

107TH CONGRESS  
2D SESSION

# S. 2013

To clarify the authority of the Secretary of Agriculture to prescribe performance standards for the reduction of pathogens in meat, meat products, poultry, and poultry products processed by establishments receiving inspection services.

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## IN THE SENATE OF THE UNITED STATES

MARCH 14, 2002

Mr. HARKIN (for himself, Mr. DURBIN, Mrs. CLINTON, and Mr. SCHUMER) 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 clarify the authority of the Secretary of Agriculture to prescribe performance standards for the reduction of pathogens in meat, meat products, poultry, and poultry products processed by establishments receiving inspection services.

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 “Meat and Poultry  
5       Pathogen Reduction and Enforcement Act”.

6       **SEC. 2. FINDINGS.**

7       Congress finds that—

1           (1) the primary purpose of the Federal meat  
2 and poultry inspection program is to protect public  
3 health;

4           (2) the Centers for Disease Control and Preven-  
5 tion report that human pathogens found in raw and  
6 cooked meat, meat food products, poultry, and poul-  
7 try products are a significant source of foodborne ill-  
8 ness;

9           (3) to reduce the public health burden of  
10 foodborne illness, the Federal meat and poultry in-  
11 spection system should focus on reducing the risk of  
12 foodborne illness associated with the presence of  
13 foodborne pathogens;

14           (4) good public health practice requires control-  
15 ling pathogens as close as practicable to the initial  
16 source of contamination to reduce pathogens and  
17 prevent foodborne illness;

18           (5) there is a need for strong safeguards at  
19 slaughter establishments during the slaughter and  
20 processing of meat and poultry products because  
21 those establishments are where pathogen contamina-  
22 tion often originates;

23           (6) while proper handling and cooking of meat  
24 and poultry products can virtually eliminate the risk  
25 of foodborne illness from the consumption of meat

1 and poultry, the presence of pathogens in raw meat  
2 and poultry products leads to cross-contamination of  
3 other foods and surrounding surfaces;

4 (7) to reduce the risk of foodborne illness and  
5 protect public health, regulatory authorities and all  
6 parties involved in the production and handling of  
7 meat, meat products, poultry, or poultry products  
8 should make a concerted effort to reduce, to the  
9 maximum extent practicable, contamination by  
10 pathogens using the best available scientific informa-  
11 tion and appropriate technology;

12 (8) the distribution of meat, meat food prod-  
13 ucts, poultry, or poultry products that contain  
14 human pathogens—

15 (A) impairs the effective regulation of  
16 wholesome meat, meat food products, poultry,  
17 or poultry products in interstate and foreign  
18 commerce; and

19 (B) destroys markets for wholesome prod-  
20 ucts;

21 (9) all articles and other animals that are sub-  
22 ject to this Act and the amendments made by this  
23 Act are either in or substantially affect interstate or  
24 foreign commerce; and

1           (10) regulation by the Secretary of Agriculture  
2           and cooperation by the States are necessary to pre-  
3           vent or eliminate burdens on interstate or foreign  
4           commerce and to protect the health and welfare of  
5           consumers.

6 **SEC. 3. PATHOGEN PERFORMANCE STANDARDS.**

7           (a) MEAT AND MEAT PRODUCTS.—The Federal Meat  
8           Inspection Act (21 U.S.C. 601 et seq.) is amended by in-  
9           serting after section 8 (21 U.S.C. 608) the following:

10 **“SEC. 8A. PATHOGEN PERFORMANCE STANDARDS.**

11           “(a) IN GENERAL.—In order to protect the public  
12           health and promote food safety, the Secretary shall pre-  
13           scribe performance standards for the reduction of patho-  
14           gens in raw meat and meat products processed by each  
15           establishment receiving inspection services under this Act.

16           “(b) LIST OF PATHOGENS.—

17           “(1) IN GENERAL.—In consultation with the  
18           Secretary of Health and Human Services, and tak-  
19           ing into account data available from the Centers for  
20           Disease Control and Prevention, the Secretary shall  
21           identify the pathogens that make a significant con-  
22           tribution to the total burden of foodborne disease as-  
23           sociated with meat and meat products.

