

116TH CONGRESS
1ST SESSION

S. _____

To provide for the regulation, inspection, and labeling of food produced using animal cell culture technology, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. ENZI (for himself and Mr. TESTER) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To provide for the regulation, inspection, and labeling of food produced using animal cell culture technology, and for other purposes.

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 “Food Safety Mod-
5 ernization for Innovative Technologies Act”.

6 **SEC. 2. REGULATION OF FOOD PRODUCED USING ANIMAL**
7 **CELL CULTURE TECHNOLOGY.**

8 Chapter IV of the Federal Food, Drug, and Cosmetic
9 Act (21 U.S.C. 341 et seq.) is amended by adding at the
10 end the following:

1 **“SEC. 424. FOOD PRODUCED USING ANIMAL CELL CULTURE**
2 **TECHNOLOGY.**

3 “(a) IN GENERAL.—The Secretary shall regulate
4 food intended for humans that is produced using animal
5 cell culture technology derived from cell lines of animals
6 other than livestock or poultry and, in coordination with
7 the Secretary of Agriculture, food intended for humans
8 that is produced using animal cell culture technology de-
9 rived from cell lines of livestock or poultry.

10 “(b) DUTIES.—Pursuant to subsection (a), the Sec-
11 retary shall—

12 “(1) conduct premarket consultation processes
13 to evaluate production materials, processes, and
14 manufacturing controls with respect to food intended
15 for humans that is produced using animal cell cul-
16 ture technology, derived from cell lines of livestock
17 or poultry and food intended for humans that is pro-
18 duced using animal cell culture technology, derived
19 from cell lines of animals other than livestock or
20 poultry, including oversight of tissue collection, cell
21 lines, cell banks, and all components and inputs;

22 “(2) oversee initial cell collection and the devel-
23 opment and maintenance of qualified cell banks, in-
24 cluding by issuing regulations or guidance and con-
25 ducting inspections, as appropriate;

1 “(3) oversee proliferation and differentiation of
2 cells through the time of cell harvest, including by
3 issuing regulations or guidance and conducting in-
4 spections, as appropriate;

5 “(4) ensure that cell bank and cell culturing fa-
6 cilities comply with facility registration, applicable
7 good manufacturing practices and preventive con-
8 trols, and requirements applicable to substances that
9 become a component of food or otherwise affect the
10 characteristics of food;

11 “(5) develop pursuant to notice and comment
12 rulemaking additional requirements for cell bank
13 and cell culturing facility conditions and processes to
14 ensure that biological material exiting the culture
15 process is safe and not adulterated within the mean-
16 ing of this chapter;

17 “(6) conduct appropriate inspections and fol-
18 low-up activities, including taking enforcement ac-
19 tion if necessary, to ensure that cell bank and cell-
20 culturing facilities are in compliance with applicable
21 laws and regulations;

22 “(7) coordinate the transfer of regulatory over-
23 sight of harvested cells derived from livestock or
24 poultry to the Secretary of the Department of Agri-
25 culture during cell harvest, including providing such

1 Secretary with any information necessary to deter-
2 mine whether harvested cells are eligible to be pro-
3 cessed into food intended for humans that is pro-
4 duced using animal cell culture technology, derived
5 from cell lines of livestock or poultry;

6 “(8) inspect establishments that process, pack-
7 age, and label food intended for humans that is pro-
8 duced using animal cell culture technology, derived
9 from cell lines other than livestock or poultry;

10 “(9) promulgate regulations regarding the safe-
11 ty and accurate labeling of food intended for humans
12 that is produced using animal cell culture tech-
13 nology, derived from cell lines other than livestock or
14 poultry; and

15 “(10) establish appropriate nomenclature for
16 food intended for humans that is produced using
17 animal cell culture technology, derived from cell lines
18 other than livestock or poultry.

