108TH CONGRESS
2D SESSION

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

IN THE SENATE OF THE UNITED STATES

JANUARY 20, 2004

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

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''BSE and Other Prion Disease Prevention and Public Health Protection Act''.

SEC. 2. DEFINITIONS.

In this Act:

(1) BSE.—The term ''BSE'' means bovine spongiform encephalopathy.

(2) COVERED ARTICLE.—

(A) IN GENERAL.—The term ''covered article'' means—

(i) food or feed for a plant, animal, or human;

(ii) a food or nutritional supplement;

(iii) a medicine;

(iv) a pituitary-derived hormone;

(v) transplant material;

(vi) a fertilizer;

(vii) a cosmetic; and

(viii) any other article of a kind that is ordinarily ingested, implanted, or otherwise taken into a living organism.

(B) EXCLUSIONS.—The term ''covered article'' does not include—

(i) an unprocessed agricultural commodity that is readily identifiable as non-animal in origin, such as a vegetable, grain, or nut;

(ii) an article described in subparagraph (A) that, based on compelling scientific evidence, the Secretary determines does not pose a risk of transmitting prion disease; or

(iii) an article regulated by the Secretary that, as determined by the Secretary—

(I) poses a minimal risk of carrying prion disease; and

(II) is necessary to protect individual or public health.

(3) CWD.—The term ''CWD'' means chronic wasting disease.

(4) PRION DISEASE.—The term ''prion disease'' means—

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

(B) any related disease, as determined by the Secretary.

(5) SPECIFIED RISK MATERIAL.—

(A) IN GENERAL.—The term ''specified risk material'' means—

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

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

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

(ii) the intestinal tract of a ruminant of any age; and

(iii) any other material of a ruminant that may carry a prion disease, as determined by the Secretary, based on scientifically credible research.

(B) MODIFICATION.—The Secretary may modify the definition of specified risk material based on scientifically credible research (including the conduct of ante-mortem and post-mortem tests certified by the Secretary of Agriculture).

(6) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

SEC. 3. PROTECTION OF BORDERS.

(a) PROHIBITIONS.—

(1) DISCLOSURE REQUIREMENT.—It shall be unlawful for any person to import a covered article—

(A) in the case of a covered article that contains animal-derived material, if the covered 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 the article contains animal-derived material from a ruminant that was in

any country at a time at which there was a risk of transmission of BSE in the country, as determined by the Secretary of Agriculture.

(b) REGULATIONS.—Not later than 1 year after the date of enactment of this Act, the Secretary, in consultation with the Secretary of Agriculture, shall promulgate regulations that establish standards for compliance with this section, including—

(1) the manner of disclosure that shall be considered to be in compliance with this subsection;

(2) any manner of disclosure that shall be considered not to be in compliance with this subsection; and

(3) definitions of the terms ''animal-derived material'', ''country of origin'', and other terms used but not defined in this section.

(c) INTERIM GUIDANCE.—Until the date on which final regulations promulgated under subsection (b) become effective, the Secretary shall provide guidance and advice on general applicability of, and compliance with, this section.

(d) ENFORCEMENT.—For the purposes of administering the customs laws of the United States, the requirement to comply with subsection (a)(1) shall be treat-

ed as a requirement to mark an article under section 304 of the Tariff Act of 1930 (19 U.S.C. 1304).

SEC. 4. PROTECTION OF FOOD AND ANIMAL FEED SUPPLIES AND PUBLIC HEALTH.

(a) COVERED ARTICLES.—

(1) PROHIBITION.—Except as provided in paragraph (2)(B), it shall be unlawful for any person to introduce into interstate or foreign commerce a covered article if the covered article contains—

(A)(i) specified risk material from a ruminant; or

(ii) any material from a ruminant that was in any foreign country at a time at which there was a risk of transmission of BSE in the country, as determined by the Secretary of Agriculture; or

(B) any material from a ruminant exhibiting signs of a neurological disease.

(2) REGULATIONS.—

(A) SECRETARY OF AGRICULTURE.—Not later than 1 year after the date of enactment of this Act, the Secretary of Agriculture, in consultation with the Secretary, shall promulgate regulations that establish standards for compliance with this subsection, including—

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

(ii) requirements for the registration with the Food Safety and Inspection Service of all renderers and all persons that engage in the business of buying, selling, or transporting—

(I) dead, dying, disabled, or diseased livestock; or

(II) parts of the carcasses of livestock that die other than by slaughter;

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

(iv) a prohibition on the use of pneumatic stunning devices to immobilize ruminants during slaughter;

(v) a requirement that slaughterhouses institute best practices to prevent contamination of material intended for human consumption with specified risk material; and

(vi) a prohibition on relabeling for human use any ruminant meat product that has been shown to include extraneous neurological tissue.

