



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

OCT 21 1994

Mr. Brian Burke
Domestic Policy Counsel
Executive Office of the President
The White House
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20500

Dear Mr. Burke:

This is in response to your request of October 20, 1994, for information to refute erroneous criticisms of the Administration's food safety record that were made during the October 12, 1994, Turning Point television program.

The portrayal of the Federal meat and inspection program that was aired October 12 on ABC's Turning Point did not accurately reflect a number of bold and aggressive food safety and public health initiatives undertaken by the Administration to strengthen and update the Federal inspection program for meat and poultry products. It is not true, as contended during the program, that the President has not kept the promise he made in the course of the 1993 E. coli 0157:H7 outbreak in the Northwest to reform the meat and poultry inspection program, nor that the Department of Agriculture has been slow to take appropriate measures to ensure the safety of meat and poultry and protect the public health.

The Department of Agriculture has embarked on an ambitious program that embraces change and innovation in the production, processing, and marketing of meat and poultry. Among the major accomplishments are the following:

- Elevated food safety to a sub-Cabinet-level responsibility within the Department of Agriculture;
- Developed pathogen reduction legislation to target microbial pathogens in meat and poultry products and reduce the risks of food-borne illness. This legislation has received strong consumer support and was introduced in the Congress by Agriculture Committee leaders in the House and Senate;
- Declared E. coli 0157:H7 in raw ground beef to be an illegal adulterant and began a sampling program for raw ground beef prepared in federally inspected plants and retail stores;

- Developed regulatory proposals planned for publication this fall to mandate microbial testing and systematic preventive controls to prevent product contamination;
- Initiated unannounced reviews and follow-up visits in 1,000 meat and poultry plants by special review teams to enforce inspection requirements;
- Strengthened enforcement of the zero tolerance policy for fecal and other contamination of meat and poultry products;
- Implemented mandatory safe cooking and handling instructions on labels of meat and poultry products;
- Developed a rapid microbial test for inplant use to detect generic bacteria on poultry, pork, and beef;
- Increased funding for food safety research in a multi-Agency effort to reduce health risks posed by animal products throughout the farm-to-table production cycle;
- Developed uniform sanitizing methods in meat and poultry plants;
- Established consistent cooking and heating temperatures to address pathogenic contamination;
- Implemented a Memorandum of Understanding with OSHA to ensure safe working conditions in meat and poultry plants.

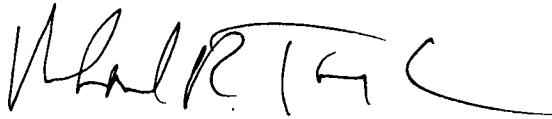
On the inspection system of the Netherlands that was cited in the television program, the Department of Agriculture has begun developing a strategic plan for research on pathogen reduction. One focus is to identify and evaluate practical, applied technologies for preventing pathogens from farm to table--including approaches used in other countries such as the Netherlands. An international symposium on practical methods of pathogen reduction is one of the mechanisms that would provide us with this information, so that we may encourage or mandate appropriate changes in both production and inspection.

Mr. Brian Burke

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We hope this information responds to your request. If we can be of further assistance, please let us know.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael R. Taylor", with a long horizontal flourish extending to the right.

Michael R. Taylor
Acting Under Secretary
Food Safety

Enclosures

A BILL

To amend the Federal Meat Inspection Act, the Poultry Products Inspection Act and animal quarantine laws to provide for improved public health and food safety through the reduction of pathogens, and for other purposes.

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

SECTION 1. This Act may be cited as "The Pathogen Reduction Act of 1994."

TITLE I

"LEGISLATIVE FINDINGS

SEC. 101. The Congress finds that:

(a) Pathogens are a significant source of foodborne illness associated with meat, meat food products, poultry, and poultry products;

(b) Proper handling of meat or products of cattle, sheep, swine, goats, horses, mules or other equines, or poultry products which may bear or contain human pathogens is necessary to prevent foodborne illness;

(c) Livestock and poultry producers, handlers, processors, distributors, transporters, and retailers all share responsibility in handling livestock, meat, meat food products, poultry, and poultry products in such a way as to protect the public health;

(d) The distribution of meat, meat food products, poultry, or poultry products which could be injurious to the public health because they contain human pathogens, would impair the effective regulation of wholesome meat, meat food products, poultry, or poultry products in interstate and foreign commerce and would destroy markets for wholesome products;

(e) In order to reduce the risk of foodborne illnesses and protect public health, a concerted effort is required on the part of regulatory authorities and all parties involved in the production and handling of meat, meat food products, poultry, and poultry products to address the problem of microbial contamination using the best available scientific information and appropriate technology; and

(f) All articles and other animals which are subject to this Act are either in interstate or foreign commerce or substantially affect such commerce, and regulation by the Secretary of Agriculture and cooperation by the States as contemplated by this Act are necessary to prevent or eliminate burdens upon such commerce and to protect the health and welfare of consumers.

AMENDMENTS TO THE FEDERAL MEAT INSPECTION ACT

SEC. 102. The Federal Meat Inspection Act (21 U.S.C. 601, et seq.) is amended:

(1) in section 1, 21 U.S.C. 601, by adding a definition of "official establishment" to read as follows:

"(w) The term "official establishment" means any establishment as determined by the Secretary at which inspection of the slaughter of cattle, sheep, swine, goats, mules and other equines, or the processing of meat and meat food products of such animals, is maintained under authority of this Act.";

(2) in section 3(a), 21 U.S.C. 603(a), by inserting "on the basis of the best available scientific and technologic data, and evaluation of the risks posed to public health and safety," after the words "That hereafter,";

(3) in section 4, 21 U.S.C. 604, by inserting ", on the basis of the best available scientific and technologic data, and evaluation of the risks posed to public health and safety," after the words "That for the purposes hereinbefore set forth".

(4) in section 301(c)(1), 21 U.S.C. 661(c)(1), by inserting "or by thirty days prior to the expiration of two years after enactment of the Pathogen Reduction Act of 1994," after the words "the Wholesome Meat Act,";

(5) in section 301(c), 21 U.S.C. 661(c), by deleting "titles I and IV", "title I and title IV", and "title I and IV", wherever they appear and inserting in lieu thereof "titles I, IV, and V"; and

(6) by adding at the end thereof a new title V to read as follows:

"TITLE V - PATHOGEN REDUCTION

"SEC. 501 (a) The Secretary is directed upon the basis of the best available scientific and technologic data, as determined by the Secretary, to prescribe by regulation such actions as the Secretary deems necessary to:

- (1) limit the presence of human pathogens in cattle, sheep, swine, goats, horses, mules, or other equines at the time they are presented for slaughter;
- (2) ensure that appropriate measures are taken to control the presence and growth of human pathogens on carcasses and parts thereof and on meat or meat food products derived from such animals prepared in any official establishment;
- (3) ensure that all ready-to-eat meat or meat food products prepared in any official establishment preparing any such article for

distribution in commerce are processed in such a manner as to destroy any human pathogens likely to cause foodborne illness; and (4) ensure that meat and meat food products other than those included in subsection (a)(3) of this section prepared at any official establishment preparing any such article for distribution in commerce are labeled with instructions for handling and preparation for consumption which, when adhered to, destroy any human pathogens likely to cause foodborne illness.

"(b) Carcasses or parts thereof and meat or meat food products prepared at any official establishment preparing any such article for distribution in commerce which are found not to be in compliance with the regulations promulgated under subsection (a)(2), (a)(3), or (a)(4) of this section shall be considered adulterated and condemned and shall, if no appeal be taken from such determination of condemnation, be destroyed for human food purposes under the supervision of an inspector:

Provided, That carcasses or parts thereof, and meat and meat food products which are not in compliance with subsection (a)(2), (a)(3), or (a)(4) of this section, but which may by reprocessing, labeling, or both, as applicable, in accordance with subsection (a)(2), (a)(3), or (a)(4) of

this section be made not adulterated need not be condemned and destroyed if so reprocessed, labeled, or both, as applicable and as determined by the Secretary, under the supervision of an inspector and thereafter inspected and found to be not adulterated. If an appeal be taken from such determination of condemnation, the carcasses or parts thereof, or meat and meat food products shall be appropriately marked, segregated and held by the official establishment pending completion of an appeal inspection. If the determination of condemnation is sustained, the carcasses or parts thereof, and meat and meat food products if not so reprocessed, labeled, or both, as applicable, as to be made not adulterated shall be destroyed for human food purposes under the supervision of a duly authorized representative of the Secretary.

"(c) The Secretary shall, within two years of the enactment of this Act, issue regulations that:

- (1) require meat and meat food products prepared in any official establishment to be tested, in such manner and with such frequency as the Secretary deems necessary, to identify human disease-causing pathogens or markers for these pathogens in the meat and meat food products;

(2) require that the results of any test conducted in accordance with subsection (c)(1) of this section be reported to the Secretary, in such manner and with such frequency as the Secretary deems necessary;

(3) establish, to the maximum extent scientifically supportable, levels of human pathogens that, when found on meat or meat food products prepared in official establishments, constitute a threat to public health. When making decisions regarding specific human pathogen levels, the Secretary shall consider the risk to human health, including the risk to infants, the elderly, persons whose immune systems are compromised, and other population subgroups, posed by consumption of the meat or meat food products containing the human pathogen; and

(4) prohibit or restrict the sale, transportation, offer for sale or transportation, or receipt for transportation of any meat or meat food products that: (A) are capable of use as human food, and (B) exceed the levels of human pathogens established in accordance with subsection (c)(3) of this section.

"(d)(1) The Secretary shall, as the Secretary deems necessary and feasible, conduct or support appropriate research regarding the establishment of levels of human pathogens that when found on meat and meat food products prepared in official establishments constitute a threat to public health and shall conduct studies to validate these levels.

(2) The Secretary is directed to review, on a regular basis, all regulations, processes, procedures and methods designed to limit and control human pathogens on carcasses and parts thereof and on meat or meat food products. This on-going review shall include, as necessary, epidemiologic and other scientific studies to ascertain the efficiency and efficacy of such regulations, processes, procedures and methods.

(3) The Secretary shall consult with the Public Health Service, the Centers for Disease Control and Prevention, the Food and Drug Administration, and any other State or Federal public health agency the Secretary deems necessary in order to carry out subsections (c)(1), (c)(3), (d)(1), and (d)(2) of this section.

**"NOTIFICATION, DISTRIBUTION, AND RECALL
REGARDING NONCONFORMING ARTICLES**

"SEC. 502 (a) Any person, firm, or corporation preparing carcasses or parts thereof, meat or meat food products for distribution in commerce which obtains knowledge providing a reasonable basis for believing that any carcasses or parts thereof or any meat or meat food products (1) are adulterated, or not produced in compliance with section 501(a) of this Act or the regulations promulgated thereunder; or (2) are misbranded, shall immediately notify the Secretary, in such manner and by such means as the Secretary may by regulation prescribe, of the identity and location of such articles.

"(b) If the Secretary finds, upon such notification or otherwise, that any carcasses or parts thereof or any meat or meat food products (1) are adulterated or not produced in compliance with section 501(a) of this Act or the regulations promulgated thereunder and that there is a reasonable probability that human consumption of such articles present a threat to the public health, as determined by the Secretary; or (2) are misbranded, the Secretary shall provide the appropriate person, firm, or corporation with an opportunity to cease distribution of such articles; notify all persons, firms, or corporations transporting or distributing such articles or to which such articles were shipped or sold to immediately cease distribution

of such articles; and to recall the articles. If the person, firm, or corporation refuses to voluntarily cease distribution, make notification, and recall the articles or does not voluntarily cease distribution, make notification, and recall the articles within the time or in the manner prescribed by the Secretary, the Secretary shall immediately issue an order requiring the person, firm, or corporation (including the official establishment which prepared the articles), as the Secretary deems necessary to: immediately cease distribution of such articles; and immediately notify all persons, firms, or corporations transporting or distributing such articles or to which such articles were shipped or sold to immediately cease distribution of such articles. The order shall provide any person, firm, or corporation subject to the order with an opportunity for an informal hearing, to be held not later than 5 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require recall of such articles. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

"(c) If, after providing an opportunity for an informal hearing under subsection (b) of this section, the Secretary determines that the articles that are the subject of an order under subsection (b) of this section must be recalled, the Secretary shall amend the order to require a recall. The Secretary shall (1) specify a timetable in which the recall will occur; (2) require periodic reports to the Secretary describing the progress of the recall; and (3) provide for notice to consumers to whom such articles were, or may have been, distributed as to how they should treat the article.

"LIVESTOCK TRACEBACK

"SEC. 503 (a). For the purpose of limiting the risk of foodborne illness from carcasses and parts thereof and meat and meat food products distributed in commerce, the Secretary shall, as the Secretary deems necessary, prescribe by regulation that cattle, sheep, swine, goats, horses, mules and other equines presented for slaughter for human food purposes be identified in the manner prescribed by the Secretary to enable the Secretary to trace each animal to any premises at which it has been held for such period prior to slaughter that the Secretary deems necessary to effectuate the purposes of this Act. The Secretary may prohibit or

restrict entry into any slaughtering establishment inspected under this Act of any cattle, sheep, swine, goats, horses, mules or other equines not identified as prescribed by the Secretary.

