

April 16, 2025



Re: Docket No. FDA-2022-P-0306

Dear Ms. Melton:

This is in response to your petition (FDA-2022-P-0306) dated March 8, 2022, requesting, FDA-CVM "to comply with, §553 of the Administrative Procedure Act, and publish the ingredient definition for the animal feed/pet food ingredient "chicken meal" on the federal register."

In support, you state that, "'Chicken meal' is an ingredient FDA allows to be used in animal feed and pet food products under FDA regulatory jurisdiction" and that, "[v]ia MOU-225-07-7001, FDA-CVM considers the definition for 'Chicken meal' to be a federal regulation for FDA regulated products. However, FDA-CVM refuses to comply with §553 of the Administrative Procedure Act and publish this ingredient term and definition on the federal register." You also reference two requests you submitted under the Freedom of Information Act (FOIA) for records related to chicken meal.^{1,2}

We deny your petition for the reasons explained below.

We disagree with your premise that "FDA-CVM refuses to comply with §553 of the Administrative Procedure Act and publish this ingredient term and definition on the federal register." Section 553 of the Administrative Procedure Act (APA), 5 U.S.C. §553, sets out requirements for notice and comment rulemaking and would apply if FDA promulgated a regulation defining chicken meal. FDA has not established a federal definition for chicken meal for use in animal food or issued any other regulation specifically for chicken meal for use in animal food. Because FDA has not established a federal regulation defining chicken meal, the APA's rulemaking requirements do not apply.

You also mention FDA's Memorandum of Understanding with the Association of American Feed Control Officials (AAFCO), which described FDA's previous role in the AAFCO Ingredient Definition Request Process. That MOU expired on October 1, 2024, and FDA no longer participates in the AAFCO Ingredient Definition Request Process. Your statement that "[v]ia MOU-225-07-7001, FDA-CVM considers the definition for "chicken meal" to be a Federal regulation for FDA regulated products[]" is incorrect. FDA does not

¹ Your FOIA requests are not relevant to the question of whether FDA complied with the notice and comment rulemaking requirements in 5 U.S.C. §553.

² Our records indicate you filed a total of seven FOIA requests for records related to "chicken meal" and that FDA provided a "no records" response for each of them (FOIA ## 2021-1135; 2021-1755; 2021-2250; 2021-3734; 2021-8542; 2022-3826; 2022-3944). In April 2021, you appealed FDA's Office of Regulatory Affair's (now the Office of Inspections and Investigations or "OII") no records response to FOIA # 2021-1755. In December 2021, the agency denied your appeal. In July 2022, you appealed CVM's May 2022 "no records" response to FOIA # 2021-8542. In December 2022, the agency denied your appeal.

consider any AAFCO ingredient definition, including the definition for "poultry meal," to be a federal regulation. Because AAFCO's ingredient definitions are not federal law, the APA's rulemaking requirements do not apply.

To the extent your petition is a request that FDA establish a federal regulation for chicken meal, you do not identify the kind of regulation you are requesting, explain the need for such a regulation, or explain how the proposed regulation will address any identified need. For example, if you are asking us to promulgate a federal regulation establishing a common or usual name for chicken meal, you should explain why such a regulation is needed.

If, on the other hand, you are asking us to promulgate a regulation establishing a definition and standard of identity under section 401 of the FD&C Act, you should also explain why such a regulation is needed. Under section 401 of the FD&C Act, the Agency may promulgate regulations to establish definitions and standards for food to "promote honesty and fair dealing in the interest of consumers." In the past, the Agency has established definitions and standards of identity for certain foods under this authority to protect against economic adulteration, maintain the integrity of food, and ensure that food meets consumer expectations. Definitions and standards of identity are established under the common or usual name of the food and set forth requirements pertaining to the content, composition, and production of the food.

You have not demonstrated that establishing a definition and standard of identity for chicken meal prevents economic adulteration, maintains the integrity of the food, or ensures that the food meets consumer expectations. Your petition does not present evidence of economic adulteration, let alone how the proposed regulation would remedy any economic adulteration. Nor does your petition explain how the proposed regulation would maintain the integrity of the food. Your petition also does not describe or present evidence of any consumer expectations of the food and how the proposed definition would ensure that the food is produced in accordance with those expectations.

For the reasons stated above and in accordance with 21 CFR 10.30(e)(3), we are denying your petition.

Sincerely,

William T. Flynn -S Date: 2025.04.16 12:28:41 - 04'00'

William F. Flynn, DVM, MS Deputy Director, Center for Veterinary Medicine

³ Although the AAFCO Official Publication does not define "chicken meal," it does include a definition for "poultry meal" and the definition states that if an ingredient "bears a name descriptive of its kind, it must correspond thereto" meaning that the poultry meal may be described as chicken meal if it contains only material derived from chickens.