24           “(2) PUBLICATION; UPDATES.—The Secretary  
25           shall—

1           “(A) publish a list of the pathogens de-  
2           scribed in paragraph (1) not later than 60 days  
3           after the date of enactment of this section; and

4           “(B) update and publish the list annually  
5           thereafter.

6           “(c) PATHOGEN SURVEYS.—

7           “(1) IN GENERAL.—Not later than 180 days  
8           after the date of enactment of this section, the Sec-  
9           retary shall initiate comprehensive, statistically rep-  
10          resentative surveys to determine the current levels  
11          and incidence of contamination of raw meat and  
12          poultry products with the pathogens listed under  
13          subsection (b), including the variation in levels and  
14          incidence of contamination among establishments.

15          “(2) PUBLICATION.—Not later than 2 years  
16          after the date of enactment of this section, the Sec-  
17          retary shall compile, and publish in the Federal Reg-  
18          ister, the results of the surveys.

19          “(3) UPDATES.—At least once every 3 years  
20          after the preceding surveys are conducted, the Sec-  
21          retary shall—

22                  “(A) conduct surveys described in para-  
23                  graph (1); and

24                  “(B) compile and publish the results of the  
25                  surveys in accordance with paragraph (2).

1       “(d) PATHOGEN REDUCTION PERFORMANCE STAND-  
2 ARDS.—

3           “(1) IN GENERAL.—The pathogen reduction  
4 performance standards required under subsection (a)  
5 shall ensure the lowest level or incidence of contami-  
6 nation that is reasonably achievable using the best  
7 available processing technology and practices.

8           “(2) CURRENT CONTAMINATION.—In deter-  
9 mining what is reasonably achievable, the Secretary  
10 shall consider data on current levels or incidence of  
11 contamination, including what is being achieved by  
12 establishments in the upper quartile of performance  
13 in controlling the level or incidence of contamination.

14           “(3) INITIAL PATHOGENS.—Not later than 3  
15 years after the date of enactment of this section, the  
16 Secretary shall propose pathogen reduction perform-  
17 ance standards for at least 2 pathogens from the list  
18 published under subsection (b).

19           “(4) SUBSEQUENT PATHOGENS.—Not later  
20 than 1 year after proposing pathogen reduction  
21 standards for the initial pathogens under paragraph  
22 (3), and each year thereafter, the Secretary shall  
23 propose a pathogen reduction performance standard  
24 for at least 1 pathogen each year from the list pub-

1 lished under subsection (b) until standards have  
2 been proposed for all pathogens on the list.

3 “(5) FINAL STANDARDS.—Not later than 1  
4 year after proposing a pathogen reduction standard  
5 for a pathogen under this subsection, the Secretary  
6 shall promulgate a final pathogen reduction stand-  
7 ard for the pathogen.

8 “(e) REVIEW OF STANDARDS.—

9 “(1) IN GENERAL.—Not later than 3 years  
10 after promulgation of a final pathogen reduction  
11 performance standard for a pathogen under sub-  
12 section (d)(5), the Secretary shall review the stand-  
13 ard to determine whether the standard continues to  
14 ensure the lowest level or incidence of contamination  
15 that is reasonably achievable using the best available  
16 processing technology and practices, taking into the  
17 most recent surveys conducted under subsection (c).

18 “(2) REVISIONS.—The Secretary shall revise  
19 the standard, as necessary, to comply with sub-  
20 section (d).

21 “(f) ENFORCEMENT.—

22 “(1) IN GENERAL.—The Secretary shall con-  
23 duct regular microbial testing in establishments pro-  
24 ducing raw meat and meat products to determine

1 compliance with the pathogen reduction performance  
2 standards promulgated under this section.

3 “(2) INSPECTIONS.—If the Secretary deter-  
4 mines that an establishment fails to meet a standard  
5 promulgated under subsection (d) and that the es-  
6 tablishment fails to take appropriate corrective ac-  
7 tion, as determined by the Secretary, the Secretary  
8 shall refuse to allow any meat or meat product sub-  
9 ject to the standard and processed by the establish-  
10 ment to be labeled, marked, stamped or tagged as  
11 ‘inspected and passed’.

12 “(g) REPORT ON HEALTH-BASED PATHOGEN PER-  
13 FORMANCE STANDARDS.—

14 “(1) IN GENERAL.—Not later than 1 year after  
15 the date of enactment of this section, the Secretary,  
16 in consultation with the Secretary of Health and  
17 Human Services, shall submit to Congress a report  
18 on the scientific feasibility of establishing health-  
19 based performance standards for pathogens in raw  
20 meat and meat products.

