

List of Subjects in 7 CFR Parts 1307 and 1308

Milk.

Codification in Code of Federal Regulations

For reasons set forth in the preamble, the Northeast Dairy Compact Commission proposes to amend 7 CFR parts 1307 and 1308 as follows:

PART 1307—PAYMENTS FOR MILK

1. The authority citation for part 1307 continues to read as follows:

Authority: 7 U.S.C. 7256

§ 1307.4 [Redesignated as §1307.5]

2. Section 1307.4 is redesignated § 1307.5.

3. A new § 1307.4 is added to read as follows:

§ 1307.4 Method of payment.

If the combined total of the handler's producer-settlement fund debit for the month as determined under § 1307.2(a) and the handler's obligation for the month as determined under § 1308.1 of this chapter is greater than \$25,000, then the handler must make payment to the compact commission by electronic transfer of funds on or before the 18th day after the end of the month.

PART 1308—ADMINISTRATIVE ASSESSMENT

1. The authority citation for part 1308 continues to read as follows:

Authority: 7 U.S.C. 7256.

2. Section 1308.1 is amended by revising the introductory text to read as follows:

§ 1308.1 Assessment for pricing regulations administration.

On or before the 18th day after the end of the month, each handler shall pay to the compact commission his pro rata share of the expense of administration of this pricing regulation. The payment shall be at the rate of 3.2 cents per hundredweight. The Commission may waive, or set the rate at an amount less than 3.2 cents, pursuant to § 1308.2. The payment shall apply to:

* * * * *

3. A new § 1308.2 is added to read as follows:

§ 1308.2 Method to waive or change the administration assessment.

The compact commission may waive or change the assessment for pricing regulation administration to maintain the operating reserve in the range of 80% to 120% of four months operating

expenses, as determined in the budget approved by the commission. The compact commission will announce, pursuant to § 1305.2 of this chapter, the waiver or change in rate of assessment.

Dated: January 22, 1999.

Kenneth M. Becker,

Executive Director.

[FR Doc. 99-1993 Filed 1-27-99; 8:45 am]

BILLING CODE 1650-01-P

DEPARTMENT OF AGRICULTURE**Animal and Plant Health Inspection Service****9 CFR Parts 1 and 3**

[Docket No. 98-106-1]

Animal Welfare; Petition for Rulemaking

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of petition and request for comments.

SUMMARY: We are notifying the public of our receipt of a petition for rulemaking, and we are soliciting public comment on that petition. The petition, sponsored by several petitioners, requests that the Secretary of Agriculture amend the definition of "animal" in the Animal Welfare Act regulations to remove the current exclusion of rats and mice bred for use in research and birds and grant such other relief as the Secretary deems just and proper."

DATES: Consideration will be given only to comments received on or before March 29, 1999.

ADDRESSES: We are accepting comments in two ways—either in hard copy or via the Internet. However, comments submitted in either method must be submitted as described below; comments sent to other than the physical address or the Internet address listed below will not be considered. For comments submitted in hard copy, please send an original and three copies to Docket No. 98-106-1, Regulatory Analysis and Development, PPD, APHIS, suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comments refer to Docket No. 98-106-1. Anyone wishing to see copies of comments received or the petition may do so by coming to USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Please call ahead on (202) 690-2817 to facilitate entry into the comment reading room. Any person

who wishes to submit a comment electronically must use a form located on the Internet at <http://comments.aphis.usda.gov>. Electronically submitted comments need only be submitted once. These comments are available for public viewing at the same Internet address.

FOR FURTHER INFORMATION CONTACT: Dr. Jerry DePoyster, Senior Veterinary Medical Officer, AC, APHIS, 4700 River Road Unit 84, Riverdale, MD 20737-1228, (301) 734-7833.

SUPPLEMENTARY INFORMATION:**Background**

Under the Animal Welfare Act (AWA) (7 U.S.C. 2131 *et seq.*), the Secretary of Agriculture is authorized to promulgate standards and other requirements governing the humane handling, care, treatment, and transportation of certain animals by dealers, research facilities, exhibitors, and carriers and intermediate handlers. The Secretary has delegated responsibility for administering the AWA to the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA). Within APHIS, the responsibility for AWA administration has been delegated to Animal Care. Regulations established under the Act are contained in the Code of Federal Regulations (CFR) in 9 CFR parts 1, 2, and 3. Part 1 contains definitions for terms used in parts 2 and 3; part 2 contains general requirements for regulated parties; and part 3 contains specific requirements for the care and handling of certain animals.

The Secretary has received a petition for rulemaking sponsored by the Alternatives Research and Development Foundation; In Vitro International and Rich Ulmer, president of In Vitro International; Barbara Orlans, senior research fellow at the Kennedy Institute of Ethics at Georgetown University; George K. Russell, professor for the Department of Biology at Adelphi University; and Ruy Tchao, associate professor for the Department of Pharmacology and Toxicology at the Philadelphia College of Pharmacy and Science. The petition requests the Secretary of Agriculture to take two actions: (1) Initiate rulemaking proceedings to amend the definition of "animal" contained at 9 CFR 1.1 to eliminate the exclusion of birds, rats, and mice; and (2) grant such other relief as the Secretary deems just and proper.

The term "animal" is defined in the AWA as follows: any live or dead dog, cat, monkey (nonhuman primate mammal), guinea pig, hamster, rabbit, or such other warmblooded animal as the Secretary may determine is

being used, or is intended for use, for research, testing, experimentation, or exhibition purposes, or as a pet; but such term excludes horses not used for research purposes and other farm animals, such as, but not limited to livestock or poultry used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber. With respect to a dog, the term means all dogs including those used for hunting, security, or breeding purposes.

We believe that the language "or such other warmblooded animal as the Secretary may determine" gives the Secretary broad power to include or exclude certain animals from AWA regulation, and we further believe that the legislative history of the AWA supports this conclusion. For example, a House Committee report on the 1970 amendments to the AWA demonstrates that Congress intended for the Secretary to have the authority to determine which warmblooded animals should be included in coverage under the Act. In promulgating the AWA regulations, the Secretary used this discretionary authority to exclude all birds and the types of rats and mice most commonly bred and used for research from coverage under the AWA. Accordingly, 9 CFR 1.1 defines "animal" for purposes of AWA enforcement as:

any live or dead dog, cat, nonhuman primate, guinea pig, hamster, rabbit, or any other warmblooded animal, which is being used, or is intended for use for research, teaching, testing, experimentation, or exhibition purposes, or as a pet. This term excludes: Birds, rats of the genus *Rattus* and mice of the genus *Mus* bred for use in research, and horses not used for research purposes and other farm animals, such as, but not limited to livestock or poultry, used or intended for use as food or fiber, or livestock or poultry used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber. With respect to a dog, the term means all dogs, including those used for hunting, security, or breeding purposes.

Through this definition, the AWA regulations since 1972 have excluded birds and laboratory rats and mice from coverage. Congress has amended the AWA numerous times since its enactment but has never expressed any dissatisfaction with this exclusion.

The reason USDA excludes the types of rats and mice commonly bred and used for research and birds from coverage under the AWA regulations is for purposes of effective resource management and because we believe that the majority of these animals are already being afforded certain protections. AWA enforcement resources are determined annually by congressional appropriation. In

administering the AWA, Animal Care constantly strives to use this finite amount of resources as prudently as possible to meet congressional intent under the law. APHIS enforces the AWA by inspecting the premises of regulated facilities and taking regulatory action against persons found to be in violation of the AWA regulations. In fiscal year 1997, a staff of about 73 Animal Care inspectors conducted almost 16,000 inspections to ensure compliance with the AWA regulations. Our goal is to provide effective protection for as many animals covered by the AWA as we can.

