plant to confirm that it does not have harmful levels of cadmium or other heavy metals or pollutants.

Question 3: What are the effects of hemp processing on the nutritional content of those ingredients?

- Limited information is available for the role of hemp processing.
- Hempseed products can be heat-sensitive and need to be handled at low temperatures so that product quality is not adversely affected. The shelf life of each product will need to be studied and verified.

Question 4: What are the safety concerns for different species of animals and their life stages? Should they be considered separately?

- Safety concerns are primarily focused on the presence of cannabinoids and the possible impact on animal and human health. Certain parts of the plant will present a lower risk than the whole plant or other parts of the plant.
- One comprehensive FAP could cover multiple species for each separate ingredient, such as hempseed oil. However, the FAP will need to provide separate information, including supporting data for each species and life stage.
- Options for species to include beef cattle, swine, poultry (eggs v. meat), and companion animals (dogs, cats, horses). The FAP can be more narrowly defined based on what the data can support regarding the safety and utility of each species.
- Companion animals and horses have different considerations concerning safety. With companion animals, there is not a food risk of human exposure. However, ingredients go into the home and broader consumer protection may be a concern.

- Another consideration for companion animals is that they may be fed products with hemp over a much longer period than livestock and long-term exposure should be considered.
- The petition should balance those species for which there are an economic benefit and enough available data.

Question 5: What are the health concerns with humans consuming animals who have been fed hemp products?

- Plant components that are unknown, such as secondary metabolites that may exert toxicity to animals that were previously unknown. (This is related to the GRAS assumption and differences that may exist in tolerable dose across species.)
- For approval in production animals intended for human consumption, the residual effects of hemp, if any, would need to be evaluated.
- Stakeholder discussion focused the question of transfer rates of cannabinoids in the animal tissues and milk. This will need to be a focus of study in order to determine how much will be passed on to someone consuming the animal food products. A FAP submission will need to address this concern.

Question 6: What is the general availability of scientific data on the utility /safety? What additional research remains to be designed and completed?

- Studies have been conducted in other countries, namely European countries and Canada. Data from these studies may be accepted in a petition provided they are related and the conditions are the same. Studies will need to be specific to what the FAP is requesting for approval.
- Generally speaking, there is publicly available data that can serve as a foundation for support for a new ingredient. In some cases, existing data may be proprietary and may or may not be available for use.

Question 7: Will the levels of inclusion differ for each species and life stage?

- Species' differences in safety and tolerability to plant components is real and should not be dismissed for hemp.
- For example, some foods (e.g. grapes) are toxic to dogs, while many other animals are fine.
- Regarding age, younger animals could be more susceptible to toxicity by dose (e.g. hemp seed dose may be an issue for some food production animals but not necessarily companion animal, with or without respect to age).

Question 8: What specifications may be added to a hemp definition to prevent marijuana from being marketed or added to animal feed?

- Regulation can set maximum acceptable THC limits for animal feed ingredients and possibly complete diets.
- The definition of hemp contains a maximum THC concentration. Hemp authorized by Colorado (certified seed) is guaranteed not to be marijuana, but there may be contamination risks for non-seed parts of the plant. Focusing on the seed avoids the majority of the challenges related to marijuana.

Question 9: How does feeding hempseed by-products to animals change the nutritional quality of the food product(s)?

- Dietary composition of the finished food product may be influenced by changes in body composition and for animal products such as egg and milk. For example, chickens fed diets high in flax seed produce eggs high in omega-3 fatty acids.
- Ruminants are influenced less by nutrition than non-ruminants.

Question 10: What research will be permitted by the State of Colorado?

- There are no CDA restrictions on research so long as you are not selling the animal feed. If you're studying it, and not distributing it, then it's not within our purview. Petitioners should consult with the FDA-CVM during any pre-petition discussions regarding the execution of new research to determine what is allowed and not allowed, such as the disposal of test animals.
- The 2014 Farm Bill provides for research on the growth, cultivation or marketing of industrial hemp inside pilot programs set up in states where industrial hemp is legal. Neither the 2014 Farm Bill or the associated state laws or Rules of the Industrial Hemp program limit the research being done at institutions of higher education in Colorado, those holding a commercial registration in a pilot program or those purchasing material grown under the state's program or imported legally.

Subgroup 3: Agricultural Economics

Question 1. How do production costs and break-even points for hemp by-products compare to other animal feed sources; including costs to transport, costs to store, and costs to process? Are there points of scale where hemp by-products become viable from a producer or processor standpoint?

