Today, I and my colleagues, Senators KEMPTHORNE and CRAIG, are introducing legislation that will help ensure that Federal firefighters continue to have access to airtanker services. The Wildfire Suppression Aircraft Transfer Act of 1996 will help facilitate the sale of former military aircraft to contractors who provide firefighting services to the Forest Service and the Department of the Interior. The existing fleet of available airtankers is aging rapidly and fleet modernization is critical to the continued success of the firefighting program.

Currently, legislative authority does not exist for the transfer or sale of excess turbine-powered military aircraft, suitable for conversion to airtankers, to private operators. This greatly hampers efforts to modernize the airtanker fleet. This bill will require that the aircraft be used only for firefighting activities.

Time is very short, but it is critical that this bill become law in this Congress. If we fail to pass this law, airtanker operators will not have access to the planes they need to update the aging airtanker fleet.

I urge my colleagues to support our efforts to ensure that Federal firefighters have the resources they need to protect the public and their property from the threat of wildfires.●

By Mr. MOYNIHAN:

S. 2079. A bill to repeal the prohibition against State restrictions on communications between government agencies and the INS; to the Committee on the Judiciary.

ALIEN INFORMATION PROVISION REPEAL LEGISLATION

● Mr. MOYNIHAN. Mr. President, on Wednesday, September 11, Mayor Rudolph W. Giuliani of New York City delivered an address at Georgetown University Law School about an obscure provision in the recently passed welfare legislation. The provision, section 434 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, states:

Notwithstanding any other provision of Federal, State, or local law, no State or local government entity may be prohibited, or in any way restricted, from sending to or receiving from the Immigration and Naturalization Service (INS) information regarding the immigration status, lawful or unlawful, of an alien in the United States.

Mayor Giuliani said it would ''create chaos in New York City.'' I agree with him that this provision is ill-advised and threatens the public health and safety of residents of New York City. It conflicts with a 1985 executive order issued by then-Mayor Edward I. Koch prohibiting city employees from reporting suspected illegal aliens to the INS unless the alien was charged with a crime. That executive order, which is similar to local laws in other States and cities, was intended to ensure that fear of deportation does not deter illegal aliens from seeking emergency medical attention, reporting crimes, and so on.

An earlier version of this provision was first introduced in welfare legislation during the 103d Congress as a part of H.R. 3500, the Responsibility and Empowerment Support Program Providing Employment, Child Care, and Training Act, sponsored by Representatives Michel, GINGRICH, and SANTORUM. On September 8, 1995, during Senate consideration of H.R. 4, the Work Opportunity Act of 1995, Senator SANTORUM, along with Senator NICKLES, offered a similar amendment. The amendment was adopted by the Senate by a vote of 91 to 6, but H.R. 4 was later vetoed by President Clinton.

This year, the provision was included in S. 1795, the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, which was signed by President Clinton on August 22, 1996.

Because this provision poses a threat to health and safety in New York City and elsewhere, I am today introducing legislation to repeal section 434 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996. I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the bill was ordered to be printed in the Record, as follows:

S. 2079

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

SECTION 1. REPEAL OF THE PROHIBITION AGAINST STATE RESTRICTIONS ON COMMUNICATIONS BETWEEN GOVERNMENT AGENCIES AND THE INS.

Section 434 of the Personal Responsibility and Work Opportunity Act of 1996 (Public Law 104–193) is repealed.●

ADDITIONAL COSPONSORS

S. 157

At the request of Mr. BUMPERS, the name of the Senator from Oregon [Mr. WYDEN] was added as a cosponsor of S. 157, a bill to reduce Federal spending by prohibiting the expenditure of appropriated funds on the United States International Space Station Program.

S. 1095

At the request of Mr. MOYNIHAN, the name of the Senator from North Carolina [Mr. FAIRCLOTH] was added as a cosponsor of S. 1095, a bill to amend the Internal Revenue Code of 1986 to extend permanently the exclusion for educational assistance provided by employers to employees.

S. 1379

At the request of Mr. SIMPSON, the names of the Senator from North Carolina [Mr. FAIRCLOTH] and the Senator from Minnesota [Mr. GRAMS) were added as cosponsors of S. 1379, a bill to make technical amendments to the Fair Debt Collection Practices Act, and for other purposes.

S. 1735

At the request of Mr. PRESSLER, the name of the Senator from California [Mrs. BOXER] was added as a cosponsor of S. 1735, a bill to establish the United States Tourism Organization as a nongovernmental entity for the purpose of promoting tourism in the United States.

S. 1870

At the request of Mr. MOYNIHAN, the name of the Senator from Oregon [Mr. HATFIELD] was added as a cosponsor of S. 1870, a bill to establish a medical education trust fund, and for other purposes.

S. 1963

At the request of Mr. ROCKEFELLER, the names of the Senator from New York [Mr. D'AMATO] and the Senator from Oklahoma [Mr. INHOFE] were added as cosponsors of S. 1963, a bill to establish a demonstration project to study and provide coverage of routine patient care costs for medicare beneficiaries with cancer who are enrolled in an approved clinical trial program.

S. 1965

At the request of Mr. KERREY, his name was added as a cosponsor of S. 1965, a bill to prevent the illegal manufacturing and use of methamphetamine.

S. 2064

At the request of Ms. SNOWE, the name of the Senator from Arkansas [Mr. PRYOR] was added as a cosponsor of S. 2064, a bill to amend the Public Health Service Act to extend the program of research on breast cancer.

SENATE JOINT RESOLUTION 52

At the request of Mr. KYL, the name of the Senator from Texas [Mr. GRAMM] was added as a cosponsor of Senate Joint Resolution 52, a joint resolution proposing an amendment to the Constitution of the United States to protect the rights of victims of crimes.