For the last 7 years, the appropriation for AWA enforcement has been basically constant at about \$9.2 million; we anticipate that this appropriation will remain at the current level in the coming years. However, because of inflation, the purchasing power of the AWA enforcement budget decreases from year to year. Level funding has necessitated the elimination of the financial equivalent of three to five Animal Care positions per year. Additional information about the Animal Care programs staffing and accomplishments may be obtained from the Animal Care home page on the Internet at <http://www.aphis.usda.gov/ac/>, by reviewing the Animal Care Annual Report to Congress, or by calling (301) 734-7799.

We believe that the cost of extending AWA enforcement to all entities and facilities that handle rats of the genus *Rattus*, mice of the genus *Mus*, and birds for purposes covered by the AWA would be substantial. We want the public to know that we believe that extending AWA coverage to laboratory rats, laboratory mice, and birds would significantly affect overall AWA enforcement, as discussed below.

We also want the public to know that we believe that extending AWA coverage to laboratory rats, laboratory mice, and birds would have a substantial financial impact on the affected entities and that the vast majority of rats, mice, and birds being used in biomedical research are already being afforded certain protections. USDA and the Public Health Service (PHS) of the U.S. Department of Health and Human Services estimate that at least 90 percent of the rats, mice, and birds being used for research in the United States are provided oversight by PHS assurance, voluntary accreditation, or both. Most biomedical research in the United States is performed in laboratories funded at least in part by PHS. The PHS Policy on Humane Care and Use of Laboratory Animals covers rats, mice, and birds, in addition to all

other live, vertebrate animals that are involved in activities supported by PHS. The PHS Policy requires an Animal Welfare Assurance, which commits the research institution to a program of animal care and use that is consistent with the *Guide for the Care and Use of Laboratory Animals*, a publication produced by the National Research Council to assist institutions in caring for and using animals in ways judged to be scientifically, technically, and humanely appropriate. The animal care standards listed in the *Guide* are at least consistent with and in many cases exceed the standards specified in the AWA regulations.

In addition to PHS oversight, many U.S. research facilities are accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC). This private organization, through inspections and reviews, accredits laboratories that meet or exceed the animal care standards specified in the *Guide*. Research facilities seek AAALAC accreditation for assistance with public relations and in receiving grants. AAALAC currently accredits approximately 600 U.S. research facilities, and approximately 40 percent of USDA-regulated research facilities are AAALAC accredited.

We have seriously considered the issue of bringing laboratory rats, laboratory mice, and birds under AWA regulation. As a regulatory agency, we are required to consider the effects of the regulations we promulgate and enforce on affected entities. Extending AWA coverage to facilities that use birds, laboratory rats, or laboratory mice would affect numerous entities, including many small businesses. As stated above, many of these entities currently meet PHS and AAALAC requirements. If these entities come under APHIS regulation, they might not incur costs associated with coming into compliance with the AWA requirements. However, these entities would incur costs pertaining to licensing or registration, and we do not necessarily believe that these new expenses would translate into a higher standard of protection for the animals, which are already being maintained in conditions that meet or exceed the AWA requirements.

The AWA requires USDA to perform at least one inspection of each regulated research facility every year. U.S. research facilities use vast numbers of rats and mice in research and testing, and many research facilities use these species exclusively. In 1990, APHIS conducted a study of the potential effects of extending AWA protection to

laboratory rats, laboratory mice, and birds. The estimated annual cost for conducting inspections of the additional research facilities that would come under AWA regulation was at least \$3.5 million (in 1990 dollars), or roughly one-third of the current Animal Care budget. This estimate represents only the minimum additional annual funding that would have been needed by APHIS to inspect research facilities that use birds, rats, and mice; it does not include the additional funding that would have been needed to conduct inspections of breeders, dealers, carriers, and intermediate handlers of birds, rats, and mice. Also excluded from this estimate are first-year implementation expenditures (for training, automobile purchases, etc.) and additional annual enforcement costs.

The following facts were derived from the 1990 study and an informal survey of Animal Care managers in 1998:

- The number of regulated research facilities in the United States in 1990 was 2,410. If rats and mice bred for use in research had been brought under AWA regulation that year, an estimated additional 2,324 research sites would have required inspection. Therefore, extending AWA protection to laboratory rats and mice alone would have doubled the number of regulated research facilities.

- Regulating the research facilities, breeders, dealers, and exhibitors that handled birds in 1990 would have added an estimated 2,302 facilities to the Animal Care inspection workload.

- To maintain the level of AWA inspections conducted in 1990 and conduct inspections of facilities that deal with rats, mice, and birds, Animal Care would have needed to hire an estimated additional 34 veterinarians and 16 animal health technicians.

As stated previously, past appropriations have necessitated reductions in Animal Care staffing. Therefore, a staffing increase of the magnitude projected in 1990 would be an impossibility within the current and anticipated Animal Care budget. However, we recognize that the estimates made in the 1990 study are dated at this point, and we would appreciate more current data. Commenters are encouraged to provide information on the numbers of facilities that would come under AWA regulation today if USDA were to regulate the care provided to rats and mice bred for use in research and birds.

Despite the resource issues, we have examined many possible courses of action to bring laboratory rats, laboratory mice, and birds under AWA protection. Four options and the known

and anticipated drawbacks of each are discussed below:

1. Regulate the care provided to all rats, mice, and birds being used for purposes covered by the AWA at all facilities, including those not currently being regulated by USDA.

- For APHIS: This option would greatly increase the Animal Care inspection workload and, therefore, would cause inspection activities for all currently regulated facilities—especially breeders, dealers, carriers, and zoos and circuses—to be dramatically curtailed.

- In addition, developing regulatory standards for the care of birds would be difficult, time-consuming, and expensive because the housing and husbandry needs of avian species vary greatly. All Animal Care inspectors would need additional training in the veterinary and husbandry care needs of birds.

- For the regulated industry: Entities not currently regulated by APHIS would need to absorb costs associated with AWA regulation.

2. Regulate the care provided to all rats, mice, and birds at research facilities only.

- This option would increase the number of research sites for Animal Care to inspect and, therefore, would seriously compromise inspection activities for other currently regulated facilities, such as breeders, dealers, carriers, and exhibitors.

- As with option 1, entities not currently subject to regulation by APHIS would become subject to such regulation, and the additional costs to these entities would not necessarily result in greater protection for the animals.

3. Regulate the care provided to all rats and mice at research facilities only.

- Again, this option would increase the number of facilities Animal Care inspects. However, the number would be less than the numbers that would result from the adoption of options 1 or 2. This increase in regulated facilities would also result in reduced inspection activities for currently regulated facilities.

- As with options 1 and 2, research facilities not currently subject to regulation by APHIS would become subject to such regulation.

4. Maintain the status quo. Do not initiate regulation of facilities dealing with rats of the genus *Rattus*, mice of the genus *Mus*, and birds.

- Current AWA inspection activities would not be adversely affected, and no additional entities would need to bear the costs of APHIS regulation.

