

2022 Regulatory Update Part 1: What We Are Watching In the Pet Products Sector

Pet Products:

Pet Food: We are monitoring discussions within the American Association of Feed Control Officials (AAFCO) -- who works with the Food and Drug Administration ("FDA") to regulate pet food in the States -- regarding proposed guidelines for "human grade" pet and specialty pet food labeling, pet food labeling modernization, and copper levels. We also continue to track FDA guidance on animal food facilities as well as both proposed and enacted state laws affecting pet food producers.

CBD: As in the past, we are monitoring proposed state and federal legislation, as well as AAFCO discussions and research which may lead to pet food labeling changes and regulatory requirements for the sale of products containing CBD.

For more detail on any of these trends please see the Bill Tracking WebPage in the Regulatory Section of the APPA website. For more information on live animal issues in particular, please contact Pet Advocacy Network at [PetAdvocacy.org](https://www.petadvocacy.org)

Pet Food:

The Association of American Feed Control Officers (AAFCO) Presents Revisions and Written Responses to Questions Submitted Regarding The Proposed Guidelines For Human Grade Pet and Specialty Pet Food Claims

As we reported in our last Regulatory Update, in December 2021 AAFCO published draft recommendations regarding guidelines for the use of the term "human grade" in the labeling of pet foods. AAFCO reiterated that pet and specialty pet foods using the "human grade" labeling claim are first and foremost animal food products and subject to inspection under 21 CFR part 507. After providing time for written and public comments and questions, at its mid-year meeting in January 2022, AAFCO presented revisions to its human grade guidelines. The revised guidelines provide a path for products manufactured and final-packed in non FDA-certified facilities (such as Food Safety and Inspection Service facilities) to meet the human grade requirements. To certify this, the revised guidelines also establish a course for a third-party audit through the U.S. Department of Agriculture (USDA) Marketing Service's (AMS) process-verified program. AAFCO is also working with the USDA on an audit for other items that might need clarification.

AAFCO and, specifically, its Pet Food Committee (PFC) continue to refine the language for consistency with the U.S. Food and Drug Administration (FDA). Guidelines will be updated to define what manufacturers need to do to make that claim.

The PFC recently voted to accept the revised Human Grade Guidelines and to present the revised Human Grade Guidelines to the AAFCO Board with a recommendation to accept. This would advance the revised Human Grade Guidelines to a vote before its full membership in August 2022, and if the vote is successful, the revised Human Grade Guidelines would take effect then.

AAFCO also published its working group's responses to questions submitted regarding the proposed human grade guidelines.

To access the draft guidelines, click here:

https://www.aafco.org/Portals/0/SiteContent/Regulatory/Committees/Pet-Food/December_2021_-_Human_Grade_Guidelines_for_Pet_and_Specialty_Pet_Food_December_2021.pdf (AAFCO)

To access the responses click here:

https://www.aafco.org/Portals/0/SiteContent/Regulatory/Committees/Pet-Food/Working_Group_Responses_to_Submitted_Comments.pdf (AAFCO)

Other AAFCO Activities

Pet Food Labeling Modernization (PFLM)

In response to consumer requests, AAFCO continues its work and research to clarify the need and design for a new pet food nutrition label that looks more like the human-food labels. Focusing on changes to labeling regarding nutritional adequacy, safe handling of pet foods, the ingredient list and feeding directions, the PFC is responding to comments and gathering additional information to determine 1) adequacy using a graphic vs. a statement to identify the type of product, and 2) nutrition box content and design.

Copper Levels

AAFCO has formed a work group that includes manufacturers, regulators, veterinarians and other industry members to explore the maximum copper levels in dog food. The group concluded that ongoing research is still needed before a recommendation can be made on whether revised copper levels need to be considered.

FDA Finalizes FSMA Guidance On Hazard Analysis And Preventive Controls For Animal Food

On July 6, the FDA published Guidance for Industry (GFI) #245: Hazard Analysis and Risk-Based Preventive Controls for Food for Animals to help animal food facilities subject to the FDA Food Safety Modernization Act (FSMA) Hazard Analysis and Risk-Based Preventive Controls for animal food requirements develop a food safety plan to prevent or significantly minimize hazards that could cause illness or injury to people or animals.

Guidance is provided on:

- the biological, chemical (including radiological), and physical agents that are known or reasonably foreseeable hazards in manufacturing, processing, packing, and holding of animal food
- the components of a food safety plan and the importance of each component
- how to conduct a hazard analysis and develop a food safety plan for the animal food that you produce
- identifying preventive controls for biological, chemical, and physical hazards associated with animal food and how to apply those preventive controls
- preventive control management components (i.e., monitoring, corrective actions and corrections, and verification (including validation))
- the recordkeeping requirements associated with the food safety plan and implementation of the food safety plan.