SENATE RESOLUTION 292

At the request of Mr. PRESSLER, the names of the Senator from Ohio [Mr. DEWINE], the Senator from Rhode Island [Mr. CHAFEE], the Senator from Pennsylvania [Mr. SPECTER], the Senator from Alaska [Mr. STEVENS], the Senator from South Carolina [Mr. THURMOND], the Senator from Tennessee [Mr. FRIST], the Senator from Virginia [Mr. WARNER], and the Senator from Mississippi [Mr. LOTT] were added as cosponsors of Senate Resolution 292, a resolution designating the second Sunday in October of 1996 as ''National Children's Day,'' and for other purposes.

AMENDMENTS SUBMITTED

THE DEPARTMENT OF THE INTERIOR AND RELATED AGENCIES APPROPRIATIONS ACT, 1997

GRAMS AMENDMENT NO. 5350

(Ordered to lie on the table.)

Mr. GRAMS submitted an amendment intended to be proposed by him to the bill (H.R. 3662) making appropriations for the Department of the Interior and related agencies for the fiscal year ending September 30, 1997, and for other purposes; as follows:

At the appropriate place in title I, insert the following:

SEC. 1 . VOYAGEURS NATIONAL PARK.

The Secretary of the Interior, acting through the Director of the National Park Service, shall, during fiscal year 1997, in cooperation with State, local, and tribal governments, other public entities, and private organizations, as appropriate, begin substantial implementation of section 401(b) of the Act entitled ''An Act to authorize the establishment of the Voyageurs National Park in the State of Minnesota, and for other purposes'', approved January 8, 1971 (16 U.S.C. 160k(b)).

PRESSLER AMENDMENT NO. 5351

Mr. PRESSLER proposed an amendment to the bill, H.R. 3662, supra; as follows:

At the end of the bill, add the following:

TITLE ____—LIVESTOCK INDUSTRY

Subtitle A—Captive Supply

SEC. ___01. CAPTIVE SUPPLY.

(a) DEFINITION OF CAPTIVE SUPPLY.—Section 2(a) of the Packers and Stockyards Act, 1921 (7 U.S.C. 182(a)), is amended by adding at the end the following:

''(12) CAPTIVE SUPPLY.—The term 'captive supply' means livestock acquired for slaughter by a packer (including livestock delivered 7 days or more before slaughter) under a standing purchase arrangement, forward contract, or packer ownership, feeding, or financing arrangement, as determined by the Secretary.''.

(b) ANNUAL REPORT ON LIVESTOCK MARKETED OR SLAUGHTERED.—Section 407 of the Packers and Stockyards Act, 1921 (7 U.S.C. 228), is amended by adding at the end the following:

''(f) ANNUAL REPORT ON LIVESTOCK MARKETED OR SLAUGHTERED.—

''(1) IN GENERAL.—The Secretary shall make available to the public an annual statistical report on the number and volume of livestock marketed or slaughtered in the United States, including—

''(A) information collected on the date of enactment of this Act; and

''(B) information on transactions involving livestock in regional and local markets.

''(2) ADMINISTRATION.—In carrying out paragraph (1), the Secretary shall ensure that—

''(A) a significant share of regional and local livestock transactions are reported; and

''(B) the confidentiality of individual livestock transactions is maintained.''.

(c) INFORMATION ON CAPTIVE SUPPLY TRANSACTIONS.—Section 407 of the Packers and Stockyards Act, 1921 (7 U.S.C. 228), as amended by subsection (b), is amended by adding at the end the following:

''(g) INFORMATION ON CAPTIVE SUPPLY TRANSACTIONS.—

''(1) IN GENERAL.—Not later than 24 hours after a transaction involving captive supply is recorded, the Secretary shall make information concerning the transaction (including the specific standing arrangement) available to the public using electronic and other means that will ensure wide availability of the information.

''(2) ONGOING LIVESTOCK TRANSACTIONS.—Any information collected on captive supply under paragraph (1) shall be reported in conjunction with ongoing livestock transactions.''.

Subtitle B—Livestock Dealer Trust

SEC. ___11. LIVESTOCK DEALER TRUST.

Title III of the Packers and Stockyards Act, 1921 (7 U.S.C. 201 et seq.), is amended by adding at the end the following:

''SEC. 318. LIVESTOCK DEALER TRUST.

''(a) FINDINGS.—Congress finds that—

''(1) a burden on and obstruction to commerce in livestock is caused by financing arrangements under which dealers and market agencies purchasing livestock on commission encumber, give lenders security interests in, or have liens placed on livestock purchased by the dealers and market agencies in cash sales, or on receivables from or proceeds of the sales, when payment is not made for the livestock; and

''(2) the carrying out of the arrangements is contrary to the public interest.

''(b) PURPOSE.—The purpose of this section is to remedy the burden on and obstruction to commerce in livestock described in paragraph (1) and protect the public interest.

''(c) DEFINITIONS.—In this section:

''(1) CASH SALE.—The term 'cash sale' means a sale in which the seller does not expressly extend credit to the buyer.

''(2) TRUST.—The term 'trust' means 1 or more assets of a buyer that (subsequent to a cash sale of livestock) constitutes the corpus of a trust held for the benefit of an unpaid cash seller and consists of—

''(A) account receivables and proceeds earned from the cash sale of livestock by a dealer or market agency buying on a commission basis;

''(B) account receivables and proceeds of a marketing agency earned on commission from the cash sale of livestock;

''(C) the inventory of the dealer or marketing agency; or

''(D) livestock involved in the cash sale, if the seller has not received payment in full for the livestock and a bona fide third-party purchaser has not purchased the livestock from the dealer or marketing agency.

''(d) HOLDING IN TRUST.—

''(1) IN GENERAL.—The account receivables and proceeds generated in a cash sale made by a dealer or a market agency on commission and the inventory of the dealer or market agency shall be held by the dealer or market agency in trust for the benefit of an unpaid cash seller of the livestock until the seller receives payment in full for the livestock.

''(2) EXEMPTION.—Paragraph (1) does not apply in the case of a cash sale made by a dealer or market agency if the total amount of cash sales made by the dealer or market agency during the preceding 12 months does not exceed $250,000.