In addition, we are exploring the possibility of obtaining partial funding

for AWA enforcement through user fee authority. USDA is considering seeking the statutory authority to charge fees for the services required to issue and renew licenses and registrations for conducting AWA-regulated activities. Our goal is to recover approximately 30 to 40 percent of our current operating expenses through user fees. However, even if such authority is granted, the amount collected would likely offset a reduction from the current appropriation and would not enable Animal Care to extend effective enforcement services to all facilities that use birds and laboratory rats and mice. In that context, we are seeking public comment on whether it would be appropriate to seek authority to charge user fees for costs associated with any services pertaining to the regulation of the care provided to laboratory rats, laboratory mice, or birds. Because these would be new, rather than existing, services, they could be funded by user fees, with no additional cost to the Federal Government.

In summary, we believe that extending AWA protection to rats and mice bred for use in research and birds with current AWA enforcement resources would have serious consequences for the protection of other species covered by the AWA regulations. To conduct annual inspections of research facilities that use rats, mice, and birds, we would need to reduce by approximately one-third the number of inspections in other areas, such as breeders and dealers of dogs and cats, commercial carriers, large and small zoos, and circuses. We believe that such a reduction in inspection services would greatly compromise our efforts to ensure AWA compliance of all currently regulated facilities and adequate protection to all currently covered species.

The petition is reprinted below. We invite comments on the proposed changes discussed in the petition. In particular, we are soliciting comments addressing the questions listed below before the petition. While we are providing this list of questions for the convenience of persons who wish to submit comments, we will accept written comments in any format or via the electronic form mentioned previously in **ADDRESSES**.

Authority: 7 U.S.C. 2131–2159; 7 CFR 2.22, 2.80, and 371.2(g).

Done in Washington, DC, this 21st day of January 1999.

Craig A. Reed,

Administrator, Animal and Plant Health Inspection Service.

BILLING CODE 3410-34-P

Comments on the Petition for Rulemaking to the Secretary of Agriculture
Regarding the Exclusion of
Rats of the Genus Rattus, Mice of the Genus Mus, and Birds
From the Definition of "Animal" in the Animal Welfare Act Regulations

Question 1: Should the definition of "animal" in 9 CFR part 1 be revised to include laboratory rats, laboratory mice, and birds, or any of the three?

Comment:

Question 2: If the definition of "animal" in 9 CFR part 1 is amended to include laboratory rats, laboratory mice, and birds, should Animal Care regulate the care provided to these species in all circumstances covered by the AWA or in certain circumstances, such as use in research, only?

Comment:

Question 3: The AWA requires that USDA inspect all research facilities at least once a year. Because of current and anticipated resources for AWA enforcement, any coverage of rats, mice, or birds would result in significantly reduced numbers of inspections for other AWA-regulated entities, such as dog and cat dealers, intermediate handlers and carriers, large and small zoos, and circuses. Should AWA enforcement activities be equal for all species covered by the AWA? If not, what should be the relative priorities?

Comment:

Question 4: If the definition of "animal" in 9 CFR part 1 is amended to include laboratory rats, laboratory mice, and birds, how many additional facilities would come under USDA regulation?

Comment:

Question 5: Other comments?

Petition for Rulemaking To Amend the USDA Regulation Excluding Birds, Rats, and Mice From Coverage Under the Animal Welfare Act

Alternatives Research and Development Foundation, 801 Old York Road, Jenkintown, PA 19046, and Rich Ulmer, President, In Vitro International, 16632 Milikan Avenue, Irvine, CA 92606, *et al.* v. Daniel Glickman, Secretary of Agriculture, U.S. Department of Agriculture, 1400 Independence Ave, S.W., Room 200A, Whitten Building, Washington, DC 20250.

I. Introduction

Pursuant to the Right to Petition Government Clause contained in the First Amendment of the United States Constitution,¹ the Administrative Procedure Act,² and the United States Department of Agriculture ("USDA") implementing regulations,³ petitioners file this petition with the USDA and respectfully request the Secretary to undertake the following actions:

(1) Initiate rulemaking proceedings to amend the definition of "animal" contained at 9 CFR 1.1 to eliminate the exclusion of birds, rats and mice; and
(2) Grant such other relief as the Secretary deems just and proper.

USDA's regulation excluding "[b]irds, rats of the genus *Rattus*, and mice of the genus *Mus* bred for use in research" (hereinafter referred to as "birds, rats, and mice") is arbitrary and capricious, an abuse of agency discretion and otherwise not in accordance with law. Petitioners request that a new rulemaking procedure be initiated that is consistent with the Animal Welfare Act ("AWA") by regulating birds, rats, and mice.

I. Petitioners

The AWA, 7 U.S.C. 2131 *et seq.*, is the only federal law regulating the use of

animals in research, testing, and education. The 1985 Amendments, 7 U.S.C. note, to the AWA were passed, in part, because Congress found that,

(2) methods of testing that do not use animals are being and continue to be developed which are faster, less expensive, and more accurate than traditional animal experiments for some purposes and further opportunities exist for the development of these methods of testing;

(3) measures which eliminate or minimize the unnecessary duplication of experiments on animals can result in more productive use of Federal funds.

Explicit provisions of the AWA require research facilities to undertake steps in the direction of using alternatives to animals when an animal experiment causes pain or distress.⁴ These requirements must be met whenever "animals" are used. Thus, in order to further the Congressional goals of developing methods of testing which do not use animals and developing measures which eliminate or minimize duplication of experiments on animals, the regulatory definition of "animal" is of critical importance. Simply put, if an animal is defined as not being an animal by regulation, there is no statutory or regulatory requirement, that alternatives, i.e., non-animal models, be considered or used instead of that animal. Because USDA has defined birds, rats, and mice as non-animals, there is no statutory or regulatory requirement that anyone consider alternatives to the use of these creatures.

This "Petition for Rulemaking to Amend the USDA Regulation Excluding Birds, Rats, and Mice from Coverage Under the Animal Welfare Act" is filed on behalf of the following petitioners:

Petitioner Alternatives Research and Development Foundation ("ARDF") is located at 801 Old York Road, Jenkintown, PA 19046. ARDF is a four year old nonprofit organization that is affiliated with the American Anti-Vivisection Society ("AAVS"). ARDF supports the development and promotes the use of non-animal methods in research, testing, and education. ARDF has funded numerous in vitro, non-animal methods, projects to promote the development and use of in vitro methods. Some of the projects ARDF has funded include, a computer graphic animations for interactive videodisc alternatives to live animal teaching, the development of an in vitro alternative to replace the isolate tissue bath assay, and the development of a simple, inexpensive alternative to replace mice for small, medium, and large scale

monoclonal antibody production. ARDF also gives the annual Cave Award to distinguished people who have developed and promoted the use of alternative methods.

Not only does ARDF sponsor alternative research, but it also works to educate researchers about the use of in vitro methods. In September 1997, the Johns Hopkins University and The Office for Protection from Research Risks of the National Institutes of Health ("NIH") hosted a workshop on the "Alternatives in Monoclonal Antibody Production." This workshop resulted from ARDF's petition to NIH concerning the ASCITES method, a painful form of animal research. ARDF also participated in several workshops sponsored by the organization, Public Responsibility in Medicine and Research "PRIM&R" in March 1998 on "In Vitro and In Vivo Production of Polyclonal and Monoclonal Antibodies." Petitioner is also organizing workshops for the Third World Congress on Alternatives and Animal Use in the Life Sciences. ARDF's programs work to promote the development and use of alternative methods, however, these programs are frustrated and impeded by USDA's illegal definition. USDA has illegally defined "animal" by excluding birds, rats, and mice. Consequently, there is no statutory requirement for researchers to consider alternatives when experimenting on birds, rats, and mice.

