chapter 3 Patterns of Animal Use

Twenty million rats, rabbits, cats, dogs, mice, and monkeys are killed each year in the name of science. And the number has quadrupled in recent years . . . 150 living creatures are sacrificed every minute.

Paul Harvey Radio broadcast of April 30, 1985

Each minute around the clock, 150 creatures are sacrificed ., . a total of 70 million a year. Included are 25,000 primates . . . and nearly 500,000 dogs and cats. parade, January 13, 1985

Each year in the United States, almost 100 million animals are used in scientific research. Nearly a million are dogs and cats.

Ed Bradley CBS News, 60 *MINUTES* October 14, 1984

OTA ignores the fact that more than one-half of all research goes unreported because unfunded. Secondly, funded researchers consistently understate the number of animals used for several reasons I won 't enumerate. My personal guess is that 120-150 million animals is the right ballpark figure.

> Sidney Gendin Eastern Michigan University **The Research News** 36(3-4):17, 198.5

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Humans "use" animals in several different ways. In addition to animal use in research, testing, and education, animals are involved in food and fiber production, the production of biological products, sports, and entertainment. Animals can also be kept as pets for the purpose of companionship. It has been roughly estimated that 2 billion to 4 billion animals are used in food and fiber production every year and that Americans have approximately 75 million dogs and cats as household pets. The uses not considered in this assessment therefore account for many times more animals than the estimated 17 million to 22 million animals used annually in research, testing, and education.

There are no easily obtainable data in the United States allowing an accurate estimate of animal use for research, testing, and education that satisfies all interested parties; estimates range over a full order of magnitude, from approximately 10 million to 100 million animals. These estimates have all been prepared by different people or institutions with different data sources under different standards (e.g., different time periods or definitions). Comparison of the various estimates is difficult and, in many cases, impossible.

The issue of numbers is important to any discussion of animal use in research, testing, and education. Most basically, a number is needed from which to consider arguments to decrease or eliminate animal use. In addition, comparing absolute numbers in different years would provide some idea of whether laboratory-animal use is increas - ing or decreasing in the United States; these numbers are powerful and important to many people. A high overall total, or high numbers of certain species (such as nonhuman primates or companion species), supports the claims of interest groups hoping to restrict or ban such experimentation. On the other hand, a low number indicates the issue is not as important as some claim. In addition, a decreasing trend in animal use supports the position that the present system will lower animal use on its own.

For this assessment, some idea was needed of the scope of animal use in terms of both the numbers of particular species used and the different major users. In addition, an analysis of different data sources helps put the various estimates of animal use into some comparative perspective. It provides the context in which to discuss alternatives and how much effect they might have. Although it is true that the development of alternatives and alternative methods does not require a perfectly accurate estimate of usage, the planning of public policy certainly should be based on firm data.

By looking critically at the different data sources and coming up with possible estimates of laboratory-animal use in the United States, this assessment attempts to base discussions on a realistic, factually backed range of figures. Without such an analysis, any discussion or decisions on policy issues and possible solutions lack an important perspective.

THE FEDERAL GOVERNMENT'S USE OF ANIMALS

To document the scope and extent of animal use for research by Federal departments and agencies, information was obtained from the Animal and Plant Health Inspection Service (APHIS) annual reports for Federal research facilities for 1983, the *Animal Welfare Enforcement Reports* for fiscal years 1978 through 1983 (both obtained from the U.S. Department of Agriculture (USDA)), and personal communications or written material about animal use in each department or agency. Together, the information illustrates:

- the extent of animal use in different departments,
- the amount and type of animals being used in the Federal Government,
- the experimental conditions under which most animal experiments are carried out,

- the general purpose for which animal research and testing is carried out in different departments and agencies, and
- how much research and testing for the Federal Government is conducted intramurally (i.e., within Federal facilities).

Federal Departments and Agencies Using Animals in Research

Six departments and four independent Federal agencies conduct intramural research or testing involving animals. Uses of animals range from combat-casualty-care investigations in the Department of the Army, to acute toxicity studies by the Consumer Product Safety Commission of potentially hazardous substances, to National Aeronautics and Space Administration research on protecting the health of American astronauts. (For additional information on the use of animals within the Federal Government, see chs. 7 and 13 and app. B.)

Department of Agriculture

USDA performs biomedical research using animals under the authority of the Animal Welfare Act in order to improve animal breeds, food, and fibers. Most of the research is conducted intramurally by the Agricultural Research Service, although some extramural research (i.e., research supported by USDA, but conducted in non-USDA facilities) is contracted out by the Cooperative State Research Service. Some of this USDA animal research involves farm animals, however, which are largely excluded from Government regulatory policies and are exempt from the Animal Welfare Act and APHIS regulations (44).

Department of Commerce

The Department of Commerce conducts a small amount of intramural research with animals and lets some extramural contracts that involve animal studies. There are no specific Commerce guidelines or policies governing the humane treatment and appropriate veterinary care for laboratory animals (33).

Department of Defense

The divisions within the Department of Defense (DOD) that conduct experimental research on animals are the Air Force, the Army, the Navy, the Uniformed Services University of the Health Sciences, the Defense Nuclear Agency, and the Armed Forces Institute of Pathology; the first three of these account for most of the research. Together, all the divisions have approximately 40 research facilities that conduct animal experimentation.

The Aerospace Medical Division (AMD) of the Air Force accounts for about 95 percent of that service's use of animals. Of this, 84 percent is due to intramural research (9). AMD research and development projects fall within the following areas:

- humans in space,
- chemical defense and threat countermeasures,
- safety and environment,
- logistics and technical training,
- air combat training,
- human components of weapons systems, and
- personnel and force management.

The safety and environment program uses the most animals, while those on human components of weapons systems and chemical defense also have some animal use *(50)*.

The Army does medical research to protect the soldier by the authority in the mission of the US. Army Medical Research and Development Command. Medical research and development (R&D) are carried out in five areas: infectious diseases (tropical disease and biological warfare defense), combat casualty care, combat systems, dental research (facial injuries), and chemical defense. About one-third of the research is done in-house and two-thirds is contracted out (38).

The Navy in fiscal year 1985 allocated \$58 million for the life sciences or biomedical research. Of this, \$37 million (64 percent) is for extramural research while the remainder is for intramural use. The two main branches of the service doing research involving animals are the Naval Medical Research and Development Command and the Office of Naval Research (ONR). The Naval Medical Research and Development Command does research in:

- submarine and diving medicine,
- electromagnetic radiation,
- aviation medicine/human performance,
- fleet health care systems,
- . infectious diseases, and
- oral and dental health.

ONR conducts research using animals in four major areas: molecular biology, neurophysiology/physiology, cellular biosystems, and psychological sciences (45).

Department of Energy

The Department of Energy has no intramural research facilities and so contracts out all its research (47). The primary research objective within its Office of Health and Environmental Research is to study the health and environmental effects of energy technologies and programs. To do this, in the past, the Department contractor used dogs. Recently, though, there has been a gradual shift from whole animals to cellular and molecular research and a much greater emphasis on rodents as opposed to companion species or primates (12).

Department of Health and Human Services

Intramural animal research or testing is carried out by four components of the Department of Health and Human Services' Public Health Service: the National Institutes of Health (NIH), the Food and Drug Administration (FDA), the National Institute on Drug Abuse (NIDA) (a part of the Alcohol, Drug Abuse, and Mental Health Administration), and the National Institute for Occupational Safety and Health (NIOSH) (a part of the Centers for Disease Control).

NIH is the largest research institution in the Federal Government and uses more animals than any other department or agency. The mission of NIH is to uncover new knowledge that will lead to better health (51). It does this by both intramural and extramural research. Approximately 88 percent of the NIH budget is spent on extramural programs while 10 percent goes to intramural research and 2 percent is used for NIH administration. Some 44 percent of the research awards go to research involving animals (28).