21 “(2) FACTORS.—In preparing the report, the  
22 Secretary shall consider—

23 “(A) the scientific feasibility of deter-  
24 mining safe levels for pathogens in raw meat  
25 and meat products;



1           “(B) the scientific and public health cri-  
2           teria that are relevant to determining the safe  
3           levels; and

4           “(C) other factors determined by the Sec-  
5           retary.

6           “(h) RELATIONSHIP TO ADULTERATION PROVI-  
7           SIONS.—Nothing in this section affects the applicability  
8           to pathogens of the provisions of this Act relating to adul-  
9           teration.”.

10          (b) POULTRY AND POULTRY PRODUCTS.—The Poul-  
11          try Products Inspection Act (21 U.S.C. 451 et seq.) is  
12          amended by inserting after section 7 (21 U.S.C. 456) the  
13          following:

14          **“SEC. 7A. PATHOGEN PERFORMANCE STANDARDS.**

15          “(a) IN GENERAL.—In order to protect the public  
16          health and promote food safety, the Secretary shall pre-  
17          scribe pathogen performance standards for the reduction  
18          of pathogens in raw poultry and poultry products proc-  
19          essed by each establishment receiving inspection services  
20          under this Act.

21          “(b) LIST OF PATHOGENS.—

22                  “(1) IN GENERAL.—In consultation with the  
23                  Secretary of Health and Human Services, and tak-  
24                  ing into account data available from the Centers for  
25                  Disease Control and Prevention, the Secretary shall

1 identify the pathogens that make a significant con-  
2 tribution to the total burden of foodborne disease as-  
3 sociated with poultry and poultry products.

4 “(2) PUBLICATION; UPDATES.—The Secretary  
5 shall—

6 “(A) publish a list of the pathogens de-  
7 scribed in paragraph (1) not later than 60 days  
8 after the date of enactment of this section; and

9 “(B) update and publish the list annually  
10 thereafter.

11 “(c) PATHOGEN SURVEYS.—

12 “(1) IN GENERAL.—Not later than 180 days  
13 after the date of enactment of this section, the Sec-  
14 retary shall initiate comprehensive, statistically rep-  
15 resentative surveys to determine the current levels  
16 and incidence of contamination of raw poultry and  
17 poultry products with the pathogens listed under  
18 subsection (b), including the variation in levels and  
19 incidence of contamination among establishments.

20 “(2) PUBLICATION.—Not later than 2 years  
21 after the date of enactment of this section, the Sec-  
22 retary shall compile, and publish in the Federal Reg-  
23 ister, the results of the surveys.

1           “(3) UPDATES.—At least once every 3 years  
2 after the preceding surveys are conducted, the Sec-  
3 retary shall—

4                   “(A) conduct surveys described in para-  
5 graph (1); and

6                   “(B) compile and publish the results of the  
7 surveys in accordance with paragraph (2).

8           “(d) PATHOGEN REDUCTION PERFORMANCE STAND-  
9 ARDS.—

10                   “(1) IN GENERAL.—The pathogen reduction  
11 performance standards required under subsection (a)  
12 shall ensure the lowest level or incidence of contami-  
13 nation that is reasonably achievable using the best  
14 available processing technology and practices.

15                   “(2) CURRENT CONTAMINATION.—In deter-  
16 mining what is reasonably achievable, the Secretary  
17 shall consider data on current levels or incidence of  
18 contamination, including what is being achieved by  
19 establishments in the upper quartile of performance  
20 in controlling the level or incidence of contamination.

21                   “(3) INITIAL PATHOGENS.—Not later than 3  
22 years after the date of enactment of this section, the  
23 Secretary shall propose pathogen reduction perform-  
24 ance standards for at least 2 pathogens from the list  
25 published under subsection (b).

1           “(4) SUBSEQUENT PATHOGENS.—Not later  
2 than 1 year after proposing pathogen reduction  
3 standards for the initial pathogens under paragraph  
4 (3), and each year thereafter, the Secretary shall  
5 propose a pathogen reduction performance standard  
6 for at least 1 pathogen each year from the list pub-  
7 lished under subsection (b) until standards have  
8 been proposed for all pathogens on the list.