Petitioner Rich Ulmer is the President of In Vitro International located at 16632 Milikan Avenue, Irvine, CA 92606. Petitioner heads a science-based, publicly traded company that develops, manufactures, and markets laboratory tests to replace animal testing. Agents represent the company in the United States and around the world. Petitioner represents one of only three in vitro companies in the world. In Vitro International, also a petitioner, was established to protect the well-being of laboratory animals by promoting the development and use of alternative methods. In Vitro International is marketing a technology that is intended to minimize animal pain and distress by promoting ocular and dermal irritation alternatives for testing the misuse of products such as cosmetics, shampoos, deodorants, and car wash fluids. Because USDA definition of "animal" excludes birds, rats, and mice from AWA protection, researchers have no requirement to consider alternative methods before testing, researching, or experimenting on these "non-animals." This exclusion affects the company's ability to successfully market non-animal methods because researchers have no incentive under the AWA to

¹ "Congress shall make no law * * * abridging * * * the right of the people * * * to petition Government for a redress of grievances." U.S. Const., amend. I. The right to petition for redress of grievances is among the most precious of the liberties safeguarded by the Bill of Rights. *United Mine Workers of America, Dist. 12 v. Illinois State Bar Ass'n*, 389 U.S. 217, 222, 88 S. Ct. 353, 356 (1967). It shares the "preferred place" accorded in our system of government to the First Amendment freedoms, and has a sanctity and a sanction not permitting dubious intrusions. *Thomas v. Collins*, 323 U.S. 516, 530, 65 S. Ct. 315, 322 (1945). "Any attempt to restrict those First Amendment liberties must be justified by clear public interest, threatened not doubtful or remotely, but by clear and present danger." *Id.* The Supreme Court has recognized that the right to petition is logically implicit in, and fundamental to, the very idea of a republican form of government. *United States v. Cruikshank*, 92 U.S. (2 Otto) 542, 552, 23 L. Ed. 588 (1875).

² 5 U.S.C. 553(e) (1994).

³ 7 CFR Subtitle A § 1.28 (1997).

⁴ 7 U.S.C. 2143(a)(3) and 7 U.S.C. 2143(b)(3).

consider alternative methods for the excluded animals. As a result, the company has a limited number of consumers interested in using in vitro methods. This is a significant impediment for the growth of the company because birds, rats, and mice encompass the majority of laboratory animals used in research. Petitioners' interest in preventing inhumane treatment of these animals is impeded by USDA's failure to require researchers to consider alternatives before using birds, rats, and mice.

Petitioner Barbara Orlans resides at 7106 Laverock Lane, Bethesda, MD 20817. Petitioner is a Senior Research Fellow at the Kennedy Institute of Ethics at Georgetown University. She received a Bachelor of Science degree in Physiology and a Masters in Science and a Ph.D. degree in Physiology. Petitioner is the author of the books *Animal Care: From Protozoa to Small Mammals*, *In the Name of Science: Issues in Responsible Animal Experimentation*, and the co-author of *The Human Use of Animals: Case Studies in Ethical Choice*. She has also written numerous articles on animals published in peer-reviewed scientific journals including, "Animal Pain Scales in Public Policy", "Regulation and Ethics of Animal Experiments: An International Comparison", and "Ethical Decision-Making About Animal Experiments." Petitioner teaches a course on ethical issues of animal research at Georgetown University because of her interest in the humane treatment of animals. She was also founding president of the Scientists Center for Animal Welfare, a non-profit organization dedicated to educating scientists about animal issues including the "three R's," reduction, refinement, and replacement of animal testing methods. For over thirty years, Orlans has worked to protect the well-being of laboratory animals. USDA's failure to regulate the use of birds, rats, and mice provides a disincentive for researchers to use alternatives and thus, harms and impedes petitioners ability to educate and encourage researchers and students to use non-animal alternatives.

Petitioner George K. Russell is a professor for the Department of Biology at Adelphi University, Garden City, NY 11530. He has an A.B. and a Ph.D. in biology. Petitioner is one of the first to develop a non-animal approach to teaching undergraduate biology courses. He is also editor of *Orion: People and Nature*. The publication is dedicated to a deeper understanding of human relationships to the environment. For the past twenty-five years, petitioner has been dedicated to protecting the well-

being of laboratory animals. He has written several articles urging teachers to avoid experiments that cause harm to animals. Due to USDA's wrongful exclusion of birds, rats, and mice from AWA protection, universities are not required under the AWA to consider the availability of alternatives or the treatment of these "non-animals" when used in animal testing. As a result, students are not educated about the humane treatment of animals or the use and availability of alternative methods.

Petitioner Ruy Tchao resides at 404 Cedar Lane, Flourtown, PA 19031. He has a Bachelor of Science degree in Chemistry and a Ph.D. in Biochemistry. He is an Associate Professor at the Philadelphia College of Pharmacy and Science in the Department of Pharmacology and Toxicology. He has written several articles on the research and development of in vitro methods and the use of these methods as a viable alternative to animal testing. He has worked with in vitro methods for seventeen years because he believes that this type of research can provide more relevant data than the data derived from animals. The AWA requires research facilities to consider alternatives when experimentation on an animal may cause pain or distress. However, USDA has defined birds, rats, and mice as non-animals and as a result, research facilities are not required to consider alternatives for these creatures. Thus, petitioner's promotion of the valuable data obtained from in vitro methods is frustrated and impeded by USDA's definition of "animal."

II. Statement of Facts

In 1966, Congress enacted the Federal Laboratory Animal Welfare Act to address the abuses that develop as a result of experimenting with animals.⁵ This Act is the only federal statute designed to protect animals used in all research facilities.

The 1970 amendments enacted a broad definition of animal which covers "warm-blooded animals, as the Secretary may determine is being used, or is intended for use, for research, testing, experimentation or exhibition purposes."⁶ This language has remained throughout both the 1976 and 1985 amendments. Despite this broad statutory definition, the USDA has excluded birds, rats, and mice from its regulation defining "animal."⁷ As a result of this exclusion, the majority of

all animals used in research are not protected by the AWA.⁸

Under the AWA, research facilities must meet requirements for animal care and treatment in order to minimize animal pain and distress.⁹ Investigators must also consider alternatives to any procedure that is likely to produce pain or distress in animals used for research.¹⁰ Contrary to Congressional intent, USDA's animal welfare regulations do not affect the vast majority of research facilities because USDA has excluded the majority of laboratory animals from AWA protection. Consequently, researchers may research, test, and experiment on birds, rats, and mice without considering the use of any non-animal alternative methods.

On April 23, 1997, AAVS petitioned USDA requesting the agency to amend its animal welfare regulations. USDA denied the petition by claiming that it does not have the resources to regulate these animals at this time.¹¹ This response is similar to the reply received by the Humane Society of the United States ("HSUS") and the Animal Legal Defense Fund's ("ALDF") petition requesting USDA to amend its definition of "animal." A United States District Court examined the validity of USDA's denial of this petition in *Animal Legal Defense Fund v. Madigan*.¹² The court held that USDA's denial of ALDF's rulemaking petition was arbitrary and capricious because USDA focused on availability of resources and personnel rather than whether these animals are used for purposes that allow them to receive AWA protection.¹³ The court also addressed whether USDA has the discretion to exclude birds, rats, and mice from AWA coverage. The court held that USDA's exclusion of these

⁸ U.S. Congress, Office of Technology Assessment, *Alternatives to Animal Use in Research, Testing, and Education 5* (Washington, D.C., 1986) (reporting that "the best data source available—the USDA/APHIS census—suggests that at least 17 million to 22 million animals were used in research and testing in the United States in 1983. The majority of animals used—between 12 million and 15 million—were rats and mice."). Also see USDA's August 6, 1997 response to AAVS' petition (explaining that in 1990 USDA analyzed the impact of covering mice, rats, and birds and concluded that it would represent "a 96 percent increase in the number of animal research sites under USDA inspection authority") [hereinafter "USDA response"].