Research in the FDA is mission-oriented, with the principal objective being to provide data to support regulatory decisions. Research is conducted to determine the safety of human and animal foods; detect contaminants in human and animal foods; determine the safety and efficacy of human and animal drugs, biological products, and medical devices; reduce unnecessary exposure to artificial radiation; and increase fundamental understanding of the toxicological effects of chemicals. Ninety percent of the dollar budget for FDA research is allocated to intramural research studies while the other 10 percent goes to extramural research (5).

Department of the Interior

The Department of the Interior does more than 95 percent of its research in-house (31). Most animal research is performed by the U.S. Fish and Wildlife Service to support its mission "to provide the Federal leadership to conserve, protect, and enhance fish and wildlife and their habitats for the continuing benefit of people." This involves maintenance of relevant research and education programs in cooperation with other State and private organizations to enhance fish and wildlife resource management (53).

Department of Transportation

The Department of Transportation conducts animal research under the authority of the Hazardous Transportation Act of 1974 to determine the level at which substances become Class B poisons (see ch. 7). Most of the research involving animals is conducted extramurally (42). The Department also performs animal research under the authority of the National Traffic and Motor Vehicle Safety Act of 1966 (10).

Consumer Product Safety Commission

The Consumer Product Safety Commission (CPSC) both relies on data provided by manufacturers and conducts its own testing to determine the toxic potential of consumer products. Animals are used by CPSC's Directorate for Health Sciences in determinations of substances' acute oral toxicity, their potential for skin and eye irritation, and their combustion toxicity (16).

Environmental Protection Agency

The Environmental Protection Agency (EPA) performs research involving animals under the statutory and regulatory authority of the Toxic Substances Control Act and the Federal Insecticide, Fungicide, and Rodenticide Act. The general purpose of this research fits into one of three categories: methods development to assess potential hazards to the environment, dose-response data for risk assessment, or low dose to high-dose data for risk assessment. EPA has two major research facilities, one in Cincinnati, OH, and the other in Research Triangle Park, NC. In addition to the intramural research done in these facilities. EPA does contract extramural research. The amount done outside the agency varies from year to year and depends on the program, but it usually does not exceed 40 percent of total research (48).

National Aeronautics and Space Administration

The National Aeronautics and Space Administration (NASA) has three facilities that maintain or conduct research with animals, although approximately 65 percent of NASA's Life Sciences research is conducted extramurally. About 12 percent of the life sciences budget was used to fund animal research in fiscal year 1984 (37).

The general purpose of NASA's research is to acquire knowledge that can be used to protect and ensure the health of American astronauts, both during their missions in space and after their return to Earth.

National Science Foundation

The National Science Foundation awards grants for scientific research involving animals but performs no intramural research.

Veterans' Administration

The Veterans' Administration (VA) has 174 facilities, 91 of which have the ability and authorization to do animal research. The VA's mandate to do research that may involve animals comes from part of the agency's defined mission to understand health maladies better, with a special emphasis on those that affect veterans. The VA uses animals in its research and development divisions and its education programs, which are located in many of its local facilities. All research funded by the VA is done intramurally, and some of the research done by the VA is funded by other agencies, such as NIH (29).

Research and development within the VA has three elements: the Medical Research Program, Rehabilitative R&D, and Health Services R&D. The Medical Research Program includes research basic to disease and deformities, while Rehabilitative R&D includes studies on artificial appliances or substances for use in restoring structure or function of parts of the human body. Finally, Health Services R&D includes research toward improvement, replacement, or discontinuance of health care delivery systems (32). Thus, the VA's mandate for research and development is extremely broad and holds the potential to use animals in many programs.

Patterns of Federal Animal Use

APHIS is the agency within the U.S. Department of Agriculture responsible for administering and enforcing the Animal Welfare Act of 1966 (Public Law 89-544) and its amendments (see ch. 13). The act defines research facility as any individual, institution, organization, or postsecondary school that uses or intends to use live animals in research, tests, or experiments and that purchases or transports live animals in commerce *or* that receives Federal funds for research, tests, or experiments. It defines "animal" to include "any live or dead dog, cat, monkey (nonhuman primate mammal), guinea pig, hamster, rabbit, or such other warm-blooded animal, as the Secretary [of the Department of Agriculture] may determine is being used, or is intended for use, for research, testing, experimentation, or exhibition purposes, or as a pet ." The act excludes horses not used for research purposes and other

Primate Involved in Behavioral Research

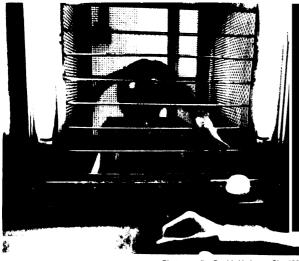


Photo credit: David Hathcox C), 1935

farm animals intended for use as food or fiber. Under this definition, dead frogs used in biology classes or animals killed prior to usage are not included. Rats, mice, and birds were specifically excluded from the act coverage by regulations promulgated in 1977 by the Secretary of Agriculture (9 C.F.R. 1.1(n); 42 FR 31022); reporting the use of these animals is voluntary.

The regulations that APHIS enforces require that each research facility fill out an Annual Report of Research Facility (see fig. 3-1) by December 1 on the preceding Federal fiscal year (October 1- September 30). Elementary and secondary schools are exempt, as are facilities using only exempt species (rats, mice, or birds). In addition, any facility that does its own in-house breeding and does not receive Federal funds does not have to file a report. Although Federal research facilities are not required to register with APHIS, many of them do fill out the annual reporting forms. Each year, APHIS reports to Congress on the data collected from these forms in its *Animal Welfare Enforcement Report*.

Since 1982, two lines on the Annual Report of Research Facility have listed rats and mice under column A, '(Animals Covered by the Act" (which is therefore no longer an accurate heading). Although not legally required, many respondents who used mandated species filled in the number of rats and mice anyway, either not realizing that reporting on these species is voluntary or electing to report their use, Thus, for many institutions a usage figure for rats and mice is given. In other cases, though, facilities reporting on mandated species omitted data on rats and mice.

Table 3-1 details the total reported animal use by research facilities within the Federal Government broken down by departments, major divisions, and agencies for fiscal year 1983. The Annual Report of Research Facility requires not only that total animals used be reported, but that the animals used be categorized as being used in research, experiments, or tests: 1) involving no pain or distress; 2) where appropriate anesthetic, analgesic, or tranquilizer drugs were administered to avoid pain or distress; or 3) involving pain or distress without administration of appropriate anesthetic, analgesic, or tranquilizer drugs (see fig. 3-1).

Several qualifications are necessary on the numbers reported in table 3-1, which are based on the annual reports obtained from APHIS:

- The 131 research reports include only intramural Federal research done at Federal facilities.
- The 131 facilities are not all the Federal facilities that might have used animals in 1983; at least 25 facilities did not file a report for that year.
- The numbers obtained were tabulated from each report. The reports were checked and corrected for improper coding of information and inaccurate addition. In many cases, these changes reflected substantial differences in the number of animals used for specific institutions.
- The numbers for mice and rats are included from any institution that reported them voluntarily. Several facilities, however, specifically mentioned that they were not required to submit these data and did not do so.

