



DEPARTMENT OF AGRICULTURE

OFFICE OF THE SECRETARY

WASHINGTON, D.C. 20250

September 13 1994

Honorable Albert Gore, Jr.
President of the Senate
Washington, D.C. 20510

Dear Mr. President:

Transmitted herewith, for the consideration of the Congress, is a draft bill to provide for improved public health and food safety through the reduction of pathogens in meat, meat food products, poultry, and poultry products, and for other purposes. The draft bill is an important part of this Administration's initiative to enhance food safety and ensure that appropriate Federal authority and resources are applied to protect the American public.

The Department has over 70 pathogen reduction activities underway, including on-farm disease control and prevention efforts, in-plant microbiological risk assessment studies, new technology pilot projects, research studies for rapid microbiological tests, and the development of a hazard analysis critical control point (HACCP) system. The draft bill would complement and strengthen these efforts by giving the Secretary of Agriculture a more complete range of authorities to complete the farm-to-table continuum envisioned under the Department of Agriculture's Pathogen Reduction Plan.

The Department of Agriculture is committed to moving to a science and risk-based inspection system. The Department will utilize legislative, regulatory, and administrative action to achieve this reform, which will require a multi-step approach. The draft bill, which is the first legislative proposal regarding the inspection system that the Department has submitted to Congress for its consideration, marks a significant step toward a science and risk-based inspection system by mandating that the Secretary determine the optimal means to incorporate microbial levels, testing, and monitoring into the inspection system.

The Department of Agriculture recommends that the draft bill be enacted.

In section 2 of the Federal Meat Inspection Act (FMIA), Congress finds that it is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are wholesome, not adulterated and properly marked, labeled, and packaged. Section 2 of the Poultry Products Inspection Act (PPIA) contains a similar finding for poultry products. The animal quarantine laws authorize the Secretary to deal with livestock and poultry diseases on the farm and in interstate and foreign commerce. The proposed legislation would contain Congressional findings, including a finding 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. The proposed amendments would provide the Secretary of Agriculture with additional means to protect the public health, particularly in the prevention of

foodborne illnesses due to pathogens in meat, meat food products, poultry, and poultry products. Specifically, the Secretary of Agriculture would be:

- directed to prescribe actions based on the best available scientific and technical data to limit and destroy human pathogens present in meat, meat food products, poultry, and poultry products from the farm to the dining table;
- directed, within two years of the enactment of the proposed legislation, to establish testing and monitoring requirements to identify human disease-causing pathogens in meat and poultry products and to establish levels of pathogens that, when found on meat and poultry products, constitute a threat to public health;
- authorized to stop the distribution and order the recall of meat, meat food products, poultry, and poultry products in situations that pose a threat to public health due to adulteration with human pathogens or that are not produced in such a manner as prescribed by the Secretary, and when meat, meat food products, poultry, and poultry products are misbranded;
- authorized to require record keeping for the purpose of tracing back to identify previous premises where livestock and poultry presented for slaughter have been held;
- provided with the ability to refuse or withdraw inspection based on repeated violations of the FMIA, the PPIA, or regulations promulgated thereunder;
- authorized to impose civil penalties for violations of the FMIA and PPIA;
- enabled to address a broader range of disease problems because disease would be defined in the animal quarantine laws to encompass not only those diseases that cause health problems in livestock and poultry, but any disease or health-related condition, including residues, that may be transmitted from livestock or poultry or their products to other animals or humans.

The January 1993 outbreak of E. coli O157:H7 in Washington State that affected more than 700 people and resulted in four deaths is an acute reminder of the risk of foodborne illness due to pathogens. The outbreak was traced to undercooked hamburgers at a fast food restaurant. Changes in Federal law governing meat and poultry inspection will facilitate improvements in the current inspection system and lead to a reduced risk of pathogens in meat and poultry from farm to table and to reduced risk of outbreaks such as the one in Washington State.

Scientific research is contributing new technology that may be useful in reducing pathogens in meat and poultry. The proposed legislation provides clear authority for the Secretary of Agriculture to take actions to reduce pathogens based on current science and technology. Further, the proposed legislation makes clear that ready-to-eat products must be free of

pathogens and that raw products when properly handled and cooked must be free of pathogens.

The Secretary of Agriculture is using the rulemaking process to develop new procedures and controls to reduce pathogens, such as the hazard analysis critical control point system and the proposed legislation will complement implementation of these new procedures.

The proposed legislation will extend inspection authority to provide for mandatory recall of adulterated or misbranded meat and poultry products. Current legislation provides only for voluntary recalls.

Steps must be taken throughout the food production chain to reduce and control pathogens. Traceback requirements will facilitate on-farm prevention programs and permit better investigation of the source of E. coli O157:H7 and other pathogens.

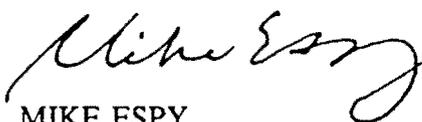
The ability to withdraw or refuse inspection for repeat violators of meat and poultry inspection laws and regulations and to assess civil penalties will strengthen the Secretary's authority to protect the public health.

While farm animals appear to be the most likely "carriers" of E. coli O157:H7, the bacterium does not cause disease in these animals as it does in humans. Consequently, the current animal quarantine laws pertaining to the spread of livestock and poultry diseases and the movement of animals do not apply to carriers of this or similar pathogens. The new definition of disease in the animal quarantine laws remedies this situation.

The Office of Management and Budget advises that there is no objection to the presentation of this proposed legislation from the standpoint of the Administration's program.

A similar letter is being sent to the Speaker of the House of Representatives.

Sincerely,



MIKE ESPY
Secretary

Enclosure

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."

**CHANGE AND OPPORTUNITY: HARNESSING INNOVATION
TO IMPROVE THE SAFETY OF THE FOOD SUPPLY**

(Final Version)

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CHANGE AND OPPORTUNITY: HARNESSING INNOVATION TO IMPROVE THE SAFETY OF THE FOOD SUPPLY

I am here today to talk about change: change in what the public expects when it comes to food safety, change in how we at the Food Safety and Inspection Service (FSIS) are approaching our job, and change in the demands being placed on all those who produce, process and market meat and poultry for American consumers.

I am here today to talk also about opportunity: the very real opportunity -- and obligation -- we have to address an important public health issue in our country. And the opportunity we have -- and must embrace -- to move beyond the politics of food safety to a collective search for real solutions to the problem of food safety.

But, as I make my first, formal public address as administrator of FSIS, just six weeks into my tenure, I want to say at the outset how fortunate I feel to be a part of this Agency. I come into this job with a very clear charge from Secretary Espy to build the best science-based inspection program we possibly can and to put the public health interests of the consuming public above all other interests. I have spent much of my time these last six weeks talking with FSIS employees -- with senior managers, scientists, leaders of our employee organizations, and inspectors and supervisors working on the front lines.

