



The Exclusion of Mice, Rats, and Birds

By Sue A. Leary

The Animal Welfare Act (AWA) is the only federal law that has enforcement authority over the use of animals in a broad array of research settings. In the 1970 amendments, coverage under the Act was extended to any “warm-blooded animal that the Secretary [of Agriculture] may determine is being used...” However, in the process of writing the regulations to implement the law, the U.S. Department of Agriculture (USDA) chose to interpret that clause as having discretion to exclude

the vast majority of warm-blooded animals used in research: mice and rats. It certainly limited their work, but former Sen. Bob Dole wrote in a 2001 letter to the Alternatives Research & Development Foundation (ARDF, an AAVS affiliate), “As someone deeply involved with the process of revising and expanding the provisions of the AWA, I assure you that the AWA was meant to include birds, mice, and rats.”

After the Humane Society of the United States and the Animal Legal Defense Fund took legal action in 1991, a federal judge agreed with their interpretation, writing that the exclusion was “arbitrary and capricious and violates the law.” But due to the groups’ lack of legal standing [see “Key Legal Terms,” page 10], the USDA’s definition remained in effect.

When the ARDF sued the USDA in 1999, a judge’s award of standing to a co-plaintiff prompted a settlement in 2000 in which the USDA agreed to proceed with timely regulatory process.

The legislative and regulatory history of the AWA is generally one of expanding protections, but in 2002, leadership in the U.S. Senate allowed an amendment to the Act that explicitly and decisively reversed the USDA’s agreement.

WHO SAYS RATS AND MICE ARE NOT “ANIMALS”?

The exclusion of mice, rats, and birds is covered in animal law classes and articles as an example of how U.S. laws fail animals in the most basic ways. Namely, if the most commonly used animals in research and testing are specifically excluded from the definition of “animal,” how can that law provide public reassurance that animals in labs are being provided basic protections? Further, how can that law claim a factual basis if its definition of “animal” excludes those who are clearly animals?

However, what many observers do not realize is that the scientific community was not united in opposition to covering mice, rats, and birds. While

KEY EVENTS

DEC 1971

Regulations exclude mice, rats, and birds from AWA

JAN 1992

U.S. District Court calls USDA exclusion of mice, rats, and birds “arbitrary...and violates the law”

AUG-SEPT 2000

NABR and Johns Hopkins University file motions to intervene in ARDF/USDA case

SEPT 2001

NABR motion to dismiss ARDF/USDA agreement denied

DEC 1970

AWA expanded to cover all warm-blooded animals

DEC 1985

AWA amendment requires consideration of alternatives, establishes Institutional Animal Care and Use Committees

MAR 1999

ARDF sues USDA for inclusion of mice, rats, and birds in AWA

OCT 2000

USDA settles with ARDF, agreeing to initiate rulemaking including mice, rats, and birds in AWA

MAY 2002

Amendment excluding “birds, rats of the genus *Rattus*, and mice of the genus *Mus*, bred for use in research” from AWA signed into law

MORE THAN
93%
OF ANIMALS
USED IN LABS
ARE EXCLUDED
FROM THE AWA

		2002	2005	2008	2011
EU	Total number of animals (millions)	10.7 ⁱ	12.1 ⁱⁱ	12 ⁱⁱⁱ	11.5 ^{iv}
	Percent not covered by AWA	92.8 ⁱ	93.2 ⁱⁱ	93 ⁱⁱⁱ	93.2 ^{iv}
U.S.	Total number AWA animals	1,137,580 ^v	1,177,566 ^{vi}	1,157,263 ^{vii}	1,117,265 ^{viii}
	Estimated total number of animals	15,799,722	16,139,581	16,532,329	16,430,368

Assumes corresponding percentage of vertebrate (rats, mice, birds, fish, etc.) use in EU and U.S.

animal research lobbyists—especially the National Association for Biomedical Research (NABR)—surely claimed on Capitol Hill to represent scientific interests, many in the research community supported covering mice, rats, and birds in AWA. Prominent organizations and companies endorsed ARDF’s position, and in a confidential poll, a majority of individual researchers did, too.