"(b) The Secretary is authorized to require that all persons, firms, and corporations required to identify livestock pursuant to subsection (a) of this section maintain accurate records, as prescribed by the Secretary, regarding the purchase, sale, and identification of such livestock; and all persons, firms, and corporations subject to such requirements shall, at all reasonable times, upon notice by a duly authorized representative of the Secretary, afford such representative access to their places of business and opportunity to examine the records thereof, and to copy any such records. Any such record required to be maintained by this section shall be maintained for such period of time as the Secretary prescribes.

"(c) No person, firm, or corporation shall falsify or misrepresent to any other person, firm, or corporation, or to the Secretary, any information as to any premises at which any cattle, sheep, swine, goats, horses, mules or other equines, or carcasses thereof, were held.

"(d) No person, firm, or corporation shall, without authorization from the Secretary, alter, detach, or destroy any records or other means

of identification prescribed by the Secretary for use in determining the premises at which were held any cattle, sheep, swine, goats, horses, mules or other equines, or the carcasses thereof.

"(e)(1) If the Secretary finds any human pathogen or any residue in any cattle, sheep, swine, goats, horses, mules, or other equines at the time they are presented for slaughter or in any carcasses, parts of carcasses, meat, or meat food product prepared in an official establishment and the Secretary finds that there is a reasonable probability that human consumption of any meat or meat food product containing the human pathogen or residue presents a threat to public health, the Secretary may take such action as the Secretary deems necessary to determine the source of the human pathogen or residue.

(2) If the Secretary identifies the source of any human pathogen or residue described in subsection (e)(1) of this section, the Secretary is authorized to prohibit or restrict the movement of any animals, carcasses, parts of carcasses, meat, meat food product, or any other article from any source of the human pathogen or residue until the Secretary determines that the human pathogen or residue at the source no longer presents a threat to public health.

(f)(1) The Secretary shall use any means of identification and record keeping methods utilized by producers or handlers of cattle, sheep, swine, goats, horses, mules, or other equines whenever the Secretary determines that such means of identification and record keeping methods will enable the Secretary to carry out the purposes of this section.

(2) The Secretary is authorized to cooperate with producers or handlers of cattle, sheep, swine, goats, horses, mules, or other equines, in which any human pathogen or residue described in subsection (e)(1) of this section is found, to develop and implement methods to limit or eliminate the human pathogen or residue at the source.

"REFUSAL OR WITHDRAWAL OF INSPECTION

"SEC. 504(a) The Secretary may for such period, or indefinitely, as the Secretary deems necessary to effectuate the purposes of this Act, refuse to provide, or withdraw, inspection service under title I of this Act with respect to any official establishment if the Secretary determines, after opportunity for a hearing is accorded to the applicant for, or recipient of, such service, that the applicant or recipient, or any person responsibly connected with the applicant or recipient, has repeatedly

failed to comply with the requirements of this Act or the regulations promulgated thereunder.

"(b) The Secretary may direct that, pending opportunity for an expedited hearing with respect to any refusal or withdrawal of inspection service and the final determination and order under subsection (a) of this section and any judicial review thereof, inspection service shall be denied or suspended if the Secretary deems such action necessary in the public interest in order to protect the health or welfare of consumers or to assure the safe and effective performance of official duties under this Act.

"(c) The determination and order of the Secretary with respect to withdrawal or refusal of inspection service under this section shall be final and conclusive unless the affected applicant for, or recipient of, inspection service files application for judicial review within 30 days after the effective date of the order; and inspection service shall be withdrawn or refused as of the effective date of the order pending any judicial review of the order unless the Secretary directs otherwise. Judicial review of any such order shall be in the United States Court of Appeals for the circuit in which the applicant for, or recipient of, inspection service has its principal place of business or in the United States Court of

Appeals for the District of Columbia Circuit and shall be upon the record upon which the determination and order are based. The provisions of section 204 of the Packers and Stockyards Act, 1921 (42 Stat. 162, as amended; 7 U.S.C. 194), shall be applicable to appeals taken under this section.

"(d) The provisions of this section shall be in addition to and not derogate from any other provision of this Act for refusal, withdrawal, or suspension of inspection service under Title I of this Act.

"CIVIL PENALTIES

"SEC. 505 (a) Any person, firm, or corporation which violates any provision of this Act, any regulation issued under this Act, or any order issued under section 502(b) or (c) of this Act may be assessed a civil penalty by the Secretary of not more than \$100,000 per day of violation. Each offense shall be a separate violation. No penalty shall be assessed unless such person, firm, or corporation is given notice and opportunity for a hearing on the record before the Secretary in accordance with sections 554 and 556 of Title 5, United States Code. The amount of such civil penalty shall be assessed by the Secretary by written order, taking into account the gravity of the violation, degree of culpability, and history

of prior offenses; and may be reviewed only as provided in subsection (b) of this section.

"(b) Any person, firm, or corporation against whom such violation is found and a civil penalty assessed by order of the Secretary under subsection (a) of this section may obtain review in the Court of Appeals of the United States for the circuit in which such party resides or has a place of business or in the United States Court of Appeals for the District of Columbia Circuit by filing a notice of appeal in such Court within 30 days from the date of such order and by simultaneously sending a copy of such notice by certified mail to the Secretary. The Secretary shall promptly file in such Court a certified copy of the record upon which such violation was found and such penalty assessed. The findings of the Secretary shall be set aside only if found to be unsupported by substantial evidence on the record as a whole.

"(c) If any person, firm, or corporation fails to pay an assessment of a civil penalty after it has become a final and unappealable order, or after the appropriate Court of Appeals has entered final judgment in favor of the Secretary, the Secretary shall refer the matter to the Attorney General, who shall institute a civil action to recover the amount assessed

in any appropriate district court of the United States. In such collection action, the validity and appropriateness of the Secretary's order imposing the civil penalty shall not be subject to review.

"(d) All penalties collected under authority of this section shall be paid into the Treasury of the United States.

"(e) Nothing in this Act shall be construed as requiring the Secretary to report for criminal prosecution or for the institution of libel or injunction proceedings, violations of this Act, whenever the Secretary believes that the public interest will be adequately served by assessment of civil penalties. Furthermore, the Secretary may, in the Secretary's discretion, compromise, modify, or remit, with or without conditions, any civil penalty assessed under this section.

AMENDMENTS TO THE POULTRY PRODUCTS INSPECTION ACT

SEC. 103. The Poultry Products Inspection Act (21 U.S.C. 451 et seq.) is amended:

(1) in section 5(c), 21 U.S.C. 454(c), by deleting "and 12-22 of this Act" and inserting in lieu thereof "12-22, and 30-34 of this Act"; and

(2) in section 5(c)(1), 21 U.S.C. 454(c)(1), by inserting "or by thirty days prior to the expiration of two years after enactment of the Pathogen

Reduction Act of 1994," after the words "the Wholesome Poultry Products Act,";

(3) in section 6(a), 21 U.S.C. 455(a), by inserting "on the basis of the best available scientific and technologic data, and evaluation of the risks posed to public health and safety," after the word "necessary";

(4) in section 6(b), 21 U.S.C. 455(b), by inserting "on the basis of the best available scientific and technologic data, and evaluation of the risks posed to public health and safety," after the words "The Secretary,";

(5) by adding at the end thereof new sections 30 through 34 as follows:

"PATHOGEN REDUCTION

"SEC. 30 (a) The Secretary is directed upon the basis of the best available scientific and technologic data, as determined by the Secretary, to prescribe by regulation such actions as the Secretary deems necessary to:

(1) limit the presence of human pathogens in poultry at the time they are presented for slaughter;

(2) ensure the appropriate means are taken to control the presence and growth of human pathogens on poultry or poultry products prepared in any official establishment;

(3) ensure that all ready-to-eat poultry and poultry products prepared in any official establishment preparing any such article for distribution in commerce are processed in such a manner as to destroy any human pathogens likely to cause foodborne illness; and

(4) ensure that poultry and poultry products other than those included in subsection (a)(3) of this section prepared at any official establishment preparing any such article for distribution in commerce are labeled with instructions for handling and preparation for consumption which, when adhered to, destroy any human pathogens likely to cause foodborne illness.

"(b) Poultry or poultry products prepared at any official establishment preparing any such article for distribution in commerce which are found not to be in compliance with the regulations promulgated under subsection (a)(2), (a)(3), or (a)(4) of this section shall be considered adulterated and condemned and shall, if no appeal be taken from such determination of condemnation, be destroyed for human food purposes under the supervision of an inspector: Provided, That poultry and poultry products which are not in compliance with subsection (a)(2), (a)(3), or (a)(4) of this section but which may by reprocessing, labeling,

or both, as applicable, in accordance with subsection (a)(2), (a)(3), or (a)(4) of this section be made not adulterated need not be condemned and destroyed if so reprocessed, labeled, or both, as applicable and as determined by the Secretary, under the supervision of an inspector and thereafter inspected and found to be not adulterated. If an appeal be taken from such determination of condemnation, the poultry or poultry products shall be appropriately marked, segregated, and held by the official establishment pending completion of an appeal inspection. If the determination of condemnation is sustained, the poultry and poultry products if not so reprocessed, labeled, or both, as applicable, as to be made not adulterated shall be destroyed for human food purposes under the supervision of a duly authorized representative of the Secretary.

"(c) The Secretary shall, within two years of the enactment of this Act, issue regulations that:

- (1) require poultry and poultry products prepared in any official establishment to be tested, in such manner and with such frequency as the Secretary deems necessary, to identify human disease-causing pathogens or markers for these pathogens in the poultry and poultry products;

(2) require that the results of any test conducted in accordance with subsection (c)(1) of this section be reported to the Secretary, in such manner and with such frequency as the Secretary deems necessary;

(3) establish, to the maximum extent scientifically supportable, levels of human pathogens that, when found on poultry and poultry products prepared in official establishments, constitute a threat to public health. When making decisions regarding specific human pathogen levels, the Secretary shall consider the risk to human health, including the risk to infants, the elderly, persons whose immune systems are compromised, and other population subgroups, posed by consumption of the poultry or poultry products containing the human pathogen; and

(4) prohibit or restrict the sale, transportation, offer for sale or transportation, or receipt for transportation of any poultry or poultry products that: (A) are capable of use as human food, and (B) exceed the levels of human pathogens established in accordance with subsection (c)(3) of this section.

"(d)(1) The Secretary shall, as the Secretary deems necessary and feasible, conduct or support appropriate research regarding the establishment of levels of human pathogens that when found on poultry and poultry products prepared in official establishments constitute a threat to public health and shall conduct studies to validate these levels.

(2) The Secretary is directed to review, on a regular basis, all regulations, processes, procedures and methods designed to limit and control human pathogens on poultry and poultry products. This on-going review shall include, as necessary, epidemiologic and other scientific studies to ascertain the efficiency and efficacy of such regulations, processes, procedures and methods.

(3) The Secretary shall consult with the Public Health Service, the Centers for Disease Control and Prevention, the Food and Drug Administration, and any other State or Federal public health agency the Secretary deems necessary in order to carry out subsections (c)(1), (c)(3), (d)(1), and (d)(2) of this section.

"NOTIFICATION, DISTRIBUTION AND RECALL

REGARDING NONCONFORMING ARTICLES

"SEC. 31 (a) Any person preparing poultry or poultry products for distribution in commerce which obtains knowledge providing a reasonable basis for believing that any poultry or poultry products (1) are adulterated or not produced in compliance with section 30(a) of this Act or the regulations promulgated thereunder; or (2) are misbranded, shall immediately notify the Secretary, in such manner and by such means as the Secretary may by regulation prescribe, of the identity and location of such poultry or poultry products.

"(b) If the Secretary finds, upon such notification or otherwise, that any poultry or poultry products (1) are adulterated or not produced in compliance with section 30(a) of this Act or the regulations promulgated thereunder and that there is a reasonable probability that human consumption of such articles present a threat to the public health, as determined by the Secretary; or (2) are misbranded, the Secretary shall provide the appropriate person with an opportunity to cease distribution of such articles; notify all persons, firms, or corporations transporting or distributing such articles or to which such articles were shipped or sold to immediately cease distribution of such articles; and to recall the articles. If the person refuses to voluntarily cease distribution, make notification,

and recall the articles or does not voluntarily cease distribution, make notification, and recall the articles within the time or in the manner prescribed by the Secretary, the Secretary shall immediately issue an order requiring the person (including the official establishment which prepared the articles), as the Secretary deems necessary to: immediately cease distribution of such articles; and immediately notify all persons, firms, or corporations transporting or distributing such articles or to which such articles were shipped or sold to immediately cease distribution of such articles. The order shall provide any person subject to the order with an opportunity for an informal hearing, to be held not later than 5 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require recall of such articles. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

"(c) If, after providing an opportunity for an informal hearing under subsection (b) of this section, the Secretary determines that the articles that are the subject of an order under subsection (b) of this section must be recalled, the Secretary shall amend the order to require a

recall. The Secretary shall (1) specify a timetable in which the recall will occur; (2) require periodic reports to the Secretary describing the progress of the recall; and (3) provide for notice to consumers to whom such articles were, or may have been, distributed as to how they should treat the article.

"POULTRY TRACEBACK

"SEC. 32 (a) For the purpose of limiting the risk of foodborne illness from poultry and poultry products distributed in commerce, the Secretary shall, as the Secretary deems necessary, prescribe by regulation that poultry presented for slaughter for human food purposes be identified in the manner prescribed by the Secretary to enable the Secretary to trace each bird to any premises at which it has been held for such period prior to slaughter that the Secretary deems necessary to effectuate the purposes of this Act. The Secretary may prohibit or restrict entry into any slaughtering establishment inspected under this Act of any poultry not identified as prescribed by the Secretary.