Throughout our Agency, we are blessed with employees who care deeply about our consumer protection mission, employees who are fully committed to the goal of protecting public health, employees who are eager to embrace the changes and opportunities that will take us where we need to go.

I find an FSIS that is ready for the future.

I also want to say that I find it fitting to be here before this audience to talk about change and opportunity. I have great respect for what you and the agricultural producers of this country do to provide the nation with an abundant and economical food supply. I also respect and appreciate the contribution this association and many in the meat and poultry industries have made to improving the safety of the food supply.

I believe our goal is the same: a food supply that is as safe as the modern tools of science and technology can make it.

safe as the modern tools of science and technology can make it. I know that much of the burden of change that is needed to meet this goal will fall on companies such as those represented here today. But the opportunity is yours as well. You know from your daily experience that improving food safety serves us all.

Public Expectations

Our agenda for change at FSIS is grounded in the expectations of the American public when it comes to the safety of the food supply.

Public expectations about food safety have always been high. Perhaps this is because food is the most fundamentally important and sensitive commodity we rely on the commercial marketplace to provide. Food provides the sustenance we need to survive; we share it in intimate family settings; we provide it to our children so they can grow and thrive.

People know very well that the safety of their food is not an absolute. But they expect -- and I believe they have a right to expect -- that those who offer food for sale in the commercial marketplace, and we in government who oversee the safety of the food supply, have done everything it is reasonably possible to do to ensure its safety.

That is the public's expectation, and, in our free and open society, the public has ample means to hold us accountable for meeting it, through their choices in the marketplace, through their elected officials, and through the media.

In one critical respect, our inspection program at FSIS does not currently meet the public expectation. There is a gap in our system, which has been recognized at least since 1985, when the National Academy of Sciences issued its report, Meat and Poultry Inspection, the Scientific Basis of the Nation's Program.

The fact is we do not deal directly enough and scientifically enough with the microbial pathogens that can make people sick. We do not take full advantage of the tools of microbiology to ensure that preventive controls are in place to reduce the risk of harmful contamination and to verify that those controls are working.

I know that many companies are moving in this direction, that microbial testing and other tools are being used by individual companies. But the public rightfully expects today that the tools of microbiology be built into the system of government oversight, that the FSIS inspection program target and take effective action to reduce or eliminate the bacteria that can make people sick.

That is a fair expectation for people to have of us. It is an expectation we intend to meet.

Meeting this expectation requires real change in how we approach our job. And I mean change at both the broad, philosophical level and at the day-to-day operational level.

Public Health Goals

Let me illustrate the kind of change I'm talking about. At the most fundamental, philosophical level, we need to change our approach by defining our goals when it comes to the safety of meat and poultry products, and by establishing goals that are driven by the protection of public health.

We say that our inspection system is intended to ensure that meat and poultry products are safe and wholesome, but we need to define more carefully what we mean by that. This is especially critical when it comes to the contamination of meat and poultry products with microbial pathogens.

If we don't understand what our public health goals are, we can't judge the adequacy of our efforts to achieve them. If we do clearly define and articulate our public health goals, we can harness the innovative capacities of the industry, the scientific community, and government to reach them.

Industry - Government Relationship

This new approach -- defining public health goals to stimulate innovation -- will bring about an important shift in the relationship between FSIS and the industries we regulate.

The tendency in the past has been for innovation in the inspection program to follow innovation in the industry. We have maintained a carcass-by-carcass inspection program that keeps up with rapid productivity gains in the industry. Make no mistake, productivity gains have value for consumers because they help provide an abundant, economical food supply.

But it's time for a shift. It's time to expand the impetus for innovation. It's time that innovation in the industry and in the inspection system be driven as much by public health goals as by productivity concerns.

Let me illustrate how this approach can work by talking briefly about one of our most critical food safety concerns, namely the contamination of ground beef with E.coli 0157:H7. The frequency of such contamination is relatively low compared to other pathogens. We estimate, based on a recent FSIS survey, that a fraction of one percent of all beef carcasses may be

contaminated with 0157:H7, while another FSIS survey indicates that 25 percent or more of broiler carcasses may be contaminated with salmonella.

0157:H7 contamination of ground beef is, nevertheless, a significant public health problem. Based on data from prospective, population-based surveys, it is likely that there are at least 10,000 cases per year in this country. The presence of less than one hundred organisms is enough to cause serious illness and even death, especially among children and the elderly. And ground beef is a staple of the American diet that, in our society, has traditionally been cooked by many people in a manner that does not destroy the organism.

Consumer education about proper cooking of ground beef clearly plays a critical role in disease prevention -- and we will continue to emphasize the importance of such education. That's why Secretary Espy worked so hard last year on the safe handling regulations.

But, we cannot escape our public health responsibility to reduce the risk of disease by relying solely on this last line of defense.

We need to act to protect public health.

In the case of 0157:H7 and raw ground beef, the only satisfactory public health goal is to eliminate contamination. That is the goal we must work toward.

We recognize that the ultimate achievement of this goal requires a long-term commitment. Achieving it -- or coming as close as it is scientifically and technologically feasible to come -- will likely require preventive measures at multiple steps in the process of producing and distributing ground beef.

We must look for ways to reduce the likelihood that contaminated animals will enter the stream of commerce, the risk that any pathogenic bacteria present in the intestinal tract will contaminate the meat during the slaughter process, and the potential for subsequent growth of any organism that may be present.

Industry Innovation

In short, technological innovation in production, slaughter and processing must be harnessed and applied aggressively if we are to move effectively toward our public health goal.

Many examples of possible interventions that could move us toward this goal and reduce the risk of illness are described in

the National Livestock and Meat Board's recent report on 0157:H7, titled A Blueprint For Industry Action.

We applaud the Board for the forthright approach taken in the report, and for the report's explicit recognition that beef safety is the meat industry's responsibility. I know that the American Meat Institute shares that view.

When it comes to the possible contamination of ground beef with E.coli 0157:H7, this responsibility means taking concrete action now to reduce risk. It means every company examining its processes, from the slaughter floor through the processing plant, and into the marketplace. And it means building in preventive measures that eliminate or reduce to the maximum extent possible the risk that a raw ground beef product will be contaminated when it leaves that company's premises.

I know many companies are taking these steps. All companies should take them.

I also know that when the product leaves the processing plant, it is still vulnerable to contamination or abuse that can contribute to the risk of foodborne illness. Those who transport the product and those who further handle it at retail have the same responsibility to take preventive measures to reduce risk.

Again, I know the Food Marketing Institute and the National Restaurant Association support this approach and that many companies are taking the initiative to do this.

I especially applaud the efforts of some of our largest restaurant chains to require their suppliers to establish preventive controls. These preventive measures, including finished product testing as a check on the systems' controls, are designed to reduce the risk that the ground beef they purchase is contaminated with E.coli 0157:H7.