⁹ 7 U.S.C. 2143(a)(3)(A).

¹⁰ *Id.* sec. 2143(a)(3)(B).

¹¹ USDA response.

¹² *Animal Legal Defense Fund v. Madigan*, 781 F. Supp. 797 (D.D.C. 1992), vacated sub nom. *Animal Legal Defense Fund v. Espy*, 23 F.3d 496 (D.C. Cir. 1994) (decision vacated because the court held that plaintiffs lacked standing to sue).

¹³ *Madigan*, 781 F. Supp. at 805–806.

⁵ Pub.L. 89–544, 80 Stat. 359 (1966).

⁶ 7 U.S.C. 2132(g) (1994).

⁷ 9 C.F.R. 1.1.

animals is arbitrary and capricious and violates the AWA.¹⁴

Despite the holding in *Madigan*, USDA continues to exclude birds, rats, and mice. Petitioners file this petition because USDA's regulation defining "animal" fails to require the use and development of non-animal laboratory research alternatives for the majority of animals used in research, testing, and experimentation. Petitioners are working to further the AWA's purpose by developing and using alternative non-animal methods but are impeded due to USDA's definition of "animal." As long as USDA excludes birds, rats, and mice, all parts of the AWA and the regulations which mandate consideration about the use of alternative methods and the minimization or elimination of painful procedures on animals *bypass* birds, rats, and mice.

Once USDA promulgates rules that are consistent with the AWA by regulating birds, rats, and mice, then the new regulatory protection afforded the majority of laboratory animals will require researchers to minimize animal distress and pain by considering alternative methods. As a result, researchers will have an incentive to use *in vitro* methods. Thus, *in vitro* marketers, users, and advocates, including petitioners, will have an opportunity to promote and encourage the use of non-animal methods.

III. Statement of the Law

A. AWA Policies and Congressional Findings

1. Congressional Statement of Policy

The Congress finds that animals and activities which are regulated under this Act (citation omitted) are either in interstate or foreign commerce or substantially affect such commerce or the free flow thereof, and that regulation of animals and activities as provided in this Act (citation omitted) is necessary to prevent and eliminate burdens upon such commerce and to effectively regulate such commerce, in order—

(1) To insure that animals intended for use in research facilities or for exhibition purposes or for use as pets are provided humane care and treatment;

(2) To assure the humane treatment of animals during transportation in commerce; and

(3) To protect the owners of animals from the theft of their animals by preventing the sale or use of animals which have been stolen.

The Congress further finds that it is essential to regulate, as provided in this Act (citation omitted), the transportation, purchase, sale, housing, care, handling, and treatment of animals by carriers or by persons or organizations engaged in using them for *research or experimental purposes* or for exhibition purposes or holding them for sale as pets or for any such purpose or use.¹⁵

2. Congressional Findings for 1985 Amendment

(1) The use of animals is instrumental in certain research and education for advancing knowledge of cures and treatment for diseases and injuries which afflict both humans and animals;

(2) *Methods of testing that do not use animals are being and continue to be developed which are faster, less expensive, and more accurate than traditional animal experiments for some purposes and further opportunities exist for the development of these methods of testing;*

(3) *Measures which eliminate or minimize the unnecessary duplication of experiments on animals can result in more productive use of Federal funds; and*

(4) Measures which help meet the public concern for laboratory animal care and treatment are important in assuring that research will continue to progress.¹⁶

B. Definitions of "Animal" Under AWA and USDA Regulations

1. Animal Welfare Act

The term "animal" means any live or dead dog, cats, monkey (nonhuman primate mammal), guinea pig, hamster, rabbit, or such other warm-blooded animal, as the Secretary may determine is being used, or is intended for use, for research, testing, experimentation, or exhibition purposes, or as a pet; but such term excludes horses not used for research purposes and other farm animals, such as, but not limited to livestock or poultry used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber. With respect to a dog, the term means all dogs including those used for hunting, security, or breeding purposes;¹⁷

2. USDA Regulations

Animal means any live or dead dog, cat, nonhuman primate, guinea pig, hamster, rabbit, or any other warm-

blooded animal, which is being used, or is intended for use for research, teaching, testing, experimentation, or exhibition purposes, or as a pet. This term excludes: Birds, rats of the genus *Rattus* and mice of the genus *Mus* bred for use in research, and horses not used for research purposes and other farm animals, such as, but not limited to livestock or poultry, sed or intended for use as food or fiber, or livestock or poultry used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber. With respect to a dog, the term means all dogs, including those used for hunting, security, or breeding purposes.¹⁸

C. AWA Standards and Certification Process for Humane Handling, Care, Treatment and Transportation of Animals

(a)(1) The Secretary shall promulgate standards to govern the humane handling, care, treatment, and transportation of animals by dealers, research facilities, and exhibitors.

(3) In addition to the requirements under paragraph (2), the standards described in paragraph (1) shall, with respect to animals in research facilities, include requirements—

(A) For animal care, treatment, and practices in experimental *procedures to ensure that animal pain and distress are minimized*, including adequate veterinary care and the appropriate use of anesthetic, analgesic, tranquilizing drugs, or euthanasia;

(B) *That the principal investigator considers alternatives to any procedure likely to produce pain to or distress in an experimental animal.*

(6)(A) Nothing in this Act (citation omitted)—

(I) Except as provided in paragraphs (7) of this subsection, shall be construed as authorizing the Secretary to promulgate rules, regulations, or orders with regard to the design, outlines, or guidelines of actual research or experimentation by a research facility as determined by such research facility;

(ii) Except as provided subparagraphs (A) and (C) (ii) through (v) of paragraph (3) and paragraph (7) of this subsection, shall be construed as authorizing the Secretary to promulgate rules, regulations, or orders with regard to the performance of actual research or experimentation by a research facility as determined by such research facility;

(7)(A) The Secretary shall require each research facility to show upon inspection, and to report at least

¹⁴ *Id.* at 806.

¹⁵ 7 U.S.C. 2131 (emphasis added).

¹⁶ *Id.* sec. 2131 note (emphasis added).

¹⁷ *Id.* sec. 2132(g).

¹⁸ 9 CFR 1.1 (1997) (emphasis added).

annually, that the provisions of this Act (citation omitted) are being followed and that professionally acceptable standards governing the care, treatment, and use of animal are being followed by the research facility during actual research or experimentation.

(B) In complying with subparagraph (A), such research facilities shall provide—

(I) Information on procedures likely to produce pain or distress in any animal and assurances demonstrating that the *principal investigator considered alternatives to those procedures*;

(ii) Assurances satisfactory to the Secretary that such facility is adhering to the standards described in this section * * * .

(d) Each research facility shall provide for the training of scientists, animal technicians, and other personnel involved with animal care and treatment in such facility as required by the Secretary. Such training shall include instruction on—

(1) The humane practice of animal maintenance and experimentation;

(2) Research or testing methods that *minimize or eliminate the use of animals* or limit animal pain or distress * * * .

(e) The Secretary shall establish an information service at the National Agricultural Library. Such service shall, in cooperation with the National Library of Medicine, provide information—

(2) Which could prevent unintended duplication of animal experimentation as determined by the needs of the research facility; and

(3) On improved methods of animal experimentation, including methods which could

(A) *Reduce or replace animal use*; and

(B) Minimize pain and distress to animals, such as anesthetic and analgesic procedures.