''(3) DISHONOR OF INSTRUMENT OF PAYMENT.—A payment in a sale described in paragraph (1) shall not be considered to be made if the instrument by which payment is made is dishonored.

''(4) LOSS OF BENEFIT OF TRUST.—If an instrument by which payment is made in a sale described in paragraph (1) is dishonored, the seller shall lose the benefit of the trust under paragraph (1) on the earlier of—

''(A) the date that is 15 business days after date on which the seller receives notice of the dishonor; or

''(B) the date that is 30 days after the final date for making payment under section 409,

unless the seller gives written notice to the dealer or market agency of the seller's intention to preserve the trust and submits a copy of the notice to the Secretary.

''(5) RIGHTS OF THIRD-PARTY PURCHASER.—The trust established under paragraph (1) shall have no effect on the rights of a bona fide third-party purchaser of the livestock, without regard to whether the livestock are delivered to the bona fide purchaser.

''(e) JURISDICTION.—The district courts of the United States shall have jurisdiction in a civil action—

''(1) by the beneficiary of a trust described in subsection (c)(1), to enforce payment of the amount held in trust; and

''(2) by the Secretary, to prevent and restrain dissipation of a trust described in subsection (c)(1).''.

Subtitle C—Cooperative Bargaining

SEC. ___21. COOPERATIVE BARGAINING.

Section 4 of the Agricultural Fair Practices Act of 1967 (7 U.S.C. 2303) is amended by adding at the end the following:

''(g) To fail to engage in good-faith negotiations with producer cooperatives (including new cooperatives), or to unfairly discriminate among producer cooperatives (including new cooperatives), with respect to the purchase, acquisition, or other handling of agricultural products.''.

Subtitle D—Meat Labeling

SEC. ___31. LABELING OF MEAT AND MEAT FOOD PRODUCTS.

Section 7(b) of the Federal Meat Inspection Act (21 U.S.C. 607(b)) is amended by striking ''require,'' and all that follows through the period at the end and inserting ''require—

''(1) the information required under section 1(n); and

''(2) if it was imported (or was produced from an animal that was located in another country for at least 120 days) and is graded, a grading labeling that bears the words 'imported', 'may have been imported', 'this product contains imported meat', 'this product may contain imported meat', 'this container contains imported meat', or 'this container may contain imported meat', as the case may be, or words to indicate its country of origin.''.

Subtitle E—Interstate Shipment of Meat and Poultry Products

SEC. ___41. FEDERAL AND STATE COOPERATION WITH RESPECT TO MEAT INSPECTION.

(a) WAIVER OF INTRASTATE DISTRIBUTION LIMITATION UNDER THE FEDERAL MEAT INSPECTION ACT.—Section 301(a) of the Federal Meat Inspection Act (21 U.S.C. 661(a)) is amended by adding at the end the following:

''(5) WAIVER OF INTRASTATE DISTRIBUTION LIMITATION.—

''(A) IN GENERAL.—On application of an appropriate State agency with which the Secretary may cooperate under this Act, the Secretary shall reevaluate the applicant State's meat inspection program to verify that its mandatory requirements are at least equal to the Federal inspection, reinspection, and sanitation requirements under title I.

''(B) WAIVERS.—If the Secretary verifies that the mandatory inspection requirements of the applicant State are at least equal to Federal inspection requirements, the limitation in paragraph (1) that restricts meat inspected by the applicant State to intrastate distribution shall be waived by the Secretary.

''(C) INSPECTIONS.—Following any waiver under subparagraph (B), the Secretary may perform random inspections of State-inspected plants within the applicant State to ensure that the mandatory State inspection requirements employed in the State are at least equal to the substantive Federal inspection requirements under title I.

''(D) PERSONNEL.—The Secretary may use Federal personnel, or may cooperate with the appropriate State agency under this Act to train and use State personnel, to perform any random inspections authorized by this paragraph.

''(E) NONCOMPLIANCE.—If a random inspection performed under this paragraph discloses that a State-inspected plant is not employing mandatory inspection requirements that are at least equal to the substantive Federal inspection requirements under title I, the Secretary shall reimpose

the restriction against the interstate distribution of meat and meat products produced at the plant until a subsequent inspection verifies that the plant has reestablished mandatory inspection requirements that are at least equal to the substantive Federal inspection requirements under title I.''.

(b) WAIVER OF INTRASTATE DISTRIBUTION LIMITATION UNDER THE POULTRY PRODUCTS INSPECTION ACT.—Section 5(a) of the Poultry Products Inspection Act (21 U.S.C. 454(a)) is amended by adding at the end the following:

''(5) WAIVER OF INTRASTATE DISTRIBUTION LIMITATION.—

''(A) IN GENERAL.—On application of an appropriate State agency with which the Secretary may cooperate under this Act, the Secretary shall reevaluate the applicant State's poultry inspection program to verify that its mandatory requirements are at least equal to the Federal inspection, reinspection, and sanitation requirements of this Act.

''(B) WAIVERS.—If the Secretary verifies that the mandatory inspection requirements of the applicant State are at least equal to Federal inspection requirements, the limitation in paragraph (1) that restricts poultry or poultry products inspected by the applicant State to intrastate distribution shall be waived by the Secretary.

''(C) INSPECTIONS.—Following any waiver under subparagraph (B), the Secretary may perform random inspections of State-inspected plants within the applicant State to ensure that the mandatory State inspection requirements employed in the State are at least equal to the substantive Federal inspection requirements under this Act.

''(D) PERSONNEL.—The Secretary may use Federal personnel, or may cooperate with the appropriate State agency under this Act to train and use State personnel, to perform any random inspections authorized by this paragraph.

''(E) NONCOMPLIANCE.—If a random inspection performed under this paragraph discloses that a State-inspected plant is not employing mandatory inspection requirements that are at least equal to the substantive Federal inspection requirements of this Act, the Secretary shall reimpose the restriction against the interstate distribution of poultry and poultry products produced at the plant until a subsequent inspection verifies that the plant has reestablished mandatory inspection requirements that are at least equal to the substantive inspection Federal requirements of this Act.''.

