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To provide better protection against bovine spongiform encephalopathy and other prion diseases.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 14, 2005

Mr. DURBIN (for himself, Mr. AKAKA, and Mr. SCHUMER) introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

A BILL

To provide better protection against bovine spongiform encephalopathy and other prion diseases.

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 “BSE and Other Prion
5 Disease Prevention and Public Health Protection Act”.

6 **SEC. 2. DEFINITIONS.**

7 In this Act:

8 (1) BSE.—The term “BSE” means bovine
9 spongiform encephalopathy.

10 (2) COVERED ARTICLE.—

1 (A) IN GENERAL.—The term “covered ar-
2 ticle” means—

- 3 (i) food or feed for a human or ani-
4 mal;
5 (ii) a food or nutritional supplement;
6 (iii) a medicine;
7 (iv) a pituitary-derived hormone;
8 (v) transplant material;
9 (vi) a fertilizer derived from animals;
10 (vii) a cosmetic; and
11 (viii) any other article of a kind that
12 is ordinarily ingested, implanted, or other-
13 wise taken into a human or animal.

14 (B) EXCLUSIONS.—The term “covered ar-
15 ticle” does not include—

- 16 (i) an unprocessed agricultural com-
17 modity that is readily identifiable as non-
18 animal in origin, such as a vegetable,
19 grain, or nut;
20 (ii) an article described in subpara-
21 graph (A) that, based on compelling sci-
22 entific evidence, the Secretary determines
23 does not pose a risk of transmitting prion
24 disease; or

1 (iii) an article regulated by the Sec-
2 retary that, as determined by the Sec-
3 retary—

4 (I) poses a minimal risk of car-
5 rying prion disease; and

6 (II) is necessary to protect ani-
7 mal health or public health.

8 (3) CWD.—The term “CWD” means chronic
9 wasting disease.

10 (4) PRION DISEASE.—The term “prion disease”
11 means—

12 (A) a transmissible spongiform
13 encephalopathy (including prion diseases that
14 affect humans, cattle, bison, sheep, goats, deer,
15 elk, and mink); and

16 (B) any related disease, as determined by
17 the Secretary in consultation with the Secretary
18 of Agriculture.

19 (5) SPECIFIED RISK MATERIAL.—

20 (A) IN GENERAL.—The term “specified
21 risk material” means—

22 (i) the skull, brain, trigeminal ganglia,
23 eyes, tonsils, spinal cord, vertebral column,
24 or dorsal root ganglia of—

1 (I) cattle and bison 30 months of
2 age and older; or

3 (II) sheep, goats, deer, and elk
4 12 months of age and older;

5 (ii) the intestinal tract of a ruminant
6 of any age; or

7 (iii) any other material of a ruminant
8 that may carry a prion disease, as deter-
9 mined by the Secretary in consultation
10 with the Secretary of Agriculture, based on
11 scientifically credible research.

12 (B) MODIFICATION.—The Secretary, in
13 consultation with the Secretary of Agriculture,
14 may modify the definition of specified risk ma-
15 terial based on scientifically credible research.

16 (6) SECRETARY.—The term “Secretary” means
17 the Secretary of Health and Human Services.

18 **SEC. 3. PROTECTION OF BORDERS.**

19 (a) PROHIBITIONS.—

20 (1) DISCLOSURE REQUIREMENT.—It shall be
21 unlawful for any person to import a covered arti-
22 cle—

23 (A) in the case of a covered article that
24 contains animal-derived material, if the covered
25 article does not exhibit or contain, or is not oth-

erwise accompanied by, a statement in English
that—

(i) states that the covered article contains animal-derived material;

(ii) states the common English name of the animal from which the material in the article is derived; and

(iii) if the animal from which the material in the covered article is derived is a ruminant—

(I) identifies the country of origin of the ruminant; and

(II) states whether specified risk material from the ruminant is or may be part of the covered article; or

(B) in the case of a covered article that does not contain animal-derived material, if the covered article does not exhibit or contain, or is not otherwise accompanied by, a statement in English that states that the covered article does not contain animal-derived material.

(2) PROHIBITION OF IMPORTATION.—It shall be unlawful for any person to import a covered article described in section 2(2)(A) if, as determined by the Secretary of Agriculture—

1 (A) the article contains animal-derived ma-
2 terial from a ruminant that was in any country
3 at a time at which there was a risk of trans-
4 mission of BSE in the country; and

5 (B) the country did not meet the guide-
6 lines on BSE established in the World Organi-
7 zation for Animal Health's (OIE) Terrestrial
8 Animal Health Code.