In addition to these general limitations on overall numbers, some specific qualifications for individual departments and agencies are also warranted:

• For FDA, table 3-1 does not include its primary research facility, the National Center for Tox-icological Research (NCTR), since no report

UNITED STATES DEPA ANIMAL AND PLANT H			1. DATE OF REPORT		RM APPROVEO
	RY SERVICE		2. HEADQUARTERS R tered with USDA, inc	ESEARCH FACILITY (Name	B NO. 05 79-0036 • & Address, as regis
ANNUAL REPORT C Required For Luch Reportion And An Attending Vet	ng Facility W	here Animals Are Held			
			3. REGISTRATION NO		
Reporting Facility - complete items Headquarters Facility, Attach additi	ional sheets if	necessary.		ITY (Name and Address, incl	ude Zip Code)
Headquarters Facility - complete iter December 1 of each year for the pre- September 30% to the Veterinarian in facility headquarters is registered.	ceding Federal Charge for th	fiscal year (October 1, to e State where the research			
REPORT OF ANIMALS USED IN A priate use of anesthetics, analgesics, a these drugs must be reported and a b	and tranquilizi	ng drugs during research, test	ERIMENTATION - Section (ing, or experimentation. E)	2.28 of Animal Welfare Regu experiments involving pain or o	lations requires appro distress without use of
A. Animals Covered By Act	B. Animais Added this Year	C. Number of animals used in research, experiments, or tests involving no pain or distress.	D. Number of animals used in research, experiments, or tests where appropriate anesthetic, analgesic, or tranquilizer drugs were administered to avoid pain or distress.	E. Number of animals used in research, experiments, or tests involving pain or distress without adminis- tration of appropriate anesthetic, analgesic, or tranquilizer drugs. (Attach brief explanation)	F. Of Animals (Cole. # + C + D + L
5. Dogs	1			1	
6 Cats					
7 Guinea Pigs					
8 Hamsters					
9. Rabbits					
10. Primates					
11. Rats			1		
2, Mice					
Wild Animals (specify) 3.					
4		·			
5.					
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VS FORM 18-23 Previous edition obsolete (AUG 81) SOURCE: Animal and Plant Health Inspection Service, U.S. Department of Agriculture.

was filed for 1983. This probably excludes a substantial number of animals since the fiscal year 1984 annual report for NCTR reported the use of 8 dogs, 334 rabbits, 29 primates, 14)621 rats, and 11,744 mice.

• The VA has 81 facilities accredited by the American Association for Accreditation of Laboratory Animal Care (AAALAC) yet only 63 reports were filed for 1983. Therefore, there is a strong possibility that the numbers for the VA are underreported.

Bearing in mind all the limitations and qualifications of the data used to generate table 3-1, OTA estimates that a minimum of 1.6 million animals are used annually by the Federal Government in intramural research. The Department of Defense, the Department of Health and Human Services, and the Veterans'Administration together account for 96 percent of reported Federal animal use. DHHS alone reported 49 percent of the total.

Among the six kind of animals whose inclusion in annual reporting forms is mandated by the Animal Welfare Act, guinea pigs are used most often twice as frequently as hamsters or rabbits (the second and third most used species). Overall, about the same number of dogs and primates are used, while far fewer cats are involved in Government experiments. Finally, table 3-1 suggests that certain agencies do research on specific species. For example, the VA uses a disproportionately large number of dogs and the Department of the Interior is the major user of wild animals.

Reports of Federal facilities indicate that most animal use falls into the experimental situation categorized as involving no pain or distress. Sixtythree percent of the animals used were in this category while 32 percent were given drugs to avoid pain or distress and only 5 percent experienced pain or distress without receiving anesthetics, analgesics, or tranquilizers. The largest user of drugs in experiments was the VA (62 percent of the animals in this category), whereas the largest user of animals experiencing pain or distress was the Department of Defense (84 percent of the animals in this category). The latter figure maybe inflated, however, by the fact that DOD has reported mice and rats voluntarily under these categories in many cases and has listed in this column all animals dying in infectious and neoplastic disease studies, which many Federal agencies may not do (43).

Table 3-2 shows the trends in animal use for Federal agencies as a group from 1978 to 1983, according to the Aninal Welfare Enforcement Reports submitted by APHIS to Congress (49). As with the numbers from the 1983 Annual Reports of Research Facilities, these data do not tell the whole story. Most important, these data do not include rats and mice, which together make up a majority of the animals used. Second, only reports that have been received by December 31 each year (the reports are due December 1) are included (26). It has been estimated that between 10 percent and 20 percent of the total reporting institutions fail to report by December 31 and are therefore not included in the Animal Welfare Enforcement Reports (17). (Thus, the 1983 data are lower in table 3-2 than in 3-1, which included all available annual reports.)

The data are difficult to interpret due to the different numbers of research facilities included each year. Therefore, no conclusions can be drawn about whether the trend in animal use is increasing or decreasing. This is also the case for trends in the use of individual species. The 1983 data do indicate, however, that no more than 8 percent of animals used in Federal programs reported here have experienced pain or distress in an experiment since 1978. The percentage of animals experiencing no pain or distress has remained between 50 and 60 percent, while drugs have been used to alleviate pain or distress for 30 to 40 percent of the animals.

ANIMAL USE IN THE UNITED STATES

OTA surveyed the available data concerning the numbers of laboratory animals used for research, testing, and education. These were summarized, corrected for methodological deficiencies, and evaluated for their statistical reliability. As a final step, estimates were made of current levels of an-

				Dej	partment of D	efense		Healt	
Animals used U	SDA	Commerce	Misc.	Air Force	Army	Navy	Total	FDA	<u>Services</u> NIDA
Facilities reporting	. 11	1	3	6	20	10	39	1	1
Dogs	. 25 <1	0 0	994 11	635 7	827 9	344 4	2,800 31	113 1	51 <1
Cats	. 39 1	0 0	491 18	61 2	214 8	36 1	802 29	o 0	84 3
Guinea pigs 6 ‱row	6,105 9	0 0	1,601 2	586 1	26,695 41	609 1	29,491 46	0 0	98 <1
Hamsters.,	7,487 21	0 0	627 2	1,352 4	4,822 14	417 1	7,218 21	:	0 0
Rabbits 1 [,] /o row	1,047 4	0 0	1,863 6	703 2	3,731 13	264 1	8,581 23	o 0	o 0
Primates .,	:	0 0	418 6	527 7	676 9	219 3	1,840 25	0 0	0 0
Rats	7,862 2	0 0	25,259 6	10,570 2	55,057 13	4,243 1	95,128 22	0 0	312 <1
Mice	,625 3	0 0	72,085 7	6,140 1	143,503 14	42,094 4	263,822 26	o 0	600 <1
Wild animals	. 24 <1 3,214	43 <1 43	1,377 10 104,715	34 <1 20,806	2,762 19 238,287	479 3 48,705	4,652 32 412,315	: 113	° 1145
•row	´3	<1	6	1	15	3	25	<1	<1

 Table 3-1.—Research=Animai Use in the Federai Government, by Major Department and Division for

 Fiscai Year 1983

KEY: USDA-United States Department of Agriculture; FDA-Food and Drug Administration; NIDA-National Institute on Drug Abuse; NIH-National Institutes of Health; CDC-Centers for Disease Control; NIOSH-National Institute for Occupational Safety and Health; DOT-Department of Transportation; EPA-Environmental Protection Agency; NASA-National Aeronautics and Space Administration; VA-Veterans' Administration; CPSC-Consumer Product Safety Commission.

Percentages may not add up to 100 due to rounding.

SOURCE: Office of Technology Assessment, from 1963 APHIS Annual Reports of Research Facilities (Form 18-23); CPSC data from K.C. Gupta, Deputy Director, Division of Health Sciences Laboratory, Directorate for Health Sciences, U.S. Consumer Product Safety Commission, Washington, DC, personal communication, Sept. 24, 19S5.

nual animal use in the United States. The purpose of this exercise was to examine numbers on animal use and compare the reliability of estimates from different data sources.

The figures published in this assessment on the number of animals used are not absolute. They are only as accurate as the data from which they were obtained. All publicly available information on past and current animal use was collected from a variety of sources, often through personal contacts. Data from the two most reliable sources, the Institute of Laboratory Animal Resources (ILAR) of the National Research Council and the USDA's Animal and Plant Health Inspection Service, were corrected to take into account the actual years of reporting and the omission of certain data that were not received before a deadline.

Laboratory-animal use was then estimated and projected using statistical techniques where appro-

priate. For this purpose, the corrected ILAR and APHIS data were used, as well as more indirect means based on National Institutes of Health funding, National Cancer Institute (NCI) usage, and NIH total usage as a function of NIH intramural use. Although the number of animals bred should lead to good estimates of animals used in the laboratory, the larger laboratory-animal breeders would not confirm or deny sales figures that had appeared in the news media and literature. Therefore, estimates based on such reports are of uncertain reliability.