The inclusion of mice, rats, and birds in AWA coverage had the support of professional associations including the American Association for Laboratory Animal Science, the Scientists Center for Animal Welfare, and AAALAC International. Companies such as Colgate Palmolive and Procter & Gamble also supported inclusion, as did academics at the Center for Alternatives to Animal Testing at the Johns Hopkins Bloomberg School of Public Health.¹

A 1999 national survey of IACUC members from 50 institutions showed that more than 73 percent supported the inclusion of rats and mice, and 69 percent supported including pigeons.²

THE CONSEQUENCES OF EXCLUSION

AAVS and other animal advocates have long called for accountability and transparency in relation to the harmful use of animals in science. As a starting point, there should be a way to answer a basic question: How many animals are used in research and testing in the U.S.? The AWA requires annual reporting from registered research institutions, but only collects information on covered species. Some estimates can be made by extrapolating from the most recent European Union (EU) statistics, as shown in the table above. These calculations indicate that more than 93 percent of animals used in U.S. labs are not covered by the AWA. That includes genetically engineered mice, who have particular welfare concerns.

ARDF maintains that inclusion of rats and mice is also an “alternatives” issue, primarily due to the 1985 AWA amendment that requires consideration of alternatives to painful procedures—but only for

covered animals. Many alternative methods are designed to replace mice or rats in toxicity testing, and reporting numbers of animals could provide support for continued investment in alternatives and clarify which areas need priority. The new wave of alternative methods could have a significant impact on animal use, but it will be difficult to assess without data. For example, as a result of a 1997 ARDF petition, the National Institutes of Health (NIH) now instructs grantees that monoclonal antibodies (MAbs, a biological product widely used in research) should be produced *in vitro*, unless a scientific justification is given. ARDF estimated that one million mice a year³ were used for this purpose before 1997, so the impact of NIH’s guidance should be significant. But without reporting on mice, it is not possible to measure the impact with certainty.

ALIGNMENT AND THE PATH FORWARD

It is worth noting that other U.S. government departments recognize that all vertebrate animals deserve protection. For example, the Environmental Protection Agency and the Interagency Coordinating Committee on the Validation of Alternative Methods are actively working on encouraging alternatives and moving away from animal use. Further, governments and companies worldwide strive for international harmonization of testing policies and procedures in attempts to stabilize standards, reduce duplication, and promote efficiency. Aligning laws, policies, and standards about animal use makes sense in terms of ethics, science, and economics.

In the short term, ARDF recommends pilot programs of targeted reporting; for example, there could be incentives for a voluntary program of self-reporting animal numbers to a federal agency. In the long term, ARDF recommends that a working group of diverse stakeholders conduct a fair assessment of scientific consensus on extending AWA coverage to all vertebrates, and address the barriers to political acceptance, since it will require a change in the law. In our view, when institutions that use animals in research and testing more honestly account to the public, the use of alternatives will accelerate. **AV**

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¹Leary, S., Schaeffer, C., and Katrinak, V. (2011). Exclusion of Birds, Rats, and Mice from Legal Protection in the U.S. *AV Magazine*, 120 (1): 15-17.

²Plous, S. and Herzog, H. (June 1999). Should the AWA Cover Rats, Mice, and Birds? The Results of an IACUC Survey. *Lab Animal*, 28, 38-40.

³Statistic based on 1991 report by Business Communications Company, which estimated 2.6 million mice were used to manufacture MAbs worldwide. U.S. was 40 percent of world total.

ⁱ European Commission. COM(2005) 7 final.

ⁱⁱ European Commission. COM(2007) 675 final.

ⁱⁱⁱ European Commission. COM(2010) 511 final/2.

^{iv} European Commission. COM(2013) 859 final.

^v USDA. (September 2008). Animal Care Annual Report of Activities, Fiscal Year 2007. p. 45.

^{vi} USDA. (September 2008). Animal Care Annual Report of Activities, Fiscal Year 2007. p. 46.

^{vii} USDA. (February 10, 2011). Annual Report Animal Usage by Fiscal Year. Total 2008. p. 2

^{viii} USDA. (November 28, 2014) Annual Report Animal Usage by Fiscal Year. All Pain Types 2011.