118TH CONGRESS
1ST Session

S.

To amend the Federal Food, Drug, and Cosmetic Act with respect to the regulation of zootechnical animal food substances.

IN THE SENATE OF THE UNITED STATES

Mr. MARSHALL (for himself, Ms. BALDWIN, Mr. MORAN, and Mr. BENNET) introduced the following bill; which was read twice and referred to the Committee on

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the regulation of zootechnical animal food substances.

1 Be it enacted by the Senate and House of Representative of the United States of America in Congress assembled,
2 SECTION 1. SHORT TITLE.
3 This Act may be cited as the “Innovative Feed Enhancement and Economic Development Act of 2023” or the “Innovative FEED Act”.
SEC. 2. REGULATION OF ZOOTECHNICAL ANIMAL FOOD SUBSTANCES.

(a) DEFINITION.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

“(tt)(1) The term ‘zootechnical animal food substance’ means a substance that—

“(A) is added to the food or drinking water of animals;

“(B) is intended to—

“(i) affect the byproducts of the digestive process of an animal;

“(ii) reduce the presence of foodborne pathogens of human health significance in an animal intended to be used for food; or

“(iii) affect the structure or function of the body of the animal, other than by providing nutritive value, by altering the animal’s gastrointestinal microbiome; and

“(C) achieves its intended effect by acting solely within the gastrointestinal tract of the animal.

“(2) Such term does not include a substance that—

“(A) is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in an animal;

“(B) is a hormone;
“(C) is an active moiety in an animal drug, which, prior to the filing of a petition under section 409 was approved under section 512, conditionally approved under section 571, indexed under section 572, or for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public;

“(D) is an ionophore; or

“(E) is otherwise excluded from the definition based on criteria established by the Secretary through notice and comment rulemaking.

“(3) A zootechnical animal food substance shall be deemed to be a food additive within the meaning of paragraph (s) and its introduction into interstate commerce shall be in accordance with a regulation issued under section 409. A zootechnical animal food substance shall not be considered a drug under paragraph (g)(1)(C) solely because the substance has an intended effect described in subparagraph (1).”.

(b) FOOD ADDITIVES.—Section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348) is amended—

(1) in subsection (b)—
(A) by redesignating paragraphs (3) through (5) as paragraphs (4) through (6), respectively; and

(B) by inserting after paragraph (2) the following:

“(3) In the case of a zootechnical animal food substance, such petition shall, in addition to any explanatory or supporting data, contain—

“(A) all relevant data bearing on the effect the zootechnical animal food substance is intended to have and the quantity of such substance required to produce the intended effect; and

“(B) full reports of investigations made with respect to the intended use of such substance, including full information as to the methods and controls used in conducting such investigations.”;

(2) in subsection (c)—

(A) by amending subparagraph (A) of paragraph (1) to read as follows:

“(A)(i) by order establish a regulation (whether or not in accord with that proposed by the petitioner) prescribing—
“(I) with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used (including specifications as to the particular food or classes of food in or on which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive as the Secretary determines necessary to assure the safety of such use); and

“(II) in the case of a zootechnical animal food substance, the conditions under which such substance may be used to achieve the intended effect; and

“(ii) notify the petitioner of such order and the reasons for such action; or”; and

(B) in paragraph (3)—

(i) in subparagraph (A), by striking “; or” and inserting a semicolon;

(ii) in subparagraph (B), by striking the period and inserting “; or”; and
(iii) by adding at the end the following:

“(C) in the case of a zootechnical animal food substance, fails to establish that the proposed use of the substance, under the conditions of use to be specified in the regulation, will achieve the intended effect.”; and

(3) by adding at the end the following:

“(l) ZOO TECHNICAL ANIMAL FOOD SUBSTANCES.—The labeling of a zootechnical animal food substance—

“(1) shall include the statement: ‘Not for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in animals.’; and

“(2) may include statements regarding the intended effect of the substance on the structure or function of the body of animals, as set forth in section 201(tt)(1).”.

(c) MISBRANDED FOOD.—Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended by adding at the end the following:

“(z) If it is a zootechnical animal food substance and the labeling of the food does not include the statement required by section 409(l)(1).”.

(d) RULE OF CONSTRUCTION.—Nothing in this section, or the amendments made by this section, shall be
construed to authorize the Secretary of Health and Human Services to require the use of any zootechnical food substance or food additive (as those terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (a)).