Limitations of Animal-Use Study

Two types of limits on this study exist: intrinsic and extrinsic. The major intrinsic limitations were funding constraints and a limited time span during which the study could be performed. This prohibited the collection of raw data and required that OTA rely on existing data sources. The extrinsic

Depa	artment o	of Health and H	uman Services							
Animals used	NIH	CDC/NIOSH	Total	Interior	DOT	EPA	NASA	VA	CPSC	Total
Facilities reporting	3	2	7	2	1	4	2	63	1	131
Dogs	756	0	920	0	30	2	14	5,187	0	8,978
	8	0	10	0	<1	<1	<1	58	0	100
Cats	503 18	0 0	587 21	0 0	0 0	0 0	40	1,304 47	0 0	2,772 100
Guinea pigs ,	23,973	0	24,071	0	0	978	58	3,747	0	84,450
	37	0	37	0	0	2	<1	6	0	100
Hamsters	14,003	10	14,013	0	0	1,723	0	4,732	0	35,173
	40	0	40	0	0	5	0	14	0	100
Rabbits	8,783	30	8,813	0	0	842	74	11,508	600	29,445
	30	<1	30	0	0	3	<1	39	2	100
Primates	4,452	287	4,739	0	0	33	184	461	0	7,257
	61	4	65	0	0	<1	3	6	0	100
Rats	196,458	3 3,750	200,520	900	150	0	3,936	122,872 '	2,080	433,449
	45	<1	46	<1	0	0	1	28	<1	100
Mice	533,094	1,120	534,814	923	4,552	0	622	188,560	0	1,023,918
	52	<1	52	<1	<1	0	<1	18	0	100
Wild animals	2,787	0	2,787	4,228	0	0	232	2,393	0	14,358
	19	0	19	29	0	0	2	17	0	100
Total	.784,809	5,197 <1	791 ,264 49	6,051 <1	4,732 <1	3,578 <1	5,160 <1	340,764 21	2,680 <1	1,619,801 100

Table 3-1 .—Research.Animal Use in the Federal Government, by Major Department and Division for Fiscal Year 1983 (Continued)

KEY: USDA-United States Department of Agriculture; FDA-Food and Drug Administration; NIDA-National Institute on Drug Abuse; NIH-National Institutes of Health; CDC-Centers for Disease Control; NIOSH-National Institute for Occupational Safety and Health; DOT-Department of Transportation; EPA-Environmental Protection Agency; NASA-National Aeronautics and Space Administration; VA-Veterans' Administration; CPSC-Consumer Product Safety Commission.

Percentages may not add up to 100 due to rounding.

SOURCE: Office of Technology Assessment, from 1983 APHIS Annual Reports of Research Facilities (Form 18-23); CPSC data from K.C. Gupta, Deputy Director, Division of Health Sciences Laboratory, Directorate for Health Sciences, U.S. Consumer Product Safety Commission, Washington, DC, personal communication, Sept. 24, 1985.

Table 3=2.—Total Numbers of Animals Used in Federal Government Facilities as Reported to Congress in APHIS Animal Welfare Enforcement Reports, 1978-83

	Fiscal year						
1978	1979	1980	1981	1982	1983		
Federal facilities							
included in reports 188	150	118	131	131			
Dogs	15,605	13,153	13,930	6,369	6,6;		
Cats 5,354	4,709	3,388	3,183	1,940	1,825		
Primates 7,286	5,031	3,459	3,081	6,907	1,837		
Guinea pigs 65,009	40,425	25,402	33,495	45,972	36,033		
Hamsters 45,291	25,213	17,830	32,367	35,220	18,992		
Rabbits , 43,867	32,205	21,631	21,962	16,209	16,355		
Wild animals 5,537	4,137	3,209	2,007	7,618	8,037		
Total animals ^a	127,325	88,052	110,025	120,235	89,747		

a Totals do not include rats or mice, two species that together account for the majority of animals used.

SOURCE: Office Technology Assessment, from APHIS Animal Welfare Enforcement Reports, 1978-1983.

limitations include various information deficiencies, such as:

- inadequacies of information on most of the survey and data collection methodologies,
- difficulties with definitions,
- problems with categorizing animals under areas of use,
- reporting requirements of different data sources, and
- an inability to verify completeness of data sources.

For example, there is often a discrepancy in the definition of the term "use." In some cases, the term reflects the number of animals acquired; in other cases, it corresponds only to those used in laboratory experiments. This distinction is frequently obscured in the data sources, and only after careful reading of the documents (and, sometimes, personal inquiry) was the definition used in each case clarified. This leads to large differences in numbers, since not all animals acquired are used in experiments. It also makes any comparative analysis between surveys very unsound.

In addition to this problem of the difference between production and use, the extrinsic problem of the number of animals not used in a procedure because they do not fit the proper criteria comes into any extrapolation of animal use from laboratory-animal market share data, A substantial proportion of the animals bred for research die or must be discarded because they do not meet protocol specifications (age, sex, weight, general health). The number has been estimated as between a few percent of those acquired to almost 50 percent. In general, the unused proportion of a species is inversely related to the cost of the animals. In other words, the more expensive the animal, the less likely it will be unused, once bred or purchased. Thus, nonhuman primates are much less likely to go unused than are mice or rats; in some cases 50 percent of a rodent species may go unused. Using only one sex of a rodent species in a given experiment, for example, would account for 50 percent of the animals going unused. This information must be borne in mind when comparing "production" with "use" and when estimating animal use.

Overall, these limitations reflect on the accuracy of the data and any projections based on them. The limitations are such that the only reasonably credible source for current use and projections is APHIS, particularly its institutional data sheets (the Annual Report of Research Facility discussed earlier). Only the detailed APHIS institutional data sheets for fiscal years 1982 and 1983 were used in this assessment, though those for earlier years were also available (although they would not have had any data on mice or rats, which were not even listed on the form until 1982). Consequently, the APHIS data are less reliable for the years before 1982 inasmuch as these are based on reports to Congress that did not contain late-reporting institutions. (The Animal Welfare Enforcement Reports to Congress underestimate use of the mandated species by 10 to 20 percent due to the cutoff date and do not treat data from Federal institutions consistently (17).) For some species, such as fish and birds, only rough estimates of use could be obtained, due to the diffuse nature of use and the fact that they are not included in the APHIS data.

Critical Evaluation of Animal-Use Estimates

In evaluating the reliability of various data sources, the following parameters were considered:

- ability to trace the methodology used in producing the numbers, including the survey technique;
- ability to extrapolate to nonreporting institutions, which implies that there is a clear statement as to which institutions did or did not report data;
- method of data collection, whether some formal manner or through a few interviews, resulting in broad estimates; and
- ability to determine the fraction of animals reported as being actually used in lab experimentation, as contrasted to, for example, animal husbandry.

These parameters were chosen because meeting these criteria permits extrapolation of the limited data to the entire population of institutions. In general, if the numbers cannot be justified through some rational process (such as the above), too much significance should not be attached to them.

These four criteria were used to assign a confidence rating to each data source. The confidence categories are: '(excellent)" "good," "fair," '(poor, " and "indeterminate ." (These ratings refer only to the published numbers, not to their usefulness as a predictive tool.) Such a confidence rating is necessarily subjective; the categories are comparative and should not be viewed as absolute.

Upon reviewing all the data sources available for predicting the laboratory-animal use in the United States, it is clear that no source accurately portrays the number of animals being used. Each has methodological problems that prevented it from accurately counting all users of animals. What follows is an analysis of the available data sources and how they rank in comparison with the other surveys in terms of confidence and reliability.