I intend to meet with these organizations to strongly encourage their continued efforts and cooperation with us in this endeavor.

Initiatives like these will make food safer, and I call upon the meat industry to continue and expand them.

Government's Role

You will not be alone. We at FSIS are acting as well.

Secretary Espy has asked Congress to build into our statutory mandate an explicit charge to directly target microbial pathogens and to incorporate the science of microbiology into our

inspection system. Prompt enactment of the Pathogen Reduction Act of 1994 will put the full weight of Congress behind our effort to address microbial pathogens.

We also are proceeding through our regulatory processes. We are working hard to enforce the requirements that clean meat be produced in a sanitary environment.

And we plan to publish this fall proposed regulations to require that every meat and poultry plant establish science-based systems -- the HACCP system, Hazard Analysis and Critical Control Points -- to reduce the risk of foodborne illness.

HACCP is the conceptual framework for the future of food safety. If implemented properly, it is a powerful tool for targeting and preventing significant foodborne hazards, such as those posed by microbial pathogens.

Through the HACCP rulemaking, we will address and invite public comment on what our public health goals should be regarding specific microbial pathogens in raw meat and poultry products. We will address, but not limit ourselves to, E.coli 0157:H7.

For example, salmonella contamination of raw poultry contributes to hundreds of thousands of cases of foodborne illness annually, through cross contamination, incomplete cooking, or other means. We believe that 25 percent or more of all broiler carcasses may be contaminated when they leave FSIS-inspected facilities. While there is some evidence the incidence of contamination has declined over the last decade, 25 percent is simply not good enough as a national average when we know that some plants are achieving rates well below 10 percent using technologies that are available today.

We need to enlist those technologies to bring the salmonella contamination incidence down across the board. And we need to address as a nation what the appropriate public health goals are for reducing the frequency and levels of salmonella contamination in poultry.

The questions we will be asking about microbial pathogens are difficult scientifically, and some of the desired public health goals may be achievable only in stages over a period of time. But, if we don't know where we are going, we can't possibly determine how to get there.

We also plan to begin this fall the rulemaking process required to determine how mandatory in-plant microbial testing can best be incorporated into our inspection program. Many companies are already using this tool for various purposes. It's

time to begin establishing how this tool can be used by all companies to improve the safety of their products.

These changes in our inspection program and in the expectations our system will place on meat and poultry plants will go a long way toward reducing the risk of foodborne illness. But they will take time to develop. That's why industry innovation today toward the goal of reduced risk is so important.

It is also why FSIS must deal aggressively with the public health challenges we face today.

Current Regulatory Policy on E.coli

To this end, I want to be sure our current regulatory policy on E.coli 0157:H7 is crystal clear. Let me state it here. First, raw ground beef contaminated with E.coli 0157:H7 poses a serious risk to public health, and contaminated lots should be excluded from commerce.

Second, we recognize that due to the low incidence of contamination and the non-uniform distribution of contamination, no finished product testing program will detect all contaminated product. But when FSIS encounters a contaminated lot, we will detain it and require its destruction or reprocessing in a manner that kills the organism.

Third, we expect companies who encounter contaminated lots of raw ground beef at any stage of the process from production and processing to the retail store to take similar action. We also expect them to notify FSIS so that we can take whatever additional measures are appropriate to protect public health.

Fourth, to clarify an important legal point, we consider raw ground beef that is contaminated with E.coli 0157:H7 to be adulterated within the meaning of the Federal Meat Inspection Act. We are prepared to use the Act's enforcement tools, as necessary, to exclude adulterated product from commerce.

Finally, we plan to conduct targeted sampling and testing of raw ground beef at plants and in the marketplace for possible contamination with E.coli 0157:H7.

This sampling program is not by itself likely to detect a significant number of contaminated lots and will not by itself significantly reduce the likelihood of future outbreaks of foodborne illness attributed to 0157:H7. It is intended to build our knowledge and experience regarding sampling and testing for this pathogen. It also will serve as an example and an incentive for those commercial enterprises that produce, process and market

raw ground beef to control their processes and conduct their own tests.

We know that the ultimate solution to the 0157:H7 problem lies not in comprehensive end-product testing but rather in the development and implementation of science-based preventive controls, with product testing to verify process control. Nevertheless, as these systems develop, we have to do what we can now to detect and exclude from commerce contaminated lots of raw ground beef. Any lot that we detect or that you detect is one less lot that could cause an outbreak of illness due to E.coli 0157:H7.

If we aggressively apply the preventive technologies we have and take strong measures to exclude contaminated ground beef from the stream of commerce, we will be on the road toward meeting the public's fair expectations and carrying out our public health responsibility when it comes to E.coli 0157:H7.

Plant Sanitation

Let me turn briefly to another topic to illustrate how we need to change our approach to achieving even our most basic and longstanding goals. The topic is plant sanitation.

Good sanitation is the foundation upon which safe food production and processing rests. Insanitary facilities and equipment and poor personal hygiene practices among employees create an environment in which pathogens can flourish. They are an indicator that a facility is not under a level of control essential to produce safe food.

Good sanitation is also one of the public's fundamental expectations. People simply want their food produced under conditions of reasonable cleanliness. Congress has made good sanitation one of the standards that plants must meet to operate under FSIS inspection.

The keys to good sanitation are obvious: a strong commitment on the part of plant management and sustained effort every day to keep the plant clean. Many plants do very well on sanitation because they have the commitment and make the effort.

Other plants do not do as well. In our ongoing unannounced reviews of 1,000 plants, including both slaughter and processing operations, the serious deficiencies we are observing involve sanitation more than any other category of deficiency.

Perhaps the management commitment is not there in some of these plants. Perhaps the facility is old and difficult to

maintain. Perhaps the investment has not been made in equipment that can make good sanitation easier to achieve.

There are no doubt many reasons for sanitation problems. Maintaining a high level of sanitation consistently, every day, is a real challenge.

We at FSIS know that we have a role to play in meeting this challenge, and there is room for improvement -- indeed a need for change -- in how we play that role. Most fundamentally, we need to clarify what our role and responsibility is in relation to the role and responsibility of plant management.

Our current sanitation regulations spell out various general standards concerning cleanliness of plant and equipment. It is implicit in these regulations -- and well understood by many companies -- that the plant's management is responsible for seeing that these requirements are met every day before operations commence. Responsible companies typically have standard operating procedures that their employees must follow every day to ensure good sanitation.

Other companies do not take the same affirmative approach to establishing and managing a real sanitation program. In some plants, we find a tendency to rely too heavily on the FSIS inspector to find problems and require their correction.

Our goal is to be sure that all plant managers understand and accept their responsibility for good sanitation and have in place basic procedures designed to produce good sanitation. This will in turn enhance the ability of the FSIS inspector to perform his or her proper role regarding sanitation, which is to verify that the plant has met its sanitation responsibility.