Subtitle F—Agricultural Credit

SEC. ___51. REVIEW OF FEDERAL AGRICULTURE CREDIT POLICIES.

The Secretary of Agriculture, in consultation with the Secretary of the Treasury, the Chairman of the Board of Governors of the Federal Reserve System, and the Chairman of the Board of the Farm Credit Administration, shall establish an interagency working group to study—

(1) the extent to which Federal lending practices and policies have contributed, or are contributing, to market concentration in the livestock and dairy sectors of the national economy; and

(2) whether Federal policies regarding the financial system of the United States adequately take account of the weather and price volatility risks inherent in livestock and dairy enterprises.

Subtitle G—Agricultural Trade

SEC. ___61. INTERNATIONAL BARRIERS TO TRADE.

It is the sense of the Senate that—

(1) the Secretary of Agriculture should continue to identify and seek to eliminate unfair trade barriers and subsidies affecting United States beef markets;

(2) the United States and Canadian Governments should expeditiously negotiate the elimination of animal health barriers that are not based on sound science; and

(3) the import ban on beef from cattle treated with approved growth hormones imposed by the European Union should be terminated.

SEC. ___62. USE OF GSM PROGRAMS TO PROMOTE AGRICULTURAL EXPORTS TO AFRICA.

It is the sense of the Senate that the Secretary of Agriculture shall use the Export Credit Guarantee Program (GSM-102) and the Intermediate Export Credit Guarantee Program (GSM-103) established under section 202 of the Agricultural Trade Act of 1978 (7 U.S.C. 5622) to promote the export of United States agricultural commodities to countries of Africa.

Subtitle H—Animal Drug Availability

SEC. 71. SHORT TITLE; REFERENCE.

(a) SHORT TITLE.—This Act may be cited as the ''Animal Drug Availability Act of 1996''.

(b) REFERENCE.—Whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.).

SEC. 72. EVIDENCE OF EFFECTIVENESS.

(a) ORIGINAL APPLICATIONS.—Section 512(d) (21 U.S.C. 360b(d)) is amended by striking paragraph (3) and by adding at the end the following:

''(4) As used in this section, the term 'substantial evidence' means evidence consisting of one or more adequate and well controlled investigations, such as a study in a target species, a study in laboratory animals, any field investigation that may be required under this section and that meets the requirements of subsection (b)(3) if a presubmission conference is requested by the applicant, a bioequivalence study, or an in vitro study, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and reasonably be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.''

(b) CONFORMING AMENDMENTS.—

(1) Section 512(c)(2)(F) (ii) and (iii) (21 U.S.C. 360b(c)(2)(F) (ii) and (iii)) is amended—

(i) by striking ''reports of new clinical or field investigations (other than bioequivalence or residue studies) and,'' and inserting ''substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or,''; and

(ii) by striking ''essential to'' and inserting '', required for''.

(2) Section 512(c)(2)(F)(v) (21 U.S.C. 360b(c)(2)(F)(v)) is amended—

(i) by striking ''(B)(iv)'' each place it appears and inserting ''(F)(iv)'' in lieu thereof;

(ii) by striking ''reports of clinical or field investigations'' and inserting ''substantial evidence of the effectiveness of the drug involved, any studies of animal safety,''; and

(iii) by striking ''essential to'' and inserting ''required for''.

(c) COMBINATION DRUGS.—Section 512(d) (21 U.S.C. 360b(d)) is amended by inserting before paragraph (4) (as added by subsection (a)) the following new paragraph:

''(3) In a case in which an animal drug contains more than one active ingredient, or the labeling of the drug prescribes, recommends, or suggests use of the drug in combination with one or more other animal drugs, and the active ingredients or drugs intended for use in the combination have previously been separately approved for particular uses and conditions of use for which they are intended for use in the combination—

''(A) the Secretary shall not issue an order under paragraph (1) (A), (B), or (D) refusing to approve the application for such combination on human food safety grounds unless the Secretary finds that the application fails to establish that:

''(i) none of the active ingredients or drugs intended for use in the combination, respectively, at the longest withdrawal time of any of the active ingredients or drugs in the combination, respectively, exceeds its established tolerance; or

''(ii) none of the active ingredients or drugs in the combination interferes with the methods of analysis for another of the active ingredients or drugs in the combination, respectively;

''(B) the Secretary shall not issue an order under paragraphs (1) (A), (B), or (D) refusing to approve the application for such combination on target animal safety grounds unless the Secretary finds that—

''(i)(I) there is a substantiated scientific issue, specific to one or more of the active ingredients or animal drugs in the combination, that cannot adequately be evaluated based on information contained in the application for the combination (including any investigations, studies, or tests for which the applicant has a right of reference or use from the person by or for whom the investigations, studies, or tests were conducted); or

''(II) there is a scientific issue raised by target animal observations contained in studies submitted to the Secretary as part of the application; and

''(ii) based on the Secretary's evaluation of the information contained in the application with respect to the issues identified in clauses (i) (I) and (II), paragraphs (1) (A), (B), or (D) apply;

''(C) except in the case of a combination that contains a nontropical antibacterial ingredient or animal drug, the Secretary shall not issue an order under paragraph (1)(E) refusing to approve an application for a combination animal drug intended for use other than in animal feed or drinking water unless the Secretary finds that the application fails to demonstrate that:

''(i) there is substantial evidence that any active ingredient or animal drug intended only for the same use as another active ingredient or animal drug in the combination makes a contribution to labeled effectiveness; or

''(ii) each active ingredient or animal drug intended for at least one use that is different from all other active ingredients or animal drugs used in the combination provides appropriate concurrent use for the intended target population; or

''(iii) where based on scientific information the Secretary has reason to believe the active ingredients or animal drugs may be physically incompatible or have disparate dosing regimens, such active ingredients or animal drugs are physically compatible or do not have disparate dosing regimens; and