"(b) The Secretary is authorized to require that all persons required to identify poultry pursuant to subsection (a) of this section, maintain accurate records, as prescribed by the Secretary, regarding the

purchase, sale, and identification of such poultry; and all persons subject to such requirements shall, at all reasonable times, upon notice by a duly authorized representative of the Secretary, afford such representative access to their places of business and opportunity to examine the records thereof, and to copy any such records. Any such record required to be maintained by this section shall be maintained for such period of time as the Secretary prescribes.

"(c) No person shall falsify or misrepresent to any other person or to the Secretary, any information as to any premises at which any poultry, or the carcasses thereof, were held.

"(d) No person shall, without authorization from the Secretary, alter, detach, or destroy any records or other means of identification prescribed by the Secretary for use in determining the premises at which were held any poultry or carcasses thereof.

"(e)(1) If the Secretary finds any human pathogen or any residue in any poultry at the time they are presented for slaughter or in any poultry carcasses, parts of poultry carcasses, or poultry products prepared in an official establishment and the Secretary finds that there is a reasonable probability that human consumption of any poultry or poultry product

containing the human pathogen or residue presents a threat to public health, the Secretary may take such action as the Secretary deems necessary to determine the source of the human pathogen or residue.

(2) If the Secretary identifies the source of any human pathogen or residue described in subsection (e)(1) of this section, the Secretary is authorized to prohibit or restrict the movement of any poultry, poultry carcasses, parts of poultry carcasses, poultry product, or any other article from any source of the human pathogen or residue until the Secretary determines that the human pathogen or residue at the source no longer presents a threat to public health.

(f)(1) The Secretary shall use any means of identification and record keeping methods utilized by producers or handlers of poultry whenever such means of identification and record keeping methods will enable the Secretary to carry out the purposes of this section.

(2) The Secretary is authorized to cooperate with producers or handlers of poultry, in which any human pathogen or residue described in subsection (e)(1) of this section is found, to develop and implement methods to limit or eliminate the human pathogen or residue at the source.

"REFUSAL OR WITHDRAWAL OF INSPECTION

"SEC. 33 (a) The Secretary may for such period, or indefinitely, as the Secretary deems necessary to effectuate the purposes of this Act, refuse to provide, or withdraw, inspection service under this Act with respect to any official establishment if the Secretary determines, after opportunity for a hearing is accorded to the applicant for, or recipient of, such service, that the applicant or recipient, or any person responsibly connected with the applicant or recipient, has repeatedly failed to comply with the requirements of this Act or the regulations promulgated thereunder.

"(b) The Secretary may direct that, pending opportunity for an expedited hearing with respect to any refusal or withdrawal of inspection service and the final determination and order under subsection (a) of this section and any judicial review thereof, inspection service shall be denied or suspended if the Secretary deems such action necessary in the public interest in order to protect the health or welfare of consumers or to assure the safe and effective performance of official duties under this Act.

"(c) The determination and order of the Secretary with respect to withdrawal or refusal of inspection service under this section shall be

final and conclusive unless the affected applicant for, or recipient of, inspection service files application for judicial review within 30 days after the effective date of the order; and inspection service shall be withdrawn or refused as of the effective date of the order pending any judicial review of the order unless the Secretary directs otherwise. Judicial review of any such order shall be in the United States Court of Appeals for the circuit in which the applicant for, or recipient of, inspection service has its principal place of business or in the United States Court of Appeals for the District of Columbia Circuit and shall be upon the record upon which the determination and order are based. The provisions of section 204 of the Packers and Stockyards Act, 1921 (42 Stat. 162, as amended; 7 U.S.C. 194), shall be applicable to appeals taken under this section.

"(d) The provisions of this section shall be in addition to and not derogate from any other provision of this Act for refusal, withdrawal, or suspension of inspection service under this Act.

"CIVIL PENALTIES

"SEC. 34 (a) Any person which violates any provision of this Act, any regulation issued under this Act, or any order issued under section 31(b) or (c) of this Act may be assessed a civil penalty by the Secretary of not more than \$100,000 per day of violation. Each offense shall be a separate violation. No penalty shall be assessed unless such person is given notice and opportunity for a hearing on the record before the Secretary in accordance with sections 554 and 556 of Title 5, United States Code. The amount of such civil penalty shall be assessed by the Secretary by written order, taking into account the gravity of the violation, degree of culpability, and history of prior offenses; and may be reviewed only as provided in subsection (b) of this section.

"(b) Any person against whom such violation is found and a civil penalty assessed by order of the Secretary under subsection (a) of this section may obtain review in the Court of Appeals of the United States for the circuit in which such party resides or has a place of business or in the United States Court of Appeals for the District of Columbia Circuit by filing a notice of appeal in such Court within 30 days from the date of such order and by simultaneously sending a copy of such notice by certified mail to the Secretary. The Secretary shall promptly file in such

Court a certified copy of the record upon which such violation was found and such penalty assessed. The findings of the Secretary shall be set aside only if found to be unsupported by substantial evidence on the record as a whole.

"(c) If any person fails to pay an assessment of a civil penalty after it has become a final and unappealable order, or after the appropriate Court of Appeals has entered final judgment in favor of the Secretary, the Secretary shall refer the matter to the Attorney General, who shall institute a civil action to recover the amount assessed in any appropriate district court of the United States. In such collection action, the validity and appropriateness of the Secretary's order imposing the civil penalty shall not be subject to review.

"(d) All penalties collected under authority of this section shall be paid into the Treasury of the United States.

"(e) Nothing in this Act shall be construed as requiring the Secretary to report for criminal prosecution or for the institution of libel or injunction proceedings, violations of this Act, whenever the Secretary believes that the public interest will be adequately served by assessment of civil penalties. Furthermore, the Secretary may, in the Secretary's

discretion, compromise, modify, or remit, with or without conditions, any civil penalty assessed under this section.

TITLE II

SEC. 201. Section 1 of the Act of July 2, 1962, (21 U.S.C. 134) is amended by adding a new subsection (e) to read:

"(e) The term "disease" means any disease of livestock or poultry, both infectious and non-infectious, and any other health-related condition that may be transmitted by livestock or poultry or their products to other animals or humans."

SEC. 202. Section 2(a) of the Act of July 2, 1962, (21 U.S.C. 134a(a)) is amended to read:

"(a) Whenever the Secretary deems it necessary in order to prevent the introduction or dissemination of a disease, the Secretary may seize, quarantine, and dispose of, in a reasonable manner taking into consideration the nature of the disease and the necessity of such action to

protect the livestock or poultry of the United States, or the health of the people of the United States because the disease may be transmitted by livestock or poultry or their products: (1) any animals which the Secretary finds are moving or are being handled or have moved or have been handled in interstate or foreign commerce contrary to any law or regulation administered by the Secretary for the prevention of the introduction or dissemination of any disease; (2) any animals which the Secretary finds are moving into the United States, or interstate, and are affected with or have been exposed to any disease; and (3) any animals which the Secretary finds have moved into the United States, or interstate, and, at the time of such movement, were affected with or exposed to any disease."

SEC. 203. Section 2(e) of the Act of July 2, 1962, (21 U.S.C. 134a(e)) is amended to read:

"(e) No such payment shall be made by the Secretary for any animal, carcass, product, or article which has been moved or handled by the owner thereof or the owner's agent in violation of a law or regulation

administered by the Secretary for the prevention of the interstate dissemination of disease, for which the animal, carcass, product, or article was destroyed or a law or regulation for the enforcement of which the Secretary enters or has entered into a cooperative agreement for the control and eradication of disease, or for any animal which has moved into the United States contrary to such law or regulation administered by the Secretary for the prevention of the introduction of a disease."

SEC. 204. Section 3 of the Act of July 2, 1962, (21 U.S.C. 134b) is amended to read:

"The Secretary, in order to protect the health of the livestock or poultry of the United States, and the health of the people of the United States because the disease may be transmitted by livestock or poultry or their products, may promulgate regulations requiring that railway cars; vessels; airplanes; trucks; and other means of conveyance; stockyards; feed, water, and rest stations; and other facilities, used in connection with the movement of animals into or from the United States, or interstate, be

maintained in a clean and sanitary condition, including requirements for inspection, cleaning, and disinfection."

SEC. 205. Section 4 of the Act of July 2, 1962, (21 U.S.C. 134c) is amended to read:

"The Secretary is authorized to promulgate regulations prohibiting or regulating the movement into the United States of any animals which are or have been affected with or exposed to any disease, or which have been vaccinated or otherwise treated for any disease, or which the Secretary finds would otherwise be likely to introduce or disseminate any disease, when the Secretary determines that such action is necessary to protect the livestock or poultry of the United States, or to protect the health of the people of the United States because the disease may be transmitted by livestock or poultry or their products."

SEC. 206. Section 5 of the Act of July 2, 1962, (21 U.S.C. 134d) is amended to read:

"Employees of the Department of Agriculture designated by the Secretary for the purpose, when properly identified, shall have authority: (1) to stop and inspect, without a warrant, any person or means of conveyance, moving into the United States from a foreign country, to determine whether such person or means of conveyance is carrying any animal, carcass, product, or article regulated or subject to disposal under any law or regulation administered by the Secretary for prevention of the introduction or dissemination of any disease; (2) to stop and inspect, without a warrant, any means of conveyance moving interstate upon probable cause to believe the means of conveyance is carrying any animal, carcass, product, or article regulated or subject to disposal under any law or regulation administered by the Secretary for the prevention of the introduction or dissemination of any disease; and (3) to enter upon, with a warrant, any premises for the purpose of making inspections and seizures necessary under any laws or regulation administered by the Secretary for the prevention of the introduction or dissemination of any disease. Any federal judge, or any judge of a court of record in the United States, or any United States commissioner, may, within such commissioner's jurisdiction, upon proper oath or affirmation indicating

probable cause to believe that there is on certain premises any animal, carcass, product, or article regulated or subject to disposal under any law or regulation administered by the Secretary for the prevention of the introduction or dissemination of any disease, issue warrants for the entry upon such premises and for inspections and seizures necessary under such laws and regulations. Warrants may be executed by any authorized employee of the Department of Agriculture."

SEC. 207. Section 6 of the Act of August 30, 1890, as amended (21 U.S.C. 104) is amended to read:

"(a) The Secretary of Agriculture is authorized to prohibit or restrict the importation of animals which are affected with disease or which have been exposed to disease prior to their importation into the United States.

(b) Any person who knowingly violates any provision of this section or sections 7 through 10 of this Act or any regulation prescribed by the Secretary of Agriculture under any such section shall be guilty of a misdemeanor and shall, on conviction, be punished by a fine not

exceeding \$5,000, by imprisonment not exceeding one year, or both.

Any person who violates any such provision or any such regulation may be assessed a civil penalty by the Secretary of Agriculture not exceeding \$1,000. The Secretary of Agriculture may issue an order assessing such civil penalty only after notice and an opportunity for an agency hearing on the record. The order shall be treated as a final order reviewable under chapter 158 of Title 28. The validity of the order may not be reviewed in an action to collect the civil penalty.

(c) For the purposes of this Act the word "disease" means any disease of livestock or poultry, both infectious and non-infectious, and any other health-related condition that may be transmitted by livestock or poultry or their products to other animals or humans."

SEC. 208. Section 8 of the Act of August 30, 1890, (21 U.S.C. 103) is amended to read:

"(a) The Secretary of Agriculture is authorized to require animals to be imported into ports in the United States designated by the Secretary of

Agriculture, with the approval of the Secretary of the Treasury, as quarantine stations. If any animals required by the Secretary of Agriculture to be imported into ports designated as quarantine stations are brought to any port of the United States where no quarantine station is established, the Secretary of Agriculture may require the animals to be moved to the nearest quarantine station at the expense of owner of the animals under such conditions as the Secretary of Agriculture determines necessary to prevent the spread of disease.

(b) The Secretary of Agriculture may destroy animals which the Secretary of Agriculture finds to be affected with or exposed to a disease dangerous to other animals, or to the health of the people of the United States because the disease may be transmitted by livestock or poultry or their products.

(c) Except as provided in subsection (d) of this section, the Secretary of Agriculture shall compensate the owner of animals destroyed in accordance with subsection (b) of this section which are exposed to disease, but not affected with disease. Such compensation shall be based

upon the fair market value of the animal at the time of destruction as determined by the Secretary of Agriculture. Compensation paid any owner under this subsection shall not include anticipated profits and shall not exceed the difference between any compensation received by the owner of the animals from any other source and the fair market value of the animal at the time of destruction. Funds in the Treasury available for carrying out animal disease control activities of the Department of Agriculture shall be used to compensate owners of animals destroyed in accordance with subsection (b) of this section.

(d) No payment shall be made by the Secretary of Agriculture for animals destroyed in accordance with subsection (b) of this section if the animal has been imported in violation of any law or regulation administered by the Secretary of Agriculture for the prevention of the introduction or dissemination of any disease."