9           “(5) FINAL STANDARDS.—Not later than 1  
10 year after proposing a pathogen reduction standard  
11 for a pathogen under this subsection, the Secretary  
12 shall promulgate a final pathogen reduction stand-  
13 ard for the pathogen.

14           “(e) REVIEW OF STANDARDS.—

15           “(1) IN GENERAL.—Not later than 3 years  
16 after promulgation of a final pathogen reduction  
17 performance standard for a pathogen under sub-  
18 section (d)(5), the Secretary shall review the stand-  
19 ard to determine whether the standard continues to  
20 ensure the lowest level or incidence of contamination  
21 that is reasonably achievable using the best available  
22 processing technology and practices, taking into the  
23 most recent surveys conducted under subsection (c).

1           “(2) REVISIONS.—The Secretary shall revise  
2 the standard, as necessary, to comply with sub-  
3 section (d).

4           “(f) ENFORCEMENT.—

5           “(1) IN GENERAL.—The Secretary shall con-  
6 duct regular microbial testing in establishments pro-  
7 ducing raw poultry and poultry products to deter-  
8 mine compliance with the pathogen reduction per-  
9 formance standards promulgated under this section.

10           “(2) INSPECTIONS.—If the Secretary deter-  
11 mines that an establishment fails to meet a standard  
12 promulgated under subsection (d) and that the es-  
13 tablishment fails to take appropriate corrective ac-  
14 tion, as determined by the Secretary, the Secretary  
15 shall refuse to allow any poultry or poultry product  
16 subject to the standard and processed by the estab-  
17 lishment to be labeled, marked, stamped or tagged  
18 as ‘inspected and passed’.

19           “(g) REPORT ON HEALTH-BASED PATHOGEN PER-  
20 FORMANCE STANDARDS.—

21           “(1) IN GENERAL.—Not later than 1 year after  
22 the date of enactment of this section, the Secretary,  
23 in consultation with the Secretary of Health and  
24 Human Services, shall submit to Congress a report  
25 on the scientific feasibility of establishing health-

1 based performance standards for pathogens in raw  
2 poultry and poultry products.

3 “(2) FACTORS.—In preparing the report, the  
4 Secretary shall consider—

5 “(A) the scientific feasibility of deter-  
6 mining safe levels for pathogens in raw poultry  
7 and poultry products;

8 “(B) the scientific and public health cri-  
9 teria that are relevant to determining the safe  
10 levels; and

11 “(C) other factors determined by the Sec-  
12 retary.

13 “(h) RELATIONSHIP TO ADULTERATION PROVI-  
14 SIONS.—Nothing in this section effects the applicability to  
15 pathogens of the provisions of this Act relating to adulter-  
16 ation.”.

17 **SEC. 4. NATIONAL ADVISORY COMMITTEE FOR MICROBI-**  
18 **LOGY CRITERIA FOR FOODS.**

19 (a) ESTABLISHMENT.—

20 (1) IN GENERAL.—In consultation with the Sec-  
21 retary of Health and Human Services, the Secretary  
22 of Agriculture (referred to in this section as the  
23 “Secretary”) shall establish a National Advisory  
24 Committee for Microbiology Criteria for Foods (re-  
25 ferred to in this section as the “Committee”).

1           (2) ADMINISTRATION.—The Committee shall  
2 report to—

3           (A) the Secretary of Agriculture, acting  
4 through the Under Secretary for Food Safety;  
5 and

6           (B) the Secretary of Health and Human  
7 Services, acting through the Assistant Secretary  
8 for Health.

9 (b) MEMBERSHIP.—

10           (1) COMPOSITION.—The Committee shall be  
11 composed of not fewer than 9 nor more than 15  
12 members appointed by the Secretary, including a  
13 Chairperson designated by the Secretary.

14           (2) QUALIFICATIONS.—In appointing members  
15 of the Committee, the Secretary shall appoint indi-  
16 viduals who—

17           (A) are qualified by education, training,  
18 and experience to evaluate scientific and tech-  
19 nical information on matters referred to the  
20 Committee; and

21           (B) to the maximum extent practicable,  
22 represent the fields of microbiology, risk assess-  
23 ment, epidemiology, public health, food science,  
24 veterinary medicine, and other relevant dis-  
25 ciplines.