''(D) the Secretary shall not issue an order under paragraph (1)(E) refusing to approve an application for a combination animal drug intended for use in animal feed or drinking water unless the Secretary finds that the application fails to demonstrate that:

''(i) there is substantial evidence that any active ingredient or animal drug intended only for the same use as another active ingredient or animal drug in the combination makes a contribution to the labeled effectiveness; or

''(ii) each of the active ingredients or animal drugs intended for at least one use that is different from other active ingredients or

animal drugs used in combination provides appropriate concurrent use for the intended target population; or

''(iii) where a combination contains more than one nontopical antibacterial ingredient or animal drug, there is substantial evidence that each of the nontopical antibacterial ingredients or animal drugs makes a contribution to the labeled effectiveness; or

''(iv) where based on scientific information the Secretary has reason to believe the active ingredients or animal drugs intended for use in drinking water may be physically incompatible, such active ingredients or animal drugs intended for use in drinking water are physically compatible.''

(d) PRESUBMISSION CONFERENCE.—Section 512(b) (21 U.S.C. 360b(b)) is amended by adding at the end the following:

''(3) Any person intending to file an application under subparagraph (1) or a request for an investigational exemption under subsection (j) shall be entitled to one or more conferences prior to such submission to reach agreement acceptable to the Secretary establishing a submission or an investigational requirement, which may include a requirement for a field investigation. A decision establishing a submission or an investigational requirement shall bind the Secretary and the applicant or requester unless (a) the Secretary and the applicant or requestor mutually agree to modify the requirement, or (b) the Secretary by written order determines that a substantiated scientific requirement essential to the determination of safety or effectiveness of the animal drug involved has appeared after the conference. No later than 25 calendar days after each such conference, the Secretary shall provide a written order setting forth scientific justification specific to the animal drug and intended uses under consideration if such decision requires more than one field investigation as being essential to provide substantial evidence of effectiveness for the intended uses of the drug. Nothing in this subparagraph shall be construed as compelling the Secretary to require field investigation.''

(e) IMPLEMENTATION.—

(1) IN GENERAL.—Not later than 6 months after the date of enactment of this Act the Secretary shall issue proposed regulations implementing the amendments made by this Act as described in paragraph (2)(A) of this subsection, and not later than 18 months after the date of enactment of this Act the Secretary shall issue final regulations implementing such amendments. Not later than 12 months after the date of enactment of this Act the Secretary shall issue proposed regulations implementing the other amendments made by this Act as described in paragraphs (2)(B) and (2)(C) of this subsection, and not later than 24 months after the date of enactment of this Act the Secretary shall issue final regulations implementing such amendments.

(2) CONTENTS.—In issuing regulations implementing the amendments made by this Act, and in taking an action to review an application for approval of a new animal drug under section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b), or a request for an investigational exemption for a new animal drug under subsection (j) of such section, that is pending or has been submitted prior to the effective date of the regulations, the Secretary shall—

(A) further define the term ''adequate and well controlled,'' as used in subsection (d)(4) of section 512, to require that field investigations be designed and conducted in a scientifically sound manner, taking into account practical conditions in the field and differences between field conditions and laboratory conditions; *Provided,* That until the regulations required by this subparagraph are issued, nothing in 21 C.F.R. 514.111(a)(5) (April 1, 1996) shall be construed to compel the Secretary to require field investigation under section 512(d)(1)(E), or to apply any of its provisions in a manner inconsistent with the considerations for scientifically sound field investigations set forth in this subparagraph;

(B) further define the term ''substantial evidence'', as defined in subsection (d)(4) of such section, in a manner that encourages the submission of applications and supplemental applications; and

(C) take into account the proposals contained in the citizen petition (FDA Docket No. 91P–0434–CP) jointly submitted by the American Veterinary Medical Association and the Animal Health Institute, dated October 21, 1991.

(f) MINOR SPECIES AND USES.—The Secretary shall consider legislative and regulatory options for facilitating the approval of animal drugs intended for minor species and for minor uses and, within 18 months after the date of enactment of this Act, announce proposals for legislative or regulatory change to the approval process for animal drugs intended for use in minor species for minor uses.

SEC. . 73. LIMITATION ON RESIDUES.

Section 512(d)(1)(F) (21 U.S.C. 360b(d)(1)(F)) is amended to read as follows:

''(F) upon the basis of information submitted to the Secretary as part of the application or any other information before the Secretary with respect to such drug, any use prescribed, recommended, or suggested in labeling proposed for such drug will result in a residue of such drug in excess of a tolerance found by the Secretary to be safe for such drug;''.

SEC. 74. IMPORT TOLERANCES.

Section 512(a) (21 U.S.C. 360b(a)) is amended by adding the following new paragraph at the end:

''(6) For purposes of section 402(a)(2)(D), a use or intended use of a new animal drug shall not be deemed unsafe under section 512 if the Secretary establishes a tolerance for such drug and any edible portion of any animal imported into the United States does not contain residues exceeding such tolerance. In establishing such tolerance, the Secretary shall rely on data sufficient to demonstrate that a proposed tolerance is safe based on similar food safety criteria used by the Secretary to establish tolerances for applications for new animal drugs filed under subsection (b)(1). The Secretary may consider and rely on data submitted by the drug manufacturer, including data submitted to appropriate regulatory authorities in any country where the new animal drug is lawfully used, or data available from a relevant international organization, to the extent such data are not inconsistent with the criteria used by the Secretary to establish a tolerance for applications for new animal drugs filed under subsection (b)(1). For purposes of this paragraph, relevant organization means the Codex Alimenterius Commission or other international organization deemed appropriate by the Secretary. The Secretary may, under procedures specified by regulation, revoke a tolerance established under this paragraph if information demonstrates that the use of the new drug under actual use conditions results in food being imported into the United States with residues exceeding the tolerance.''

SEC. 75. VETERINARY FEED DIRECTIVES.

