

On December 7, U.S. Representative Greg Pence (R-IN) <u>introduced</u> the Innovative Feed Enhancement and Economic Development Act of 2023 (the <u>Innovative FEED Act</u>).

Sen. Roger Marshall (R-KS) introduced the Senate version of the bill earlier this year.

The bill would amend the Federal Food, Drug, and Cosmetic Act (FDCA) to establish a regulatory pathway for zootechnical animal food substances, a new category of animal feed substances. The bill's proponents <u>argue</u> that the legislation is necessary to move such substances out of the FDA's animal drug approval process and improve the competitive environment for these products.

Currently, FDA's Center for Veterinary Medicine (CVM) considers certain animal foods regulated as drugs under its <a href="Policy and Procedures Manual">Policy and Procedures Manual (PPM) 1240.3605</a>, Regulating Animal Foods With Drug Claims. Under this policy, CVM considers the intended use of the product to determine whether the product should be regulated as a food or as a drug. Pursuant to the policy, certain ingredients making production claims or structure/function claims are usually regulated as drugs. Under the proposed bill, FDA would instead regulate zootechnical animal food substances as food additives.

The proposed bill would amend the FDCA to define a zootechnical animal food substance, in part, as a substance added to the food or drinking water of animals that would alter the animal's gastrointestinal (GI) microbiome by acting solely within the GI tract of the animal. The category would exclude, among other things, hormones and substances used in the diagnosis, cure, mitigation, treatment, or prevention of disease in an animal.

The House of Representatives referred the bill to the House Committee on Energy and Commerce. The House version has 17 <u>cosponsors</u>, including 15 Republicans and two Democratic members. Senator Marshall's Senate version has six <u>cosponsors</u>: Senators Tammy Baldwin (D-WI), Jerry Moran (R-KS), Michael Bennet (D-CO), Rand Paul (R-KY), Susan Collins (R-ME), and Amy Klobuchar (D-MN). The text of the bill is available here.

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