In pursuit of this, we will review our sanitation regulations and consider whether the responsibility of plant management for sanitation should be made more explicit.

It is not the job of FSIS to mandate in detail how good sanitation is to be achieved in every plant we inspect. But, we do need to consider spelling out such basic responsibilities as having in place a sanitation plan for the plant, having supervisory personnel who are trained adequately to carry out the plan, and conducting sufficient pre-operational checks to verify that the plan is working.

We also need to update the technical guidance we provide to plants on how good sanitation can be achieved. This is especially important for small plants who may lack the resources to stay up to date themselves on advances in sanitation procedures and technology. Before the end of the year, we plan

to issue an updated version of our Sanitation Handbook, which we expect will be a valuable resource for both inspectors and plants.

Good sanitation is an objective the meat industry and FSIS share. It is a topic that deserves and requires steady attention to achieve and maintain good results.

I want to emphasize that, as we step up our focus on microbial pathogens, we will not lose sight of the basic need for good sanitation.

Conclusion

I've talked today about two of our most critical program goals -- safe food and clean plants -- and about the change underway in our program as we pursue these goals.

I have not talked about how we will be changing and expanding our interaction with the scientific community, improving our coordination with other food safety regulatory authorities, and reexamining some important labeling policies.

Yes, the agenda for change at FSIS is ambitious. Your involvement and support will be important to our success. We welcome your support. We invite your support. And I know that on the goal of improving food safety by bringing the science of microbiology into our inspection program, we have your support.

The agenda for change is ambitious, but the opportunity for progress is great. By embracing change and innovation in how you produce, process, and market your products and in how we conduct our inspection program, we can together improve protection of public health in this country and earn the confidence of the American consumer in what we do.

Thank you.



Division of Bacterial and Mycotic Diseases

PulseNet

The National Molecular Subtyping Network for Foodborne Disease Surveillance

Press Release: National Computer Network in Place to Combat Foodborne Illness

What is PulseNet?

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What is PulseNet?

PulseNet is a national network of public health laboratories that performs DNA "fingerprinting" on bacteria that may be foodborne. The network permits rapid comparison of these "fingerprint" patterns through an electronic database at the Centers for Disease Control and Prevention (CDC). The DNA "fingerprinting" method is called pulsed-field gel electrophoresis (PFGE).

Why was PulseNet developed?

In 1993, a large outbreak of foodborne illness caused by the bacterium *Escherichia coli* O157:H7 occurred in the western United States. Scientists at CDC performed DNA "fingerprinting" by PFGE and determined that the strain of *E. coli* O157:H7 found in patients had the same PFGE pattern as the strain found in hamburger patties served at a large chain of regional fast food restaurants. Because this outbreak and its cause were recognized quickly, the ground beef patties were recalled, and an estimated 800 illnesses were prevented. At that time, few state public health laboratories performed DNA "fingerprinting" by PFGE, and each used slightly different methods, which made the results difficult to compare. Because PFGE had such an important role in this investigation, and state health departments had increasing demands for DNA "fingerprinting," CDC developed standardized PFGE methods so that patterns from different laboratories could be generated the same way and could be compared accurately. Since then, some local and state health departments have gained more experience with DNA "fingerprinting" by PFGE of *E. coli* O157:H7 in several outbreaks, in which it was critical in identifying and

controlling the source of the infection.

In collaboration with the Association of State and Territorial Public Health Laboratory Directors, CDC created PulseNet so that scientists at public health laboratories throughout the country could rapidly compare the PFGE patterns of bacteria isolated from ill persons and determine whether they are similar. Similar PFGE patterns suggest that the bacteria isolated from ill persons come from a common source, for example, a widely distributed contaminated food product. Strains isolated from food products by regulatory agencies can also be compared with those isolated from ill persons. Identifying these connections can help to detect outbreaks and remove contaminated foods from the marketplace.



How does DNA "fingerprinting" by PFGE work?

Bacteria replicate themselves by dividing in two. When a bacterium divides, the two daughter bacteria have the same genetic makeup as the parent bacterium, like identical twins. Even after many generations, bacteria descended from the same original parent will have virtually identical genetic material, or DNA. DNA "fingerprinting" by PFGE is a simple way of comparing genetic material that involves cutting up the DNA into pieces, then measuring the number and sizes of these pieces. The pieces are separated by a kind of a sieve, made of a jelly-like substance (gel). The DNA that has been cut in pieces is placed at one end of the gel. A pulsing electric field applied across the gel drives the DNA pieces across the gel over a period of hours. The smallest pieces slip through the sieve more quickly, so the pieces are separated as distinct bands on the gel. This pattern of bands, which resembles a bar code, is the "fingerprint." An example of a DNA "fingerprint" is shown on the left.

How does PulseNet work?

Laboratories participating in PulseNet perform DNA "fingerprinting" by PFGE on disease-causing bacteria isolated from humans and from suspected food using standardized equipment and methods. Once PFGE patterns are generated, they are entered into an electronic database of DNA "fingerprints" at the state or local health department and transmitted to CDC where they are filed in a central computer. When PulseNet is fully operational, all participating laboratories will have a direct link with the central computer at CDC. These laboratories will be able to submit new patterns to the national database online and

obtain epidemiologic information associated with patterns in the database. If patterns submitted by laboratories in different locations during a defined time period are found to match, the CDC computer will alert PulseNet participants of a possible multistate outbreak so that a timely investigation can be done.

Who are participants in PulseNet?

CDC began to set up PulseNet in 1995 in conjunction with the state public health laboratories in Massachusetts, Minnesota, Texas, and Washington (henceforth termed area laboratories) and the laboratory at the U.S. Department of Agriculture - Food Safety and Inspection Service (USDA-FSIS). These area laboratories perform PFGE typing on isolates from their own state as well as from surrounding states that do not have PFGE capability.

Additional public health laboratories that have received funding through sources such as CDC's Emerging Infections Program or Epidemiology and Laboratory Capacity Enhancement Program perform DNA "fingerprinting" by PFGE on isolates from their own states using the standardized equipment and methods developed by CDC. These PulseNet participants include the public health laboratories of California, Colorado, Georgia, Florida, Hawaii, Illinois, Indiana, Iowa, Kansas, Los Angeles County, New Hampshire, New Jersey, New York, New York City, Ohio, Oregon, Tennessee, Utah, Virginia, and Wisconsin. The laboratory of the Food and Drug Administration, Center for Food Safety and Applied Nutrition also recently joined the network.

What foodborne disease-causing bacteria are currently being tracked by PulseNet?

Currently, PulseNet participants perform DNA "fingerprinting" by PFGE on *E. coli* O157:H7 isolates. In February 1998, CDC introduced a standardized method for PFGE analysis of *Salmonella* serotype Typhimurium that uses the same equipment. Over time, additional foodborne disease-causing bacteria will be tracked by PulseNet depending on their public health importance and the availability of specific DNA "fingerprinting" methods for that pathogen.

