August 2, 2024

Leslie Novosel
(b) (6)

Re: Docket No. FDA-2022-P-0213

Dear Ms. Novosel:

This is in response to your petition dated February 22, 2022, requesting "FDA-CVM to withdraw MOU 225-07-7001, an agreement between FDA and private corporation AAFCO [the Association of American Feed Control Officials]." You assert that FDA should "develop animal feed terms and definitions publicly via public meetings in compliance with §553 of the Administrative Procedure Act."

In accordance with 21 CFR 10.30(e) and for the reasons set forth in the enclosed response to Citizen Petition FDA-2021-P-0436, which requested the same action, we are denying your petition. However, though we are not granting your specific request(s), the enclosed response explains that we will not be entering into a new MOU with AAFCO when the current MOU expires on October 1, 2024.

Sincerely,

Tracey H. Forfa, J.D., M. of Div.
Director, Center for Veterinary Medicine

Enclosure

U.S. FOOD & DRUG ADMINISTRATION

August 2, 2024

Kohl Harrington
(b) (6)

Re: Docket No. FDA-2021-P-0436

Dear Mr. Harrington:

This is in response to your petition dated May 6, 2021, requesting "FDA-CVM to withdraw MOU 225-07-7001, an agreement between FDA and private corporation AAFCO [the Association of American Feed Control Officials]." You assert that FDA should instead "develop animal feed terms and definitions **publicly** and **in compliance with §553 of the Administrative Procedure Act**." We also reviewed two comments to the docket for your petition.[1]

In support of your petition, you state that FDA attends "private 'AAFCO' meetings where FDA helps develop in 'private' what ultimately becomes recognized as federally acceptable for use in animal feed and pet food products in interstate commerce." You state that these meetings are distinct from "public" meetings that comply with various State and Federal administrative procedure laws, and that the public is charged large entrance fees to attend these meetings. You also state that "[a]s many as 30-40 [FDA] employees regularly attend AAFCO meetings" and "FDA uses federal funds for each FDA employee to attend these meetings, and employees are attending these meetings while on their official federal employee time."

Your petition states that:

> FDA has a MOU with AAFCO, where FDA "recognizes" the "official definitions" of AAFCO, which FDA has a major hand in the development of these ingredients. This is MOU 225-07-7001. FDA performs a "scientific review" for each AAFCO ingredient, yet this review is not performed in compliance with § 553 of the Administrative Procedure Act even though FDA's sole intention is to "recognize" these official definitions for regulatory use in animal feed and pet food products in interstate commerce.

You also argue that FDA participates in developing "'official feed terms', which FDA fully intends to then 'recognize' as official feed terms at the federal level, all while knowing they will be 'copyrighted' by this private association of public employees." You say that "[i]t is impossible to understand who proposed a particular ingredient, and what the 'science' of that ingredient is, due to AAFCO refusing to provide this information to the public."

[1] One comment consists of your posting a letter from FDA responding to your question regarding when you would be receiving a response to your petition. The other comment contains thoughts on FDA's letter. Neither cites any evidence or authority to support the requests in the petition.

Finally, you assert that the same attorney who provides legal counsel to the American Feed Industry Association (AFIA) also represents AAFCO, presenting what you characterize as a "massive conflict of interest for the interests of public 'regulators' to be represented by the same attorney that represents the interests of the so called 'regulated.'"

In accordance with 21 CFR 10.30(e) and for the reasons set forth below, we are denying your petition. However, though we are not granting your specific requests, we explain that we will not be entering into a new MOU with AAFCO.

Background

The Federal Food, Drug, and Cosmetic Act (FD&C Act) gives FDA the authority to regulate substances used in animal food, including substances that are food additives and substances that are generally recognized as safe (GRAS) for their intended uses in animal food. The FD&C Act also gives FDA authority to require that certain information, including ingredient names, be included on food labels and labeling,[2] and to promulgate regulations to establish definitions and standards of identity for foods to "promote honesty and fair dealing in the interest of consumers."[3] Each State also regulates animal food within its borders.

The AAFCO ingredient definition process is operated by AAFCO, with the FDA voluntarily providing scientific and technical assistance. The MOU that you are requesting we withdraw,[4] MOU 225-07-7001, explains the AAFCO ingredient definition request process and the roles that AAFCO and FDA play in that process. FDA uses its scientific expertise to assess an ingredient, including its use, proposed for listing in the AAFCO Official Publication (OP). The definitions adopted through the AAFCO ingredient definition request process are not Federal regulations and they do not bind FDA or animal food manufacturers under Federal law. Because most States adopt the ingredient definitions listed in the AAFCO OP into their State laws, the AAFCO ingredient definition request process facilitates the marketing of animal food ingredients under those State laws. FDA's participation in the process helps FDA be aware of new ingredients that are marketed in interstate commerce and any potential safety concerns associated with them.

Discussion

You have requested that FDA develop animal feed terms and definitions publicly and in compliance with section 553 of the Administrative Procedure Act (APA). Section 553 of the APA sets out requirements for notice and comment rulemaking by federal agencies.

Your petition does not request any particular rule or provide the wording or other details of any regulation you are requesting. FDA regulations set out the required format of a citizen petition, including that, "if the petition requests the Commissioner to issue, amend, or revoke a regulation,

[2] E.g., 21 U.S.C. § 343(e), (f), (i).

[3] 21 U.S.C. § 341.