To access the FDA's announcement regarding the new guidance document, click here:

https://www.fda.gov/animal-veterinary/cvm-updates/fda-finalizes-fsma-guidance-hazard-analysis-and-preventive-controls-animal-food?utm_medium=email&utm_source=govdelivery (FDA)

To access the guidelines, click here:

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-245-hazard-analysis-and-risk-based-preventive-controls-food-animals> (FDA)

State Action

States have also passed or are considering legislation affecting pet food producers. Introduced on February 18 of this year, California Senate Bill 1462 would authorize a person who manufactures a processed pet food to apply to the State Department of Public Health for a designation for a processed pet food as human food grade, as specified. A hearing was conducted on May 19 and the bill is under submission.

Still pending in Minnesota, Senate Bill 1610 and companion House Bill 2014 would allow cottage food producers (individuals who prepare and sell home-processed pet treats for dogs and cats) to sell homemade pet foods direct to consumers, provided certain conditions such as individual registration, non-hazardous ingredients, baked or dehydrate, labeling, etc.

Under consideration in Illinois, House Bill 4112 provides that commercial feed, pet food, and specialty pet food that contains peanuts, may contain peanuts, or is processed in a facility that processes peanuts, shall contain a prominent warning label stating that the product contains peanuts or may contain peanuts.

Some states are considering modifying registration fees on pet food products or animal feed. Nebraska adopted new regulations that would increase the inspection fee for commercial feed, and Oregon is considering an increase in license and registration fees.

CBD:

FDA Action

Although consumer demand for CBD (cannabidiol) pet products continues to increase, the United States Food and Drug Administration (FDA) has yet to expand its approval of any CBD product beyond the one prescription human epilepsy drug (Epidiolex). However, the FDA has taken some enforcement action against companies it determined were selling such products illegally.

Food & Drug Administration (FDA) Warns Four Companies For Illegally Selling CBD Products Intended For Use in Food-Producing Animals

On May 26, 2022, the FDA issued warning letters to four companies illegally selling unapproved animal drugs containing cannabidiol (CBD) that are intended for use in food-producing animals. The companies include Haniel Concepts dba Free State Oils, Hope Botanicals, Plantacea LLC dba Kahm CBD and Kingdom Harvest. While the FDA does not know the current extent of CBD use in food-producing animals, the agency is taking steps regarding these unapproved and potentially unsafe products now to help protect animals and the safety of the food supply. Under the Federal Food, Drug, and Cosmetic (FD&C) Act, any product intended to treat a disease or otherwise have a therapeutic or medical use, and any product (other than a food) that is intended to affect the structure or function of the body of humans or animals, is a drug. The FDA has not approved any human or animal products containing CBD other than one prescription drug product to treat rare, severe forms of epilepsy in children. Therefore, all other CBD products intended for use as a drug are considered unapproved drugs and are illegal to sell. Some of the claims made by the companies in the warning letters refer to helping “farm animals with stress, anxiety, pain, inflammation, injuries...” and providing “support to help manage normal stress, promote a calming effect, maintain a healthy gut, maintain a normal and balanced behavior, maintain healthy joints, maintain a normal inflammatory response....” These claims, among others, establish the intended use of the products as drugs. The FDA is concerned about these CBD products for food-producing animals not only because CBD could pose a safety risk for the animals themselves, but also because of lack of data about the safety of the human food products (meat, milk and eggs) from the animals that have consumed these CBD products.

https://www.fda.gov/animal-veterinary/cvm-updates/fda-warns-four-companies-illegally-selling-cbd-products-intended-use-food-producing-animals?utm_medium=email&utm_source=govdelivery (FDA)

FDA Issues Warning Letters to Companies Illegally Selling CBD and Delta-8 THC Products

On May 4, the FDA issued warning letters to five companies for selling products labeled as containing delta-8 tetrahydrocannabinol (delta-8 THC) in ways that violate the Federal Food, Drug, and Cosmetic Act (FD&C Act). This action is the first time the FDA has issued warning letters for products containing delta-8 THC. Delta-8 THC has psychoactive and intoxicating effects and may be dangerous to consumers. The FDA has received reports of adverse events experienced by patients who have consumed these products. There are no FDA-approved drugs containing delta-8 THC. Any delta-8 THC product claiming to diagnose, cure, mitigate, treat, or prevent diseases is considered an unapproved new drug. The FDA has not evaluated whether these unapproved drug products are effective for the uses

manufacturers claim, what an appropriate dose might be, how they could interact with FDA-approved drugs or other products, or whether they have dangerous side effects or other safety concerns.