9 (b) REGULATIONS.—Not later than 1 year after the
10 date of enactment of this Act, the Secretary, in consulta-
11 tion with the Secretary of Agriculture, shall promulgate
12 regulations that establish standards for compliance with
13 this section, including—

14 (1) the manner of disclosure that shall be con-
15 sidered to be in compliance with this subsection;

16 (2) any manner of disclosure that shall be con-
17 sidered not to be in compliance with this subsection;
18 and

19 (3) definitions of the terms “animal-derived ma-
20 terial”, “country of origin”, and other terms used
21 but not defined in this section.

22 (c) INTERIM GUIDANCE.—Until the date on which
23 final regulations promulgated under subsection (b) become
24 effective, the Secretary shall provide guidance and advice

1 on general applicability of, and compliance with, this sec-
 2 tion.

3 (d) ENFORCEMENT.—For the purposes of admin-
 4 istering the customs laws of the United States, the re-
 5 quirement to comply with subsection (a)(1) shall be treat-
 6 ed as a requirement to mark an article under section 304
 7 of the Tariff Act of 1930 (19 U.S.C. 1304).

8 **SEC. 4. PROTECTION OF FOOD AND ANIMAL FEED SUP-**
 9 **PLIES AND PUBLIC HEALTH.**

10 (a) COVERED ARTICLES.—

11 (1) PROHIBITION.—It shall be unlawful for any
 12 person to introduce into interstate or foreign com-
 13 merce a covered article if the covered article con-
 14 tains—

15 (A)(i) specified risk material from a rumi-
 16 nant; or

17 (ii) any material from a ruminant that was
 18 in any foreign country at a time at which there
 19 was a risk of transmission of BSE in the coun-
 20 try and the country did not meet the guidelines
 21 on BSE established in the World Organization
 22 for Animal Health’s (OIE) Terrestrial Animal
 23 Health Code, as determined by the Secretary of
 24 Agriculture; or

1 (B) any material from a ruminant exhib-
2 iting signs of a neurological disease.

3 (2) REPORTING.—The Secretary of Agriculture
4 will make publicly available quarterly reports con-
5 taining the number of noncompliance reports relat-
6 ing to regulations on specified risk materials and the
7 reasons for noncompliance.

8 (3) PUNITIVE OR RETALIATORY ACTION.—It
9 shall be unlawful to take punitive or retaliatory ac-
10 tion against inspectors and other employees who re-
11 port cases of noncompliance.

12 (4) REGULATIONS.—

13 (A) SECRETARY OF AGRICULTURE.—Not
14 later than 1 year after the date of enactment of
15 this Act, the Secretary of Agriculture, in con-
16 sultation with the Secretary, shall promulgate
17 regulations that establish standards for compli-
18 ance with this subsection, including—

19 (i) requirements for the disposal of
20 dead and nonambulatory ruminants on a
21 farm or ranch so that the prion disease, if
22 present in the animals, will not be recycled
23 or expose other animals;

24 (ii) requirements for the registration
25 with the Food and Drug Administration of

1 all renderers and all persons that engage
2 in the business of buying, selling, or trans-
3 porting—

4 (I) dead, dying, disabled, or dis-
5 eased livestock; or

6 (II) parts of the carcasses of live-
7 stock that die other than by slaughter;

8 (iii) requirements for the handling,
9 transportation, and disposal of dead,
10 dying, disabled, and diseased livestock that
11 are condemned on ante-mortem or post-
12 mortem inspection in accordance with any
13 policy that is developed for the disposal of
14 dead or nonambulatory ruminants on the
15 farm; and

16 (iv) a requirement that slaughter-
17 houses institute best practices to prevent
18 contamination of material intended for
19 human consumption with specified risk
20 material.

21 (B) SECRETARY.—Not later than 1 year
22 after the date of enactment of this Act, the Sec-
23 retary, in consultation with the Secretary of Ag-
24 riculture, shall promulgate regulations that es-
25 tablish standards for compliance with this sub-

1 section, including a prohibition on the use of
2 salvaged pet food, plate waste, poultry litter,
3 and blood and blood products in animal feed in-
4 tended for food producing ruminants, with an
5 exemption for the use of blood and blood prod-
6 ucts in bovine biologics.

7 (b) ANIMAL FEED.—

8 (1) MONITORING AND EVALUATION.—The Sec-
9 retary shall annually conduct a formal evaluation of
10 the implementation of section 589.2000 of title 21,
11 Code of Federal Regulations (or a successor regula-
12 tion), including an assessment of coordination be-
13 tween the Food and Drug Administration, the De-
14 partment of Agriculture, and State agencies.