- It's challenging to know the value of the crop because we have not yet achieved price discovery. Hemp is an emerging market with significant changes year after year. It is too early to draw economic conclusions since production practices vary greatly and have yet to be standardized. Because of the fluctuation of the industry, data has been tough to find. It may be necessary to consider using other countries markets to establish rough numbers; however, laws and practices in other countries will not necessarily translate to Colorado.
- Colorado State University Extension has developed a fact sheet that includes a fiber budget and a seed budget. This offers a format for the information, though much of the information is extrapolated from other crops. Colorado State University Extension will need help from hemp producers that have financial records that will provide data necessary to develop budgets for Colorado. The hemp industry in Colorado could provide the names of 6-8 producers to determine what information is known and what holes exist.
- There are two different approaches to hemp production: 1) the traditional farmer with industrial intent, and 2) female-only non-pollinated growers who grow from clones that are growing for cannabinoid value. Analysis of the traditional farming approach would be the most appropriate economic review given the focus on the hemp seed and its by-products, and not the rest of the plant.

- The cost of water is a key driver to consider. Cost per acre-foot of water is materially higher in some areas of Colorado versus others, making statewide conclusions about economic viability less reliable.

Processing:

- There are a variety of hemp processors in Colorado that could provide information on processing costs, maintenance requirements, transportation, etc. It is recommended groups of commercial processors that include large scale animal feed processors be convened to examine the economic considerations of processing. They may need to extrapolate from existing hemp crops because it is likely that they might not have enough product flowing through the pipeline.
- There is emerging interest in a business model in which farmers will produce hemp seed, process it themselves, and animal feed it to animals on the farm.

Question 2: What end forms are most practical/economically viable for animal feeds?

- Least cost ration formulation is a key method for evaluation in livestock animal feed; protein content is 45% for soybean meal v. 35% for hemp meal. Hempseed by-products need to be on par with production costs for established animal feed options. The yields need to be higher to compete for the commodity pricing that exists, particularly for protein.
- Pet markets do not work on the least cost ration formulation and they do not change the formulation as often as would a livestock animal feed manufacturer.
- Transportation costs from the processor to the animal feed location would play a role in the economic feasibility. There are processing capabilities currently in Colorado, any examination would benefit from local processing.
- Hemp seed is just one of the by-products of the harvest. This might allow for farmers to make money while selling the seed and other components (e.g. CBDs & fiber) separately into different markets. There may well be more co-product benefit with hemp associated with the dry material.
 - Price per unit is less commoditized/competitive in the pet food industry.
 - Volume overall will be far greater as a livestock animal feed versus pet products.
- Production and processing standards for hemp still needs to develop.

Question 3. How might hemp factor into the rotation of traditional crops such as wheat and corn (e.g. what impact does it have on the soil)?

- Estimating the economic benefit of crop rotation for hemp is beyond the scope and research available at this time. However, interest on hemp as a rotational crop was high among stakeholders. It was recommended to pursue further exploration into crop rotation. However, this specific question goes beyond the economic focus on hemp by-products in animal feed. We do not have enough information on hemp as it pertains to Colorado soils, climate, and conditions. Canada has good data, but we cannot extrapolate it.

Question 4. What role can the State of Colorado play on agricultural economics, through state universities, to assist in determining economic viability?

- Colorado universities and colleges are working various studies on hemp, including economic viability. These institutions could help pursue the development of any economic (and nutritional) research needed specific to the use of hemp as an animal feed ingredient. Economic research could focus on hemp production and processing as well as an animal feed option for livestock producers.
- Economists with CSUE are another resource to help explore the economics, though funding will need to be justified and secured. CSU also has farm test plots and eventually will cooperate with producers for on-farm testing.
- Collaboration can occur among producers in regard to production data.

Question 5. How is the estimated economic value of hemp calculated? (Every part of the plant, primary and secondary products)

- The economic value is still hard to quantify because of the lack of research. Stakeholders conclude completion of additional research that focuses on production data for hemp producers, as well as an economic comparison to other animal feed ingredient options for livestock producers and animal feed manufactures, is needed.
- While the focus on a FAP would be for hempseed by-products, the economic value is currently focused on cannabinoids-particularly CBD. However, CBD and other cannabinoids are beyond consideration as an animal feed ingredient because of their designation by the FDA as a drug. Nevertheless, from an economic perspective, it is important to note.

Question 6. What negative/positive economic impacts could hemp in animal feed for livestock have on farmers, livestock producers, and animal feed producers for companion animals following legislative approval?

- Increasing the supply would likely lower prices and expand the market. Currently, the market is a very small niche, primarily for pet treats. Receiving federal approval would also create a marketing advantage. Once approved, hemp by-products could result in increasing demands for other hemp-based pet products.
- The livestock animal feed issue (as an ingredient and as a crop) is one of substitution: if hemp is planted, something else cannot be planted. If the seed is used in animal feed, then other ingredients will not be used. Colorado is a livestock-feeding state, so there is a potential upside if the ration equation works out.

Appendix D: List of Stakeholder Participants

Stakeholders:

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Bill Bookout, *President*, National Animal Supplement Council

David Bossman, Agwin Group, LLC

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