19 “(c) COLLABORATION WITH USDA.—In carrying out
20 this section, the Secretary shall share information, as ap-
21 propriate, with the Department of Agriculture, including
22 notifying the Department of Agriculture if objectionable
23 conditions are identified at a facility carrying out any of
24 the activities described in subsection (b), including condi-
25 tions which may result in production of adulterated or

1 misbranded food, collaborating with such department to
2 address such conditions with respect to the harvesting of
3 cell cultures, and rely on the Department of Agriculture
4 to address such conditions with respect to processing,
5 packaging, and labeling.

6 “(d) LIMITATION.—The Secretary shall not inspect
7 activities of an establishment that are solely regulated by
8 the Secretary of Agriculture.

9 “(e) DEFINITIONS.—In this section—

10 “(1) the term ‘livestock’ means cattle, sheep,
11 swine, goats, and fish of the order Siluriformes; and

12 “(2) the term ‘poultry’ means any domesticated
13 bird, whether live or dead.

14 “(f) AUTHORITIES RELATED TO LIVESTOCK AND
15 POULTRY.—Notwithstanding any other provision of law,
16 the provisions of this section shall not derogate from any
17 authority under the Federal Meat Inspection Act or Poul-
18 try Product Inspection Act, as in effect on the date of
19 enactment of the Food Safety Modernization for Innova-
20 tive Technologies Act, with respect to the regulation of
21 meat and poultry produced in the traditional manner.

22 “(g) NO INSPECTION OF FARMS.—Nothing in this
23 section shall be construed to authorize the Secretary to
24 conduct an inspection of a farm.”.

1 **SEC. 3. INSPECTION AND LABELING OF FOOD PRODUCED**
2 **USING ANIMAL CELL CULTURE TECHNOLOGY**
3 **FROM LIVESTOCK AND POULTRY CELL**
4 **LINES.**

5 (a) DEFINITIONS.—In this section:

6 (1) ADULTERATED.—The term “adulterated”,
7 with respect to food intended for humans that is
8 produced using animal cell culture technology, de-
9 rived from cell lines of livestock or poultry, means
10 food—

11 (A) that bears or contains any poisonous
12 or deleterious substance which may render it in-
13 jurious to health, except that the food shall not
14 be considered adulterated if the substance is
15 not an added substance and the quantity of the
16 substance in the food does not ordinarily render
17 the food injurious to health;

18 (B)(i) that bears or contains any added
19 poisonous or added deleterious substance (other
20 than a substance that is a pesticide chemical
21 residue in or on a raw agricultural commodity
22 or processed food, a food additive, or a color
23 additive) that is unsafe within the meaning of
24 section 406 of the Federal Food, Drug, and
25 Cosmetic Act (21 U.S.C. 346);

1 (ii) that bears or contains a pesticide
2 chemical residue that is unsafe within the
3 meaning of section 408(a) of that Act (21
4 U.S.C. 346a(a)); or

5 (iii) that bears or contains—

6 (I) any food additive that is unsafe
7 within the meaning of section 409 of that
8 Act (21 U.S.C. 348); or

9 (II) a new animal drug (or conversion
10 product thereof) that is unsafe within the
11 meaning of section 512 of that Act (21
12 U.S.C. 360b);

13 (C) that consists in whole or in part of any
14 filthy, putrid, or decomposed substance, or if
15 the food is otherwise unfit for food;

16 (D) that has been prepared, packed, or
17 held under insanitary conditions whereby it may
18 have become contaminated with filth or ren-
19 dered injurious to health;

20 (E) that, in whole or in part, is the prod-
21 uct of a diseased animal or of an animal which
22 has died otherwise than by slaughter;

23 (F) the container of which is composed, in
24 whole or in part, of any poisonous or deleterious

1 substance which may render the contents inju-
2 rious to health;

3 (G) that has been intentionally subjected
4 to radiation, unless the use of the radiation was
5 in conformity with a regulation or exemption in
6 effect pursuant to section 409 of that Act (21
7 U.S.C. 348);

8 (H)(i) of which any valuable constituent
9 has been in whole or in part omitted or ab-
10 stracted therefrom;

11 (ii) for which any substance has been sub-
12 stituted in whole or in part;

13 (iii) for which damage or inferiority has
14 been concealed in any manner; or

15 (iv) to which any substance has been added
16 or mixed or packed so as to increase the bulk
17 or weight of the food, reduce the quality or
18 strength of the food, or make the food appear
19 better or of greater value than the food is;

20 (I) that bears or contains a color additive
21 which is unsafe within the meaning of section
22 721(a) of that Act (21 U.S.C. 379e(a)); or

23 (J) that is transported or offered for
24 transport by a shipper, carrier by motor vehicle
25 or rail vehicle, receiver, or any other person en-

1 gaged in the transportation of food under con-
2 ditions that are not in compliance with regula-
3 tions promulgated under section 416 of that
4 Act (21 U.S.C. 350e).