15 (2) REGISTRATION OF BUSINESSES.—Not later
16 than 1 year after the date of enactment of this Act,
17 the Secretary shall promulgate regulations for the
18 registration with the Food and Drug Administration
19 of all animal feed manufacturers, transporters, on-
20 farm mixers, and other animal feed industry busi-
21 nesses that are subject to section 589.2000 of title
22 21, Code of Federal Regulations (or a successor reg-
23 ulation).

24 (3) PREVENTION OF ADMIXING.—Not later
25 than 1 year after the date of enactment of this Act,

1 the Secretary, in consultation with the Secretary of
2 Agriculture, shall promulgate regulations and an in-
3 spection plan to prevent admixing of ruminant and
4 nonruminant feed by animal feed manufacturers,
5 animal feed transporters, and producers that feed
6 both ruminants and nonruminants on the same
7 farm.

8 (4) ENFORCEMENT PLAN.—

9 (A) IN GENERAL.—The Secretary shall de-
10 velop and implement a plan for enforcing sec-
11 tion 589.2000 of title 21, Code of Federal Reg-
12 ulations (or a successor regulation).

13 (B) CONTENTS.—The plan shall include—

14 (i) a computer database that would
15 allow for effective management of inspec-
16 tion data;

17 (ii) a hierarchy of enforcement actions
18 to be taken;

19 (iii) timeframes for persons that are
20 subject to that section to correct violations;
21 and

22 (iv) timeframes for followup inspec-
23 tions to confirm that violations are cor-
24 rected.

1 (5) REVIEW OF EXCLUSION OF CERTAIN POR-
 2 TIONS OF ANIMALS FROM DEFINITION OF PROTEIN
 3 DERIVED FROM MAMMALIAN TISSUES.—On the mo-
 4 tion of the Secretary or on the petition of any per-
 5 son that, citing scientifically credible evidence, dem-
 6 onstrates that there is reason to believe that any of
 7 the portions of mammalian animals excluded from
 8 the definition of protein derived from mammalian
 9 tissues in section 589.2000(a) of title 21, Code of
 10 Federal Regulations (or a successor regulation), may
 11 carry prion disease, the Secretary shall commence a
 12 proceeding to determine whether the exclusion
 13 should be modified or stricken.

14 (6) LABELING REQUIREMENTS FOR ANIMAL
 15 FEED.—Animal feed intended for export shall be
 16 subject to the labeling requirements for animal feed
 17 described in section 589.2000 of title 21, Code of
 18 Federal Regulations (or a successor regulation).

19 **SEC. 5. SURVEILLANCE OF BSE AND PRION DISEASES IN**
 20 **HUMANS AND ANIMALS.**

21 (a) RUMINANT IDENTIFICATION PROGRAM.—Title I
 22 of the Federal Meat Inspection Act (21 U.S.C. 601 et
 23 seq.) is amended by adding at the end the following:

1 **“SEC. 25. RUMINANT IDENTIFICATION PROGRAM.**

2 “(a) IN GENERAL.—The Secretary shall accelerate
3 the establishment of a ruminant identification program,
4 so that, not later than 1 year after the date of enactment
5 of this section, the program will be capable of tracing,
6 within 48 hours after an animal is diagnosed with any re-
7 portable animal disease or any condition that can cause
8 disease in humans, the movements of all exposed animals
9 from birth to slaughter.

10 “(b) REQUIREMENTS.—

11 “(1) IN GENERAL.—Under the ruminant identi-
12 fication program, the Secretary shall identify cattle,
13 sheep, goats, bison, deer, and elk and any other ru-
14 minant species intended for human consumption
15 through a nationally recognizable uniform num-
16 bering system under which an identification number
17 is assigned to—

18 “(A) each premises of a producer; and

19 “(B) each individual animal or group or lot
20 of animals, as determined by the Secretary.

21 “(2) CONTINUATION OF EXISTING PRO-
22 GRAMS.—The program shall augment, and not sup-
23 plant, nationally recognized systems in existence on
24 the date of enactment of this section, such as the
25 program for scrapie traceback and eradication in
26 sheep and goats.

1 “(c) PROHIBITION OR RESTRICTION ON ENTRY.—
2 The Secretary may prohibit or restrict entry into any
3 slaughtering establishment inspected under this Act of any
4 cattle, sheep, goats, bison, deer, elk, or other ruminant
5 intended for human consumption that is not identified
6 under the program.

7 “(d) RECORDS.—

8 “(1) IN GENERAL.—The Secretary may require
9 that a producer required to identify livestock under
10 the program maintain records, as prescribed by the
11 Secretary, regarding the purchase, sale, and identi-
12 fication of livestock for such period of time as the
13 Secretary prescribes.

