



Montana Department of Agriculture

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HEMP AND CANNABIDIOL POLICY FOR USE IN ANIMAL FEED

PURPOSE

The purpose of this policy is to clarify the definition of livestock and address inquiries from entrepreneurs, animal feed manufacturers, livestock producers/owners, pet and specialty pet owners who want to add hemp ingredients, cannabidiol (CBD), and/or other cannabinoids to animal feed. This policy also addresses the legal aspects of product distribution through the channels of interstate commerce.

SUMMARY

ALLOWED. Hemp and hemp related ingredients that <u>will</u> be allowed only in pet, specialty pet and horse feed:

1. Hemp or substances derived from hemp containing no greater than 0.3% tetrahydrocannabinol (THC) or its derived products that contributes nutrition, taste, or aroma, or has a technical effect on the consumed material.

UNALLOWED. Hemp and hemp related ingredients that <u>will not</u> be allowed in any animal feed:

- 1. Added CBD, THC, or Cannabis derived products containing greater than 0.3% THC. This does not include natural occurring cannabinoids in plant material.
- 2. Hemp-derived products that <u>do not</u> contribute nutrition, taste, or aroma, or have a technical effect on the consumed material. A technical effect would be an approved substance added to feed during manufacturing that assist in the production of feed such as, but not limited to, pelleting aids, carriers, binding agents, preservatives, dust control agents, and anti-caking agents.
- 3. Hemp-derived products intended to provide therapeutic relief or affects the structure or any function of the body of animals.

PRODUCT DISTRIBUTION

Hemp and hemp-derived feed ingredients should not be distributed through interstate commerce.

CBD for use in all animal feed or animal feed products containing CBD should not enter intrastate or interstate commerce

Federally, all ingredients in animal food must be the subject of an approved food additive petition or generally recognized as safe (GRAS) for their intended use in the intended species. If an animal food contains an ingredient that is not the subject of an approved food additive petition or GRAS for its intended use in the intended species, that animal food would be adulterated under section 402(a)(2)(C)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. § 342(a)(2)(C)(i)]. In coordination with state feed control officials, the Center for Veterinary Medicine (CVM) also recognizes ingredients listed in the Official Publication (OP) of the Association of American Feed Control Officials (AAFCO) as being acceptable for use in animal food. At this time, there are no approved food additive petitions or ingredient definitions listed in the AAFCO OP for any substances derived from hemp, and FDA is unaware of any GRAS conclusions regarding the use of any substances derived from hemp in animal food.

The introduction or delivery for introduction into interstate commerce of any animal food that is adulterated is a prohibited act under section 301(a) of the FD&C Act [21 U.S.C. § 331(a)]. The adulteration of any animal food in interstate commerce is a prohibited act under section 301(b) of the FD&C Act [21 U.S.C. § 331(b)]. The receipt in interstate commerce of any animal food that is adulterated, and the delivery or proffered delivery thereof for pay or otherwise is a prohibited act under section 301(c) of the FD&C Act [21 U.S.C. § 331(c)]. Under section 201(b) of the FD&C Act [21 U.S.C. § 321(b)], the term "interstate commerce" means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.

BACKGROUND

House Bill 396 was signed into law during the 2021 Legislative Session to amend the definition of Commercial Feed to include the use of hemp, or a substance derived from hemp for use as feed or for mixing in feed for pets, specialty pets or horses in Montana. Livestock, other than horses, may not be fed hemp or substances derived from hemp until an approval is issued by the Food and Drug Administration.

In the Commercial Feeds Act 80-9-101(11) "Hemp" means all parts and varieties of the plant *Cannabis sativa L.* containing no greater than 0.3% tetrahydrocannabinol."

Currently, hemp or its derived products do not have federal approval for use in animal feed or feed supplements, nor does it have an ingredient definition for use approved by the Association of American Feed Control Officials (AAFCO). To date, only one submission has been made to AAFCO as a definition request for laying hen chickens. The request was reviewed by the AAFCO's Oilseeds investigator then forwarded to FDA's Center for Veterinary Medicine Division of Animal Feeds (FDA/CVM/DAF) for expert review. AAFCO has a Memorandum of Understanding with FDA https://www.fda.gov/about-fda/domestic-mous/mou-225-07-7001 to provide scientific

and technical assistance in all feed ingredient definitions prior to animal feed ingredient approval and publication.

CBD is not allowed in animal feed or feed supplements. CBD is federally regulated by the Food and Drug Administration (FDA) as a prescription drug and a pharmaceutical ingredient for human.use.only. The FDA considers nearly all CBD products unapproved drugs. FDA has one approval of CBD as the active ingredient in the drug, Epidiolex label.gov), to treat rare, severe forms of epilepsy in humans. Therefore, CBD does not meet the legal definition as an animal feed ingredient, nor is it an approved feed additive or generally recognized as safe (GRAS) for use in any animal food.