1           (3) PROHIBITION ON FEDERAL GOVERNMENT  
2 EMPLOYMENT.—A member of the Committee ap-  
3 pointed under paragraph (1) shall not be an em-  
4 ployee of the Federal Government.

5           (4) DATE OF APPOINTMENTS.—The appoint-  
6 ment of an initial member of the Committee shall be  
7 made not later than 90 days after the date of enact-  
8 ment of this Act.

9           (5) TERM.—A member of the Committee shall  
10 be appointed for a term established by the Sec-  
11 retary.

12       (c) MEETINGS.—

13           (1) INITIAL MEETING.—Not later than 30 days  
14 after the date on which all members of the Com-  
15 mittee have been appointed, the Committee shall  
16 hold the initial meeting of the Committee.

17           (2) MEETINGS.—The Committee shall meet at  
18 the call of the Chairperson, in consultation with the  
19 Secretary.

20           (3) QUORUM.—A majority of the members of  
21 the Committee shall constitute a quorum, but a less-  
22 er number of members may hold hearings.

23           (4) CONFLICTS OF INTEREST.—

24           (A) IN GENERAL.—Notwithstanding sec-  
25 tions 201 through 209 of title 18, United



1 States Code, a conflict of interest involving the  
2 appointment of a member of the Committee  
3 shall be waived under section 208(b)(3) of that  
4 title only if the member with the conflict of in-  
5 terest is essential to the completion of the work  
6 of the Committee.

7 (B) VOTING.—Notwithstanding subpara-  
8 graph (A), a member of the Committee with a  
9 conflict of interest on a matter before the Com-  
10 mittee shall not be allowed to vote on the mat-  
11 ter.

12 (d) DUTIES.—

13 (1) IN GENERAL.—The Committee shall provide  
14 such independent, impartial, scientific advice to Fed-  
15 eral food safety agencies as may be requested by the  
16 Secretary for use in the development of an inte-  
17 grated national food safety systems approach from  
18 farm-to-final consumption to ensure the safety of do-  
19 mestic, imported, and exported foods and reduce the  
20 public health burden of foodborne illness.

21 (2) FOOD SAFETY STANDARDS AND REGULA-  
22 TIONS.—

23 (A) IN GENERAL.—At the time at which  
24 the Secretary submits to any Federal agency  
25 for formal review and comment any standard or

1 regulation proposed under the Federal Meat In-  
2 spection Act (21 U.S.C. 601 et seq.), the Poul-  
3 try Products Inspection Act (21 U.S.C. 451 et  
4 seq.), or any program administered by the  
5 Under Secretary for Food Safety, the Secretary  
6 shall make available to the Committee—

7 (i) the standard or regulation; and

8 (ii) relevant scientific and technical  
9 information possessed by the Secretary on  
10 which the proposed standard or regulation  
11 is based.

12 (B) ADVICE AND COMMENTS.—Not later  
13 than a date specified by the Secretary that is  
14 not later than 90 days after receipt of the  
15 standard or regulation, the Committee may  
16 make available to the Secretary the advice and  
17 comments of the Committee on the adequacy of  
18 the scientific and technical basis for the pro-  
19 posed standard or regulation, together with any  
20 additional information the Committee considers  
21 appropriate.

22 (C) CONTEMPORANEOUS REVIEW.—To the  
23 maximum extent practicable, the review by the  
24 Committee under subparagraph (A) shall be

1           conducted contemporaneously with review by  
2           other Federal agencies.

3           (e) POWERS.—

4           (1) HEARINGS.—The Committee may hold such  
5           hearings, sit and act at such times and places, take  
6           such testimony, and receive such evidence as the  
7           Committee considers advisable to carry out this sec-  
8           tion.

9           (2) INFORMATION FROM FEDERAL AGENCIES.—

10           (A) IN GENERAL.—The Committee may  
11           secure directly from a Federal agency such in-  
12           formation as the Committee considers necessary  
13           to carry out this section.

14           (B) PROVISION OF INFORMATION.—On re-  
15           quest of the Chairperson of the Committee, the  
16           head of the agency shall provide the informa-  
17           tion to the Committee.