14 “(2) ACCESS.—A producer shall, at all reason-
15 able times, on notice by an authorized representative
16 of the Secretary, allow the representative access to
17 examine and copy the records described in para-
18 graph (1).

19 “(e) PROHIBITIONS.—It shall be unlawful for a pro-
20 ducer to—

21 “(1) falsify or misrepresent to any other person
22 or to the Secretary any information relating to any
23 premises at which any cattle, sheep, swine, goats,
24 bison, deer, elk, or other ruminant intended for

1 human consumption, or carcasses thereof, are held;
2 or

3 “(2) alter, detach, or destroy any records or
4 means of identification prescribed by the Secretary
5 for use in determining the premises at which any
6 cattle, sheep, swine, goats, bison, deer, elk, or other
7 ruminant intended for human consumption, or car-
8 casses thereof, are held.”.

9 (b) PROGRAMS.—

10 (1) IN GENERAL.—Not later than 1 year after
11 the date of enactment of this Act—

12 (A) the Secretary of Agriculture shall de-
13 velop programs to—

14 (i)(I) waive diagnostic laboratory
15 charges for the diagnosis of neurological
16 disease in ruminants and mink;

17 (II) provide compensation for each
18 submission payable to the attending veteri-
19 narian to pay the costs of obtaining and
20 processing neurological samples; and

21 (III) develop a program to pay a fee
22 to renderers or producers for each cattle
23 head not already tested that is submitted
24 to a certified lab for BSE testing;

1 (ii)(I) fund the development of the na-
 2 tional animal health laboratory network;

3 (II) expand the network to include all
 4 certified Federal, State, and university vet-
 5 erinary diagnostic laboratories; and

6 (III) facilitate the timely processing of
 7 samples from surveillance and epidemiolog-
 8 ical investigation;

9 (iii) require rapid prion disease
 10 screening tests on—

11 (I) all cattle and bison 30
 12 months of age and older and all
 13 sheep, goats, deer, and elk 12 months
 14 of age and older presented for slaugh-
 15 ter and intended for human consump-
 16 tion; and

17 (II) all such livestock of a young-
 18 er age than either of the ages speci-
 19 fied in subclause (I) if the Secretary
 20 determines, based on scientifically
 21 credible research, that screening of
 22 livestock of a younger age should be
 23 conducted;

24 (iv) require rapid prion disease
 25 screening tests on all nonambulatory

1 ruminants, including all ruminants exhib-
2 iting neurological signs, when presented at
3 a slaughterhouse or for disposal;

4 (v) ensure that—

5 (I) any ruminant tested for BSE
6 is excluded from use in any animal
7 feed until the test is confirmed nega-
8 tive in writing that clearly identifies
9 the carcass with the negative test re-
10 sult; and

11 (II) all ruminants exhibiting neu-
12 rological signs are excluded from the
13 human food supply regardless of the
14 results of the BSE test;

15 (vi) expand, in conjunction with the
16 Secretary of the Interior, the collection of
17 animal tissue by Federal, State, tribal, and
18 local agencies for testing for chronic wast-
19 ing disease;

20 (vii) develop programs to require
21 CWD herd certification and interstate
22 movement restrictions for farm raised deer
23 and elk;

(viii) develop a coordinated strategy to identify resources needed to increase inspections of imported goods; and

(ix) allow qualified entities to conduct additional voluntary rapid prion disease screening tests; and

(B) the Secretary shall develop programs to—

(i) expand survey efforts for prion diseases in humans, in conjunction with the National Prion Disease Pathology Research Center at Case Western Reserve University;

(ii) evaluate the effectiveness of practices in effect as of the date of enactment of this Act to—

(I) protect the human blood supply from contamination from blood infected with prion disease; and

(II) prevent transmission of BSE through contaminated medical equipment; and

(iii) develop a coordinated strategy to identify resources needed to increase inspections of imported goods.

1 (2) DEFINITION OF QUALIFIED ENTITY.—For
 2 purposes of paragraph (1)(A)(ix), the term “quali-
 3 fied entity” means a person or a State that—

4 (A) uses rapid test technology approved by
 5 the Secretary of Agriculture for the detection of
 6 BSE in cattle; and

7 (B) meets or exceeds standards established
 8 by the Secretary for—

9 (i) laboratory sample collection and
 10 chain of custody;

11 (ii) sample and laboratory methods
 12 quality control; and

13 (iii) laboratory safety and quality.