[4] MOU 225-07-7001 provides for the agreement to be either "extended" or "terminated." We construe your request for withdrawal as a request that FDA pursue termination of the MOU.

the exact wording of the existing regulation (if any) and the proposed regulation or amendment requested" must be provided. 21 CFR 10.30(b)(3).

Even assuming your petition met the required elements discussed above, FDA would deny your petition because you do not provide any data or other information indicating that codified definitions of any animal foods are required or needed at this time. Although the APA's notice and comment rulemaking provisions would apply if FDA promulgated regulations establishing common or usual names for animal foods under 21 CFR part 502, or definitions and statements of identity under section 401 of the FD&C Act, there is no Federal requirement that animal food ingredients be defined by regulation. It is unclear what you mean by "develop animal feed terms and definitions," you have not provided information supporting this request, and FDA does not believe codified definitions are needed at this time; therefore, we are denying your request.

Section 403(i) of the FD&C Act requires that ingredients be declared on the labels of foods by their common or usual names. A common or usual name is the name by which an article is known to the American public. A common or usual name may be established by regulation or by common usage. There is no Federal requirement that common or usual names of food be established by regulation, and, in fact, FDA has established very few common or usual names for animal food ingredients by regulation. Hence, most animal food ingredients are declared on the labels of animal food by their common usage names. These names are typically consistent with the names in the AAFCO OP, which have come into common usage through adoptions by States, manufacturer compliance, and consumer recognition. You have not provided any justification establishing a need for such regulation for any ingredient, nor are we otherwise aware of the need, at this time.

Further, under section 401 of the FD&C Act, FDA can promulgate a regulation to establish a definition and standard of identity to "promote honesty and fair dealing in the interest of consumers." Such regulations have been established by FDA to protect against economic adulteration, maintain the integrity of food, and ensure that food meets consumer expectations. Definitions and standards of identity, which generally are established under the common or usual name of the food, set forth requirements related to the content, composition, and production of the food. Your petition did not demonstrate the need for FDA to establish definitions and standards of identity under section 401 of the FD&C Act.

You also have requested that FDA withdraw MOU 225-07-7001. A concern you raise is that AAFCO meetings are not "public meetings" that comply with various State and Federal administrative procedure laws, and that AAFCO charges a fee for the public to attend these meetings. You also state that FDA does not make the AAFCO animal feed ingredient definitions available to the public and that "[i]t is impossible to understand who proposed a particular ingredient, and what the 'science' of that ingredient is, due to AAFCO refusing to provide this information to the public." AAFCO is a private, non-profit, organization, and is not obligated to make their meetings open to the public or make ingredient request submissions public. Moreover, the decision to charge a fee, and the amount of the fee, is a business decision made by AAFCO, not FDA. AAFCO publishes the ingredient definitions in its OP. Due to copyright laws, FDA is not able to release the AAFCO ingredient definitions. However, in 2021, AAFCO began making the ingredient definition chapter of the previous year's AAFCO OP available, free

of charge, on its website (see, https://www.aafco.org/resources/official-publication/op-chapter-6-public-access/). We also note that AAFCO offers a listen-only, call-in telephone number for every ingredient meeting at no cost to the public.[5]

You also assert that FDA spends Federal funds to send employees to AAFCO meetings and that these meetings result in "what ultimately becomes recognized as federally acceptable for use in animal feed and pet food products in interstate commerce." AAFCO ingredient definitions are not Federal regulations and do not have the force and effect of law. However, FDA has voluntarily worked with AAFCO to provide our scientific expertise, and our participation in the AAFCO ingredient definition process has furthered the mission of the agency by helping us ensure the safety of our nation's human and animal food supply. FDA's participation in the process has helped FDA to be aware of new ingredients that are marketed in interstate commerce and any potential safety concerns associated with them. Although AAFCO definitions are not Federal law, most States adopt the ingredient definitions listed in the AAFCO OP under their State laws. The AAFCO ingredient definition request process facilitates the marketing of animal food ingredients under those State laws.

Finally, you express concern that the same attorney represents AAFCO, an association of feed control regulators, and members of the industry they regulate, including the AFIA. Even if we assume, for purposes of this response, that your concern has merit, ending FDA's participation in the AAFCO ingredient definition request process would not address your concern, therefore your argument does not support your request to withdraw the MOU.

For the reasons explained above, FDA does not find the concerns you have raised sufficient to compel us to pursue termination of MOU 225-07-7001.

FDA's Participation in the AAFCO Ingredient Definition Request Process

For many years, FDA has participated in the AAFCO ingredient definition request process, providing scientific expertise to review the safety of animal food ingredients proposed for listing in the AAFCO OP. Such participation has furthered a mission of the Agency to ensure the safety of our nation's human and animal food supply. FDA's participation in the process has helped ensure FDA is aware of, and has assessed safety information on, many ingredients that are marketed in interstate commerce.

[5] See https://www.aafco.org/about/committees/ingredient-definitions/ to register for such meetings. Although we do not have a breakdown of the number of non-member participants taking advantage of the listen-only option, the minutes for the January 2023 in-person and virtual Ingredient Definition Committee meeting, posted on AAFCO's website, document the participation of over 400 attendees.

However, today FDA is announcing that it will not enter into a new MOU with AAFCO when the current MOU expires on October 1, 2024. For more information, please see our Letter to Stakeholders at https://www.fda.gov/animal-veterinary/animal-food-feeds/fda-letter-stakeholders-acknowledgment-expiring-fda-aafco-mou.

Sincerely,

Tracey H. Forfa, J.D., M. of Div.
Director, Center for Veterinary Medicine