USDA Animal and Plant Health Inspection Service (APHIS)

The 1982 and 1983 data were analyzed on a caseby-case basis. Copies of the original report forms were obtained from USDA; they were sorted by institution type, checked, coded, and entered into a computer database. Comparing the 1982 and 1983 APHIS data (see table 3-5, in the 'Summary and Analysis of Estimates" section) with the USDA Animal Welfare Enforcement Report for 1980 (the APHIS 1980 data in table 3-5) reveals a large discrepancy. The USDA reports invariably contain lower numbers for all species, as the data sheets received after the December 31 cutoff date are not included in reports in either the current or the next fiscal year. It is estimated that between 10 and 20 percent of the reports are not used to compile the report to Congress in a given year (17). This limitation does not apply to the results contained in the present compilation for 1982 and 1983, since all data for a given year were used no matter when received. The assumption is made that copies of virtually all of the data sheets received by USDA in the 1982 and 1983 are used

in this study. No verification was made of which institutions did not report.

The number of institutions reporting to APHIS has hovered around 1,000 since 1972. The numbers for 1982 and 1983 (shown in table 3-6, in the "Summary and Analysis of Estimates" section) were tabulated from the actual summary data sheets provided to APHIS by the institutions and include all possible reports. Even these figures—1, 127 for 1982 and 1,146 for 1983—are probably low, as not all institutions submit reports. (The total number of institutions registered by APHIS was 1,113 in 1982 and 1,166 in 1983; this excludes Federal agencies, which are not required to register.) Some of the institutions may not report because they have not used any animals that year, or because they have only used exempt species.

For the six required species listed on the form (dogs, cats, guinea pigs, hamsters, rabbits, and primates), the numbers reported provide a very close approximation of the animals actually used. Thus these data were assigned a confidence rating of '(excellent ." (For a summary of all the data sources discussed in this section and their confidence ratings, see table 3-3.) For exempt species (primarily rats and mice), it is possible to estimate the number of unreported rats and mice by extrapolating from the numbers reported (see the section on '(Estimate Using Corrected APHIS Data"). Some commentators (1)3)2 7) claim, however, that a certain number of exempt animals go unreported—and would be missed in an extrapolation-because they are purchased directly by the user and not reported to the central facility. This contention could not be confirmed. Therefore, the voluntarily reported data on rats and mice on the 1982 and 1983 APHIS annual reports received a confidence rating of "good.'

ILAR Surveys

The Institute for Laboratory Animal Resources, a component of the National Research Council, periodically surveys users of laboratory animals (18,19,20,21,22,23), although it is generally more concerned with facilities and personnel than with quantity of animals used. The ILAR data represent the number of animals "acquired by own

Source	Years covered	Confidence rating	Strength(s)	Limitation(s)
USDA/APHIS: Mandated species	1982-83	Excellent	Required by law. Data available by institution, thus extrapolation to nonreporters is possible	
Mandated species	1972-81	Fair	Required by law. Data by institution available, but not used	10 to 20 percent of institutions not included in reports to Con- gress. Totals not consistent (some years include Federal agencies, others do not)
Exempt species	1982-83	Good	Data by institution available. Rats and mice were on the form so anyone who reported probably provided an accurate number. Many did not realize that these were voluntary since they were listed on form. Extra- polation possible	Not required by law
ILAR Surveys of Laboratory Animal Use	1965-71	Poor	Of some use in establishing trends for that period	Old data. Cannot extrapolate to missing data
1968 Survey	1967	Fair	Statistically sound survey. Possibility of extrapolating to other institutions	Limited to 683 Federal-grant- eligible institutions
1980 Survey	1978	Fair	Thorough and statistically solid. Extrapolation to non- reporting institutions possible	Primary attention given to nonprofit Federal-grant-eligible institutions. Not required by law to be filled out
W.B. Saunders & Co.	1965	Indeterminate		Company defunct, survey methodology unclear; no evaluation possible
Foster D. Snell	1975	Indeterminate		Data appear to be based on in- terviews with two breeders
				Methodology unclear. Person- nel no longer available

Table 3-3.-Reliability of Various Data Sources

SOURCE: Office of Technology Assessment.

breeding and from commercial sources," not necessarily the number actually used in experimentation.

The ILAR and APHIS surveys are so different in their organization and methodology that it is not meaningful to compare the two sources, even in years for which data from both are available. It is also difficult to point out significant changes within this data source because the ILAR methodology varied over time and could not be verified adequately, so changes in numbers are difficult to substantiate.

ILAR *Surveys of Laboratory Animal Use (20)* consist of tables summarizing the results of questionnaires on the number of animals used for research. As ILAR personnel cannot discern who was surveyed and who responded, extrapolation for missing data is impossible. The surveys could, however, be of some use in assessing trends between 1965 and 1971. A "poor" confidence rating was given.

The **1968** Survey of Laboratory Animal Facilities and Resources (21) appears to have been a very thorough and statistically sound survey including all known users of laboratory animals. The results shown, however, are only for the 683 organizations eligible for Federal grants that responded because of the interest of the survey sponsor (NIH). It is possible, however, to normalize for missing data based on the reported biomedical research expenditures for these 683 organizations of \$920

_	Years	Confidence		
Source	covered	rating	Strength(s)	Limitation(s)
Alex Brown & Sons	represent best		At the time, it was thought to represent best estimate for lab animals in U.S. market	Data based on a few inter- views, and mostly broad estimates
Andrew N. Rowan	1985	985 Poor Data distinguishes between production, acquisition, and actual use		Broad analysis with many assumptions. Based mainly on one breeding facility
Amphibians:	1090	indotorminoto		Cichol actimates
Emmons	1989	indeterminate		Giobal estimates
Culley	1981	Indeterminate		Many assumptions
Nace	1974-81	Fair	Fair detail for basis of estimates	Difficult to know actual numbers due to large number of users
Various, on fish usage	1983	Fair	Data consistent	Global estimates only
Various, on bird usage	1983	Poor	Good detail by institutions	Uncertainty about nonreporting institutions, and fraction of fowl used by lab experimentatior
Data on animal trends: Wadsworth Center, NY	1980-83	Poor	Good detail of different Difficult to predict	
Johns Hopkins, MD	1975-85	Poor	species used	Limited data that are impossible to analyze

Table 3-3.–Reliabiiity	of	Various	Data	Sources	(Continued)
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SOURCE: Office of Technology Assessment.

million in fiscal year 1967. (The results for all respondents, while not mentioned in the report, were compiled and reported for comparison purposes in the ILAR 1980 survey,) The confidence rating was "fair."

The ILAR National Survey of Laboratory Animal Facilities and Resources (22) also appears to be a thorough and statistically solid report, although the data (for fiscal year 1978) are now 8 years old. Since it also was funded by NIH, primary attention was given to nonprofit biomedical research institutions eligible for Federal grants. In addition, data were received from Federal organizations, commercial research labs, and the pharmaceutical industry. Seventy-two percent of the 2,637 questionnaires were returned; 47 percent of those were acceptable, thus providing 1,252 respondents (including 992 nonprofit Federal-granteligibles, 137 commercial laboratories, 25 components of the DOD, 21 units of NIH, and 77 components of other Federal agencies). Although the individual identities of the respondents are unknown, the biomedical research expenditures of the nonprofit organizations are known. Since their data are reported separately from all respondents, an extrapolation to the unknown cases can be attempted based on the known national (meaning "all use in the United States") biomedical research expenditures. This source was assigned a confidence rating of '(fair."

W.B. Saunders & Company

W.B. Saunders&Company (41) surveyed the laboratory animal market in 1965 and projected figures for 1970. The survey and its estimates are widely quoted as one of the first estimates of animal use. The survey methodology is unclear and the company no longer exists, so these data fall under the "indeterminate" category.

Foster D. Snell, Inc., for Manufacturing Chemists Association

A study performed by Foster D. Snell, Inc., for the Manufacturing Chemists Association (25) estimated that 35 million mice and 40 million rats were produced domestically in the United States in 1975, and that 20,000 monkeys were imported from India. The report's authors could not be located and the methodology is unclear, thus making it impossible to validate. It appears that the data are based on interviews with personnel at two animal breeding facilities (Charles River Breeding Labs, Inc., and White Eagle Farms) and perhaps a few other people in industry, academia, and government. As it is difficult to give any credibility to such data, the source was assigned a confidence rating of "indeterminate."