5 (2) LIVESTOCK.—The term “livestock” has the
6 meaning given the term in section 424(e) of the
7 Federal Food, Drug, and Cosmetic Act.

8 (3) MISBRANDED.—The term “misbranded”,
9 with respect to food intended for humans that is
10 produced using animal cell culture technology, de-
11 rived from cell lines of livestock or poultry, means
12 food—

13 (A) the label of which—

14 (i) does not bear—

15 (I) the name of the food, in ac-
16 cordance with subsection (c);

17 (II) in the case of the food being
18 fabricated from 2 or more ingredients,
19 the common or usual name of each in-
20 gredient, except that spices,
21 flavorings, and colorings may, when
22 authorized by the appropriate agency
23 head, be designated as spices,
24 flavorings, and colorings without nam-
25 ing each, provided that to the extent

1 that compliance is impracticable, or
2 results in deception or unfair competi-
3 tion, exemptions shall be established
4 by regulations promulgated by the
5 Secretary; or

6 (III) an official inspection legend
7 directly on the food or on the con-
8 tainer of the food and such other in-
9 formation as the Secretary requires to
10 assure that the food will not have
11 false or misleading labeling and that
12 the public will be informed of the
13 manner of handling required to main-
14 tain the food in a wholesome condi-
15 tion;

16 (B) the label of which is false or mis-
17 leading;

18 (C) that is in a package or other container
19 the label of which does not bear—

20 (i) the name and place of business of
21 the manufacturer, packer, or distributor;
22 or

23 (ii) an accurate statement of the
24 quantity of the contents in terms of

1 weight, measure, or numerical count, sub-
2 ject to—

3 (I) reasonable variations per-
4 mitted by the Secretary; and

5 (II) in the case of a small pack-
6 age or container, exemptions estab-
7 lished by the Secretary by regulation;

8 (D) for which any word, statement, or
9 other information required by the Secretary to
10 appear on the label is not prominently placed
11 on the label with such conspicuousness (com-
12 pared to any other words, statements, designs,
13 or devices on the label) and in such terms as
14 to render it likely to be read and understood by
15 the ordinary individual under customary condi-
16 tions of purchase and use;

17 (E) that is offered for sale under the name
18 of another food;

19 (F) that is an imitation of another food,
20 unless the label bears the word “imitation”, in
21 type of uniform size and prominence, and the
22 name of the food imitated immediately after the
23 word “imitation”;

24 (G) the container of which is made,
25 formed, or filled as to be misleading;

1 (H) that purports to be or is represented
2 for special dietary uses but the label of which
3 does not bear such information concerning the
4 vitamin, mineral, and other dietary properties
5 of the food as the Secretary, after consultation
6 with the Secretary of Health and Human Serv-
7 ices, determines to be, and by regulations pre-
8 scribes as, necessary in order to inform pur-
9 chasers fully of the value of the food for those
10 uses; or

11 (I) that bears or contains any artificial fla-
12 voring, artificial coloring, or chemical preserva-
13 tive but the label of which does not state that
14 fact, subject to exemptions established by the
15 Secretary by regulation in cases of compliance
16 being impracticable.

17 (4) OFFICIAL INSPECTION LEGEND.—The term
18 “official inspection legend” means the symbol de-
19 scribed in subsection (b)(2).

20 (5) POULTRY.—The term “poultry” has the
21 meaning given the term in section 424(e) of the
22 Federal Food, Drug, and Cosmetic Act.