(B) SECRETARY.—Not later than 1 year after the date of enactment of this Act, the Secretary, in consultation with the Secretary of Agriculture, shall promulgate regulations that establish standards for compliance with this subsection, including a prohibition on the use of salvaged pet food and poultry litter in feed intended for food producing ruminants.

(C) INTERIM GUIDANCE.—Until the date on which final regulations promulgated under subparagraphs (A) and (B) become effective, the Secretary of Agriculture or the Secretary, as appropriate, shall provide guidance and advice on general applicability of, and compliance with, this subsection.

(b) RUMINANT FEED.—

(1) MONITORING AND EVALUATION.—The Secretary shall—

(A) monitor the implementation of section 589.2000 of title 21, Code of Federal Regulations; and

(B) annually conduct a formal evaluation of that section and the implementation of that section.

(2) ENFORCEMENT PLAN.—

(A) IN GENERAL.—The Secretary shall develop and implement a plan for enforcing section 589.2000 of title 21, Code of Federal Regulations.

(B) CONTENTS.—The plan shall include—

(i) a computer database that would allow for effective management of inspection data;

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

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

(iv) timeframes for followup inspections to confirm that violations are corrected.

(3) REVIEW OF EXCLUSION OF CERTAIN PORTIONS OF ANIMALS FROM DEFINITION OF PROTEIN DERIVED FROM MAMMALIAN TISSUES.—On the motion of the Secretary or on the petition of any person that, citing scientifically credible evidence, demonstrates that there is reason to believe that any of the portions of mammalian animals excluded from the definition of protein derived from mammalian tissues in section 589.2000(a) of title 21, Code of Federal Regulations, may carry prion disease, the Secretary shall commence a proceeding to determine whether the exclusion should be modified or stricken.

(c) ANIMAL FEED PREPARATION AND FEEDING PRACTICES.—

(1) SURVEY.—

(A) IN GENERAL.—During the 18-month period beginning on the date of enactment of this Act, the Secretary and the Secretary of Agriculture shall jointly conduct a survey of animal feed preparation practices and animal feeding practices to determine—

(i) the extent of compliance with this section; and

(ii) the extent to which ruminants are being fed feed that contains no ruminant-derived material.

(B) REPORTS.—

(i) INTERIM REPORT.—Not later than 180 days after the date of enactment of this Act, the Secretary and the Secretary of Agriculture shall jointly submit to Congress an interim report on the results of the surveys conducted under subparagraph (A).

(ii) FINAL REPORT.—Not later than 18 months after the date of enactment of this Act, the Secretary and the Secretary of Agriculture shall jointly submit to Congress a final report on the results of the survey conducted under subparagraph (A).

(2) PREVENTION OF ADMIXING.—

(A) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary, in consultation with the Secretary of Agriculture, shall promulgate regulations requiring producers that feed both ruminants and nonruminants on the same farm to institute a

system to prevent admixing of ruminant feed and nonruminant feed.

(B) RECORDKEEPING.—The regulations under subparagraph (A) shall require a producer to maintain feed purchase invoices and related records for a minimum of 2 years.

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

(a) REPORTS ON SURVEILLANCE OF PRION DISEASES.—The Secretary, in consultation with the Secretary of Agriculture, shall annually submit to Congress a report that describes—

(1) the surveillance programs to assess the prevalence of prion diseases in the United States; and

(2) the surveillance of prion disease infectivity and the testing of cattle in the United States.

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

"SEC. 25. RUMINANT IDENTIFICATION PROGRAM.

''(a) IN GENERAL.—The Secretary shall establish a ruminant identification program that is capable of tracing, within 48 hours, after an animal is diagnosed with any reportable animal disease or any condition that can cause

disease in humans, the movements of all exposed animals from birth to slaughter.

''(b) REQUIREMENTS.—

''(1) IN GENERAL.—Under the ruminant identification program, the Secretary shall identify cattle, sheep, goats, bison, deer, and elk and any other ruminant species intended for human consumption through a nationally recognizable uniform numbering system under which an identification number is assigned to—

''(A) each premises of a producer; and

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

''(2) CONTINUATION OF EXISTING PROGRAMS.—The program shall augment, and not supplant, nationally recognized systems in existence on the date of enactment of this section, such as the program for scrapie traceback and eradication in sheep and goats.

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

''(d) RECORDS.—

''(1) IN GENERAL.—The Secretary may require that a producer required to identify livestock under the program maintain records, as prescribed by the Secretary, regarding the purchase, sale, and identification of livestock for such period of time as the Secretary prescribes.