Alex Brown & Sons

An Alex Brown&Sons (2) report on Charles River Breeding Labs, Inc., stated that the company produces 22 million animals annually worldwide, specializing in mice, rats, guinea pigs, hamsters, and primates. It did not give any breakdown by species, nor do any other analyses of Charles River. The number was primarily a guess based on a few interviews and so its value must be questioned. The confidence rating of this source was "poor."

Andrew N. Rowan

In a 1984 book, *Of Mice, Models, & Men:A Critical* Evaluation *of Animal* Research, Andrew N. Rowan estimated that approximately 71 million laboratory animals are used each year, including 45 million mice and 15 million rats (39), These figures were obtained by looking at all the available data sources for animal use in the United States, especially information on Charles River breeding production. In 1985, Rowan revised these estimates to distinguish between production, acquisition, and actual use. The new estimates on animals used suggest that between 25 and 35 million animals are used per year (40). As these are based on a very broad analysis with many assumptions, they have been given a confidence rating of "poor."

Surveys and Estimates on Amphibians, Fish, and Birds

There is little good survey information on laboratory use of amphibians, fish, or birds. Use of these animals is not required to be reported on the USDA/ APHIS annual reports. Therefore, the only sources of estimates are personal communications with experts in these fields. The most recent assessments of amphibian use were the ILAR surveys of 1965-71, which indicated the use of 3.37 million amphibians in 1971. As mentioned earlier, however, it is not known how to normalize for institutions that did not report, so the usefulness of these data are questionable and the confidence rating is "indeterminate."

Several individuals who use or produce amphibians were surveyed, yielding a wide range of estimates. A former general manager of a major supplier of amphibians estimated that approximately 9 million frogs were shipped by suppliers in 1969 for educational and teaching purposes (13). This is a global estimate and so its confidence rating was considered "indeterminate." An amphibian researcher at Louisiana State University did a survey of the use of bullfrogs that estimated that 150,000 bullfrogs and 200,000 tadpoles" could have been used in 1981 (a decrease since 1971, he found). He then assumed that bullfrogs represent roughly 10 percent of amphibian use and estimated that about 1 million frogs and 2 million tadpoles were used in the United States for teaching and research in 1981 (8). The assumptions in this method are very general and so the value of this estimate is questionable; an "indeterminate" rating was assigned. Finally, George Nace (34,35) estimated that about 9 million frogs were shipped by suppliers in 1971, but that this dropped to roughly 4.5 million in 1981 and stabilized at that level in 1984, with 90 percent of the usage educational and 10 percent research. There is fairly good detail for the basis of the estimates, but it is difficult to confirm the totals due to the large number of users. This source was given a confidence rating of "fair."

Reliable data on fish used in laboratories were particularly difficult to obtain. Estimates were received from commercial and institutional (including Government) users in the field. For fish over half an inch long, the yearly use appears to range between 500,000 and 1 million. For smaller fish, the best estimate is that 2 million to 3 million are used yearly. Most are used for toxicological studies. Although the numbers are fairly consistent from source to source, they are only global estimates and so were given a confidence rating of "fair." These numbers apply only to laboratory use. They do not include fish that are used in the wild in propagation, contamination, feeding, and other ecological studies.

For birds, many of those completing the APHIS data sheets voluntarily reported bird use under the "wild animal" category. According to these data, at least 33,910 birds were used in fiscal year 1982 and 29,781 in fiscal year 1983. Of these, the University of Maryland used 17)915 birds in 1982, and 12,305 in 1983 (46). Since this one institution used such a large fraction of the reported total, inquiries about other large possible users indicated that many of the poultry research institutions (mostly land-grant universities in the East and South) did not report birds on their APHIS forms, The largest of these, in terms of poultry research, is North Carolina State University, from whom it was learned that approximately 41,000 birds were used for poultry science and 1,100 in veterinary schools (7). Checking the APHIS data sheets for other landgrant institutions showed that most had reported bird usage. In addition, discussions with researchers at several institutions established that only 80 to 85 percent of the poultry science usage is in laboratories with the remainder mostly in feeding, management, and breeding studies. Therefore, although there is good detail for many institutions on bird use, there is uncertainty in the APHIS data about nonreporting institutions and about the proportion of fowl used in actual experimentation.

Several individuals have estimated bird use in the United States. James Will of the Animal Resource Center at the University of Wisconsin in Madison, WI, estimated that 25,000 to 100,000 avian individuals are used for laboratory experimentation (54). Andrew N. Rowan of Tufts University School of Veterinary Medicine in Boston, MA, estimated that at least 500,000 birds are used in biomedical research (00). Both of these figures are based on very weak data and so are assigned a confidence rating of "poor." Thus, using these estimates and the APHIS bird data, an annual use of between 100,000and 500,000 birds is as accurate an estimate as can be made.

Data on Trends in Animal Use

Several limited data sources exist that suggest trends in animal use in the past several years. At Wadsworth Center for Laboratories and Research, New York State Department of Health (Albany, NY), the use of mandated species decreased 40 percent from 2,925 in 1980 to 1,754 in 1983. The use of rats and mice also decreased substantially (22 percent), from 72,796 in 1980 to 56,681 in 1983, at a time when total research dollars available continued to increase (11. At The John Hopkins School of Hygiene and Public Health in Baltimore, MD, the daily census of animals decreased from over 8,000 in 1975 to approximately 2,000 in 1985 while animal care personnel dropped from 10 to 4 and research expenditures more than doubled (14). These data sources are limited in scope, use different counting mechanisms, and can be considered anecdotal in nature. They were assigned a confidence rating of "poor."

Calculating Rat and Mouse Usage

Using these same data sources, estimates for annual laboratory use of rats and mice in the United States were calculated. The criteria and scales described earlier were also applied to assign confidence ratings to the estimates. To gauge annual laboratory-animal use, minimum average costs of \$4 per rat and \$2 per mouse (6,15,24,30,36,55) were assumed to represent conservative prices for a typical research subject. This permitted extrapolations based on price to represent an expected maximum of animals that could be purchased.

Three different methods were used to estimate the use of rats and mice in the United States. The first involved using indirect means for the calculations, while a second method used 1978 ILAR data. The third, and most reliable, method relied on corrected USDA/APHIS data and involved calculations using regression equations.

Indirect Estimates

Possible methods for estimating rat and mouse usage under this category involve extrapolations from data based on NIH funding, NCI usage, NIH total use as a function of intramural use, and animal breeder information. For example, an estimate based on NIH funding involves the following steps and assumptions:

- NIH funds 37 percent of all national biomedical research expenditures (52).
- In 1983, NIH awarded \$582,571)000 in direct costs to 5,011 extramural projects utilizing rats and other species (4). If it is assumed that all

expenditures went to projects that used only rats, an upper limit can be extrapolated for rats purchasable using NIH funds.

- Twelve percent of direct costs of NIHsponsored research funds go toward the purchase of supplies, glassware, chemicals, research animals, and items listed as expendable (55).
- If it is assumed that half of the supply funds went toward the purchase of animals, then \$34,954,260 would be available for the purchase of rats.
- At \$4 a rat, 8.7 million rats could be purchased.
- In 1983, NIH awarded \$531,519)000 in direct costs to 4,080 projects using mice. At an average cost of \$2 per mouse, 16 million mice could be purchased with NIH funds.
- Assuming that NIH supports 37 percent of animal use in the country, then the potential number of these two species purchasable in the United States is estimated at 23.6 million rats and 43.1 million mice. This indirect method (whether it uses NIH data or NCI data or ani. mal breeder information) involves many assumptions, limited data sources, and cannot be considered very reliable. It was assigned a "poor" confidence **rating.**

Estimate Using Corrected ILAR Data, 1978

The results of the **1978** *National Survey (22)* permit approximation of animal use for all users with techniques that fill in the missing data of nonrespondents based on a method such as the following:

- The NIH-grant-eligible nonprofit biomedical research organizations responding to the survey reported biomedical research expenditures of \$2,2 billion for 1978.
- Total national biomedical research expenditures are estimated at \$6.27 billion for 1978 (52).
- If it is assumed that animal use (in numbers) is proportional to the dollar amount spent on research utilizing them and that the usage rate of animals by all institutions is proportional to that of nonprofit institutions, national usage equals (nonprofit ILAR 1980) X 6.27/2.2. This yields an estimate of 16 million mice and 5.6 million rats used in 1978. Such methods do in-

volve some assumptions not easily justifiable and so the confidence rating is somewhat lower than for the ILAR data on which they are based. In addition, they are based on information already 8 years old.