Why is PulseNet important to public health?

PulseNet will play a vital role in surveillance and investigation of foodborne illness outbreaks that were previously difficult to detect. In the past, foodborne illness outbreaks that were identified tended to be local events that were easily recognized; for example, everyone who ate the potato salad at the local church picnic became ill. However,

this may not be the predominant scenario in foodborne illness outbreaks now. Instead, foodborne outbreaks now often occur over widely dispersed geographic areas, caused by consumption of a widely distributed product with a low level of contamination. Using DNA "fingerprinting" techniques, PulseNet can help public health authorities recognize when cases of foodborne illness occurring at the same time in geographically separate locales are caused by the same strain of bacteria and may be due to a common exposure, such as a food item. An epidemiologic investigation of those cases can then determine what they have in common. If a bacterial strain is isolated from a suspected food, the strains from humans and suspected food can be compared quickly. Thus, matching patterns can indicate possible nationwide outbreaks and lead to public health actions such as epidemiologic investigations, product recalls, and ultimately to changes that prevent such widespread outbreaks in the first place.

How is PulseNet different from previous laboratory practices?

State and local public health laboratories are a critical element in the public health system that protects the country. In the area of foodborne diseases, they test a variety of specimens, support outbreak investigations, and conduct laboratory-based surveillance for infections, such as *Salmonella* or *E. coli* O157:H7.

Before PulseNet, most public health laboratories did not have DNA "fingerprinting" capability. A few laboratories had recognized the value of DNA "fingerprinting" but had developed techniques independently using a variety of equipment or laboratory methods. Laboratories without PFGE capabilities could forward isolates to CDC as needed for DNA "fingerprinting." As requests for DNA "fingerprinting" by PFGE increased, however, results could not always be obtained as quickly as needed in foodborne outbreak investigations. Also, patterns of DNA "fingerprints" from different laboratories that performed PFGE using nonstandardized techniques were not comparable. In both these situations, valuable time was lost as isolates suspected to be related were shipped from different sites to a central location for PFGE analysis to confirm whether they were the same strain.

Because PulseNet participants use a standardized protocol and have the capability to exchange information electronically, laboratorians and epidemiologists in different states can rapidly compare DNA "fingerprints" of submitted strains with those in the PulseNet database, leading to enhanced outbreak detection and public health response to prevent further foodborne illness.

How has DNA "fingerprinting" by PFGE been used to prevent foodborne illness?

- In 1996, epidemiologists traced two concurrent outbreaks of *E. coli* O157:H7 infections occurring in Connecticut and Illinois to a common source, mesclun lettuce (a mixture of baby lettuce leaves) grown on the same California farm. DNA "fingerprinting" by PFGE identified these two outbreaks as linked to a common source. As a result of this investigation, lettuce growing and processing practices are being reviewed and guidelines for good manufacturing practices are being developed by public health agencies in collaboration with the fresh produce industry to prevent further outbreaks of this kind.
- In 1996, epidemiologists traced an outbreak of *E. coli* O157:H7 infections in patients from four states and one Canadian province to commercial unpasteurized apple juice. DNA "fingerprinting" by PFGE by the Washington State public health laboratory showed that isolates from patients and the apple juice were the same strain. Prompt recognition of the commercial apple juice as the source of this outbreak resulted in rapid recall of the widely distributed product.
- In 1997, the Colorado State Health Department identified a cluster of ill persons from whom *E. coli* O157:H7 isolates with identical PFGE patterns were cultured. About the same time, the USDA laboratory isolated an *E. coli* O157:H7 strain from a ground beef patty from the same package as a patty consumed by an ill person and performed DNA "fingerprinting" by PFGE on the isolate. Both the Colorado state public health laboratory and the USDA-FSIS used the standardized protocol for DNA "fingerprinting" by PFGE. The patterns from the patient isolates from Colorado and the ground beef isolate at the USDA laboratory were transmitted electronically to CDC via the Internet, where they were found to be indistinguishable. This outbreak pattern was then transmitted to PulseNet sites and was compared with patterns from over 300 other recent *E. coli* O157:H7 isolates. No matching patterns were found, providing strong evidence that the outbreak was not nationwide.

DNA "fingerprinting" by PFGE can also help differentiate between a real outbreak--an increase in the number of epidemiologically related cases--and a pseudo-outbreak--an increase in the number of cases that are not epidemiologically linked to a common source. In summer 1994, an outbreak of *E. coli* O157:H7 infections in New

Jersey was suspected when the number of reported cases in the state increased nearly 10-fold after clinical laboratories were asked to report all cases of *E. coli* O157:H7 infection to the health department. DNA "fingerprinting" by PFGE showed that the pseudo-outbreak was related to increased reporting of cases and was not a common-source outbreak, as 17 different "fingerprints" were identified among 23 patient isolates. By identifying these pseudo-outbreaks as such, health departments can conserve resources by investigating only true outbreaks.

What is in the future for PulseNet?

Using DNA "fingerprinting," PulseNet sites will continue to help identify and investigate outbreaks of *E. coli* O157:H7 infections and other important foodborne pathogens, such as *Salmonella* serotype Typhimurium. Over time, CDC will set up additional databases of DNA "fingerprints" for other foodborne illness-causing bacteria.

Recognized outbreaks are only the tip of the iceberg of foodborne illness. Most foodborne infections are sporadic, meaning there is no link to a known outbreak. PulseNet will be an early warning system that links seemingly sporadic human illnesses together; as a result, more outbreaks should be recognized, especially those that are spread over many states. Investigation of these outbreaks should result in identification of hazards and implementation of new measures to increase the safety of our food supply.

How can I find out more about PulseNet or other programs for foodborne disease surveillance?

For more information on foodborne disease surveillance, DNA "fingerprinting" by PFGE, or PulseNet, contact your state health department. For information from CDC, visit the CDC home page on the Internet at www.cdc.gov or contact CDC at:

Foodborne and Diarrheal Diseases Branch
Division of Bacterial and Mycotic Disease,
National Center for Infectious Diseases,
Centers for Disease Control and Prevention
1600 Clifton Rd, MS A-38
Atlanta GA 30333

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Release No. 0049.95

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USDA'S NAL INITIATES INFORMATION SERVICE ON FOODBORNE ILLNESS PREVENTION

WASHINGTON, Jan. 25, 1995--The U.S. Department of Agriculture's National Agricultural Library has initiated a new service which provides information on foodborne illness prevention.

The new service, called the Foodborne Illness Education Information Center, is designed for educators, trainers and organizations developing education and training materials for food workers and consumers.

The center is a joint program of USDA's Food Safety and Inspection Service and the Food and Drug Administration.

According to Cindy Roberts, coordinator of the new information center, USDA and FDA established it in May 1994 as part of a national campaign to reduce the risk of foodborne illness and to increase knowledge of food-related risks at all stages of food handling and preparation, from producers to consumers.