(f) In any case in which a Federal agency funding a research project determines that conditions of animal care, treatment, or practice in a particular project have not been in compliance with standards promulgated under this Act (citation omitted), despite notification by the Secretary or such Federal agency to the research facility and an opportunity for correction, such agency shall suspend or revoke Federal support for the project * * * 19

IV. Consistent With Congressional Intent Under the Animal Welfare Act, USDA Should Initiate Rulemaking Proceedings To Redefine "Animal" To Include Birds, Rats, and Mice

Congress enacted the Animal Welfare Act ("AWA") and subsequent amendments to protect animals used in research.²⁰ In order to further congressional intent, petitioners request that USDA promulgate regulations that are consistent with the AWA's definition of "animal." The AWA states that:

The term "animal" means any live or dead dog, cat, monkey (nonhuman primate mammal), guinea pig, hamster, rabbit, or such other warm-blooded animal, as the Secretary may determine is being used, or is intended for use, for research, testing, experimentation, or exhibition purposes or as a pet; but such term excludes horses not used for research purposes and other farm animals, such as but not limited to livestock or poultry, used or intended for use as food or fiber, or livestock or poultry used or intended for improving animal nutrition, breeding, management or production efficiency, or for improving the quality of food or fiber. With respect to a dog the term means all dogs including those used for hunting, security, or breeding purposes.²¹

Under the AWA, USDA must provide protection to all warm-blooded animals used in research. Instead of complying with this mandate, USDA's regulation excludes birds, rats, and mice from AWA protection despite the fact that these animals encompass the majority of animals used in laboratory research. USDA's exclusion of these animals is arbitrary and capricious and not in accordance with law based upon the Supreme Court's holding in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*²² The holding in *Chevron* directs a court to apply a two-part test when reviewing an agency's construction of a statute. First, the court is to look at the plain meaning of the statute.²³ If the statute is unambiguous, then the court and the agency must give effect to Congress' intent.²⁴ Only if a statute is silent or ambiguous must the court then move to the second step under *Chevron* which requires the court to look at whether the agencies interpretation of the statute is reasonable.²⁵

²⁰ *Id.* §§ 2131-2157.

²¹ *Id.* sec. 2132(g).

²² 467 U.S. 837 (1984)

²³ *Id.* at 842-3.

²⁴ *Id.*

²⁵ *Id.* at 843.

A. The First Step of the Chevron Analysis Shows That the Purpose and Plain Meaning of the Animal Welfare Act Does Not Support the USDA's Definition of "Animal"

When promulgating a regulation, an agency must first determine whether Congress has directly addressed the subject matter at issue. Under *Chevron*, an agency must make this decision by determining the plain meaning of the statute. Ordinarily, the words of a statute must be interpreted in light of the purpose that Congress intended to serve. In this case, Congress specifically passed the AWA to provide for the humane care and treatment of animals used in research, for exhibition, and as pets.²⁶

USDA's exclusion of birds, rats, and mice from AWA protection directly contravenes the AWA's statutory purpose of assuring the humane treatment of laboratory animals. The effect of USDA's regulation is that the regulated industry will never be in violation of the AWA regardless of how it treats birds, rats, and mice. For example, under the AWA, research facilities can deny these animals food, water, appropriate housing and can also inflict excruciating pain without providing an analgesic. In this case, not only does the exclusion of these animals have no relevance to any of the stated purposes of the Act, but the *inclusion* of these animals would insure that animals used in research facilities are provided humane care and treatment as the AWA requires.

Furthermore, the Congressional findings for the 1985 amendments state that "methods of testing that do not use animals are being and continue to be developed which are faster, less expensive, and more accurate than traditional animal experiments for some purposes and further opportunities exist for the development of these methods of testing."²⁷ Due to USDA's failure to provide birds, rats, and mice AWA protection, the use of alternative methods for these species is rarely, if ever, undertaken. In fact, in USDA's response to the AAVS petition, the agency stated that regulating birds, rats, and mice would constitute a ninety-six percent increase in regulated research facilities. USDA's own figure indicates that the majority of researchers are choosing to use birds, rats, or mice instead of alternatives. By using these animals, facilities can escape inspection and bypass the Act's requirement that they consider alternatives. Because

²⁶ 7 U.S.C. 2131.

²⁷ *Id.* sec. 2131 note (emphasis added).

¹⁹ 7 U.S.C. 2143 (emphasis added).

USDA has exempted these animals from the definition of "animal", there is no incentive for the use or advancement of alternative methods for the majority of animals used in research. This practice is contrary to the AWA's purpose of advancing alternatives. Therefore, in light of the general tenet "to favor interpretation which would render statutory design effective in terms of policies behind its enactment and to avoid interpretation which would make such policies more difficult of fulfillment,"²⁸ the AWA's purpose supports the definition of birds, rats, and mice as animals and their regulation in research.

The plain meaning of the AWA also shows that USDA's regulation defining "animal" is inconsistent with the statute. The AWA indicates that if an animal is warm-blooded and used for research, testing, or experimentation, then the animal is an "animal" for AWA purposes. Furthermore, Congress has explicitly stated which limited subset of animals the Secretary is authorized to exclude by stating:

Such term (animal) excludes horses not used for research purposes and other farm animals, such as, but not limited to livestock or poultry, used or intended for use as food or fiber, or livestock or poultry used or intended for improving animal nutrition, breeding, management or production efficiency, or for improving the quality of food or fiber. With respect to a dog the term means all dogs including those used for hunting, security, or breeding purposes.²⁹

Although, birds, rats, and mice are not included in this list of excluded animals, the Secretary has arbitrarily decided to exclude them from the protections of this Act.

A Congressional report issued in 1986 provides further evidence that USDA's regulation contradicts the AWA's plain meaning. The Office of Technology Assessment ("OTA") conducted a study to analyze the scientific, regulatory, economic, legal, and ethical considerations involved in alternative technologies in biomedical and behavioral research, toxicity testing, and education.³⁰ The report lays out numerous policy issues and options for Congressional action and reiterates the AWA's inconsistency with USDA's regulation. The OTA report concludes that the exclusion of mice and rats from

the protections of the AWA is inconsistent with the language of the Act and "appears to frustrate the policy Congress sought to implement in 1970 and consequently to be beyond the Secretary's authority."³¹

In support of its exclusion of birds, rats, and mice, the USDA argues in its response to the AAVS petition that the AWA "gives the Secretary of Agriculture broad discretionary authority to exclude rats of the genus *Rattus*, mice of the genus *Mus*, and birds."³² This argument, however, is in direct contrast to USDA's prior position where it stated that it had no discretion to exclude warm-blooded animals used in research. The agency previously explained:

* * * Gerbils became a regulated species when the 1970 amendments to the Act expanded the definition of "animal" to include "such other warm-blooded animal, as the Secretary may determine is being used, or is intended for use for research, testing * * * ." We do not have the authority to remove these animals from the coverage of the regulations.³³

USDA admits in the gerbil example that it has no discretionary authority to deny protection to warm-blooded animals used in research under the AWA. In fact, the Secretary has promulgated an entire subset of generic animal welfare regulations that govern the care and handling of animals not specifically mentioned in the statute but are covered by the AWA because they are warm-blooded and used for research.³⁴ These generic regulations address animal care including feeding, watering, temperature, cage space, and handling.