Estimate Using Corrected APHIS Data

About two-thirds of the institutions completing APHIS annual reports for 1982 and 1983 volunteered information on the number of rats and mice used. Regression equations based on those institutions reporting the specific species on the Annual Report of Research Facility forms were used to estimate the numbers of rats and mice for those institutions not reporting these species (17). The estimates obtained using these regression equations and then simply applying the mean value for reporting institutions to the nonreporters are shown in table 3-4 (which summarizes all the estimates discussed). These regression equations yield estimates of 8.5 million mice and between 3.4 million and 3.7 million rats used annually in 1982 and 1983; applying the mean value for reporting institutions to those that did not report yields higher estimates. Given the fairly detailed database to which the regression equations were applied, these estimates received a confidence rating of "good." The estimates generated from these corrected APHIS data are likely the most accurate that can be obtained with data currently available.

Summary and Analysis of Estimates

Table 3-5 summarizes the various estimates on animal use discussed in this chapter. Several factors reduce the usefulness of these data, however: APHIS's definition of animal (which excludes rats, mice, and birds) and the exemption from regulation of research facilities that do in-house breeding and receive no Federal funds. These limitations may cause the numbers generated from the APHIS data to be underestimations of the total animal use in the United States for research, testing, and education. For example, the Directory of Toxicology Testing Laboratories published by the Chemical Specialties Manufacturers Association, Inc., lists 110 facilities in the United States. In checking these against the list of APHIS registered research facil-

	(Mice millions)	(m	Rats nillions)		
Basis of estimation	1978	1982	1983	1978	1982	1983	Confidence rating
Indirect means-NIH funding	–		43.1	_	_	23.6	Poor
Corrected ILAR data: Nonprofit funding share Corrected APHIS data:	16.0	_	_	5.6	_	_	Fair
Regression						3.7 4.6	Good Good

Table 3-4—Estimates of Rat and Mouse Usage in Laboratories, 1978, 1982, 1983

SOURCE: Off Ice of Technology Assessment.

ities, 40 percent were not registered and so would not file a report. Any animals used in those facilities would not be reported in the APHIS data. The 1978 ILAR National Survey of Laboratory Animal *Facilities and Resources* stated that 35 percent of mice and 19 percent of rats acquired for research were bred in-house by the researchers (22), so these too might not appear on the the APHIS data sheets. Thus, all these limitations mean the APHIS data may be underestimations of total animal use, but it is impossible to estimate if the difference is significant. Ideally, the results based on APHIS data could be compared with estimates based on animal breeder numbers. However, since information on distribution of costs per animal is proprietary, such an analysis is impossible. Therefore, although the data contained in the APHIS reports are the most reliable, they do not include all possible users of laboratory animals.

Inspection of some 150 institutional Annual Report of Research Facility forms raises several other doubts as to the accuracy of the data collected by APHIS. In general, the form seems to lack any instruction to the individual institutions on how it should be filled out. As a result, there is no consistency in the ways in which forms are completed. The reliability of the data on the forms today is in question. Figures 3-2, 3-3, and 3-4, which exemplify the reporting problems, are actual forms returned to APHIS for 1983, although the institution names have been deleted. For example:

• Some forms have an error that can lead to miscalculations of the number of animals used: Column F asks for the addition of columns B +C +D +E. The actual number desired is C +D +E. **Thus, some reports have dou**- **bled the number of animals used** (since B = C + D + E) (see fig. 3-2). These types of miscalculations, along with normal mathematical errors, were corrected in the OTA estimate of animal use in the Federal Government. Thus, the numbers for Federal agencies in these two sections are different for the same APHIS institutional reports. (For Federal agencies, this difference is fairly small.)

- In many cases, respondents did not seem to understand how to classify the animals used in the different experimental categories. If the APHIS form is read literally, any animal given drugs to avoid pain or distress is also an animal that experiences no pain or distress and could be counted in both categories (See fig. 3-3).
- The answers to the category "wild animals" differed greatly. Some forms listed legitimate wild animals, such as seals, while others included as wild such animals as gerbils, cattle, sheep, and pigs (see fig. 3-4). In fact, the "wild animals" line was often filled in with farm animals, which are exempt from being reported.
- The forms are now improperly labeled in that rats and mice are included under column A, "Animals Covered by the Act," yet they are specifically exempted by USDA regulation from coverage by the Animal Welfare Act. Many institutions that filled out APHIS forms may have been unaware that reporting rats and mice was voluntary.

These examples serve to characterize the present system as lacking clarity and uniformity in definition and accurate reporting, Redesign and enhanced explanation of the APHIS form would lead to collection of more accurate data on animal use.

Designs timate) 1983
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175,716 000,000 150,000 154,479 521,237
509,052
237,771 55,346 182,42 <u>5</u>
_
59,336

Group	Species	W. B. Saunder (estimate) 1965	S W. B. Saunders (projection) 1970	ILAR 1967	ILAR 1970	ILAR 1978	APHIS 1980°	APHIS 1982⁵	APHIS 1983 [⊾]	Health Design (estimate) 1983
Number of repo	orting institutions		_	1,371	1,523	1,252	975	1,127	1,146	-
Rodents	Total Mice Rats Hamsters Guinea pigs Other rodents	$\begin{array}{c} 58.440.000\\ 36.840.000\\ 15.660.000\\ 3.300.000\\ 2.520.000\\ 120,000\end{array}$	94,480,000 59,560,000 25,320,000 5,340,000 4,070,000 190,000	30,363,000 22,772,300 6,131,000 785,900 613,300 60,500		7 18,646,171 7 13,413,813 4,358,766 368,934 426,665 79,993	828,216 405,826 422,390	$10,530,685 \\ 6,889,744 \\ 2,725,814 \\ 417,267 \\ 497,860 \\ -$	$12,156,377 \\7,913,167 \\3,269,494 \\454,479 \\521,237 \\-$	$13,175,716\\8,500,000\\3,700,000\\454,479\\521,237$
Rabbits	Total	1,560,000	2,520,000	504,500	494,591	439,986	471,297	547,312	509,052	509,052
Carnivores	Total Cats Dogs Other carnivores	_ _ _	-	370,400 99,300 262,000 9,100	247,310 56,646 182,728 7,936	242,961 54,908 183,063 4,990	257,265 68,482 188,783	254,628 59,961 194,867	237,771 55,346 182,425	237,771 55,346 182,425

106,200

57,700

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2,070,500

33,472,300

95,636

54,437

667,263

2,039,490

2,022,755

601,663

41,667.767 19,956,386

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59,336

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12.964.536

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500.000[°]

4,000,000 °'f

18,561,875

54,565

144,595

30,323

450,352

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58,024

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1,661,904 11,387,390

49,102°

Table 3-5.—Various Estimates of the Number of Animals Used in the United States

*D,t obtained from A"/ma/ we/fare Enforcement Ffepoti to Congress for 1950. They do not include any numbers for rats and mice

60.000.000

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bu ~ ..., b, H Ih @signs, L, (RWhester, Ny) with all available Annual Reports of Re-arch Facilities The data for rats and mice are from volunta- reporting of the use of these species.

