

**AMENDMENT TO THE AMENDMENT IN THE  
NATURE OF A SUBSTITUTE TO H.R. 1418  
OFFERED BY M . \_\_\_\_\_**

Add at the end the following:

1 **SEC. 304. 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)(i) is added to the food or drinking water  
9 of animals;

10 “(ii) is intended to—

11 “(I) reduce the presence of foodborne  
12 pathogens of human health significance in an  
13 animal intended to be used for food;

14 “(II) affect the structure or function of the  
15 body of the animal by altering the animal’s gas-  
16 trointestinal microbiome;

17 “(III) affect the structure or function of  
18 the body of the animal, other than by providing

1 nutritive value, for any other purpose as deter-  
2 mined by the Secretary through rulemaking; or

3 “(IV) affect emissions from an animal or  
4 its waste; and

5 “(iii) achieves its intended effect by acting sole-  
6 ly within the gastrointestinal tract of the animal; or

7 “(B) is otherwise included in the definition  
8 based on criteria established by the Secretary  
9 through notice and comment rulemaking.

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

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

14 “(B) is a hormone;

15 “(C) is an active moiety in an animal drug,  
16 which, prior to the filing of a petition under section  
17 409 was approved under section 512, conditionally  
18 approved under section 571, indexed under section  
19 572, or for which substantial clinical investigations  
20 have been instituted and for which the existence of  
21 such investigations has been made public;

22 “(D) is an ionophore; or

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

1       “(3) A zootechnical animal food substance shall be  
2 deemed to be a food additive within the meaning of section  
3 (s) and its introduction into interstate commerce shall be  
4 in accordance with a regulation issued under section 409.  
5 A zootechnical animal food substance shall not be consid-  
6 ered a drug under subsection (g)(1)(C) solely because the  
7 substance has an intended effect described in paragraph  
8 (1).”.

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

12               (1) in subsection (b)—

13                       (A) by redesignating paragraphs (3)  
14 through (5) as paragraphs (4) through (6), re-  
15 spectively; and

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

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

21                       “(A) all relevant data bearing on the effect  
22 the zootechnical animal food substance is in-  
23 tended to have and the quantity of such sub-  
24 stance required to produce the intended effect;  
25 and

1           “(B) full reports of investigations made  
2 with respect to the intended use of such sub-  
3 stance, including full information as to the  
4 methods and controls used in conducting such  
5 investigations.”;

6           (2) in subsection (c)—

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

9           “(A)(i) by order establish a regulation  
10 (whether or not in accord with that proposed by  
11 the petitioner) prescribing—

12           “(I) with respect to 1 or more  
13 proposed uses of the food additive in-  
14 volved, the conditions under which  
15 such additive may be safely used (in-  
16 cluding specifications as to the par-  
17 ticular food or classes of food in or on  
18 which such additive may be used, the  
19 maximum quantity which may be used  
20 or permitted to remain in or on such  
21 food, the manner in which such addi-  
22 tive may be added to or used in or on  
23 such food, and any directions or other  
24 labeling or packaging requirements  
25 for such additive as the Secretary de-

1 termines necessary to assure the safe-  
2 ty of such use); and

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

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

11 (B) in paragraph (3)—

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

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

16 (iii) by adding at the end the fol-  
17 lowing:

18 “(C) in the case of a zootechnical animal  
19 food substance, fails to establish that the pro-  
20 posed use of the substance, under the condi-  
21 tions of use to be specified in the regulation,  
22 will achieve the intended effect.”; and

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

24 “(1) ZOOTECHNICAL ANIMAL FOOD SUBSTANCES.—

25 The labeling of a zootechnical animal food substance—

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

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

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

11          “(z) If it is or it bears or contains a zootechnical ani-  
12          mal food substance and the labeling of the food does not  
13          include the statement required by section 409(l)(1).”.

