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(Original Signature of Member)

118TH CONGRESS
1ST SESSION

H. R. _____

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

IN THE HOUSE OF REPRESENTATIVES

Mr. PENCE introduced the following bill; which was 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 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) RULE OF CONSTRUCTION.—Nothing in this sec-
4 tion, or the amendments made by this section, shall be
5 construed to authorize the Secretary of Health and
6 Human Services to require the use of any zootechnical
7 food substance or food additive (as those terms are defined
8 in section 201 of the Federal Food, Drug, and Cosmetic
9 Act, as amended by subsection (b)).

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

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

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

17 “(B) is intended to—

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

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

23 “(iii) affect the structure or function of the
24 body of the animal, other than by providing nu-
25 tritive value, by altering the animal’s gastro-
26 intestinal microbiome; and

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

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

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

7 “(B) is a hormone;

8 “(C) is an active moiety in an animal drug,
9 which, prior to the filing of a petition under section
10 409 was approved under section 512, conditionally
11 approved under section 571, or indexed under sec-
12 tion 572, or for which substantial clinical investiga-
13 tions have been instituted and for which the exist-
14 ence of such investigations has been made public;

15 “(D) is an ionophore; or

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

19 “(3) A zootechnical animal food substance shall be
20 deemed to be a food additive within the meaning of para-
21 graph (s) and its introduction into interstate commerce
22 shall be in accordance with a regulation issued under sec-
23 tion 409. A zootechnical animal food substance shall not
24 be considered a drug under paragraph (g)(1)(C) solely be-

1 cause the substance has an intended effect described in
2 subparagraph (1).”.

3 (c) FOOD ADDITIVES.—Section 409 of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 348) is amend-
5 ed—

6 (1) in subsection (b)—

7 (A) by redesignating paragraphs (3)
8 through (5) as paragraphs (4) through (6), re-
9 spectively; and

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

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

15 “(A) all relevant data bearing on the effect
16 the zootechnical animal food substance is in-
17 tended to have and the quantity of such sub-
18 stance required to produce the intended effect;
19 and

20 “(B) full reports of investigations made
21 with respect to the intended use of such sub-
22 stance, including full information as to the
23 methods and controls used in conducting such
24 investigations.”;

25 (2) in subsection (c)—

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

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

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

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

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

25 (B) in paragraph (3)—

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

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

5 (iii) by adding at the end the fol-
6 lowing:

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

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

13 “(l) ZOOTECHNICAL ANIMAL FOOD SUBSTANCES.—
14 The labeling of a zootechnical animal food substance—

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

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

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

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