SEC. 209. Section 1 of the Act of February 2, 1903, as amended (21 U.S.C. 121) is amended to read:

(a) Whenever the Secretary of Agriculture issues a certificate showing that the Secretary of Agriculture had inspected any livestock and/or live poultry which were about to be exported from the United States or moved interstate, and had found them free of any disease, such animals, so inspected and certified, may be transported into and through any state, or they may be exported from the United States without further inspection or the exaction of fees of any kind, except such as may at anytime be ordered or exacted by the Secretary of Agriculture; and all such animals shall at all times be under control and supervision of the Secretary of Agriculture for the purposes of such inspection.

(b) For the purposes of this Act, the word "disease" means any disease of livestock or poultry, both infectious and non-infectious, and any other health-related condition that may be transmitted by livestock or poultry or their products to other animals or humans.

(c) For the purposes of this Act, the word "state" means any of the several states of the United States, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the District of

Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

SEC. 210. Section 2 of the Act of February 2, 1903, as amended (21 U.S.C. 111) is amended to read:

"(a) The Secretary of Agriculture is authorized to make such regulations and take such measures as the Secretary of Agriculture deems necessary to prevent the introduction or dissemination of any disease from a foreign country into the United States or from one state to another.

(b) The Secretary of Agriculture is authorized to seize, quarantine, and dispose of any hay, straw, forage, or similar material, or any meats, hides, or other animal products coming from a foreign country in which disease exists to the United States, or from one state in which disease exists to another state, whenever in the Secretary of Agriculture's judgment such action is advisable in order to prevent the introduction or spread of disease."

SEC. 211. Section 3 of the Act of May 29, 1884, as amended (21 U.S.C. 114) is amended to read:

"(a) The Secretary of Agriculture is authorized to prepare regulations for the speedy and effectual suppression and eradication of diseases, and to certify such regulations to the executive authority of each state, and invite these executive authorities to cooperate in the execution and enforcement of this Act and section 2 of the Act of February 2, 1903. Whenever the plans and methods of the Secretary of Agriculture shall be accepted by any state in which a disease is declared to exist, or any state shall have adopted plans and methods for the suppression and eradication of diseases, and the state plans and methods are accepted by the Secretary of Agriculture, and whenever the governor of a state or other properly constituted authorities signify their readiness to cooperate for the suppression or eradication of any disease in conformity with this Act and section 2 of the Act of February 2, 1903, the Secretary of Agriculture is authorized to expend so much of the money appropriated for carrying out this Act and section 2 of the Act of February 2, 1903, as may be necessary in such investigations, and in such disinfection and quarantine

measures as may be necessary to prevent the spread of the disease from one state into another.

(b) For the purposes of this Act, the word "disease" means any disease of livestock or poultry, both infectious and non-infectious, and any other health-related condition that may be transmitted by livestock or poultry or their products to other animals or humans."

(c) For the purposes of this section, the word "state" means any of the several states of the United States, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

SEC. 212. Section 4 of the Act of May 29, 1884, as amended (21 U.S.C. 112) is amended to read:

"In order to promote the exportation of livestock and/or live poultry from the United States, the Secretary of Agriculture is authorized to investigate

the existence of any disease, along the dividing lines between the United States and foreign countries, and along the lines of transportation from all parts of the United States to ports from which livestock and/or live poultry are exported, and may establish regulations concerning the exportation and transportation of livestock and/or live poultry as the results of the investigations may require."

SEC. 213. Section 5 of the Act of May 29, 1884, as amended (21 U.S.C. 113) is amended to read:

"In order to prevent the exportation from the United States to any foreign country of livestock and/or live poultry affected with disease or exposed to disease, the Secretary of Agriculture is authorized to take such steps and adopt such measures, as the Secretary of Agriculture may deem necessary."

SEC. 214. Sections 4 and 5 of the Act of May 29, 1884, as amended (21 U.S.C. 120) are amended to read:

"(a) In order to enable the Secretary of Agriculture to effectually suppress and eradicate diseases, and to prevent the spread of diseases, the Secretary of Agriculture is authorized to establish such regulations concerning the exportation and transportation of livestock and/or live poultry from any place within the United States where the Secretary of Agriculture may have reason to believe diseases may exist into and through any state and to foreign countries as the Secretary of Agriculture may deem necessary."

(b) For the purposes of these sections, the word "state" means any of the several states of the United States, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

SEC. 215. Section 6 of the Act of May 29, 1884, as amended (21 U.S.C. 115) is amended to read:

"(a) No person, company, or corporation shall transport, receive for transportation, deliver for transportation, move, or cause to be moved from one state to another any livestock and/or live poultry affected with any disease except in accordance with regulations prescribed by the Secretary of Agriculture to protect the livestock and poultry of the United States and the health of the people of the United States."

(b) For the purposes of this section, the word "state" means any of the several states of the United States, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

SEC. 216. Section 11 of the Act of May 29, 1884, as amended (21 U.S.C. 114a) is amended to read:

(a) The Secretary of Agriculture, either independently or in cooperation with states or political subdivisions of states, farmers' associations and similar organizations, and individuals, is authorized to: (1) control and

eradicate any diseases which in the opinion of the Secretary of Agriculture constitute an emergency and threaten the livestock industry or poultry industry of the United States, or the health of the people of the United States because the disease may be transmitted by livestock or poultry or their products; and (2) pay claims growing out of destruction of animals (including poultry), and of materials, affected by or exposed to any communicable disease, in accordance with such regulations as the Secretary of Agriculture may prescribe.

(b) The Secretary of Agriculture is authorized to prescribe and collect fees to recover the costs of carrying out this section which relate to veterinary diagnostics.

(c) For the purposes of this section, the word "state" means any of the several states of the United States, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

SEC. 217. Section 1 of the Act of March 3, 1905, as amended (21 U.S.C. 123) is amended to read:

(a) The Secretary of Agriculture is authorized to quarantine by regulation any state, or any portion of any state, when the Secretary of Agriculture shall determine the fact that any animals or live poultry in such state are affected with any disease or that the contagion of any disease exists or that vectors which may disseminate any disease exist in such state.

(b) For the purposes of this Act, the word "disease" means any disease of livestock or poultry, both infectious and non-infectious, and any other health-related condition that may be transmitted by livestock or poultry or their products to other animals or humans.

(c) For the purposes of this section, the word "state" means any of the several states of the United States, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

SEC. 218. Section 1 of the Act of May 6, 1970, (21 U.S.C. 135) is amended by designating the current section as subsection "(a)"; by deleting the words "livestock or poultry disease or pests" and by inserting in lieu thereof "diseases or livestock or poultry pests"; by deleting "livestock or poultry diseases or pests" and by inserting in lieu thereof "diseases or livestock or poultry pests"; and by adding a new subsection (b) to read:

"(b) For the purposes of this Act, the word "diseases" means any diseases of livestock or poultry, both infectious and non-infectious, and any other health-related condition that may be transmitted by livestock or poultry or their products to other animals or humans."

SEC. 219. Section 12 of the Act of March 4, 1907, as amended (21 U.S.C. 612) is amended to read:

"(a) The Secretary is authorized to inspect all cattle, sheep, swine, goats, horses, mules, and other equines intended and offered for export to foreign countries at such times and places, and in such manner as the

Secretary may deem proper, to ascertain whether such cattle, sheep, swine, goats, horses, mules, and other equines are free from disease.

(b) For the purpose of this section, the word "disease" means any disease of cattle, sheep, swine, goats, horses, mules, and other equines, both infectious and non-infectious, and any other health-related condition that may be transmitted by cattle, sheep, swine, goats, horses, mules, and other equines or their products to other animals or humans."

SEC. 220. The Act of September 28, 1962, (7 U.S.C. 450) is amended to read:

"(a) In order to avoid duplication of functions, facilities, and personnel, and to attain closer coordination and greater effectiveness and economy in administration of federal and state laws and regulations relating to the production and marketing of agricultural products and to the control or eradication of plant diseases, plant pests, animal diseases, and animal pests, the Secretary of Agriculture is authorized, in the administration and enforcement of such federal laws within the Secretary of Agriculture's

area of responsibility, whenever the Secretary of Agriculture deems it feasible and in the public interest, to enter into cooperative arrangements with state departments of agriculture and other state agencies charged with the administration and enforcement of such state laws and regulations and to provide that any such state agency which has adequate facilities, personnel, and procedures, as determined by the Secretary of Agriculture, may assist the Secretary of Agriculture in the administration and enforcement of such federal laws and regulations to the extent and in the manner the Secretary of Agriculture deems appropriate in the public interest.

(b) The Secretary is authorized to coordinate the administration of such federal laws and regulations with such state laws and regulations wherever feasible. However, nothing in this Act shall affect the jurisdiction of the Secretary of Agriculture under any federal law, or any authority to cooperate with state agencies or other agencies or persons under existing provisions of law, or affect any restrictions of law upon such cooperation.

(c) For the purposes of this Act the term "animal diseases" means any diseases of animals, both infectious and non-infectious, and any other health-related condition that may be transmitted by animals or their products to other animals or humans."

SEC. 221. Section 101(d) of the Act of September 21, 1944, (7 U.S.C. 430) is amended to read:

"(a) The Secretary of Agriculture may purchase in the open market from applicable appropriations samples of all tuberculin, serums, antitoxins, or other products, of foreign or domestic manufacture, which are sold in the United States, for the detection, prevention, treatment, or cure of diseases of domestic animals, test the same, and disseminate the results of the tests in such manner as the Secretary of Agriculture may deem best."

"(b) For the purposes of this section, the word "diseases" means any diseases of domestic animals, both infectious and non-infectious, and any

other health-related condition that may be transmitted by domestic animals or their products to other animals or humans."

SECTION-BY-SECTION-ANALYSIS
THE PATHOGEN REDUCTION ACT OF 1994

Title I

Section 1. Section 1 would provide that the Act may be cited as "The Pathogen Reduction Act of 1994".

Section 101. Legislative Findings. This section contains the Congressional findings. In section 101, the Congress finds, inter alia, that pathogens are a significant source of foodborne illness and that proper handling of meat, products of certain specified animals, and poultry products is necessary to prevent foodborne illness. Congress further finds that producers, handlers, processors, distributors, transporters, and retailers all share responsibility for protecting public health. Additionally, Congress finds that the distribution of meat, meat food products, poultry, and poultry products which could be injurious to health because they contain pathogens, impairs the effective regulation of wholesome meat, meat food products, poultry, and poultry products in interstate and foreign commerce. Further, in order to reduce the risk of foodborne illnesses and protect public health, Congress finds that a concerted effort is required on the part of regulatory authorities and all parties involved in the production and handling of meat, meat food products, poultry, and poultry products to address the problem of microbial contamination using the best available scientific information and appropriate technology. Finally, Congress finds that all animals and other articles subject to the Act are in interstate or foreign commerce or substantially affect such commerce and that regulation by the Secretary of Agriculture and cooperation by the States are necessary to protect the health and welfare of consumers.

Section 102. Amendments to the Federal Meat Inspection Act.

Paragraph (1) of section 102 would amend section 1 of the Federal Meat Inspection Act (FMIA) by adding a definition of the term "official establishment". The definition of this term is the same as the definition currently in the Poultry Products Inspection Act (PPIA).

Paragraph (2) and (3) of section 102 of the bill would amend section 3(a) and section 4 of the FMIA to explicitly provide that the Secretary is to ensure that ante mortem and post mortem inspection are to be made on the basis of the best available scientific and technologic data, and evaluation of the risks posed to public health and safety.

Paragraph (4) of section 102 of the bill would require that State meat inspection requirements must, in addition, be at least equal to requirements imposed under the new title V which paragraph (5) of this section of the bill would add to the FMIA.

When section 301 was added to the FMIA in 1967, the States were accorded a grace period of two years (plus one additional year, in the Secretary's discretion) to make their meat inspection requirements at least equal to those of the FMIA. By amending section 301 of the FMIA to include title V, the States will have two years (with the possibility of one additional year) to institute requirements at least equal to those in title V.

Paragraph (5) of section 102 would further amend 301(c) of the FMIA by substituting "titles I, IV and V" for references to titles I and IV wherever these references appear. Section 301 of the FMIA requires that the Secretary of Agriculture designate any State whose meat inspection requirements with respect to transactions wholly within such State are not at least equal to those of titles I and IV of the FMIA. Upon such designation, titles I and IV would apply to such intrastate transactions and no meat or meat food products could be sold unless inspected for wholesomeness and passed by inspectors of the Food Safety and Inspection Service (FSIS).

Paragraph (6) of section 102 would add at the end of the Federal Meat Inspection Act new sections 501 through 506 comprising a new title V, entitled "Pathogen Reduction".

Carcasses and parts thereof, and meat and meat food products may be contaminated by harmful levels of human pathogens in the production and distribution process; and everyone in the chain of distribution -- producers, handlers, processors, distributors, transporters, and retailers -- must share in the effort to prevent foodborne illness. Pathogens that get into the food supply and cause illness may be reduced if care in handling is exercised at critical points. The incidence of harmful pathogens may be reduced by changing animal husbandry practices, by implementing certain sanitation interventions in the slaughtering and processing plants, by temperature control, or by handling and cooking in accordance with the labeling instructions.

Section 501(a) would direct the Secretary to prescribe by regulation such action as the Secretary deems necessary, based on the best available scientific and technologic data, to limit the presence of human pathogens in livestock at the time they are presented for slaughter; to ensure that appropriate measures are taken to control the presence and growth of human pathogens on meat, meat food products, carcasses or parts thereof prepared in any official establishment; to ensure that all ready-to-eat meat and meat food products prepared in any official establishment for distribution in commerce are prepared in such a manner to destroy any human pathogens which are likely to cause foodborne illness; and to ensure that meat and meat food products, other than ready-to-eat meat and meat food products prepared in any official establishment for distribution in commerce are labeled with handling and preparation instructions for consumption which, when

followed, will destroy any human pathogens likely to cause foodborne illness.