18           (3) SUBCOMMITTEES AND INVESTIGATIVE PAN-  
19           ELS.—

20           (A) IN GENERAL.—The Committee may  
21           establish such subcommittees and investigative  
22           panels as the Secretary and the Committee de-  
23           termine necessary to carry out this section.

1           (B) CHAIRPERSON.—Each subcommittee  
2           and investigative panel shall be chaired by a  
3           member of the Committee.

4           (4) POSTAL SERVICES.—The Committee may  
5           use the United States mails in the same manner and  
6           under the same conditions as other agencies of the  
7           Federal Government.

8           (5) GIFTS.—The Committee may accept, use,  
9           and dispose of gifts or donations of services or prop-  
10          erty.

11          (f) COMMITTEE PERSONNEL MATTERS.—

12           (1) COMPENSATION OF MEMBERS.—A member  
13           of the Committee shall be compensated at a rate  
14           equal to the daily equivalent of the annual rate of  
15           basic pay prescribed for level IV of the Executive  
16           Schedule under section 5315 of title 5, United  
17           States Code, for each day (including travel time)  
18           during which the member is engaged in the perform-  
19           ance of the duties of the Committee.

20           (2) TRAVEL EXPENSES.—A member of the  
21           Committee shall be allowed travel expenses, includ-  
22           ing per diem in lieu of subsistence, at rates author-  
23           ized for an employee of an agency under subchapter  
24           I of chapter 57 of title 5, United States Code, while  
25           away from the home or regular place of business of

1 the member in the performance of the duties of the  
2 Committee.

3 (3) STAFF.—

4 (A) IN GENERAL.—The Chairperson of the  
5 Committee may, without regard to the civil  
6 service laws (including regulations), appoint  
7 and terminate an executive director and such  
8 other additional personnel as are necessary to  
9 enable the Committee to perform the duties of  
10 the Committee.

11 (B) CONFIRMATION OF EXECUTIVE DIREC-  
12 TOR.—The employment of an executive director  
13 shall be subject to confirmation by the Com-  
14 mittee.

15 (C) COMPENSATION.—

16 (i) IN GENERAL.—Except as provided  
17 in clause (ii), the Chairperson of the Com-  
18 mittee may fix the compensation of the ex-  
19 ecutive director and other personnel with-  
20 out regard to the provisions of chapter 51  
21 and subchapter III of chapter 53 of title 5,  
22 United States Code, relating to classifica-  
23 tion of positions and General Schedule pay  
24 rates.

1                   (ii) MAXIMUM RATE OF PAY.—The  
2                   rate of pay for the executive director and  
3                   other personnel shall not exceed the rate  
4                   payable for level V of the Executive Sched-  
5                   ule under section 5316 of title 5, United  
6                   States Code.

7                   (4) PROCUREMENT OF TEMPORARY AND INTER-  
8                   MITTENT SERVICES.—The Chairperson of the Com-  
9                   mittee may procure temporary and intermittent serv-  
10                  ices in accordance with section 3109(b) of title 5,  
11                  United States Code, at rates for individuals that do  
12                  not exceed the daily equivalent of the annual rate of  
13                  basic pay prescribed for level V of the Executive  
14                  Schedule under section 5316 of that title.

15                  (g) AUTHORIZATION OF APPROPRIATIONS.—

16                  (1) IN GENERAL.—There are authorized to be  
17                  appropriated such sums as are necessary to carry  
18                  out this section, to remain available until expended.

19                  (2) EXISTING FUNDS.—Any funds that are  
20                  available to the National Advisory Committee on  
21                  Microbiological Criteria in existence on the date of  
22                  enactment of this Act shall be made available to the  
23                  Committee.

1 **SEC. 5. REGULATIONS.**

2 (a) **IN GENERAL.**—Consistent with section 553 of  
3 title 5, United States Code, the Secretary of Agriculture  
4 shall have the authority to enforce the pathogen perform-  
5 ance standards of the Secretary in effect on January 1,  
6 2000.

7 (b) **CHALLENGES.**—Subsection (a) does not prevent  
8 a challenge to the standards described in subsection (a)  
9 on any basis other than the basis that the Secretary lacks  
10 the authority to issue and enforce pathogen performance  
11 standards promulgated in accordance with section 553 of  
12 title 5, United States Code.

○