"The center's primary function is the development and maintenance of an educational database," Roberts said. "The database is a compilation of consumer and food worker education materials developed by universities, private companies and government agencies."

Materials listed in the database include computer software educational research, audiovisuals, posters, games, and teaching guides--all for elementary and secondary school curricula. Also included are training materials for managers and workers at retail food markets and food service institutions.

Roberts said that reports of the database are free and available by modem via the Internet from the gopher of NAL's Food and Nutrition Information Center. To access the database via gopher, telnet to a favorite gopher, choose "All other gophers," then "Gopher servers in the USA," then "Maryland," then "Food and Nutrition Information Center, USDA." From the menu displayed look under "USDA/FDA Foodborne Illness Education Information Center."

The center can also be accessed through NAL's electronic bulletin board ALF, and through PENpages International Food and Nutrition Database (IFAN).

Roberts said that floppy disk copies of the database are available from the center.

Additional information on the database and the center are available by contacting Roberts at:

USDA/FDA Foodborne Illness Education Information Center
c/o Food and Nutrition Information Center
National Agricultural Library
Beltsville, MD 20705-2351
(301) 504-5719
Fax (301) 504-6409
Internet address: croberts@nalusda.gov

NAL is one of three national libraries of the United States, with the

Library of Congress and the National Library of Medicine. Part of USDA's Agricultural Research Service, NAL is the largest agricultural library in the world.

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Release No. 0071.95

Mary Dixon (202) 720-4623

Statement

by
RICHARD ROMINGER
ACTING SECRETARY OF AGRICULTURE
January 31, 1995

It is a pleasure to be here today to announce a food safety proposal which will bring sweeping changes in the way USDA will inspect meat and poultry. The proposal is a major step toward improving our food safety inspection system and further protecting the American consumer from foodborne illness.

We are at a crossroads. We are proposing to reinvent the meat and poultry inspection system, which is currently based primarily on sight, touch, and smell, by utilizing science and the latest technology, including bacterial testing. This initiative is not just about making changes. It's about making changes that will make food safer. It is not about more regulation -- it's about better, more effective and more sensible regulation. It's about providing safer food for American families.

The Clinton Administration has initiated and implemented many food safety initiatives, including:

- Conducting unannounced reviews in 1,000 plants to enforce inspection requirements,
- Mandating safe cooking and handling instructions on the labels of meat and poultry products,
- Increasing our funding for food safety research,
- Elevating food safety to a sub-Cabinet position within the Department and consolidating all Departmental food safety activities under that position,
- Declaring E. coli 0157:H7 in raw ground beef to be an illegal adulterant and initiating a program to sample for the pathogen, and
- Streamlining the approval process for antimicrobial treatments to help industry move faster to install new technologies to reduce pathogens.

These are important steps, but our job to improve food safety is not yet done. It is now time for us to make fundamental changes in how we carry out our job of meat and poultry inspection. The proposal we are announcing today would allow us to take a number of important steps -- steps which are the most significant food safety reform since the passage of the meat and poultry inspection laws were first enacted in 1907 and 1957.

Under our proposal, slaughter plants would be required to develop and implement a science-based system for producing safe food known as HACCP -- Hazard Analysis and Critical Control Points. The philosophy of HACCP was created by industry and is widely accepted as an effective, prevention-based system of food production. In fact, some industry leaders already operate under HACCP systems, but the current inspection system and most plants do not.

That would change under this proposal -- the inspection system and all plants would operate under HACCP. And that will fundamentally reform our inspection program into a science-based system -- a system which will ensure an even safer food supply.

Change of this magnitude will take time. We recognize that change cannot happen overnight in a system which has been built up over decades. At the same time, we believe that there are improvements in the production and inspection systems that need to be made as we make this transition to HACCP. And that is why our proposal includes several near-term initiatives, the most significant of which is that plants would be required to test their products for pathogenic bacteria and would be required to meet specified targets for pathogen reduction. Together, these proposed initiatives would address the immediate need for improvements in our meat and poultry inspection system and would begin the process of transforming the inspection program into a science-based system.

HACCP is ultimately about moving away from command and control regulations to a more flexible, performance-based system that focuses on prevention to improve food safety. With this goal, we know that there may be some concern about these proposed short-term initiatives. While we at USDA understand this concern, we strongly believe that some immediate steps must be taken to improve food safety as we make this transition to HACCP. We know that we can do more to reduce the regulatory burden that our current inspection system places on industry. That's why FSIS is currently reviewing its regulations to see where we can either eliminate costly and unnecessary regulations or establish more flexible, performance-based standards without compromising food safety. We want to hear comments from all interested parties about this issue.

Everyone supports HACCP -- from industry and consumers to the National Academy of Sciences and the General Accounting Office. But we may disagree about what a HACCP system should include and how we should make the transition to HACCP. Today, we are releasing USDA's proposal, and I would like to thank Mike Taylor and all the FSIS employees who have worked hard to bring us to this point. The proposal would allow us to do what food safety experts have said we should do. It would allow us to do what Congress has mandated that we do. And it would allow us to do what the public rightfully expects us to do -- make the meat and poultry supply as safe as possible.

The effort to reform our inspection system will require the input and support from all of the Department's customers, and I encourage you to read the proposal and provide us with your comments, suggestions and criticisms. Together, we will be able to achieve our common goal -- to improve the safety of our meat and poultry.

I will now ask Mike Taylor, our Acting Under Secretary for Food Safety and Administrator of the Food Safety and Inspection Services, to describe our proposals and our overall food safety strategy.

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NEWS

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Release No. 0009.96

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USDA REGULATORY REFORMS TO IMPROVE MEAT AND POULTRY SAFETY

WASHINGTON, Jan. 2, 1996—Regulatory reform actions announced today are part of the Department of Agriculture's strategy to improve food safety, said USDA Acting Under Secretary for Food Safety Michael R. Taylor.

"By adopting modern regulatory tools and streamlining or eliminating old rules and requirements, we will enhance the safety of meat and poultry products on the tables of America," said Taylor.

"The changes are part of our comprehensive overhaul of the nation's meat and poultry inspection program," said Taylor. "The reforms are intended to support the new food safety measures USDA plans to adopt for all federally inspected meat and poultry plants." On Feb. 3, 1995, USDA proposed that all federally inspected meat and poultry plants adopt a science-based preventive system of food safety controls known as HACCP (Hazard Analysis and Critical Control Points) and plans to publish a final rule in 1996.

"These reform proposals reflect the fundamental change underway in USDA's food safety program. To make our new food safety strategy work, we must broadly reform our existing requirements and procedures, many of which have simply outlived their usefulness," said Taylor, who also serves as administrator of the Food Safety and Inspection Service, the agency responsible for ensuring the nation's meat and poultry supply is safe, wholesome, and accurately labeled.