In addition to the violations related to FDA-regulated products containing delta-8 THC, several of the warning letters outline additional violations of the FD&C Act, including marketing CBD products claiming to treat medical conditions in humans and animals, promoting CBD products as dietary supplements, and adding CBD to human and animal foods. CBD and delta-8 THC are unapproved food additives for use in any human or animal food product, as the FDA is not aware of any basis to conclude that the substances are generally recognized as safe (GRAS) or otherwise exempt from food additive requirements. One of the letters expresses concerns regarding CBD products marketed for food-producing animals, and the potential safety concerns related to human food products (e.g., meat, milk, eggs) from animals that consume CBD, as there is a lack of data on safe CBD residue levels.

To access the FDA press release in its entirety, click here:

<https://www.fda.gov/news-events/press-announcements/fda-issues-warning-letters-companies-illegally-selling-cbd-and-delta-8-thc-products> (FDA)

Warning Letters and Test Results for Cannabidiol-Related Products

On May 6, the FDA published a year by year summary of CBD warning letters and test results. Over the past several years, FDA has issued several warning letters to firms – including several that produce pet products – that market unapproved new drugs that allegedly contain cannabidiol (CBD). As part of these actions, FDA has tested the chemical content of cannabinoid compounds in some of the products, and many were found to not contain the levels of CBD they claimed to contain. It is important to note that these products are not approved by FDA for the diagnosis, cure, mitigation, treatment, or prevention of any disease. Consumers should beware purchasing and using any such products.

To view the FDA's posting, click here:

<https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products> (FDA)

Legislative Action

Federal

Still pending is the bipartisan “**CBD Product Safety and Standardization Act of 2021**” (HB 6134) which would establish federal standards and require the FDA to regulate cannabidiol (CBD) in foods and beverages. The Act would allow the FDA to regulate CBD as a food additive. If passed, it would require the Agency to issue regulations specifying the maximum amount of CBD derived from hemp per serving, labeling and packaging requirements, and conditions of intended use.

In a press release, Representative Rice stated that “CBD products are exploding in popularity, but the lack of federal regulation surrounding them has put consumers at risk and left businesses looking for clarity. The bipartisan CBD Product Safety and Standardization Act will establish the

clear regulatory framework needed to provide stability for business and ensure unsafe products stay off the shelves.”

The bill remains in the House Subcommittee on Health.

<https://www.natlawreview.com/article/house-introduces-bill-to-regulate-cbd-food> (National Law Review)

To access the text of the bill, click here:

<https://hempsupporter.com/assets/uploads/CBD-Product-Safety-and-Standardization-Act.pdf>

Similarly pending on the Senate side is “**The Hemp Access and Consumer Safety Act of 2021**”, Senate Bill 1698, which would establish a legal pathway for certain hemp-derived CBD products by exempting hemp-derived CBD and therefore allowing such products to be FDA-regulated like all other new dietary ingredients, foods, and beverages. As reported in the last regulatory update, there has been no further action taken with regard to the bill, which was referred to the Committee on Health, Education, Labor, and Pensions on May 19. To access the bill, click here:

<https://www.congress.gov/bill/117th-congress/senate-bill/1698/all-info>

State

A number of states are contemplating or have passed legislation having to do with hemp or CBD products. Pending in New Hampshire is HB 272, which would regulate the labeling and sale of hemp products containing CBD. In March Utah enacted HB0385, which relates to the production and sale of industrial hemp and cannabinoid products. On June 16, Louisiana’s governor signed into law HB 758, which regulates industrial hemp products. Pending in New Hampshire is HB 272, which would regulate the labeling and sale of hemp products containing CBD.

AAFCO

AAFCO Publishes Its Joint Open Letter of Concern over the Allowance of Hemp in Animal Feed

On February 9, 2022, AAFCO published its joint letter urging agricultural leaders and state policymakers to “Support Education and Research to Ensure Safe Use of Hemp as an Ingredient.”

As leading organizations for the advancement of livestock production, pet nutrition, veterinary services, laboratory research, animal feed manufacturing, and public health, the undersigned wish to share our unified concerns regarding the current interest in using hemp, including its derivatives and by-products (herein collectively referred to as “hemp”), in animal feed. It is our position that sufficient scientific research to support the safety and utility of hemp in animal feed must be completed prior to any Federal or state approval.

To access the joint letter, click

here: <https://www.aafco.org/Portals/0/SiteContent/Announcements/Hemp%20Joint%20Open%20Letter%20-%20AAFCO%20-%20FINAL%203.pdf> (AAFCO)