''(2) ACCESS.—A producer shall, at all reasonable times, on notice by an authorized representative of the Secretary, allow the representative access to examine and copy the records described in paragraph (1).

''(e) PROHIBITIONS.—It shall be unlawful for a producer to—

''(1) falsify or misrepresent to any other person or to the Secretary any information relating to any premises at which any cattle, sheep, swine, goats, horses, mules, or other equines, or carcasses thereof, are held; or

''(2) alter, detach, or destroy any records or other means of identification prescribed by the Secretary for use in determining the premises at which any cattle, sheep, swine, goats, horses, mules, or other equines, or the carcasses thereof are held.''.

(c) PROGRAMS.—Not later than 1 year after the date of enactment of this Act—

(1) the Secretary of Agriculture shall develop programs to—

(A)(i) waive diagnostic laboratory charges for the diagnosis of neurological disease in ruminants and mink;

(ii) provide compensation for each submission payable to the attending veterinarian to pay the costs of obtaining and processing neurological samples; and

(iii) develop a program to pay a fee to renderers for each cattle head not already tested that is submitted to a certified lab for BSE testing;

(B)(i) fund the development of the national animal health laboratory network;

(ii) expand the network to include all certified Federal, State, and university veterinary diagnostic laboratories; and

(iii) facilitate the timely processing of samples from surveillance and epidemiological investigation;

(C) require rapid prion disease screening tests on—

(i) all cattle and bison 30 months of age and older and all sheep, goats, deer, and elk 12 months of age and older presented for slaughter and intended for human consumption; and

(ii) all such livestock of a younger age than either of the ages specified in clause (i) if the Secretary determines, based on scientifically credible research, that screening of livestock of a younger age should be conducted;

(D) require rapid prion disease screening tests on all nonambulatory ruminants, including all ruminants exhibiting neurological signs, when presented at a slaughterhouse or for disposal;

(E) ensure that any ruminant tested for BSE is excluded from use in any animal feed until the test is confirmed negative in a writing that clearly identifies the carcass with the negative test result and that all ruminants exhibiting neurological signs are excluded from the human food supply regardless of the results of the BSE test;

(F) establish standards for the collection, chain of custody, and storage of appropriate neurological samples for BSE testing;

(G) assess consumer response to the first BSE case and further develop a communication strategy to address public concern regarding the safety of ruminant products;

(H) expand, in conjunction with the Secretary of the Interior, the collection of animal tissue by Federal, State, tribal, and local agencies for testing for chronic wasting disease;

(I) develop programs to require CWD herd certification and interstate movement restrictions for farm raised deer and elk; and

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

(2) the Secretary shall develop programs to—

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

(B) evaluate the effectiveness of practices in effect as of the date of enactment of this Act

to protect the human blood supply from contamination from blood infected with prion disease; and

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

(d) LIAISON.—Each of the Secretary and the Secretary of Agriculture shall establish liaison positions at each appropriate Undersecretary level to ensure adequate coordination and communication between the Department of Health and Human Services and the Department of Agriculture regarding prion diseases.

(e) TASK FORCE.—

(1) IN GENERAL.—As soon as practicable after the date of enactment of this Act, the Secretary and the Secretary of Agriculture shall jointly establish a task force on prion diseases to provide recommendations 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 among Federal agencies that exercise jurisdiction over food safety and other aspects of public health protection;

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

(i) genetics markers for all species affected by prion disease;

(ii) in vivo diagnostic tests;

(iii) human blood supply diagnostic tests;

(iv) therapies for humans and animals;

(v) processing techniques that denature the prion protein in carcasses and other materials; and

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

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

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

(6) FINAL RECOMMENDATIONS.—Not later than 1 year after the date of enactment of this Act, the task force shall submit to Congress the final recommendations of the task force.

SEC. 6. ENFORCEMENT.

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

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

(c) REMEDIES.—In addition to any remedies available under other provisions of law, the head of a Federal agency may enforce this Act by—

(1) seizing and destroying an article that is introduced into interstate or foreign commerce in violation of this Act; or

(2) issuing an order requiring any person that introduces an article into interstate or foreign commerce in violation of this Act—

(A) to cease the violation;

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

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

(C) to destroy the article or forfeit the article to the United States for destruction; or

(D) to cease operations at the facility at which the article is produced until the head of

the appropriate Federal agency determines that the operations are no longer in violation of this Act.

SEC. 7. AUTHORIZATION OF APPROPRIATIONS.

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

(1) $100,000,000 for each of fiscal years 2004 and 2005; and

(2) such sums as are necessary for each subsequent fiscal year.

(b) ALLOCATION OF FUNDS.—

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

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

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

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

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