Taylor said that as part of its food safety initiative and to carry out President Clinton's call for reform of federal regulations, FSIS has completed a page-by-page review of all of its existing rules, including rules regarding food labeling and other non-safety matters. Agency staff has identified more than 400 pages of regulations, nearly three-fourths of the total, as candidates for elimination or change to make them simpler, less burdensome, or more performance-based.

"Some of our labeling rules limit the flexibility companies need to produce nutritionally improved meat and poultry products that consumers want," said Taylor. "By modernizing these rules and streamlining others, we can reduce unnecessary burdens on industry and improve the way we serve America's consumers."

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Four documents published in the Dec. 29, 1995, Federal Register: (1) An advance notice of proposed rulemaking describing USDA's reform strategy, listing regulations identified for repeal or revision and requesting public comments on these and other rules needing reform; (2) a final rule expanding the kinds of product labels no longer requiring prior FSIS approval and substituting one review for two formerly required; (3) a proposal to allow familiar terms, such as "low-fat" or "light turkey" on products like hot dogs and turkey ham made with substitute ingredients that change the nutritional profile; and (4) a proposal to eliminate duplicative rulemaking by the Food and Drug Administration and FSIS on substances that may be safely used in foods, including meat and poultry products.

Taylor said three other regulatory revisions are being developed for publication in early 1996. They are: (1) a proposal to revise "command-and-control" regulations for processing certain meat and poultry products by incorporating objective performance standards for the safe production of these products; (2) a proposal to eliminate requirements for industry to obtain FSIS prior approval for facility blueprints and equipment and for most quality control programs; and (3) an advance notice of proposed rulemaking soliciting comments, and information on whether to modify or eliminate specific standards and whether and how to modify the agency's overall approach to product standards of identify and composition.

"Our goal is an integrated, science-based system of regulatory oversight that makes the best use of both government and industry resources to improve food safety," Taylor said. "These reform proposals are an important step in that direction."

FSIS is performing a critical review of how the Agency carries out its regulatory role, through inspection and other means, allocates its resources, and is organized in both headquarters and field offices.

The proposed rules are open for public comment for 60 days. By Feb. 27, 1996, an original and two copies of comments should be sent to the Docket Clerk, USDA, FSIS, Room 4352-South Bldg, Washington, DC 20250-3700.

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NOTE: USDA news releases and media advisories are available on the Internet. Either access the USDA Home Page on the World Wide Web at <http://www.usda.gov> or go directly to <gopher://gopher.usda.gov>

Office of the Under Secretary for Food Safety
Food Safety and Inspection Service

THE FINAL RULE ON PATHOGEN REDUCTION AND HACCP

It's a pleasure to have the opportunity to meet with you today. Your timing for this meeting is impeccable-- this is the first group I have addressed where I can actually discuss the details of the final rule on HACCP and Pathogen Reduction.

Needless to say, we are very pleased that the rule has finally been published. We believe the final product meets the needs of everyone involved--government, all segments of industry, and consumers.

During the development of the rule, we made a concerted effort to listen to everyone and address as many concerns as possible. If you have had a chance to read the final rule, I believe you will see many examples of areas where we were able to make adjustments without compromising food safety. We appreciate all of the input your organization and others provided during the rulemaking process.

Overview of the Final Rule

As many of you know, the final rule was published in the Federal Register on July 25. It has four key provisions: (1) Sanitation Standard Operating Procedures (SOPs), (2) Hazard Analysis and Critical Control Points (HACCP), (3) Testing for generic E. coli, and (4) Performance Standards for Salmonella.

The sanitation SOPs are mandatory in all plants. Establishments must prepare and implement plant-specific SOPs for sanitation to ensure they are meeting their responsibility to keep their facilities and equipment clean. The written sanitation SOPs must describe the specific activities plant management has determined are necessary to maintain good sanitation to prevent direct product contamination.

Remarks prepared for delivery by Thomas J. Billy, Associate Administrator of the Food Safety and Inspection Service, U.S. Department of Agriculture, before the National Cattlemen's Beef Association, August 2, 1996, Nashville, Tenn.

This requirement clarifies that sanitation is the establishment's responsibility, and it will make it easier for our inspectors to perform their proper role of verifying that plant management is carrying out its sanitation responsibilities. This requirement becomes effective 6 months after publication of the final rule, or on January 27, 1997. The final rule contains two draft appendices that address SOPs--Appendix A, Guidelines for developing SOPs, and Appendix B, Model of an SOP for sanitation. The public is invited to comment on these drafts during the 60-day comment period, which ends on September 23, to ensure they are clear and effective before they are finalized.

Establishments also will be responsible for developing and adopting a HACCP program to ensure that they have in place science-based controls to prevent and reduce food safety hazards. Establishments will be required to develop HACCP plans based on the seven principles established by the National Advisory Committee on Microbiological Criteria for Foods. HACCP systems will be required to have critical control points that address product safety hazards, as opposed to control measures related to economic adulteration and quality.

FSIS will not approve HACCP plans in advance but will review them for conformance with the final HACCP regulation and continually verify their effectiveness.

Implementation will be phased in based on plant size. Large plants with 500 or more employees will have until January 26, 1998 to have in place their HACCP plans. For small plants with 10 or more but fewer than 500 employees, the implementation date is January 25, 1999. In very small plants, with fewer than 10 employees or annual sales of less than \$2.5 million, the implementation date is January 25, 2000. Two draft appendices in the final rule address HACCP-- Appendix C, Guidebook for the preparation of HACCP plans, and Appendix D, Hazards and Preventive Measures Guide. These drafts are available for comment for 120 days, until November 22, to ensure they meet industry needs.

Slaughter establishments will also have to begin testing for generic E. coli to verify process control for fecal contamination. E. coli was chosen as a more appropriate microorganism to use as a verification of slaughter process control than the originally proposed Salmonella based on numerous comments and the results of the scientific conferences and public meetings we held during the final rule.

E. coli performance criteria for various product classes were based on nationwide baseline surveys conducted by FSIS. We will not use the test results themselves to take any regulatory action, but they will guide us on when to look for other information to evaluate whether a problem exists that requires regulatory action. The E. coli testing requirement becomes effective at the same time as the sanitation SOPs--January 27, 1997. Two draft appendices to the final rule address the E. coli testing requirement--Appendix F, Guidelines for E. coli testing in cattle and swine

plants, and Appendix G, Guidelines for E. coli testing in poultry plants. Comments on these draft appendices will be accepted until September 23. A meeting on certain technical aspects of the E.coli verification testing will be held in Washington, D.C. on September 12 and 13.

The pathogen reduction performance standards for Salmonella apply to chilled carcasses and raw ground products. We have adopted these performance standards to verify that slaughter and grinding HACCP systems are effective in reducing and controlling contamination. Salmonella was selected as the target pathogen because it is the leading cause of foodborne illness among enteric pathogens, it is present at varying frequencies on all types of raw meat and poultry products, and it can easily be tested for in a variety of products.