Section 501(a)(1) would direct the Secretary to promulgate regulations to limit the presence of human pathogens in livestock at the time they are presented for slaughter. Scientific and technologic data on human pathogens is being developed on an on-going basis. If this data indicates that a method or procedure is effective in limiting human pathogens in livestock at the time they are presented for slaughter, the Secretary would issue regulations to require the use of such method or procedure.

Section 501(a)(2) would clarify the authority of the Secretary to prescribe regulations to ensure that appropriate measures are taken to control the presence of human pathogens on carcasses, parts of carcasses, and meat and meat food products prepared in any official establishment. The Secretary has permitted the use of antimicrobial sprays on beef, pork, and other meat carcasses to control the presence and growth of human pathogens. As scientific research provides new information, the Secretary may mandate the use of these or other processes to ensure the control of human pathogens on carcasses, parts of carcasses, meat or meat food product.

Section 501(a)(3) would require the Secretary, as deemed necessary, to issue regulations to require ready-to-eat products to be produced in such a manner that any human pathogens likely to cause foodborne illness are destroyed. Processed, ready-to-eat products shall not contain human pathogens likely to cause foodborne illness.

Section 501(a)(4) would require the Secretary, as deemed necessary, to issue regulations to require meat and meat food products other than ready-to-eat meat and meat food products to be labeled with instructions for safe handling and preparation, which, when followed, will destroy any human pathogens likely to cause foodborne illness.

Section 501(b) would provide that carcasses or parts thereof and meat or meat food products prepared in an official establishment for distribution in commerce, which are found not to be in compliance with the regulations promulgated under section 501(a)(2), (a)(3), or (a)(4), shall be considered adulterated and condemned. For example, meat or meat food products found either not processed sufficiently to destroy harmful pathogens or carcasses or parts thereof not labeled with instructions for handling and preparation would be considered adulterated and condemned. However, the official establishment would be given the opportunity to reprocess, label, or reprocess and label, as applicable and as determined by the Secretary, the article so as to be made not adulterated and thereby avoid unnecessary loss of product. Section 501(b) also provides for an

appeal from the determination of condemnation. In the event that an appeal is taken, section 501(b) would require that the article be appropriately marked, segregated, and held by the establishment pending the completion of the appeal inspection. If no appeal is taken or the determination of condemnation is sustained, the product can be reprocessed or labeled, or both, as applicable. If the product is not reprocessed or relabeled, or both, as applicable, the product will be destroyed for human food purposes under the supervision of a duly authorized representative of the Secretary.

Section 501(c) would require the Secretary, within two years of the enactment of the Act, to issue regulations that: (1) require meat and meat food products prepared in any official establishment to be tested, in such manner and with such frequency as the Secretary deems necessary to identify human disease-causing pathogens or markers for these pathogens in the meat and meat food products; (2) require that the results of any test conducted in accordance with section 501(c)(1) be reported to the Secretary, in such manner and with such frequency as the Secretary deems necessary; (3) establish, to the maximum extent scientifically supportable, levels of human pathogens that, when found on meat or meat food products prepared in official establishments, constitute a threat to public health. When making decisions regarding specific human pathogen levels, the Secretary would be required to consider the risk to human health, including the risk to infants, the elderly, persons whose immune systems are compromised, and other population subgroups, posed by consumption of the meat or meat food products containing the human pathogen; and (4) prohibit or restrict the sale, transportation, offer for sale or transportation, or receipt for transportation of any meat or meat food products that: (A) are capable of use as human food, and (B) exceed the levels of human pathogens established in accordance with section 501(c)(3).

Section 501(d)(1) would require the Secretary, as the Secretary deems necessary and feasible, to conduct or support appropriate research regarding the establishment of levels of human pathogens that when found on meat and meat food products prepared in official establishments, constitute a threat to public health and to conduct studies to validate these levels.

Section 501(d)(2) would direct the Secretary to review, on a regular basis, all regulations, processes, procedures and methods designed to limit and control human pathogens on carcasses and parts of carcasses and on meat or meat food products. This ongoing review would include, as necessary, epidemiologic and other scientific studies to ascertain the efficiency and efficacy of such regulations, processes, procedures and methods.

Section 501(d)(3) would require the Secretary to consult with the Public Health Service, the Centers for Disease Control

and Prevention, the Food and Drug Administration, and any other State or Federal public agency the Secretary deems necessary in order to carry out sections 501(c)(1), (c)(3), (d)(1), and (d)(2).

Section 502, Notification, Distribution, and Recall Regarding Nonconforming Articles, would require persons preparing carcasses, parts of carcasses, meat or meat food products for distribution in commerce to notify the Secretary of the identity and location of adulterated and misbranded products. Further, section 502 would provide the Secretary with authority to issue orders to cease distribution of and orders to recall adulterated and misbranded products. Section 502 would provide a mechanism to prevent such articles from reaching consumers.

Section 502(a) would require any person, firm, or corporation that prepares carcasses or parts thereof, and meat or meat food products for distribution in commerce with knowledge providing a reasonable basis for believing that any such article is adulterated or not produced in compliance with section 501(a) or the regulations promulgated under section 501(a), or misbranded, immediately to notify the Secretary of the identity and location of such article. The immediate notification of the identity and location of articles believed to be adulterated or misbranded is necessary to provide the Secretary with the opportunity to limit the distribution of such articles, and possibly avoid consumers becoming ill. The Secretary intends to prescribe by regulation the means and manner that notification is to be provided.

Section 502(b) would provide that if the Secretary finds, through notification or otherwise, that any carcasses, parts of carcasses, meat, or meat food products are adulterated, were not produced in compliance with section 501(a) or the regulations promulgated under section 501(a) and that there is a reasonable probability that human consumption of such article presents a threat to public health, or are misbranded, the Secretary would provide persons, firms or corporations with an opportunity to voluntarily cease distribution of such articles; notify all persons, firms, or corporations transporting or distributing such articles or to which such articles were shipped or sold to immediately cease distribution of such articles; and to recall the articles. If the person, firm, or corporation refuses to voluntarily cease distribution, make notification, and recall the articles within the time or in the manner prescribed by the Secretary, the Secretary shall immediately issue an order requiring the appropriate person, firm, or corporation immediately to cease distribution of the article and to notify all persons, firms, or corporations transporting or distributing the article or to which the article was shipped or sold to immediately cease distribution. The order would provide for an opportunity for an informal hearing within 5 days of issuance of

the order to allow the affected person, firm, or corporation the opportunity to contest the order. Further, the informal hearing could concern whether the order should be amended to require recall of articles. The Secretary would prescribe by regulation the rules of practice that would govern these informal hearings. If, after opportunity for a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary would be required to vacate the order.

Under Section 502(c), the Secretary may determine, after opportunity for a hearing under section 502(b), that the order should be amended to require a recall of the product. Upon this determination, the Secretary shall amend the order to require a recall. The order would specify a timetable for the recall, require periodic reports describing the progress of the recall, and provide for notice to consumers, to whom the article was or may have been distributed, as to how they should treat the article. Such consumer information would detail how the article should be handled and prepared to reduce the risk to health.

Section 502 would enable the Secretary to better protect the public from receiving products that present a reasonable probability that human consumption of the product presents a threat to public health, or that are misbranded. Authorized representatives of the Secretary currently have authority to detain products for 20 days that are found outside an official establishment and not in compliance with the FMIA (see section 402 of the FMIA). Under present authority, FSIS must institute an action in the appropriate U.S. District Court in order to get a judicial seizure and condemnation order. The present authority is resource intensive and obtaining a court order often takes a long time. FSIS frequently relies on voluntary recalls by official establishments. This new authority to require recall of certain adulterated or nonconforming articles would allow FSIS to protect consumers faster and more completely. The Secretary would immediately be able to stop distribution of such articles and would be able to require the return of such articles to an official establishment where the Secretary would have both authority and control over the articles. Once the articles are returned to an official establishment, a determination will be made by the Secretary as to whether the articles can be reprocessed or labeled so as to make them not adulterated, or whether the articles should be destroyed for human food purposes.

Section 503, Livestock Traceback, would enable the Secretary to trace back livestock presented for slaughter to their previous premises.

Section 503(a) would direct the Secretary to require identification of livestock presented for slaughter for human food purposes in order to enable the Secretary to trace livestock back to the farm, feedlot or other premises where they were held

for such period prior to slaughter as the Secretary deems necessary to effectuate the purpose of the Act. The Secretary would have the authority to prohibit or restrict entry into any slaughtering establishment inspected under the FMIA of any livestock not identified in the manner prescribed by the Secretary.

Section 503(b) would authorize the Secretary to require all persons, firms, and corporations that are required to identify livestock under section 503(a) to maintain accurate records, as prescribed by the Secretary, regarding the purchase, sale, and identification of such livestock. The records are to be available for inspection and copying by an authorized representative of the Secretary at all reasonable times. By keeping a record of the premises where livestock has been held, a system of data will be created that would enable the Secretary to identify which premises produce animals that have a higher probability of carrying human pathogens or residues.

Section 503(c) would provide that no person, firm, or corporation shall falsify or misrepresent to any other person, firm, or corporation, or to the Secretary, any information as to any premises at which any cattle, sheep, swine, goats, horses, mules or other equines or, or carcasses thereof, were held.

Section 503(d) would provide that no person, firm, or corporation shall, without authorization from the Secretary, 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 carcasses thereof, were held.

Section 503(e)(1) would provide that if the Secretary finds any human pathogen or residue in any cattle, sheep, swine, goats, horses, mules, or other equines at the time they are presented for slaughter or in any carcasses, parts of carcasses, meat, or meat food product prepared in an official establishment and finds that there is a reasonable probability that human consumption of any meat or meat food product containing the human pathogen or residue presents a threat to public health, the Secretary may take such action as the Secretary deems necessary to determine the source of the human pathogen or residue. Section 503(e)(1) would authorize the Secretary to utilize any means, including the identification and record keeping system authorized under sections 503(a) and 503(b), to locate the source of the human pathogen or residue described in section 503(e)(1). The sources of these pathogens could include, but are not limited to, farms, feedlots, stockyards, conveyances on which and facilities through which animals are moved, premises from which feed, water, bedding, vaccines, or other articles used for the care or handling of animals are derived, and official establishments in which animals are slaughtered.

Section 503(e)(2) would authorize the Secretary to prohibit or restrict the movement of any animals, carcasses, parts of carcasses, meat, meat food product, or any other article from any source of human pathogens or residue described in section 503(e)(1) until the Secretary determines that the human pathogens or residues at the source no longer present a threat to public health. The broad authority provided in section 503(e)(2) is necessary to ensure that the Secretary can prevent the introduction of any human pathogen or residue that may present a threat to public health into the human food chain.

Section 503(f)(1) would require the Secretary to use any means of identification and record keeping methods utilized by producers or handlers of cattle, sheep, swine, goats, horses, mules, or other equines whenever the Secretary determines that such means of identification and record keeping methods will enable the Secretary to carry out the purposes of section 503.

Section 503(f)(2) would authorize the Secretary to cooperate with producers and handlers of livestock, in which any human pathogen or residue described in section 503(e)(1) is found, to develop and implement methods to limit or eliminate the human pathogen or residue at the source.

Section 504, Refusal or Withdrawal of Inspection, would provide the Secretary with additional grounds upon which to refuse or withdraw inspection service. Section 401 of the FMIA currently authorizes the Secretary, after opportunity for a hearing, to refuse to provide or to withdraw inspection service based upon a determination that the applicant or recipient of service is unfit to engage in any business requiring inspection under the FMIA because the applicant or recipient (or anyone responsibly connected with the applicant or recipient) has been convicted in Federal or State court of certain violations of law.

Section 504(a) would provide that the Secretary may refuse to provide or withdraw inspection service from an applicant or recipient when it has been determined, after an opportunity for hearing, that the applicant or recipient (or any person responsibly connected with the applicant or recipient) has repeatedly violated any provision of the Act or the regulations promulgated under the Act. This provision does not require a determination of unfitness, nor is a prior criminal conviction required.

Section 504(b) would authorize the Secretary, if such action is deemed necessary in the public interest in order to protect the health or welfare of consumers or to assure the safe and effective performance of official duties under the Act, to deny or suspend inspection service pending an opportunity for an expedited hearing with respect to refusal or withdrawal of inspection service under section 504(a) and the final

determination and order and any judicial review thereof. The Secretary would have the authority to take immediate action against a violator if such action is deemed necessary to protect the health or welfare of consumers or to assure the safe and effective performance of official duties under the Act. This authority to take immediate action is very important when there is the possibility of substantial and imminent health risk from articles that may contain harmful pathogens or risk the safety of FSIS personnel.

Section 504(c) would provide that when the Secretary, after opportunity for a hearing, orders that inspection service be withdrawn or refused, such action will be taken as of the effective date of the Secretary's order, pending any judicial review of the Secretary's order, unless the Secretary directs otherwise. The risk to public health of the continued production or distribution of articles adulterated with human pathogens would be a circumstance in which the Secretary would not stay the order of refusal or withdrawal of inspection services pending judicial review. The application for judicial review of the Secretary's order must be made within thirty days after the effective date of the Secretary's order. Section 504(c) also provides for judicial review of the orders of withdrawal or refusal of inspection in the United States Court of Appeals for the circuit in which the applicant or recipient of inspection service has its principal place of business or the U.S. Court of Appeals for the District of Columbia. The provisions of section 204 of the Packers and Stockyards Act would be applicable to appeals taken under section 504(c).