USDA has also admitted that birds, rats, and mice are used for the purposes described in the AWA.³⁵ However, USDA's generic animal care regulations do not cover birds, rats, and mice. This exclusion leaves these species with no minimum standards for their care, no protections under the Act, and no legal barriers preventing cruelty, intentional or negligent deprivation of food, water, shelter or veterinary care. These effects are contrary to Congress' stated purpose under the AWA of providing humane care and treatment for animals used in research.³⁶

Based on this information, the purpose and plain meaning of the AWA indicates that USDA's exclusion of birds, rats, and mice contradicts and

frustrates the AWA. Furthermore, the interpretation of the AWA as explained in the OTA report, USDA's admissions, and USDA's own regulations indicates that the exclusion is inconsistent with the statute. A *Chevron* step one analysis shows that the statute is unambiguous and, therefore, USDA should immediately redefine the term "animal" and regulate birds, rats, and mice.

B. The Second Step of the *Chevron* Analysis Shows That the Definition of "Animal" Is Not Reasonable

The second step of the *Chevron* analysis is only necessary if the statute is ambiguous. The key issue is "whether the agency's view that [its construction] is appropriate in the context of this particular program is a reasonable one."³⁷ In this case, even if the AWA statutory language is ambiguous, USDA's regulation is not reasonable. Applying *Chevron* to this case presents the issue of whether USDA has the discretion to exclude birds, rats, and mice from the definition of "animal."

1. The Animal Welfare Act's Legislative History Does Not Support USDA's Regulation Defining "Animal"

Congress first passed the AWA in 1966 and defined "animal" as a "live dog, cat, monkey (nonhuman primate mammal), guinea pig, hamster and rabbit."³⁸ This language limited AWA protection to six specific species. However in 1970, Congress amended the statute to include "such other warm-blooded animal as the Secretary may determine is being used, or intended for use, for research, testing, experimentation."³⁹ This language broadened the number of species protected under the Act and has remained throughout both the 1976 and 1985 amendments.

The legislative history of the AWA provides no indication that Congress authorized the Secretary's regulation excluding birds, rats, and mice. When the AWA was amended in 1970, Congress was aware of the wide use of birds, rats, and mice in research but did not explicitly deny these animals protection under the Act. Instead, Congress used the phrase "warm-blooded animal" in order to expand the species of animals protected by the Act.

If Congress had intended for the Secretary to have unlimited discretion to designate which warm-blooded animals were to be protected under the Act, then the legislature would have specifically stated it in the statute. Not

²⁸ *Motor & Equipment Manufacturers Ass'n, Inc. v. E.P.A.*, 627 F.2d 1095 (D.C. Cir. 1979), cert. denied, *General Motors Corp. v. Costle*, 446 U.S. 952 (1980).

²⁹ *Id.* sec. 2132(g).

³⁰ U.S. Congress, Office of Technology Assessment, *Alternatives to Animal Use in Research, Testing, and Education* (1986) [hereinafter OTA Report].

³¹ *Id.* at 278.

³² USDA response at 1.

³³ 54 FR 10824 (March 15, 1989).

³⁴ 9 CFR 3.125 (subpart f).

³⁵ *Madigan*, 781 F. supp. at 801.

³⁶ U.S.C. 2131.

³⁷ *Chevron*, 467 U.S. at 845.

³⁸ 80 Stat. 350, 351 (1966).

³⁹ 7 U.S.C. 2132(g).

only is there no statutory language granting USDA unlimited discretion, but the legislative history also reveals that Congress did not intend for the Secretary to have broad discretion. This intent is evident by Congress' rejection of Representative Whitehurst's proposed amendment which defined "animal" to include "any warm-blooded animal, as determined by the Secretary."⁴⁰ This amendment would have given the Secretary the discretion to choose which warm-blooded animals would be protected by the Act and thus would support USDA's exclusion of birds, rats, and mice.

Instead of amending the AWA to give the Secretary broad discretion to exclude animals, Congress wanted to expand the definition of "animal" to include more species while specifically delineating which animals would be exempted. The house and floor discussions support this assertion:

Rep. Thomas Foley (D-Washington), speaking on behalf of the House Agriculture Committee, remarked that "(t)his bill, within its definition includes all warm-blooded animals designated by the Secretary, with certain specific limitations and defined exceptions."⁴¹

Rep. Catherine May (R-Washington), urging her colleagues to approve the legislation described the bill: "First, it expands the definition of the term 'animal' to include more species. The present law applies only to live dogs, cats, rabbits, hamsters, guinea pigs, and monkeys. All warm-blooded animals designated by the Secretary of Agriculture, with limited exceptions would be included."⁴²

Rep. Wiley Mayne (R-Iowa) agreed that the bill "expands the definition of covered animals to include all warm-blooded animals designated by the Secretary, rather than just live dogs, cats, rabbits, hamsters, guinea pigs, and monkeys."⁴³

Rep. Wilmer Mizell (R-North Carolina) explained that "[t]his bill includes provisions regulating the transportation, purchase, sale, housing, care, handling and treatment of warm-blooded animals used in research * * * (m)ore species of animals will be protected: all warm-blooded animals designated by the Secretary of Agriculture, with but a few specific exceptions."⁴⁴

Rep. Robert Price (R-Texas) remarked that the bill "extends the definition to include all warm-blooded animals designated by the

Secretary of Agriculture, with certain specific limitations and defined exceptions."⁴⁵

The Supreme Court has stated that when "statements of individual legislators * * * are consistent with the statutory language and legislative history, they provide evidence of Congress' intent."⁴⁶ The statements from these individual legislatures all indicate that Congress intended the AWA to cover all warm-blooded animals used in research, including birds, rats, and mice with only a few specific exceptions.

A House Committee on Agriculture report which accompanied the proposed bill also supports this premise: "This bill includes within its definition all warm-blooded animals designated by the Secretary with only limited and specifically defined exceptions."⁴⁷ Additionally, a letter from then Secretary of Agriculture J. Phil Campbell to W.R. Poage, Chairman of the Committee on Agriculture, explained that "(i)f Federal regulation of laboratory animals is extended to all warm-blooded animals, we suggest it would be appropriate and consistent to extend the species of animals presently regulated under (the AWA) to include all warm-blooded animals." Not only does the legislative history show Congress' intent in expanding the number of animals protected by the AWA, but it also shows that the Secretary of Agriculture understood and supported Congress' purpose.

Based on the legislative history, it is unreasonable to conclude that Congress amended the AWA in order to provide more animals protection while also giving the Secretary the broad discretion to exclude the majority of animals used in research, testing, and experimentation. The only discretion Congress granted the Secretary was the authority to determine whether warm-blooded animals are being used for research, testing, or experimentation. Indeed, in *Madigan*, the court looked at USDA's discretionary authority and found that, "since the USDA does not dispute that birds, rats, and mice are used for [research] purposes, it is inconsistent with the plain meaning of the statute and 'the unambiguously expressed intent of Congress to exclude them from coverage under the Act.'" ⁴⁸

The court also conducted a *Chevron* step two analysis and found that the

agency's definition of "animal" was not supported by the legislative history.⁴⁹

The legislative history along with the reasoning in the *Madigan* decision shows that USDA does not have the discretion to choose which warm-blooded animals used in research it will deny AWA protection. The effect of USDA's exclusion demonstrates its illegality, because the majority of laboratory animals are not presently covered by USDA's animal welfare regulations. Based on this information, USDA's exclusion of birds, rats, and mice is ultra vires because Congress has not specifically granted the agency authority to decide on a matter that Congress has already addressed.