Plants will be required to achieve a prevalence of Salmonella contamination through their HACCP programs that is below national baseline prevalence for each raw product as reflected in the FSIS baseline surveys. These are regulatory standards that FSIS will require the plant to meet consistently over time as a condition to maintaining inspection.

FSIS will be responsible for conducting the testing to ensure compliance with the standards. We will conduct initial testing prior to actual enforcement of the performance standards to determine how each plant is doing to meet the standard.

These first-phase results will assist plants in preparing for the implementation of HACCP and the pathogen reduction performance standards. The frequency and intensity of the second-phase compliance testing, which begins according to the HACCP implementation dates, will be based on past plant performance and other factors. Appendix E to the final rule outlines FSIS sample collection procedures for Salmonella. In approximately 15 months, we will convene a public conference to review available Salmonella data and discuss whether they warrant refining the Salmonella performance standards.

Implementation of the Final Rule on Pathogen Reduction and HACCP

There is much work ahead to implement the final rule. We intend to have a fully public process during the implementation period like we had during the rulemaking process. We are committed to doing whatever we can to ensure that SOPs and HACCP are effectively implemented in all establishments.

We have a number of opportunities planned for continuing dialogue on important implementation issues related to the final rule. We are now scheduling these public meetings and will announce the dates and locations through the Federal Register.

In addition to the meeting on certain technical aspects of the E. coli verification testing in slaughter plants, which is scheduled for September 12 and 13, we have finalized the dates for the National Implementation Conference. It will be held in Washington, D.C. from September 30 to October 3. The first and last days will be half days. The national meeting will be followed by a series of regional conferences.

We will have available a number of additional assistance materials and activities--beyond the appendices to the final rule I already mentioned--to help establishments implement HACCP and the other requirements of the final rule. For instance, we will have available generic HACCP models for the major process categories to assist small plants in preparing their HACCP plans. We will also be carrying out demonstration projects for small plants to show how HACCP can work for various products and under actual operating conditions.

Consistency in the Regulation of Meat and Poultry

We believe the final rule will provide many benefits. One benefit that I know is particularly important to the meat and poultry industries relates to consistency in the regulation of meat and poultry products. Because the final rule establishes a common, consistent regulatory framework for ensuring the safety of meat and poultry products, it will help to eliminate regulatory disparities.

For instance, there has been some concern that certain sanitation requirements imposed on meat processors were not required for poultry processors. Under the final rule, all inspected establishments, both meat and poultry, will be required to develop, implement, and maintain written standard operating procedures for sanitation. Because the rule provides establishments with the flexibility to customize their sanitation plans, this begins eliminating the effects of any disparate "command and control" sanitation requirements currently found in the regulations.

To complete this harmonizing process in the area of sanitation, we will be publishing a proposal to completely revamp the longstanding sanitation regulations. Like the new HACCP rule, there will be one set of requirements that applies to both meat and poultry. Many old requirements will be eliminated and others converted to performance standards.

I want to caution you, however, not to equate consistency with the traditional "command and control" regulations. Consistency under the new, HACCP-based system means that we are providing a consistent regulatory framework. It is our goal to apply the same principles of prevention and pathogen reduction in a consistent manner. But within that framework, there can be variations in requirements based on species of animal, product class, the establishment's particular risks, and a host of other factors.

The Salmonella performance standards are a good example. I know that there are some concerns that the new rules actually perpetuate inequities by permitting a greater prevalence of Salmonella on raw poultry than on raw meat products. I want to respond to these concerns, because I believe this issue is very important.

The Salmonella performance standards in the rule are based on a uniform, consistent regulatory framework. That is, as a starting point, all slaughter plants and plants that produce ground products must achieve at least the current national baseline level of performance with respect to Salmonella for the product classes they produce.

We recognize that the FSIS nationwide baseline data on prevalence of Salmonella vary greatly for each product category. Currently, there are major differences in what is being achieved by producers of the various categories of products tested. However, we have set the initial Salmonella performance standards based on these data.

Yes, the initial numerical standards are different, but we believe they are an equitable first step in pathogen reduction. We should focus our energies on improvements across the board--not just in Salmonella, but in all pathogens found on meat and poultry.

We believe the approach we have taken with performance standards for Salmonella will begin necessary progress on pathogen reduction across all species while we continue to collect more data and take other steps to refine the performance standards. While these standards are based on what is currently being achieved by producers, this does not mean we are encouraging the status quo. There are many establishments that are not achieving the current baseline levels. It is our intent to get those establishments to reach the level that other establishments have managed to reach. Thus, even with establishing performance standards at the baseline levels, we expect improvements to occur.

The fact that we have higher numbers for poultry at the beginning of the process means that we can expect future reductions to be more dramatic among the poultry classes. The poultry industry will have more work to do to get their numbers down for Salmonella. Secretary Glickman is committed to making the standards as similar as possible as quickly as possible. The standards in the HACCP rule are based on the best data we have at this time. When we do more testing and get more data, we will be making appropriate reductions in the standards.

Let me review some other activities we are undertaking to improve consistency between the regulations governing meat and poultry products. We agree that there are a number of asymmetries in the meat and poultry inspection regulations that have existed for some time. A June 1993 Research Triangle Institute study commissioned

by FSIS found numerous differences between the meat and poultry inspection regulations. We intend to correct as many of them as we can through several ongoing or planned rulemaking procedures.

For instance, on the issue of feces and ingesta on dressed poultry, we proposed a regulation enforcing a zero tolerance for feces on poultry entering the chiller. We have studied the comments we received and will soon be publishing a final rule on this matter that reinforces the zero tolerance and strengthens enforcement.

We also are reviewing the standards of identity and composition that have been established over the years for meat and poultry food products and will explore all issues relating to meat and poultry standards in a forthcoming advance notice of proposed rulemaking (ANPR). One option to be presented in the ANPR would require labeling disclosure of the percentage of meat or poultry contained in products. This disclosure would apply equally to both meat and poultry products. The ANPR will also solicit comments and specific data relating to the issues of allowable moisture content of similar further-processed meat and poultry products, such as turkey ham and ham, and the disclosure of detached skin in the ingredients statement on the labels of processed poultry products.

Finally, with regard to the issue of added moisture in chilled poultry carcasses, we are completing an analysis of options to address this issue.

Closing

In closing, we look forward to working with you on implementing the final rule on Pathogen Reduction and HACCP. As I mentioned, we are planning a number of opportunities for further dialogue on the many issues involved in the final rule, and we are developing a number of materials to assist establishments in meeting the new requirements.

Among the many benefits of the final rule will be elimination of some inequities that currently exist between meat and poultry. Beyond the final rule, however, we are examining our regulations and will be correcting situations where such inequities unnecessarily exist.