(a) Section 503(f)(1)(A) (21 U.S.C. 353(f)(1)(A)) is amended by inserting after ''other than man'' the following: '', other than a veterinary feed directive drug intended for use in animal feed or an animal feed bearing or containing a veterinary feed directive drug,''.

(b) New Section 504 (21 U.S.C. 354) is added, to read as follows:

''SEC. 504. VETERINARY FEED DIRECTIVE DRUGS.

''(a)(1) A drug intended for use in or on animal feed which is limited by an approved application filed pursuant to Section 512(b) to use under the professional supervision of a licensed veterinarian is a veterinary feed directive drug. Any animal feed bearing or containing a veterinary feed directive drug shall be fed to animals only by or upon a lawful veterinary feed directive issued by a licensed veterinarian in the course of the veterinarian's professional practice. When labeled, distributed, held, and used in accordance with this section, a veterinary feed directive drug and any animal feed bearing or containing a veterinary feed directive drug shall be exempt from Section 502(f).

''(2) A veterinary feed directive is lawful if it:

''(A) Contains such information as the Secretary may by general regulation or by order require; and

''(B) Is in compliance with the conditions and indications for use of the drug set forth in the notice published pursuant to Section 512(i).

''(3)(A) Any persons involved in the distribution or use of animal feed bearing or containing a veterinary feed directive drug and the licensed veterinarian issuing the veterinary feed directive shall maintain a copy of the veterinary feed directive applicable to each such feed, except in the case of a person distributing such feed to another person for further distribution, such person distributing the feed shall maintain a written acknowledgment for the person to whom the feed is shipped stating that that person shall not ship or move such feed to an animal production facility without a veterinary feed directive or ship such feed to another person for further distribution unless that person has provided the same written acknowledgment to its immediate supplier.

''(B) Every person required under the previous subparagraph to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

''(C) Any person who distributes animal feed bearing or containing a veterinary feed directive drug shall upon first engaging such distribution notify the Secretary of that person's name and place of business. The failure to provide such notification shall be deemed to be an act which results in the drug being misbranded.

''(b) a veterinary feed directive drug and any feed bearing or containing a veterinary feed directive drug shall be deemed to be misbranded if their labeling fails to bear such cautionary statement and such other information as the Secretary may be general regulation or by order prescribe, or their advertising fails to conform to the conditions and indications for use published pursuant to Section 512(i) or fails to contain the general cautionary statement prescribed by the Secretary.

''(c) Neither a drug subject to this section, nor animal feed bearing or containing such a drug, shall be deemed to be a prescription article under any federal or state law.''

(c) Section 512 (21 U.S.C. 360b) is amended as follows:

(1) In subsection (i) by inserting after the words ''including special labeling requirements'' the following: ''and any requirement that an animal feed bearing or containing the new animal drug be limited to use under

the professional supervision of a licensed veterinarian''.

(2) In subparagraph (a)(2)(C) by inserting after ''its labeling,'' the following: ''its distribution, its holding,''.

(3) In subparagraph (m)(4)(B)(i) by inserting after ''paragraph (5)(A)'' the following: ''or under section 504(a)(3)(A)''; and by inserting after ''subparagraph (B) of such paragraph'' the following: ''or section 504(a)(3)(B)''.

(d) Section 301(e) (21 U.S.C. 331(e)) is amended by inserting after ''by section 412'' the following: '', 504,''; and by inserting after ''under Section 412,'' the following: ''504,''.

SEC. 76. FEED MILL LICENSES.

(a) Section 512(a)(1) and (2) (21 U.S.C. 360b(a)(1) and (2)) is amended to read as follows:

''(a) (1) A new animal drug shall, with respect to any particular use or intended use of such drug, be deemed unsafe for the purposes of section 501(a)(5) and section 402(a)(2)(D) unless—

''(A) there is in effect an approval of an application filed pursuant to subsection (b) of this section with respect to such use or intended use of such drug, and

''(B) such drug, its labeling, and such use conform to such approved application.

A new animal drug shall also be deemed unsafe for such purposes in the event of removal from the establishment of a manufacturer, packer, or distributor of such drug for use in the manufacture of animal feed in any State unless at the time of such removal such manufacturer, packer, or distributor has an unrevoked written statement from the consignee of such drug, or notice from the Secretary, to the effect that, with respect to the use of such drug in animal feed, such consignee—

''(i) holds a license issued under subsection (m) of this section and has in its possession current approved labeling for such drug in animal feed; or

''(ii) will, if the consignee is not a user of the drug, ship such drug only to a holder of a license issued under subsection (m) of this section.

''(2) An animal feed bearing or containing a new animal drug shall, with respect to any particular use or intended use of such animal feed, be deemed unsafe for the purposes of section 501(a)(6) unless—

''(A) there is in effect an approval of an application filed pursuant to subsection (b) of this section with respect to such drug, as used in such animal feed,

''(B) such animal feed is manufactured at a site for which there is in effect a license issued pursuant to subsection (m)(1) of this section to manufacture such animal feed, and

''(C) such animal feed bears approved labeling, and such use conforms to the conditions and indications of use published pursuant to subsection (i) of this section.''

(b) Section 512(m) (21 U.S.C. 360b(m)) is amended to read as follows:

''(m) (1) Any person may file with the Secretary an application for a license to manufacture animal feeds bearing or containing new animal drugs. Such person shall submit to the Secretary as part of the application (A) a full statement of the business name and address of the specific facility at which the manufacturing is to take place and the facility's registration number, (B) the name and signature of the responsible individual or individuals for that facility, (C) a certification that the animal feeds bearing or containing new animal drugs are manufactured and labeled in accordance with the applicable regulations published pursuant to subsection (i) of this section, and (D) a certification that the methods used in, and the facilities and controls used for, manufacturing, processing packaging, and holding such animal feeds are in conformity with current good manufacturing practice as described in section 501(a)(2)(B).