14 (c) LIAISON.—Each of the Secretary and the Sec-
 15 retary of Agriculture shall establish liaison positions at
 16 each appropriate Undersecretary level to ensure adequate
 17 coordination and communication between the Department
 18 of Health and Human Services and the Department of Ag-
 19 riculture regarding prion diseases.

20 (d) TASK FORCE.—

21 (1) IN GENERAL.—As soon as practicable after
 22 the date of enactment of this Act, the Secretary and
 23 the Secretary of Agriculture shall jointly establish a
 24 task force on prion diseases to provide recommenda-

tions to Congress on the status of all surveillance and research programs.

(2) MEMBERSHIP.—The Task Force shall include representatives of—

(A) the Food Safety and Inspection Service;

(B) the Animal and Plant Health Inspection Service;

(C) the Agricultural Research Service;

(D) the Food and Drug Administration;

(E) the Centers for Disease Control and Prevention;

(F) the National Institutes of Health;

(G) the Customs Service;

(H) the National Prion Research Program;

(I) the Public Health Service; and

(J) any other Federal Agency the assistance of which the President determines is required to carry out this subsection.

(3) EXISTING TASK FORCE.—The Secretary may expand or amend an existing task force to perform the duties of the task force under this section.

(4) DUTIES.—The task force shall—

(A) evaluate, with respect to prion diseases, the need for structural changes in and

1 among Federal agencies that exercise jurisdic-
2 tion over food safety and other aspects of public
3 health protection;

4 (B) prioritize prion disease resource and
5 prion disease research needs at all Federal
6 agencies that exercise jurisdiction over matters
7 relating to prion diseases, including—

8 (i) genetic markers for all species af-
9 fected by prion disease;

10 (ii) in vivo diagnostic tests;

11 (iii) human blood supply diagnostic
12 tests;

13 (iv) therapies for humans and ani-
14 mals;

15 (v) processing techniques that dena-
16 ture the prion protein in carcasses and
17 other materials; and

18 (vi) development of stunning devices
19 that are humane, protect worker safety,
20 and do not allow contamination of meat
21 products; and

22 (C) perform such other duties pertaining
23 to surveillance and research of prion disease as
24 the Secretary may specify.

1 (5) PRELIMINARY RECOMMENDATIONS.—Not
2 later than 180 days after the date of enactment of
3 this Act, the task force shall submit to Congress any
4 preliminary recommendations of the task force.

5 (6) FINAL RECOMMENDATIONS.—Not later than
6 1 year after the date of enactment of this Act, the
7 task force shall submit to Congress the final rec-
8 ommendations of the task force.

9 **SEC. 6. ENFORCEMENT.**

10 (a) COOPERATION.—The Secretary and the heads of
11 other Federal agencies, as appropriate, shall cooperate
12 with the Attorney General in enforcing this Act.

13 (b) DUE PROCESS.—Any person subject to enforce-
14 ment action under this section shall have the opportunity
15 for an informal hearing on the enforcement action as soon
16 as practicable after, but not later than 10 days after, the
17 enforcement action is taken.

18 (c) REMEDIES.—In addition to any remedies avail-
19 able under other provisions of law, the head of a Federal
20 agency may enforce this Act by—

21 (1) seizing and destroying an article that is in-
22 troduced into interstate or foreign commerce in vio-
23 lation of this Act; or

1 (2) issuing an order requiring any person that
2 introduces an article into interstate or foreign com-
3 merce in violation of this Act—

4 (A) to cease the violation;

5 (B)(i) to recall any article that is sold; and

6 (ii) to refund the purchase price to the
7 purchaser;

8 (C) to destroy the article or forfeit the ar-
9 ticle to the United States for destruction; or

10 (D) to cease operations at the facility at
11 which the article is produced until the head of
12 the appropriate Federal agency determines that
13 the operations are no longer in violation of this
14 Act.

15 **SEC. 7. AUTHORIZATION OF APPROPRIATIONS.**

16 (a) AUTHORIZATION OF APPROPRIATIONS.—There
17 are authorized to be appropriated to carry out this Act—

18 (1) \$100,000,000 for each of fiscal years 2007
19 and 2008; and

20 (2) such sums as are necessary for each subse-
21 quent fiscal year.

22 (b) ALLOCATION OF FUNDS.—

23 (1) IN GENERAL.—Of the funds made available
24 for each fiscal year under subsection (a)—

1 (A) 30 percent shall be available to the
2 Secretary; and

3 (B) 70 percent shall be available to the
4 Secretary of Agriculture.

5 (2) MODIFICATION OF ALLOCATIONS.—The
6 President may alter the allocation of funding under
7 paragraph (1) as needed to better protect the public
8 against prion disease.

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