Section 504(d) would provide that the authority granted by section 504(d) is in addition to the authority in other provisions of the Act to refuse, withdraw, or suspend inspection service under Title I of the Act.

Section 505, Civil Penalties, would authorize the Secretary to assess civil monetary penalties for violations of any provision of the Act, the regulations promulgated under the Act, and any order issued under sections 502(b) or 502(c) of the Act.

Section 505(a) would authorize the Secretary to impose civil penalties of not more than \$100,000 per day of violation against any person, firm or corporation which violates any provision of the Act, the regulations under the Act, or any order issued under sections 502(b) or 502(c) of the Act. These penalties would be assessed after the person, firm, or corporation has received notice and an opportunity for a hearing on the record in accordance with 5 U.S.C. 554 and 556. The sanction would be based upon the gravity of the violation, degree of culpability, and history of prior offenses. Criminal sanctions are vital in assuring the enforcement of the FMIA, but are not enough.

Criminal prosecution is a lengthy and cumbersome process in an already overburdened judicial system. Civil penalties, on the other hand, can be imposed administratively, insuring that the violator will be dealt with in a more timely and effective manner. Moreover, a monetary penalty is more tangible to most than a distant and lengthy legal process that may or may not be instituted and may or may not lead to a conviction. The proposed civil penalty amount is reasonable and will deter potential violators. Civil penalties would therefore be an effective enforcement tool.

Section 505(b) would provide that orders of the Secretary assessing a civil penalty may be reviewed in the U.S. Court of Appeals for the circuit in which the party resides or has a place of business or the U.S. Court of Appeals for the District of Columbia by filing a notice of appeal within 30 days from the date of such order and by simultaneously sending a copy of such notice by certified mail to the Secretary. The standard of review of the Secretary's order would be the substantial evidence test.

Section 505(c) would provide that failure to pay the civil penalty after the order assessing the penalty has become final and unappealable or after the appropriate Court of Appeals has entered final judgement in favor of the Secretary shall result in the Secretary referring the matter to the Attorney General who shall institute a civil action to recover the assessed penalty. The validity of the Secretary's order would not be reviewable in such a collection action.

Section 505(d) would require that the civil penalties assessed pursuant to section 505 shall be paid into the U.S. Treasury.

Section 505(e) would provide that nothing in the Act shall require the Secretary to report for criminal prosecution or for the institution of libel or injunction proceedings, violations of the Act, when the Secretary believes that the public interest will be adequately served by the assessment of civil penalties. The Secretary may, in the Secretary's sole discretion, compromise, modify, or remit, with or without conditions, any civil penalty assessed under section 505.

Section 103. Amendments to the Poultry Products Inspection Act. Paragraph (1) of section 103 would amend section 5(c)(1) of the Poultry Products Inspection Act (PPIA) by substituting "12-22, and 30-34 of this Act" for the reference to sections 12-22. Section 5(c) of the PPIA requires that the Secretary designate any State whose poultry products inspection requirements with respect to transactions wholly within such State are not at least equal to those of sections 1-4, 6-10, and 12-22 of the PPIA. Upon such designation, sections 1-4, 6-10, and 12-22 would apply

to such intrastate transactions and no poultry or poultry products could be sold unless inspected for wholesomeness and passed by inspectors of the Food Safety and Inspection Service (FSIS).

Paragraph (2) of section 103 of the bill would require that State poultry inspection requirements must, in addition, be at least equal to requirements under sections 30 through 34 which paragraph (1) of section 103 of the bill would add to the PPIA. The states were accorded a grace period of two years (plus one additional year, in the Secretary's discretion) to make their poultry and poultry products inspection requirements at least equal to those of the PPIA. By amending section 5(c)(1) of the PPIA to include proposed sections 30 through 34, the States will have two years (with the possibility of one additional year) to institute requirements at least equal to those in proposed sections 30-34.

Paragraphs (3) and (4) of section 103 of the bill would amend section 6 of the PPIA to explicitly provide that the Secretary is to ensure that ante mortem and post mortem inspection are to be made on the basis of the best available scientific and technologic data, and evaluation of the risks posed to public health and safety.

Section 103(5) of the bill would add at the end of the PPIA new sections 30 through 34, entitled "Pathogen Reduction".

Poultry and poultry products may be contaminated by harmful levels of human pathogens in the distribution process; and everyone in the chain of distribution -- producers, handlers, processors, distributors, transporters, and retailers -- must share in the effort to prevent foodborne illness. Pathogens that get into the food supply and cause illness may be reduced if care in handling is exercised at critical points. The incidence of harmful levels of human pathogens may be reduced by changing animal husbandry practices, by implementing certain sanitation interventions in the slaughtering and processing plants, by temperature control, or by handling and cooking in accordance with the labeling instructions.

Section 30(a) would direct the Secretary to prescribe by regulation such action as the Secretary deems necessary, based on the best available scientific and technologic data, to limit the presence of human pathogens in poultry at the time they are presented for slaughter; to ensure that appropriate measures are taken to control the presence and growth of human pathogens on poultry and poultry products prepared in any establishment; to ensure that ready-to-eat poultry and poultry products prepared in any official establishment for distribution in commerce are processed in such a manner to destroy any human pathogens which are likely to cause foodborne illness; and to ensure that poultry

carcasses or parts thereof other than ready-to-eat articles prepared in any official establishment for distribution in commerce are labeled with handling and preparation instructions for consumption which, when followed, will destroy any human pathogens likely to cause foodborne illness.

Section 30(a)(1) would direct the Secretary to promulgate regulations to limit the presence of human pathogens in poultry at the time they are presented for slaughter. Scientific and technologic data on human pathogens is being developed on an on-going basis. If this data indicates that a method or procedure is effective in limiting human pathogens in poultry at the time they are presented for slaughter, the Secretary would issue regulations to require the use of such method or procedure.

Section 30(a)(2) would clarify the authority of the Secretary to ensure that appropriate measures are taken to control the presence and growth of human pathogens on poultry and poultry products prepared in any official establishment. All live animals contain pathogens. The Secretary has permitted the use of Trisodium Phosphate (TSP) and irradiation in poultry processing to control the presence and growth of pathogens. As scientific research provides new information, the Secretary may mandate the use of these or other processes to ensure the control of human pathogens on poultry and poultry products.

Section 30(a)(3) would require the Secretary, as deemed necessary, to issue regulations to require ready-to-eat poultry products to be produced in such a manner that any human pathogens likely to cause foodborne illness are destroyed. Processed, ready-to-eat poultry products shall not contain human pathogens likely to cause foodborne illness.

Section 30(a)(4) would require the Secretary, as deemed necessary, to issue regulations to require poultry and poultry products other than ready-to-eat poultry and poultry products be labeled with instructions for safe handling and preparation, which, when followed, will destroy any human pathogens likely to cause foodborne illness.

Section 30(b) would provide that poultry or poultry products which are found not to be in compliance with regulations promulgated under section 30(a)(2), (a)(3), or (a)(4) shall be considered adulterated and condemned. For example, poultry and poultry products found either not processed sufficiently to destroy harmful pathogens or poultry carcasses or parts thereof not labeled with instructions for handling and preparation would be considered adulterated and condemned. However, the official establishment would be given the opportunity to reprocess, label, or reprocess and label, the article so as to be made not adulterated and thereby avoid unnecessary loss of product. Section 30(b) also provides for an appeal from the determination

of condemnation. In the event that an appeal is taken, section 30(b) would require that the product be appropriately marked, segregated, and held by the establishment pending the completion of the appeal. If no appeal is taken or the determination of condemnation is sustained, the product can be reprocessed or labeled or both, as applicable and as determined by the Secretary. If the product is not reprocessed or relabeled, or both, as applicable, the product will be destroyed for human food purposes under the supervision of a duly authorized representative of the Secretary.

Section 30(c) would require the Secretary, within two years of the enactment of the Act, to issue regulations that: (1) require poultry and poultry products prepared in any official establishment to be tested, in such manner and with such frequency as the Secretary deems necessary, to identify human disease-causing pathogens or markers for these pathogens in the poultry and poultry products; (2) require that the results of any test conducted in accordance with section 30(c)(1) be reported to the Secretary, in such manner and with such frequency as the Secretary deems necessary; (3) establish, to the maximum extent scientifically supportable, levels of human pathogens that, when found on poultry or poultry products prepared in any official establishment, constitute a threat to public health. When making decisions regarding specific human pathogen levels, the Secretary would be required to consider the risk to human health, including the risk to infants, the elderly, persons whose immune systems are compromised, and other population subgroups, posed by consumption of the poultry and poultry products containing the pathogen; and (4) prohibit or restrict the sale, transportation, offer for sale or transportation, or receipt for transportation of any poultry and poultry products that: (A) are capable of use as human food, and (B) exceed the levels of human pathogens established in accordance with section 30(c)(3).

Section 30(d)(1) would require the Secretary, as the Secretary deems necessary and feasible, to conduct or support appropriate research regarding the establishment of levels of human pathogens that when found on poultry and poultry products prepared in official establishments, constitute a threat to public health and to conduct studies to validate these levels.

Section 30(d)(2) would direct the Secretary to review, on a regular basis, all regulations, processes, procedures and methods designed to limit and control human pathogens on poultry or poultry products. This on-going review shall include, as necessary, epidemiologic and other scientific studies to ascertain the efficiency and efficacy of such regulations, processes, procedures and methods.

Section 30(d)(3) would direct the Secretary to consult with the Public Health Service, the Centers for Disease Control and

Prevention, the Food and Drug Administration, and any other State or Federal public health agency the Secretary deems necessary in order to carry out sections 30(c)(1), (c)(3), (d)(1), and (d)(2).

Section 31, Notification, Distribution, and Recall Regarding Nonconforming Articles, would require persons preparing poultry or poultry products for distribution in commerce to notify the Secretary of the identity and location of adulterated and misbranded products. Further, section 31 would provide the Secretary with authority to issue orders to cease distribution of and orders to recall adulterated and misbranded products. Section 31 would provide a mechanism to prevent such articles from reaching consumers.

Section 31(a) would require any person that prepares poultry or poultry products for distribution in commerce with knowledge providing a reasonable basis for believing that any such article is adulterated or not produced in compliance with section 30(a) or the regulations promulgated under section 30(a), or misbranded, immediately to notify the Secretary of the identity and location of such article. The immediate notification of the identity and location of articles believed to be adulterated or misbranded is necessary to provide the Secretary with the opportunity to limit the distribution of such articles, and possibly avoid consumers becoming ill. The Secretary intends to prescribe by regulation the means and manner that notification is to be provided.

Section 31(b) would provide that if the Secretary finds, through notification or otherwise, that any poultry or poultry product is adulterated or not produced in compliance with section 30(a) or the regulations promulgated under section 30(a) and that there is a reasonable probability that human consumption of such article presents a threat to public health, or is misbranded, the Secretary would provide the appropriate person with an opportunity to voluntarily cease distribution of such articles; notify all persons, firms, or corporations transporting or distributing such articles or to which such articles were shipped or sold to immediately cease distribution of such articles; and recall the articles. If the person, firm, or corporation refuses to voluntarily cease distribution, make notification, and recall the articles within the time or in the manner prescribed by the Secretary, the Secretary shall immediately issue an order requiring the appropriate person immediately to cease distribution of the article and to notify all persons, firms, or corporations transporting or distributing the article or to which the article was shipped or sold to immediately cease distribution. The order would provide for an opportunity for an informal hearing within 5 days of issuance of the order to allow the affected person, firm, or corporation the opportunity to contest the order. Further, the informal hearing could concern whether the order should be amended to require recall of articles. The Secretary would prescribe by regulation the rules

of practice that would govern these informal hearings. If, after opportunity for a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary would be required to vacate the order.

Under Section 31(c), the Secretary may determine, after opportunity for a hearing under section 31(b), that the order should be amended to require a recall of the product. Upon this determination, the Secretary shall amend the order to require a recall. The order would specify a timetable for the recall, require periodic reports describing the progress of the recall, and provide for notice to consumers, to whom the article was or may have been distributed, as to how they should treat the article. Such consumer information would detail how the article should be handled and prepared to reduce the risk to health.

Section 31 would enable the Secretary to better protect the public from receiving products that would present a reasonable probability that human consumption of the products presents a threat to public health or that are misbranded. Authorized representatives of the Secretary currently have authority to detain products for 20 days that are found outside an official establishment and not in compliance with the FPIA (see section 19 of the PPIA). Under present authority, FSIS must institute an action in the appropriate U.S. District Court in order to get a judicial seizure and condemnation order. The present authority is resource intensive and obtaining a court order often takes a long time. FSIS frequently relies on voluntary recalls by official establishments. This new authority to require recall of certain adulterated or nonconforming articles would allow FSIS to protect consumers faster and more completely. The Secretary would immediately be able to stop distribution of such articles and would be able to require the return of such articles to an official establishment where the Secretary would have both authority and control over the articles. Once the articles are returned to an official establishment, a determination will be made by the Secretary as to whether the articles can be reprocessed or labeled so as to make them not adulterated, or whether the articles should be destroyed for human food purposes.