''(2) Within 90 days after the filing of an application pursuant to subsection (m)(1), or such additional period as may be agreed upon the Secretary and the applicant, the Secretary shall either (A) issue an order approving the application if the Secretary then finds that none of the grounds for denying approval specified in paragraph (3) applies, or (B) give the applicant notice of an opportunity for a hearing before the Secretary under paragraph (3) on the question whether such application is approvable. The procedure governing such a hearing shall be the procedure set forth in the last two sentences of subsection (c)(1).

''(3) If the Secretary, after due notice to the applicant in accordance with paragraph (2) and giving the applicant an opportunity for a hearing in accordance with such paragraph, finds, on the basis of information submitted to the Secretary as part of the application, on the basis of a preapproval inspection, or on the basis of any other information before the Secretary—

''(A) that the application is incomplete, false, or misleading in any particular;

''(B) that the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such animal feed are inadequate to preserve the identity, strength, quality, and purity of the new animal drug therein; or

''(C) that the facility manufacturers animal feeds bearing or containing new animal drugs in a manner that does not accord with the specifications for manufacture, or labels animal feeds bearing or containing new animal drugs in a manner that does not accord with the conditions or indications of use that are published pursuant to subsection (i) of this section; the Secretary shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that subparagraphs (A) through (C) do not apply, the Secretary shall issue an order approving the application. An order under this subsection approving an application for a license to manufacture animal feeds bearing or containing new animal drugs shall permit a facility to manufacture only those animal feeds bearing or containing new animal drugs for which there are in effect regulations pursuant to subsection (i) of this section relating to the use of such drugs in or on such animal feed.

''(4)(A) The Secretary shall, after due notice and opportunity for hearing to the applicant, revoke a license to manufacture animal feeds bearing or containing new animal drugs under this subsection if the Secretary finds—

''(i) that the application contains any untrue statement of a material fact; or

''(ii) that the applicant has made changes that would cause the application to contain any untrue statements of material fact or that would affect the safety or effectiveness of the animal feeds manufactured at the facility unless the applicant has supplemented the application by filing with the Secretary adequate information respecting all such changes and unless there is in effect an approval of the supplemental application.

If the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the health of humans or of the animals for which such animal feed is intended, the Secretary may suspend the license immediately, and give the applicant prompt notice of the action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this sentence shall not be delegated.

''(B) The Secretary may also, after due notice and opportunity for hearing to the applicant, revoke a license to manufacture animal feed under this subsection if the Secretary finds—

''(i) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports in accordance with a regulation or order under paragraph (5)(A) of this subsection or section 504(a)(3)(A), or the applicant has refused to permit access to, or copying or verification of, such records as required by subparagraph (B) of such paragraph or section 504(a)(3)(B);

''(ii) that on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when such license was issued, the methods used in, or the facilities and controls used for, the manufacture, processing, packing, and holding of such animal feed are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drug therein, and were not made adequate within a reasonable time after receipt of written notice from the Secretary, specifying the matter complained of;

''(iii) that on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when such license was issued, the labeling of any animal feeds, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or

''(iv) that on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when such license was issued, the facility has manufactured, processed, packed, or held animal feed bearing or containing a new animal drug adulterated under section 501(a)(6) and the facility did not discontinue the manufacture, processing, packing, or holding of such animal feed within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of.

''(C) The Secretary may also revoke a license to manufacture animal feeds under this subsection if an applicant gives notice to the Secretary of intention to discontinue the manufacture of all animal feed covered under this subsection, and waives an opportunity for a hearing on the matter.

''(D) Any order under paragraph (4) of this subsection shall state the findings upon which it is based.

''(5) When a license to manufacture animal feeds bearing or containing new animal drugs has been issued:

''(A) the applicant shall establish and maintain such records, and make such reports to the Secretary, or (at the option of the Secretary) to the appropriate person or persons holding an approved application filed under subsection (b), as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) or paragraph (4) of this subsection;

''(B) every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

''(6) To the extent consistent with the public health, the Secretary may promulgate

regulations for exempting from the operation of this subsection facilities that manufacture, process, pack, or hold animal feeds bearing or containing new animal drugs.''

(c) TRANSITIONAL PROVISION.—A person engaged in the manufacture of animal feeds bearing or containing new animal drugs who holds at least one approved medicated feed application for an animal feed bearing or containing new animal drugs, the manufacture of which was not otherwise exempt from the requirement for an approved medicated feed application at the time of enactment of this Act, shall be deemed to hold a license for the manufacturing site identified in the approved medicated feed application. The revocation of license provisions of section 512(m)(4) of the Federal Food, Drug, and Cosmetic Act, as amended by this Act, shall apply to such licenses. Such license shall expire within 18 months from the date of enactment of this Act unless the person submits to the Secretary a completed license application for the manufacturing site accompanied by a copy of an approved medicated feed application for such site, which license application shall be deemed to be approved upon receipt by the Secretary.

WYDEN AMENDMENT NO. 5352

Mr. WYDEN proposed an amendment to the bill, H.R. 3662, supra; as follows:

At the appropriate place in title I, insert the following:

SEC 10. WATERSHED RESTORATION AND ENHANCEMENT AGREEMENTS.

(a) IN GENERAL.—For fiscal year 1997 and each fiscal year thereafter, appropriations made for the Bureau of Land Management may be used by the Secretary of the Interior for the purpose of entering into cooperative agreements with willing private landowners for restoration and enhancement of fish, wildlife, and other biotic resources on public or private land or both that benefit these resources on public lands within the watershed.

(b) DIRECT AND INDIRECT WATERSHED AGREEMENTS.—The Secretary of the Interior may enter into a watershed restoration and enhancement agreement—

(1) directly with a willing private landowner: or

(2) indirectly through an agreement with a State, local, or tribal government or other public entity, educational institution, or private nonprofit organization.

