

118TH CONGRESS  
1ST SESSION

**S.** \_\_\_\_\_

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

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IN THE SENATE OF THE UNITED STATES

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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 \_\_\_\_\_

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**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 Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Innovative Feed En-  
5 hancement and Economic Development Act of 2023” or  
6 the “Innovative FEED Act”.

1 **SEC. 2. REGULATION OF ZOOTECHNICAL ANIMAL FOOD**  
2 **SUBSTANCES.**

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

6 “(tt)(1) The term ‘zootechnical animal food sub-  
7 stance’ means a substance that—

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

10 “(B) is intended to—

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

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

16 “(iii) affect the structure or function of the  
17 body of the animal, other than by providing nu-  
18 tritive value, by altering the animal’s gastro-  
19 intestinal microbiome; and

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

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

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

26 “(B) is a hormone;

1           “(C) is an active moiety in an animal drug,  
2           which, prior to the filing of a petition under section  
3           409 was approved under section 512, conditionally  
4           approved under section 571, indexed under section  
5           572, or for which substantial clinical investigations  
6           have been instituted and for which the existence of  
7           such investigations has been made public;

8           “(D) is an ionophore; or

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

12          “(3) A zootechnical animal food substance shall be  
13          deemed to be a food additive within the meaning of para-  
14          graph (s) and its introduction into interstate commerce  
15          shall be in accordance with a regulation issued under sec-  
16          tion 409. A zootechnical animal food substance shall not  
17          be considered a drug under paragraph (g)(1)(C) solely be-  
18          cause the substance has an intended effect described in  
19          subparagraph (1).”.

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

23                  (1) in subsection (b)—

1 (A) by redesignating paragraphs (3)  
2 through (5) as paragraphs (4) through (6), re-  
3 spectively; and

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

6 “(3) In the case of a zootechnical animal food  
7 substance, such petition shall, in addition to any ex-  
8 planatory or supporting data, contain—

9 “(A) all relevant data bearing on the effect  
10 the zootechnical animal food substance is in-  
11 tended to have and the quantity of such sub-  
12 stance required to produce the intended effect;  
13 and

14 “(B) full reports of investigations made  
15 with respect to the intended use of such sub-  
16 stance, including full information as to the  
17 methods and controls used in conducting such  
18 investigations.”;

19 (2) in subsection (c)—

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

22 “(A)(i) by order establish a regulation (whether  
23 or not in accord with that proposed by the peti-  
24 tioner) prescribing—

1           “(I) with respect to one or more proposed  
2 uses of the food additive involved, the condi-  
3 tions under which such additive may be safely  
4 used (including specifications as to the par-  
5 ticular food or classes of food in or on which  
6 such additive may be used, the maximum quan-  
7 tity which may be used or permitted to remain  
8 in or on such food, the manner in which such  
9 additive may be added to or used in or on such  
10 food, and any directions or other labeling or  
11 packaging requirements for such additive as the  
12 Secretary determines necessary to assure the  
13 safety of such use); and

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

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

20           (B) in paragraph (3)—

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

23           (ii) in subparagraph (B), by striking  
24 the period and inserting “; or”; and

1 (iii) by adding at the end the fol-  
2 lowing:

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

8 (3) by adding at the end the following:

9 “(1) ZOOTECHNICAL ANIMAL FOOD SUBSTANCES.—  
10 The labeling of a zootechnical animal food substance—

11 “(1) shall include the statement: ‘Not for use in  
12 the diagnosis, cure, mitigation, treatment, or preven-  
13 tion of disease in animals.’; and

14 “(2) may include statements regarding the in-  
15 tended effect of the substance on the structure or  
16 function of the body of animals, as set forth in sec-  
17 tion 201(tt)(1).”.

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

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

24 (d) RULE OF CONSTRUCTION.—Nothing in this sec-  
25 tion, or the amendments made by this section, shall be

1 construed to authorize the Secretary of Health and  
2 Human Services to require the use of any zootechnical  
3 food substance or food additive (as those terms are defined  
4 in section 201 of the Federal Food, Drug, and Cosmetic  
5 Act, as amended by subsection (a)).