Section 32, Poultry Traceback, would enable the Secretary to trace back poultry presented for slaughter to their previous premises.

Section 32(a) would direct the Secretary to require identification of poultry presented for slaughter for human food purposes in order to enable the Secretary to trace poultry back to the farm or other premises where they were held for such period prior to slaughter as the Secretary deems necessary to effectuate the purpose of the Act. The Secretary would have the authority to prohibit or restrict the entry into any slaughtering

establishment inspected under the Act of any poultry not identified in the manner prescribed by the Secretary.

Section 32(b) would authorize the Secretary to require all persons that are required to identify poultry under section 32(a) to maintain accurate records as prescribed by the Secretary regarding the purchase, sale, and identification and copying of such poultry. The records are to be available for inspection by an authorized representative of the Secretary at all reasonable times. By keeping a record of the premises where poultry has been held, a system of data will be created that would enable the Secretary to identify which premises produce poultry that have a higher probability of carrying human pathogens or residues.

Section 32(c) would provide that no person shall falsify or misrepresent to any other person or to the Secretary, any information as to any premises at which any poultry or poultry carcasses, were held.

Section 32(d) would provide that no person shall, without authorization from the Secretary, alter, detach, or destroy any records or other means of identification prescribed by the Secretary for use in determining the premises at which any poultry or poultry carcasses were held.

Section 32(e) (1) would provide that if the Secretary finds any human pathogen or residue in any poultry at the time they are presented for slaughter or in any poultry carcasses, parts of poultry carcasses, or poultry products prepared in an official establishment and the Secretary finds that there is a reasonable probability that human consumption of any poultry or poultry product containing the pathogen or residue presents a threat to public health, the Secretary may take such action as the Secretary deems necessary to determine the source of the human pathogen. Section 32(e) (1) would authorize the Secretary to utilize any means, including the identification and record keeping system authorized under sections 32(a) and 32(b), to locate the source of human pathogens or residues described in section 32(e) (1). The sources of these human pathogens or residues could include, but are not limited to, farms, conveyances on which and facilities through which poultry are moved, premises from which feed, water, bedding, vaccines, or other articles used for the care or handling of poultry are derived, and official establishments in which poultry are slaughtered.

Section 32(e) (2) would authorize the Secretary to prohibit or restrict the movement of any poultry, poultry carcasses, parts of poultry carcasses, poultry product or any other article from any source of human pathogens or residues described in section 32(e) (1) until the Secretary determines that the human pathogens or residues at the source no longer present a threat to public

health. The broad authority provided in section 32(e)(2) is necessary to ensure that the Secretary can prevent the introduction of any human pathogen or residue that may present a threat to public health into the human food chain.

Section 32(f)(1) would require the Secretary to use any means of identification and record keeping methods utilized by producers or handlers of poultry whenever such means of identification and record keeping methods will enable the Secretary to carry out the purposes of section 32.

Section 32(f)(2) would authorize the Secretary to cooperate with producers and handlers of poultry, in which any human pathogen or residue described in section 32(e)(1) is found, to develop and implement methods to limit or eliminate the human pathogen or residue at the source.

Section 33, Refusal or Withdrawal of Inspection, would provide the Secretary with additional grounds upon which to refuse or withdraw inspection service. Section 18 of the PPIA currently authorizes the Secretary, after opportunity for a hearing, to refuse to provide or to withdraw inspection service based upon a determination that the applicant or recipient of service is unfit to engage in any business requiring inspection under the PPIA because the applicant or recipient (or anyone responsibly connected with the applicant or recipient) has been convicted in a Federal or State court of certain violations of law.

Section 33(a) would provide that the Secretary may refuse to provide or withdraw inspection service from an applicant or recipient when it has been determined, after an opportunity for hearing, that the applicant or recipient (or any person responsibly connected with the applicant or recipient) has repeatedly violated the Act or the regulations promulgated under the Act. This provision does not require a determination of unfitness, nor is a prior criminal conviction required.

Section 33(b) would authorize the Secretary, if such action is deemed necessary in the public interest in order to protect the health or welfare of consumers, to deny or suspend inspection service pending an opportunity for an expedited hearing with respect to the refusal or withdrawal of inspection service under section 33(a) and the final determination and order and any judicial review thereof. The Secretary would have the authority to take immediate action against a violator if such action is deemed necessary to protect the health or welfare of consumers. This authority to take immediate action is very important when there is the possibility of substantial and imminent health risk from articles that may contain harmful pathogens.

Section 33(c) would provide that when the Secretary, after opportunity for a hearing, orders that inspection service be withdrawn or refused, such action will be taken as of the effective date of the Secretary's order, pending any judicial review of the Secretary's order unless the Secretary directs otherwise. The risk to public health of the continued production or distribution of articles adulterated with human pathogens would be a circumstance in which the Secretary may not stay the order of refusal or withdrawal of inspection services pending judicial review. The application for judicial review of the Secretary's order must be made within thirty days after the effective date of the Secretary's order. Section 33(c) also provides for judicial review of the orders of withdrawal or refusal of inspection in the United States Courts of Appeals for the circuit in which the applicant or recipient of inspection service has its principal place of business or the U.S. Court of Appeals for the District of Columbia. The provisions of section 204 of the Packers and Stockyards Act shall be applicable to appeals taken under section 33(c).

Section 33(d) would provide that the authority granted by section 33 is in addition to the authority in other provisions of the Act to refuse, withdraw, or suspend inspection service under the Act.

Section 34, Civil Penalties, would authorize the Secretary to assess civil monetary penalties for violations of any provision of the Act, the regulations promulgated under the Act, and any order issued under sections 31(b) or 31(c) of the Act.

Section 34(a) would authorize the Secretary to impose civil penalties of not more than \$100,000 per violation against any person, firm, or corporation which violates any provision of the Act, regulations under the Act, or any order issued under sections 31(b) or 31(c) of the Act. These penalties shall be assessed after the person, firm, or corporation has received notice and an opportunity for a hearing on the record in accordance with 5 U.S.C. 554 and 556. The sanction would be based upon the gravity of the violation, degree of culpability, and history of prior offenses. Criminal sanctions are vital in assuring the enforcement of the PPIA, but are not enough. Criminal prosecution is a lengthy and cumbersome process in an already overburdened judicial system. Civil penalties, on the other hand, can be imposed administratively, insuring that the violator will be dealt with in a more timely and effective manner. Moreover, a monetary penalty is more tangible to most than a distant and lengthy legal process that may or may not be instituted and may or may not lead to a conviction. The proposed civil penalty amount is reasonable and will deter potential violators. Civil penalties could therefore be an effective enforcement tool.

Section 34(b) would provide that orders of the Secretary assessing a civil penalty may be reviewed in the U.S. Court of Appeals for the circuit in which the party resides or has a place of business or the U.S. Court of Appeals for the District of Columbia by filing a notice of appeal within 30 days from the date of such order and by simultaneously sending a copy of such notice by certified mail to the Secretary. The standard of review of the Secretary's order shall be the substantial evidence test.

Section 34(c) would provide that failure to pay the civil penalty after the order assessing the penalty has become final and unappealable, or after the appropriate Court of Appeals has entered final judgment, shall result in the Secretary referring the matter to the Attorney General who shall institute a civil action to recover the assessed penalty. The validity and appropriateness of the Secretary's order shall not be reviewable in such a collection action.

Section 34(d) would require that the civil penalties assessed pursuant to section 34 shall be paid into the U.S. Treasury.

Section 34(e) would provide that nothing in the Act shall require the Secretary to report for criminal prosecution or for the institution of libel or injunction proceedings, violations of the Act, when the Secretary believes that the public interest will be adequately served by the assessment of civil penalties. The Secretary may, in the Secretary's discretion, compromise, modify or remit, with or without conditions, any civil penalty assessed under section 34.

Title II

Section 201 of the bill would amend section 1 of the Act of July 2, 1962 (21 U.S.C. 134; hereinafter referred to as the "1962 Act") by adding to that section a new definition of the word "disease." "Disease" would mean "any disease of livestock or poultry, both infectious and non-infectious, and any other health-related condition that may be transmitted by livestock or poultry or their products to other animals or humans." The 1962 Act presently contains no separate definition of the word "disease" and confers upon the Secretary of Agriculture authority to take regulatory action only against "communicable diseases of livestock and poultry" or "communicable animal diseases" (i.e. only those diseases that are communicable among animals). The new definition of the term "disease", in conjunction with conforming amendments elsewhere in the bill to sections 2(a), 2(e), 3, 4, and 5 of the 1962 Act, would empower the Secretary to take the regulatory measures authorized by those sections to combat pathogens, residues, and all other diseases and health-related conditions that may be transmitted by livestock or

poultry or their products to other animals or humans. Thus, the Secretary would be authorized to utilize the 1962 Act to combat any health-related condition which threatens the health of the people of the United States because the condition may be transmitted to people by livestock or poultry or their products, even though such pathogens, residues, diseases, or conditions might not affect the health of livestock or poultry.

Section 202 of the bill would amend section 2(a) of the 1962 Act (21 U.S.C. 134a(a)), which presently authorizes the Secretary of Agriculture, when necessary, to seize, quarantine, and dispose of animals moving in interstate or foreign commerce contrary to any law administered by the Secretary or animals which are affected with or exposed to a communicable disease dangerous to livestock or poultry. The amendment would empower the Secretary to take these measures, when necessary, to combat any "disease", as that term would be newly-defined in section 1 of the 1962 Act, and would specifically authorize the Secretary to employ such measures when necessary to protect the health of the people of the United States. Finally, the amendment would render all references to the Secretary gender-neutral.

Section 203 of the bill would amend section 2(e) of the 1962 Act (21 U.S.C. 134a(e)), which presently prohibits indemnification of an owner for animals disposed of by the Secretary if the owner "knowingly" handled the animals in violation of a law or regulation administered by the Secretary to protect against communicable diseases of livestock or poultry. The amendment would replace references to "communicable disease" and "communicable diseases of livestock or poultry" with the term "disease" to conform with the new definition of that term in section 1 of the 1962 Act. More importantly, the amendment would also delete the requirement that, in order to be denied indemnification, the owner's violation must have been "knowing". Deletion of this requirement significantly lessens the Secretary's burden of proof and, therefore, the Secretary's exposure to liability for payment of indemnities. Finally, this amendment would render the reference to the owner's agent gender-neutral.

Section 204 of the bill would amend section 3 of the 1962 Act (21 U.S.C. 134b), which presently authorizes the Secretary of Agriculture, in order to protect the health of the livestock or poultry of the Nation, to issue regulations requiring that facilities and means of conveyance used in moving animals to or from the United States or interstate be maintained in a clean and sanitary condition. The amendment would specifically empower the Secretary to utilize this authority to protect, as well, the health of the people of the United States.

Section 205 of the bill would amend section 4 of the 1962 Act

(21 U.S.C. 134c), which presently authorizes the Secretary, when necessary to protect the livestock or poultry of the United States, to regulate movement into the United States of animals affected with, exposed to, or vaccinated or treated for any communicable animal disease. The amendment would specifically authorize the Secretary to employ the same measures to protect the health of the people of the United States when the disease may be transmitted by livestock or poultry or their products. The amendment would also render all references to the Secretary gender-neutral.

Section 206 of the bill would amend section 5 of the 1962 Act (21 U.S.C. 134d), which presently authorizes employees of the Department of Agriculture designated by the Secretary to stop and search any means of conveyance moving into the United States or interstate and to search any premises in the United States for any animal, carcass, product, or article regulated or subject to disposal under any law or regulation administered by the Secretary for the prevention of the introduction or dissemination of any communicable animal disease. The amendment would replace references to "communicable animal disease" with the term "disease" as newly-defined in the amendment to section 1 of the 1962 Act, thus empowering the Secretary to utilize the Secretary's authority under this section of the Act to combat any disease of livestock or poultry and any health-related condition that may be transmitted by livestock or poultry or their products to other animals or humans. The amendment would also render reference to the United States Commissioner gender neutral.

Section 207 of the bill would amend section 6 of the Act of August 30, 1890 (21 U.S.C. 104; hereinafter the "1890 Act") which (with limited exceptions) presently prohibits importation into the United States of cattle, sheep and other ruminants, and swine infected with, or exposed within 60 days prior to export from country of origin to, any disease. Section 6 further provides that any person who "knowingly" violates this prohibition, or sections 7, 8, 9 or 10 of the 1890 Act, or the regulations of the Secretary thereunder, is subject to prosecution for a misdemeanor punishable by a fine not exceeding \$5,000 or imprisonment for not more than one year, or both. In addition, the Secretary may assess against any such violator (whether "knowing" or not) a civil penalty of not to exceed \$1,000. The amendment would add to section 6 of the 1890 Act a definition of the word "disease" for purposes of the 1890 Act which is identical to the definition of that term added to the 1962 Act, viz: "any disease of livestock or poultry, both infectious and non-infectious, and any other health-related condition that may be transmitted by livestock or poultry to other animals or humans." The amendment also would delete the prohibition upon importation of diseased and exposed animals and instead entrust to the Secretary discretion to prohibit or restrict importation of animals which are affected with, or exposed prior to importation to, disease.