(c) TERMS AND CONDITIONS.—In order for the Secretary to enter into a watershed restoration and enhancement agreement—

(1) the agreement shall—

(A) include such terms and conditions mutually agreed to by the Secretary and the landowner:

(B) improve the viability of and otherwise benefit the fish, wildlife, and other biotic resources on public land in the watershed.

(C) authorize the provision of technical assistance by the Secretary in the planning of management activities that will further the purposes of the agreement;

(D) provide for the sharing of costs of implementing the agreement among the Federal Government, the landowner, and other entities, as mutually agreed on by the affected interests: and

(E) ensure that any expenditure by the Secretary pursuant to the agreement is determined by the Secretary to be in the public interest; and

(2) the Secretary may require such other terms and conditions as are necessary to protect the public investment on private lands, provided such terms and conditions are mutually agreed to by the Secretary and the landowner.

BUMPERS (AND OTHERS) AMENDMENT NO. 5353

Mr. BUMPERS (for himself, Mr. GREGG, and Mr. KERRY) proposed an amendment to the bill, H.R. 3662, supra; as follows:

At the end of the pending committee amendment ending on line 4 on page 25, add the following:

SEC. . GRAZING FEES.

(a) GRAZING FEE.—Notwithstanding any other provision of law and subject to subsections (b) and (c), the Secretary of the Interior and the Secretary of Agriculture shall charge a fee for domestic livestock grazing on public rangelands as provided for in section 6(a) of the Public Rangelands Improvement Act of 1978 (43 U.S.C. 1905(a)) and Executive Order 12548 (51 F.R. 5985).

(b) DETERMINATION OF FEE.—(1) Permittees or lessees, including related persons, who own or control livestock comprising less than 2,000 animal unit months on the public rangelands pursuant to one or more grazing permits or leases shall pay the fee as set forth in subsection (a).

(2) Permittees or lessees, including related persons, who own or control livestock comprising more than 2,000 animal unit months or the public rangelands pursuant to one or more grazing permits or leases shall pay the fee as set forth in subsection (a) for the first 2,000 animal unit months. For animal unit months in excess of 2,000, the fee shall be the higher of either—

(A) the average grazing fee (weighted by animal unit months) charged by the State during the previous grazing year for grazing on State lands in which the lands covered by the permit or lease are located; or

(B) the Federal grazing fee set forth in subsection (a), plus 25 percent.

(c) DEFINITIONS.—For the purposes of this section—

(1) State lands shall include school, education department, and State lands board lands;

(2) individual members of a grazing association shall be considered as individual permittees or lessees in determining the appropriate grazing fee; and

(3) related persons includes—

(i) the spouse and dependent children (as defined in section 152 of the Internal Revenue Code of 1986), of the holder of the permit or lease; and

(ii) a person controlled by, or controlling, or under common control with the holder of the permit or lease.

THE ALASKA NATIONAL INTEREST LANDS CONSERVATION ACT AMENDMENT ACT OF 1996

MURKOWSKI AMENDMENT NO. 5354

(Ordered referred to the Committee on Energy and Natural Resources.)

Mr. MURKOWSKI submitted an amendment intended to be proposed by him to the bill (S. 1920) to amend the Alaska National Interest Lands Conservation Act, and for other purposes; as follows:

(a) Section 1(a) is amended by adding ''and an ANCSA'' after the word ''ANILCA'' on page 1, line 10, and page 2, line 4.

(b) Section 1(b) is deleted.

(c) Section 1(d) is deleted.

(d) Section 1(e) is deleted.

Section 1(r) is amended by striking all after the word ''follows'' and inserting in lieu thereof: ''Inability to provide the service, after enactment of this Act, for up to a two-year period shall not constitute a relinquishment of a right under this section.''.

(e) Section 1(s) is deleted.

(f) At the end of the bill add a new section, section (2) as follows:

''SEC. 2. STATUTORY CONSTRUCTION.

Nothing in this Act is intended to affect—

(1) the provisions for subsistence uses in Alaska set forth in the Alaska National Interest Lands Conservation Act (Public Law 96–487), including those in titles III and VIII of that Act;

(2) the provisions of section 102 of the Alaska National Interest Lands Conservation Act, the jurisdiction over subsistence uses in Alaska, or any assertion of subsistence used in the Federal courts; and

(3) the manner in which section 810 of the Alaska National Interest Lands Conservation Act is implemented in refuges in Alaska, and the determination of compatible use as it relates to subsistence uses in these refuges.''.

Mr. MURKOWSKI. Mr. President, today I rise for the purpose of submitting an amendment to legislation within the jurisdiction of the Senate Committee on Energy and Natural Resources.

This amendment addresses some of the concerns raised by Alaskans on S. 1920 as introduced. I plan to discuss the bill and the amendment at a hearing to be held in the Senate and Energy and Natural Resources Committee on Wednesday, September 18, 1996.

ADDITIONAL STATEMENTS

CHANGES TO THE BUDGET RESOLUTION DISCRETIONARY SPENDING LIMITS, APPROPRIATE BUDGETARY AGGREGATES, AND APPROPRIATIONS COMMITTEE ALLOCATION

● Mr. DOMENICI. Mr. President, section 103(c) of Public Law 104–121, the Contract With America Advancement Act, requires the chairman of the Senate Budget Committee to adjust the discretionary spending limits, the appropriate budgetary aggregates, and the Appropriations Committee's allocation contained in the most recently adopted budget resolution—in this case, House Concurrent Resolution 178—to reflect additional new budget authority and outlays for continuing disability reviews, CDR's, as defined in section 201(g)(1)(A) of the Social Security Act. The maximum amount of such adjustments was modified by section 211 of Public Law 104–193, the Personal Responsibility and Work Opportunity Reconciliation Act of 1996.

I hereby submit revisions to the nondefense discretionary spending limits for fiscal year 1997 contained in section 301 of House Concurrent Resolution 178 in the following amounts:

Budget Authority:	
Current nondefense discretionary spending limit	$230,988,000,000
Adjustment	175,000,000
Revised nondefense discretionary spending limit	$231,163,000,000