2. USDA Has Not Reasonably Justified Its Regulation Excluding Birds, Rats, and Mice From Animal Welfare Protection

USDA's interpretation of the AWA is not reasonable because it does not satisfy the *Chevron* step-two framework. In *Chevron*, the Supreme Court found that EPA's construction of the Clean Air Act was reasonable because the agency: (1) Advanced a reasonable explanation for its conclusion that the regulations serve the statutory objectives; (2) balanced competing statutory concerns in a technical and complex regulatory scheme; and (3) engaged consistently and historically in a search to review and question its policy on a continuing basis.⁵⁰

In this case, USDA has failed to show the reasonableness of its regulation. In fact, USDA enacted its regulation excluding birds, rats, and mice in 1971 without any explanation showing how the exclusion of these animals meets the AWA's objective in providing for the humane treatment of animals.⁵¹ In 1989, when questioned about the exclusion, the agency stated "we do have the authority to regulate these animals, though except for wild rats and mice, we have never covered them in our regulations. However, * * * we are considering developing regulations and standards for them."⁵² Nine years have passed since this statement and during this time, the agency has failed to initiate any rulemaking proceedings to regulating birds, rats, and mice. USDA's failure to give any explanation for its arbitrary exclusion of these animals does not demonstrate reasoned decision-making. The Supreme Court addressed the issue of agency deference by stating:

⁴⁹ *Id.* at 802.

⁵⁰ *Chevron*, 467 U.S. 863-65.

⁵¹ 36 FR 24917-27 (Dec. 24, 1971).

⁵² 54 FR 10823 (March 15, 1989).

⁴⁰ *Hearings before the Subcommittee on Livestock and Grains of the House Agricultural Committee on H.R. 13957 to Amend the 1966 Act, 91st Cong., 2d Sess. 84 (1970).*

⁴¹ 116 Cong. Rec. H40154 (Dec. 7, 1970) (emphasis added).

⁴² 116 Cong. Rec. H40156 (Dec. 7, 1970) (emphasis added).

⁴³ 116 Cong. Rec. H40158 (Dec. 7, 1970) (emphasis added).

⁴⁴ 116 Cong. Rec. H40159 (Dec. 7, 1970) (emphasis added).

⁴⁵ 116 Cong. Rec. H40159 (Dec. 7, 1970) (emphasis added).

⁴⁶ *Brock v. Pierce County*, 476 U.S. 253, 106 S.Ct. 1834 (1986).

⁴⁷ H.R. Rep. No. 1651, 91st Cong., 2d Sess., reprinted in 1970 U.S.C.A.N. 5103, 5104 (emphasis added).

⁴⁸ 781 F. Supp. at 801 (citation omitted).

Agency deference has not come so far that we will uphold regulations wherever it is possible to conceive a basis for administrative action * * * Thus the mere fact that there is "some rational basis within the knowledge and experience of the (regulators)" under which they "might have concluded" that the regulation was necessary to discharge their statutorily authorized mission, will not suffice to validate agency decisionmaking * * * Our recognition of Congress need to vest administrative agencies with ample power to assist in the difficult task of governing a vast and complex industrial Nation carries with it the correlative responsibility of the agency to explain the rationale and factual basis for its decision, even though we show respect for the agency's judgement in both.⁵³

Whether USDA has discretionary authority under the AWA to exclude these animals was addressed in *Madigan*. Judge Richey found that USDA's argument for discretionary authority under the Act was "strained and unlikely."⁵⁴ USDA has not shown that excluding birds, rats, and mice is reasonable. Therefore, USDA should redefine "animal" in accordance with the AWA.

C. USDA Was Arbitrary and Capricious in Refusing AAVS's Petition To Initiate Rulemaking Proceedings

The only explanation USDA gave for denying AAVS' petition for rulemaking was that it was not economically practical.⁵⁵ In denying AAVS' petition, USDA analyzed the increase cost that would result from regulating birds, rats, and mice. Based on that information, USDA decided not to grant these animals AWA protection. USDA's reliance on budgetary constraints is arbitrary and capricious because the agency failed to consider the many parts of the Act that are self implementing.⁵⁶

In *Madigan*, the court explained that "birds, rats, and mice could be included in the definition without requiring the expenditure of significant agency resources" because the AWA includes many provisions that are self-implementing by the regulated industry.⁵⁷ By regulating these animals, researchers would be required to treat animals humanely without any action from the agency. In *Madigan*, the court held that USDA's denial of ALDF's

rulemaking petition based upon the availability of resources and increase cost was arbitrary and capricious and not in accordance with law.⁵⁸ Based upon the *Madigan* decision, USDA's denial of a rulemaking petition to redefine "animal" based solely on economic reasons is not valid. Therefore, USDA should grant this petition by initiating rulemaking proceedings to regulate birds, rats, and mice consistently with the AWA.

V. Agency Action Requested

The AWA's purpose and plain meaning, Congress' legislative intent, and the reasoning in *Madigan* show that birds, rats, and mice should be granted protection under the AWA. Furthermore, the USDA has acknowledged that it has the authority to regulate rats and mice and has admitted that the agency was considering developing regulations for these animals.⁵⁹ However, the agency's continual delay in addressing this matter along with its justification for denying these animals protection is unreasonable and demands further consideration.

Therefore, for the reasons cited in this petition, the petitioner requests that the USDA immediately amend its current definition to include mice, rats, and birds under the AWA. The proposed regulation should be amended to read as follows:

Animal means any live or dead dog, cat, nonhuman primate, guinea pig, hamster, rabbit, or any other warm-blooded animal, which is being used, or is intended for use for research, teaching, testing, experimentation, or exhibition purposes, or as a pet. This term excludes horses not used for research purposes and other farm animals, such as, but not limited to livestock or poultry, used or intended for use as food or fiber, or livestock or poultry used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber. With respect to a dog, the term means all dogs, including those used for hunting, security, or breeding purposes.

Except as described above, petitioners know of no other similar issue, act, or transaction to this petition currently being considered or investigated by any USDA office, other federal agency, department, or instrumentality, state municipal agency or court, or by any law enforcement agency.

As required by 7 CFR Subtitle A § 1.28, the USDA is required to give this

petition prompt consideration. Petitioner is requesting a substantive response to this petition within ninety (90) calendar days. In the absence of an affirmative response, petitioners will be compelled to consider litigation in order to achieve the agency actions requested.

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data known to the petitioner which are unfavorable to the petition.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98-NM-225-AD]

RIN 2120-AA64

Airworthiness Directives; Boeing Model 757 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain Boeing Model 757 series airplanes. This proposal would require revising the Airworthiness Limitations Section of the Instructions for maintenance manual [757 Airworthiness Limitations Instructions (ALI)]. The revision would incorporate certain inspections and compliance times to detect fatigue cracking of principal structural elements (PSE). This proposal is prompted by analysis of data that identified specific initial inspection thresholds and repetitive inspection intervals for certain PSE's to be added to the ALI. The actions specified by the proposed AD are

⁵³ *Bowen v. Am. Hosp. Ass'n.*, 476 U.S. 610, 627 (1986) (citations omitted).

⁵⁴ *Animal Legal Defense Fund*, 781 F. Supp. at 800-806

⁵⁵ USDA response at 1-2.

⁵⁶ See e.g., 7 U.S.C. 2143 (a)(7)(A) (requiring each research facility to provide information on procedures that may produce pain or distress in animals and also provide assurances that alternatives were considered) 7 U.S.C. 2136 (every research facility shall register with the Secretary).

⁵⁷ 781 F. Supp. at 803.

⁵⁸ *Id.*

⁵⁹ 54 FR 10,823.