Section 208 would amend section 8 of the 1890 Act (21 U.S.C. 103) which prohibits importation of animals into the United States except at ports designated for the purpose by the Secretary of Agriculture with the approval of the Secretary of the Treasury. Section 8 authorizes the Secretary of Agriculture to slaughter animals found to be infected with any contagious disease or so exposed to infection as to be dangerous to other animals. Finally, section 8 authorizes the Secretary to pay indemnities to the owners of non-infected animals slaughtered because exposed to infection. The amendment would delete the outright prohibition upon importation of animals except at designated ports and instead provide the Secretary with discretion to require their importation at ports designated as quarantine stations. The Secretary's power to destroy animals would be extended to include specifically animals affected with or exposed to any disease "dangerous to other animals, or to the health of the people of the United States because the disease may be transmitted by livestock or poultry or their products". Due to the new definition of the term "disease" added by section 207 of the bill to section 6 of the 1890 Act, the Secretary's power to destroy animals would also be extended to include those affected with or exposed to pathogens, residues, or other health-related conditions so long as such pathogens, residues, or other health-related conditions are similarly dangerous. While the broadening of the definition of the term "disease" would enlarge the categories of animals subject to destruction, indemnities would continue to be paid only for animals destroyed because they are "exposed to" and not for those "affected with" disease. Further, the method by which the value of animals destroyed is determined would be amended so that it is consistent with the evaluation method in section 2(e) of the 1962 Act.

Section 209 of the bill would amend section 1 of the Act of February 2, 1903 (21 U.S.C. 121; hereinafter the "1903 Act") which preempts state animal quarantine laws by providing that any cattle, other livestock, or live poultry certified by an inspector of the Bureau of Animal Industry (BAI) as free from infectious, contagious, or communicable disease (including some specifically named) shall be considered under BAI control and may be transported interstate or exported without further inspection or fee apart from those required by the Secretary of Agriculture. The amendment would delete references to inspectors of the Bureau of Animal Industry and to infectious, contagious, or communicable diseases and instead confer the power to inspect upon the Secretary of Agriculture and add to section 1 of the 1903 Act a new definition of "disease" for purposes of that Act which is identical to the definition of that term which the bill would add to the 1962 and 1890 Acts, viz: "any disease of livestock or poultry, both infectious and non-infectious, and any other health-related condition that may be transmitted by livestock or poultry or their products to other animals or humans". Expansion of the definition of "disease" thus would further preempt

possible state measures by empowering the Secretary to certify cattle or other livestock and/or live poultry as free from specific pathogens or residues and other diseases or health-related conditions that may be transmitted by livestock or poultry or their products to other animals or humans.

Section 210 of the bill would amend section 2 of the 1903 Act (21 U.S.C. 111) which authorizes the Secretary of Agriculture to make such regulations and take such measures as he may deem proper to prevent the introduction or dissemination of the contagion of any contagious, infectious, or communicable disease of animals and/or live poultry from a foreign country into the United States or from one state or territory or the District of Columbia to another. Such measures specifically include seizure, quarantine, and disposal of any hay, straw, forage, or similar material, or any meats, hides, or other animals products coming from a foreign country in which disease exists to the United States or coming from a state or territory or the District of Columbia in which disease exists whenever, in the Secretary of Agriculture's judgment, such action is advisable to prevent the introduction or spread of disease. The amendment would delete references to "contagious, infectious, or communicable disease of animals and/or live poultry" and authorize the Secretary to employ the same regulations and measures with respect to "disease" (as that term would be newly-defined in section 1), thus extending the Secretary's authority to protect against importation or interstate dissemination of pathogens, residues, and any other disease or health-related condition that may be transmitted by livestock or poultry or their products to other animals or humans. The amendment would also make all references to the Secretary gender neutral.

Section 211 of the bill would amend section 3 of the Act of May 29, 1884 (21 U.S.C. 114; hereinafter the "1884 Act") which makes it the duty of the Secretary of Agriculture to prepare and certify to the states and territories rules and regulations for the speedy and effectual suppression and extirpation of pleuropneumonia and other dangerous, contagious, infectious, and communicable diseases and authorizes the Secretary to cooperate in combatting such diseases with any state where such diseases are declared to exist which accepts the Secretary's rules and regulations or devises alternative plans or methods acceptable to the Secretary. The amendment would delete references to "pleuropneumonia and other dangerous, contagious, infectious, and communicable diseases" and replace them with the term "disease", which would be defined for purposes of the 1884 Act (as for the 1962, 1890, and 1903 Acts) as "any disease of livestock or poultry, both infectious and non-infectious, and any other health-related condition that may be transmitted by livestock or poultry or their products to other animals or humans." Thus the Secretary would be able to cooperate with the states in combatting pathogens, residues, and any disease or any health-

related condition that may be transmitted by livestock or poultry or their products to other animals or humans. The amendment also would specifically authorize the Secretary to cooperate with the states in the enforcement of the 1903 Act.

Section 212 of the bill would amend section 4 of the 1884 Act (21 U.S.C. 112) which requires the Secretary of Agriculture to investigate as to the existence of pleuropneumonia or any contagious, infectious, or communicable disease along United States borders and along routes to export ports and establish such regulations concerning the exportation and transportation of livestock and/or live poultry as the results of the investigations may require. The amendment would make the Secretary's authority to conduct such investigations discretionary and change the target of such investigations to any "disease" as that term would be newly-defined in section 3 of the 1884 Act.

Section 213 of the bill would amend section 5 of the 1884 Act (21 U.S.C. 113) which authorizes the Secretary of Agriculture to take such measures as he may deem necessary to prevent exportation from any port in the United States to any port in a foreign country of livestock and/or live poultry affected with any contagious, infectious, or communicable disease, and especially pleuropneumonia. The amendment would delete reference to "contagious, infectious, or communicable disease, and especially pleuropneumonia" and authorize the Secretary to take the same measures to prevent export to any foreign country of any livestock and/or live poultry affected with or exposed to any disease, as that term would be newly-defined in section 3 of the 1884 Act. The amendment would also render references to the Secretary gender neutral.

Section 214 of the bill would amend sections 4 and 5 of the 1884 Act (21 U.S.C. 120) which authorize and direct the Secretary from time to time to establish such rules and regulations concerning the interstate transportation and exportation of livestock and/or live poultry from any place within the United States in which the Secretary may have reason to believe that contagious pleuropneumonia, foot-and-mouth disease, and other dangerous contagious, infectious, and communicable diseases of cattle and other livestock and/or live poultry exist in order to effectually suppress and extirpate and prevent the spread of such diseases. The amendment would delete reference to such diseases and replace them with the term "disease" as that term would be newly-defined in section 3 of the 1884 Act, thus broadening the Secretary's authority to combat pathogens, residues, and any disease or health-related condition that may be transmitted by livestock or poultry or their products to other animals or humans. The amendment would also render references to the Secretary gender neutral.

Section 215 of the bill would amend section 6 of the 1884 Act (21 U.S.C. 115) which, except in circumstances the Secretary determines such action will not endanger the livestock or poultry of the United States, prohibits any person from transporting interstate or delivering for interstate transportation, and any railroad company or master or owner of any steam or sailing vessel from receiving for interstate transportation, any livestock and/or live poultry affected with any contagious, infectious, or communicable disease, and especially the disease known as pleuropneumonia. The amendment would delete references to such diseases and replace them with "disease" as that term would be newly-defined in section 3 of the 1884 Act. The amendment would also specifically provide that the statute be employed to protect the health of the people of the United States as well as livestock and poultry. Finally, the amendment would delete reference to "railroad company" and owners or masters of any steam or sailing or other vessel or boat" and address the statute's prescriptions to any person, company, or corporation.

Section 216 of the bill would amend section 11 of the 1884 Act (21 U.S.C. 114a) which authorizes the Secretary, either independently or in cooperation with states or political subdivisions thereof (including the District of Columbia, Puerto Rico, and the territories and possessions of the United States), farmers' associations and similar organizations, and individuals, to control and eradicate any communicable diseases of livestock or poultry (including several specifically named), incipient or potentially serious minor outbreaks of diseases of animals, and contagious or infectious diseases of animals (such as foot-and-mouth disease, rinderpest, and contagious pleuropneumonia) which in the opinion of the Secretary constitute an emergency and threaten the livestock industry of the country. The Secretary is also authorized, in accordance with such regulations as the Secretary may prescribe, to pay claims growing out of destruction of animals (including poultry), and of materials affected by or exposed to any such disease.

The amendment would delete reference to specific animal diseases and instead authorize the Secretary to control and eradicate any diseases (as newly-defined in section 3 of the 1884 Act) which, in the opinion of the Secretary, constitute an emergency and threaten the livestock industry or the poultry industry of the United States, or the health of the people of the United States because the disease may be transmitted by livestock or poultry or their products to other animals or humans, including the payment of claims attributable to destruction of animals or poultry or materials affected by or exposed to any communicable disease. The amendment would also add the Commonwealth of the Northern Mariana Islands to the definition of "state".

Section 217 of the bill would amend section 1 of the Act of March 3, 1905 (21 U.S.C. 123; hereinafter the "1905 Act") which

authorizes the Secretary to quarantine by regulation all or any portion of any state, territory, or the District of Columbia when he determines that any animals or live poultry in such state, territory, or the District of Columbia are affected with any contagious, infectious, or communicable disease of livestock or poultry or that the contagion of the disease or vectors which may disseminate it exist there. The amendment would delete reference to "contagious, infectious, or communicable disease of livestock or poultry" and replace it with a reference to "disease", which the amendment would define "disease" for purposes of the 1905 Act (as for the 1962, 1890, 1903, and 1884 Acts) as "any disease of livestock or poultry, both infectious and non-infectious, and any other health-related condition that may be transmitted by livestock or poultry or their products to other animals or humans." The amendment would thus make the Secretary's quarantine authority available to control pathogens, residues, or any other disease or health-related condition that may be transmitted by livestock or poultry or their products to other animals or humans.

Section 218 of the bill would amend section 1 of the Act of May 6, 1970 (21 U.S.C. 135; hereinafter the "1970 Act") which authorizes the Secretary to establish on an island within the territory of the United States an international animal quarantine station at which maximum animal disease and pest security measures can be maintained and to which (notwithstanding the provisions of any other law to prevent the introduction or dissemination of livestock or poultry diseases or pests) animals from any country (including a country in which foot-and-mouth disease or rinderpest exists) may be brought and, subject to such conditions as the Secretary may impose, subsequently moved to other parts of the United States. The amendment would delete reference to "livestock or poultry disease(s)" and replace those references with the word "diseases", which would be defined for purposes of the 1970 Act as "any diseases of livestock or poultry, both infectious and non-infectious, and any other health-related condition that may be transmitted by livestock or poultry or their products to other animals or humans."

Section 219 of the bill would amend section 12 of the Act of March 4, 1907 (21 U.S.C. 612; hereinafter the "1907 Act") which requires the Secretary to inspect cattle, sheep, swine, goats, horses, mules, and other equines intended and offered for export to foreign countries in order to ascertain whether such animals are free from disease. The amendment would delete this requirement and instead provide the Secretary with discretionary authority to inspect such animals to ascertain that they are free of disease. The amendment also would define "disease" for purposes of this section of the 1907 Act as "any disease of cattle, sheep, swine, goats, horses, mules, and other equines, both infectious and non-infectious, and any other health-related condition that may be transmitted by cattle, sheep, swine, goats,

horses, mules, and other equines or their products to other animals or humans. Thus the Secretary's authority would be expanded to include inspection for pathogens and residues, as well as other diseases or health-related conditions that may be transmitted by cattle, sheep, swine, goats, horses, mules, and other equines or their products to other animals or humans.

Section 220 of the bill would amend the Act of September 28, 1962 (7 U.S.C. 450; hereinafter the "Talmadge-Aiken Act") which authorizes the Secretary in the administration of federal laws relating to the marketing of agricultural products or control or eradication of plant and animal diseases and pests (and without prejudice to any other authority of the Secretary) to cooperate with state departments of agriculture and other state agencies charged with administration of similar state laws and to permit state agencies which have adequate facilities, personnel, and procedures to assist in the administration of such federal laws and regulations to the extent and in the manner he deems appropriate in the public interest. The amendment would define the term "animal diseases" for the purposes of the Talmadge Aiken Act as "any diseases of animals, both infectious and non-infectious, and any other health-related condition that may be transmitted by animals or their products to other animals or humans." Thus the Secretary's authority to cooperate with, and enlist the assistance of, state agencies would be expanded to include control or eradication of pathogens, residues, and other animal diseases that may be transmitted by animals or their products to other animals or humans. References to the Secretary would be rendered gender neutral.

Section 221 of the bill would amend subsection (d) of section 101 of the Act of September 21, 1944 (7 U.S.C. 430; hereinafter the "1944 Act") which authorizes the Secretary to purchase in the open market samples of tuberculin, serums, antitoxins, or analogous products of foreign or domestic manufacture which are sold in the United States for the detection, prevention, treatment, or cure of diseases of domestic animals, to test the products, and to disseminate the results of the tests. The amendment would add to subsection (d) a new definition of the term "diseases" for purposes of section 101 of the 1944 Act. "Diseases" would mean "any diseases of domestic animals, both infectious and non-infectious, and any other health-related condition that may be transmitted by domestic animals or their products to other animals or humans". Thus the Secretary's authority under section 101(d) of the 1944 Act would be expanded to include purchase and testing of products for the detection, prevention, treatment, or cure of pathogens and residues as well as other diseases or health-related conditions that may be transmitted by domestic animals or their products to other animals or humans.