FDA/CVM and majority of states accept AAFCO's feed terms and feed ingredient definitions in the AAFCO Official Publication. No hemp or hemp derived products have been defined by AAFCO. Therefore, hemp and hemp byproducts are considered unapproved ingredients and should not be distributed through interstate commerce.

Under MCA 15-24-921 (3) "livestock" means cattle, sheep, swine, poultry, honeybees, goats, horses, mules, asses, llamas, alpacas, domestic bison, ostriches, rheas, emus, and domestic ungulates. From this definition of livestock, the only livestock species allowed for immediate approval for hemp in animal feed are horses. All other "livestock" approval is contingent on Section 4(2), which states "Section 1(3)(b)(ii) is effective on the date that the director of the Montana department of agriculture certifies to the code commissioner that the food and drug administration has approved hemp, or any substance derived from hemp as an approved additive or defined ingredient in animal food or medicated feed for livestock."

On farm livestock animals, other than horses, that are fed feed products containing hemp or substances derived from hemp should not enter commerce in whole or part. Livestock animals, meat from livestock animals, or products from those animals that enter commerce could be considered adulterated and regulated in that manner. As reference, please see the FDA Regulation of Cannabis and Cannabis-Derived Products, including Cannabidiol (CBD), and pay particular interest to questions & answer numbers 10, 24, 25 and 26.

All manufacturers of commercial feed and those whose name appear on the label as a guarantor are required to be licensed with the department. A separate license is required for each facility that distributes commercial feed within Montana. A license is not required for a person who distributes only pet food or specialty pet food.

A distributor of horse feed and/or horse feed supplements is required to be licensed annually.

A manufacturer/guarantor of horse feed/feed supplement is required to submit an annual tonnage report and pay the associated fees.

All pet food and specialty pet food products require product registration annually.

RESOURCES:

AAFCO's Guidelines on Hemp in Animal Food:

https://www.aafco.org/Portals/0/SiteContent/Announcements/Guidelines on Hemp in Animal Food July 2020.pdf

List of State Feed Control Officials: https://www.aafco.org/Regulatory/State-Information

Definition of livestock utilized by Montana Department of Agriculture's Feed Program: https://leg.mt.gov/bills/mca/title-0150/chapter-0240/part-0090/section-0210/0150-0240-0090-0210.html

FDA Regulation of Cannabis and Cannabis-Derived Products, including Cannabidiol (CBD): https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd

Montana Commercials Feeds Act Part 2, 80-9-201 for license and registration requirements:

https://leg.mt.gov/bills/mca/title 0800/chapter 0090/part 0020/sections index.html

POLICY

The Montana Department of Agriculture will regulate feed and feed ingredients of hemp and substances derived from hemp for pet, specialty pet, and horses as any other approved animal feed ingredient. Manufacturers and distributors of such feed must understand they fall under regulation of Montana's Commercial Feeds Act and must abide by all laws and rules applied to commercial feed.

ALLOWED. Hemp and hemp related ingredients that <u>will be</u> allowed only in pet, specialty pet and horse feed:

- 1. Hemp or substances derived from hemp containing no greater than 0.3% tetrahydrocannabinol (THC)
 - a. Ingredients, including but not limited to, hemp seed, hemp seed cake, hemp seed meal, hemp seed protein, hemp seed flour, hemp seed oil, hemp forage products, and hemp silage.

UNALLOWED. Hemp and hemp related ingredients that <u>will not be</u> allowed in any animal feed.

- Cannabis and substances derived from Cannabis with greater than 0.3 % THC;
 and
- 2. Any, and all CBD products, including CBD oil, derived from industrial hemp; and
- 3. Industrial hemp seed oil with added CBD or other cannabinoids; and
- 4. Any hemp substance intended for the use in the diagnosis, cure, mitigation, treatment or prevention in animals, or a substance other than feed intended to affect the structure or any function of the body of animals

ENFORCEMENT. If there is reasonable cause to believe that a feed or feed ingredient in commerce or intended for introduction into commerce may contain suspected illegal levels of THC or CBD, the Montana Department of Agriculture or representative thereof may procure a sample for testing under the provisions allowed by the Montana Commercial Feeds Act and may implement enforcement actions based on the results. Violations of the Montana Commercial Feeds Act may be subject to civil penalties up to \$1,000. Each violation set forth in ARM 4.12.403 is a separate offense and each offense is subject to a civil penalty not to exceed \$1,000.

Any questions concerning medicated feeds or animal supplements not intended for use as feed, should contact the Food and Drug Administration's Center for Veterinary Medicine, Division of Animal Feeds (FDA/CVM/DAF).

Contact Information:

U.S. Food and Drug Administration Center for Veterinary Medicine Division of Animal Feeds 12225 Wilkins Avenue Rockville, Maryland 20852 Phone 240-402-7077 Fax 240-453-6882