23 (6) SECRETARY.—The term “Secretary” means
24 the Secretary of Agriculture.

25 (b) INSPECTIONS.—

1 (1) IN GENERAL.—The Secretary shall inspect
2 establishments that process, package, and label food
3 intended for humans that is produced using animal
4 cell culture technology, derived from cell lines of live-
5 stock or poultry—

6 (A) to ensure that—

7 (i) the food is—

8 (I) not adulterated; and

9 (II) not misbranded; and

10 (ii) the establishment is operating in
11 accordance with the regulations promul-
12 gated under paragraph (3).

13 (2) OFFICIAL INSPECTION LEGEND.—The Sec-
14 retary shall establish an official inspection legend for
15 the food described in paragraph (1), which shall be
16 a symbol that shows that a product made from that
17 food was inspected and passed in accordance with
18 the regulations described in paragraph (3).

19 (3) REGULATIONS.—The Secretary shall pro-
20 mulgate regulations regarding—

21 (A) the manner and frequency of inspec-
22 tions required for—

23 (i) the food described in paragraph
24 (1); and

1 (ii) establishments that process, pack-
2 age, and label that food; and

3 (B) the requirements for a product of the
4 food described in paragraph (1) to satisfactorily
5 pass an inspection and receive an official in-
6 spection legend, including—

7 (i) sanitation and physical product in-
8 spection requirements;

9 (ii) food product testing and record-
10 keeping requirements; and

11 (iii) the requirement for Hazard Anal-
12 ysis and Critical Control Points
13 verification.

14 (4) LIMITATION.—The Secretary shall not in-
15 spect activities of an establishment under section
16 424 of the Federal Food, Drug, and Cosmetic Act
17 that are solely regulated by the Secretary of Health
18 and Human Services.

19 (c) LABELING.—

20 (1) IN GENERAL.—The Secretary shall—

21 (A) approve, before introduction into com-
22 merce, the labeling of food intended for humans
23 that is produced using animal cell culture tech-
24 nology, derived from cell lines of livestock or
25 poultry; and

1 (B) verify the accuracy of that labeling
2 through inspection.

3 (2) REQUIREMENTS.—The Secretary shall es-
4 tablish, after providing notice and an opportunity for
5 comment, any appropriate requirements in addition
6 to the requirements under paragraph (1) to ensure
7 the safety and accurate labeling of the food de-
8 scribed in paragraph (1)(A).

9 (3) REGULATIONS.—The Secretary shall pro-
10 mulgate regulations—

11 (A) to establish appropriate nomenclature
12 for the labeling approved under paragraph
13 (1)(A); and

14 (B) to carry out paragraph (1)(B).

15 (d) ENFORCEMENT.—The Secretary shall, pursuant
16 to relevant enforcement authorities governing the regula-
17 tion of amenable species (as defined in section 1 of the
18 Federal Meat Inspection Act (21 U.S.C. 601)), conduct
19 such enforcement action as is necessary to ensure that
20 food intended for humans that is produced using animal
21 cell culture technology, derived from cell lines of livestock
22 or poultry, that is adulterated or misbranded does not
23 enter or is removed from commerce.

24 (e) COLLABORATION WITH HHS.—In carrying out
25 this section, the Secretary shall—

1 (1) review information shared by the Secretary
2 of Health and Human Services under section 424(c)
3 of the Federal Food, Drug, and Cosmetic Act;

4 (2) share appropriate information relating to
5 food intended for humans that is produced using
6 animal cell culture technology, derived from cell lines
7 of livestock or poultry, with the Secretary of Health
8 and Human Services, as appropriate; and

9 (3)(A) notify the Secretary of Health and
10 Human Services if objectionable conditions at an es-
11 tablishment are identified under an inspection under
12 subsection (b)(1);

13 (B) collaborate with the Secretary of Health
14 and Human Services to address those conditions
15 with respect to cell harvesting; and

16 (C) rely on the Secretary of Health and Human
17 Services to address those conditions with respect to
18 initial cell collection, development and maintenance
19 of qualified cell banks, and proliferation and dif-
20 ferentiation of cells.