



September 12, 2023

Mr. Harry Duty

(b) (6)

Re: Docket No. FDA-2022-P-0126

Dear Mr. Duty,

This is in response to your petition, dated February 7, 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 ‘corn gluten meal’ on the federal register.”

In support, you state that, “‘Corn Gluten 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 ‘corn gluten 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.”

We deny your petition.

We disagree with your statement that “[v]ia MOU-225-07-7001, FDA-CVM considers the definition for ‘corn gluten meal’ to be a federal regulation for FDA regulated products.” The MOU clarifies how FDA intends to interact with the Association of American Feed Control Officials (AAFCO) during AAFCO’s animal feed ingredient definition process. FDA does not consider the feed ingredient definition for “corn gluten meal” established by AAFCO to be a federal regulation. We also disagree with your statement that “FDA-CVM refuses to comply with § 553 of the Administrative Procedure Act and publish this ingredient term and definition on the federal register.” The portion of the Administrative Procedure Act codified at 5 U.S.C. § 553 sets out requirements for notice and comment rulemaking for federal agencies and does not apply to AAFCO or AAFCO’s ingredient definitions.

As we stated in our January 24, 2022, response to a related petition you submitted asking us to “issue a regulation for the ingredient ‘corn gluten meal’ for use in FDA regulated animal feed and pet food products,”<sup>1</sup> FDA has not established a definition for corn gluten meal for use in animal food or any other regulation specifically for corn gluten meal for use in animal food. Therefore, there is no FDA regulation to publish in the Federal Register.

If you are requesting that we publish in the Federal Register the ingredient definition for corn gluten meal established by AAFCO and published in the AAFCO Official Publication, we

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<sup>1</sup> [FDA-2021-P-0912](#)



direct you to the FOIA appeal decision letter dated April 6, 2022 (see attached) in which we explained to you that the ingredient definitions in the AAFCO Official Publication (including the AAFCO ingredient definition for corn gluten meal) are protected by copyright law. However, as noted in that letter, you can access the AAFCO definition of “corn gluten meal” on the AAFCO website, free of charge.<sup>2</sup>

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

Sincerely,

William T. Flynn -S

Digitally signed by William T.  
Flynn -S  
Date: 2023.09.12 17:55:19 -04'00'

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

Attachment

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<sup>2</sup> <https://www.aafco.org/resources/official-publication/op-chapter-6-public-access/>