_

97,000,000

'Estimates stated are highest value Of a rough ran9e.

Total

Total

Total

Total

TOTAL

Frogs and toads

'Marine mammals, fish, and reptiles. 'Wild animals.

Nonhuman primates Total

Ungulates

Amphibians

ALL ANIMALS

Birds

Other

'Fish.

SOURCE: Office of Technology Assessment.

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Figure 3-2.—Example A of APHIS "Annual Report of Research Facility"

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SOURCE: Animal and Plant Health Inspection Service, U.S. Department of Agriculture.

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Figure 3=3.-Example B of APHIS "Annual Report of Research Facility"

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5. Dogs			14		14				
6. Cats		6	6		12				
7. Guinea Pigs		18	18		36				
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9. Rabbits		130	130		260				
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SOURCE: Animal and Plant Health Inspaction Service, U.S. Department of Agriculture.

Figure 3=4.—Example C of APHIS ^c'Annual Report of Research Facility"

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SOURCE: Animal and Plant Health Inspection Service, U.S. Department of Agriculture.

Even with these limitations and qualifications, the numbers generated by the APHIS data provide a range that can be used in discussions of animal use. The totals include: 1.8 million mandated species, 100,000 to 500,000 birds, 100)000 to 500,000 amphibians, 2.5 million to 4.0 million fish, and 12.2 million to 15.25 million mice and rats. Therefore, **it appears that between 17 million and 22 million animals are used in united States laboratories annually.**

The largest group is represented by mice and rats. For reporting institutions, mice represent 60.8 percent of all animals used, and rats 25.1 percent. In addition, for the mandated species, certain institutions use specific species disproportionately to their percentage of overall total use (see table 3-6). Fifty percent or more of all cats and dogs are used by universities and medical schools. Guinea pigs are used mostly by the pharmaceutical industry, whereas hamsters are used more often in biomedical research, and to a lesser extent in universities, medical schools, and the pharmaceutical firms. Sixty-two percent of rabbits are used in universities, medical schools, and the pharmaceutical industry, as are 75.6 percent of the primates.

For rats and mice, the trends indicated in table 3-6 are clouded by the fact that there was more reporting of rat and mouse usage in 1983 than in

Table 3-6.–USDA/APHIS Data, Changes 1982-83 (reporting Institutions only)

	Institution type									
	Universities & medical schools	Hospitals nonuni- versity	Bio- medical research	Toxicology testing labs	Chemical companies	Pharmaceu- tical, device & diagnosis	State & local government	Food, feed & miscel. laneous	Federal agencies	— Total
<mark>rear</mark> Rats: 1982 1983 ∞ change	1,079,208 1,234,864 14	86,472 108,430 23	343,915 408,938 18	97,237 144,162 48	176,874 114,215 -35	558,630 778,425 39	11,299 30,378 168	12,700 14,355 13	359,479 439,729 22	2,725,814 3,269,494 19
Mice: 1982 1983 ∞change	1,678,300 1,951,466 16	203,768 222,080 8	1,579,664 1,512,424 —4	431,464 495,087 14	161,659 158,752 —1	1,669,629 2,021,157 21	200,150 477,250 138	6,247 3,632 -41	958,863 1,071,339 11	6,889,744 7,913,167 14
Dogs: 1982 1983 ‰ change	98,983 90,001 - 9	13,622 12,605 - 7	22,291 21,483 —3	3,457 5,003 44	2,194 1,591 –27	37,604 38,311 1	322 436 35	3,698 3,400 - 8	12,696 9,595 –24	194,867 182,425 —6
Cats: 1982 1983 ∞ change	34,555 32,535 —5	2,716 2,265 —16	7,697 6,788 -12	137 172 25	115 44 –61	9,073 8,624 -4	87 72 -17	2,040 2,092 2	3,541 2,774 –21	59.961 55,346 - 7
<i>Guinea pigs:</i> 1982 1983 0/0 change	82,198 64,554 -21	6,104 7,195 17	25,225 30,696 21	35,145 28,753 -18	18,182 14,722 – 19	272,405 297,849 9	9,044 10,090 11	1,504 930 –38	48,053 66,448 38	497,860 521,237 4
Hamsters: 1982 1983 1983	151,365 115,483 –23	5,501 5,472 - 0.5	65,146 169,272 159	12,954 11,922 -7	3,180 612 –80	131,227 112,618 – 14	8,401 3,193 <i>—</i> 61	23 22 -4	39,490 35,885 - 9	417,267 454,479 9
Rabbits: 1982 1983 ‰ change	173,716 158,058 - 9	15,171 15,042 -0.8	63,863 64,626 1	60,785 55,785 - 8	20,970 22,034 5	177,289 159,276 - 1 0	2,102 1,948 -7	1,862 2,504 34	31,554 29,779 —5	547,312 509,052 —6
<i>Primates:</i> 1982 1983 ∿change	23,353 22,201 - 4	557 1,059 90	13,543 13,272 –2	2,577 5,809 125	144 25 –82	7,709 9,376 21	329 243 -26	66 82 24	6,287 7,269 15	54,565 59,338 8
Institutions reporting: 1982 1983 on change	410 402 - 2	129 140 8	167 159 —4	:: 8	27 31 14	145 155 6	19 18 - 5	26 32 23	125 123 —2	1,127 1,146 2

SOURCE: Office of Technology Assessment.

1982. So, although it appears from table 3-6 that the usage increased, this was in fact not so (as can be seen from table 3-4). Data for all institutions from the regression equations show no change in mice and a small increase in the use of rats. However, since the same pattern of increase by institutional group reporting can be seen from table 3-6, there has likely been no increase or decrease in use of these two species between 1982 and 1983.

In table 3-6, the number of reporting institutions includes those that reported any number for any species, whether these included rats or mice or not. Few significant changes occurred as a function of institution type for the 2 years surveyed. No trend in animal use can be identified between 1982 and 1983, and the available data provide no justification for predicting either increases or decreases in future years. It would have been possible to examine the 1981 APHIS data sheets and determine whether, on the basis of 3 years' data, a trend for the mandated species existed, but the 1981 data sheets would not indicate trends for rats and mice. The other methods of estimating laboratory-animal use do not match the reliability of the APHIS data, and thus do not lend much credence to the numbers reported in the past.

Future Animal Censuses

The major limitation with this estimate of annual laboratory-animal usage was the need to depend on available data sources, with all the limitations just described. Although the APHIS data sheets were of considerable value, they still do not substitute for an appropriately designed stratified random sampling of all possible users. Only then would all possible institutions be represented. The APHIS scheme depends on institutions to request certification. Some may be operating and not reporting to APHIS. Still, with considerable further effort, a post-hoc stratification could be done based on the APHIS data.

Estimates could be improved by two major approaches. The first, and least expensive, would involve the use of all annual APHIS reporting forms following an imperative redesign of the form-as well as thoroughly determining which registered institutions in each year did and did not report. Then appropriate statistical estimation techniques could be used on an institution-type and yearspecific basis to correct for missing data. The second, and more ambitious, approach would be to conduct a stratified random sample study of all possible users. The stratification would be by type of institution, size of institution, and species of animals. From such a sample, appropriate statistical techniques could be used to project to the entire population of user institutions.

In 1985, the National Research Council's Institute of Laboratory Animal Resources announced plans for another in its series of surveys of experimental animal usage. The 1986 census will include mammals and birds, but omit fish, amphibians, and reptiles.

SUMMARY AND CONCLUSIONS

A rough analysis of the number of laboratory animals used is important to provide some nontext in which to discuss alternatives to using animals, evaluate progress toward the goal of using fewer animals, and judge the effect that alternatives might have. OTA therefore evaluated existing data on the number of laboratory animals used each year in the United States.

The data sources considered included various reports and surveys published by the National Research Council's Institute of Laboratory Animal Resources, various market surveys, and the annual reports submitted to USDA's Animal and Plant Health Inspection Service. For the latter source, the individual annual reports furnished by each registered facility for 1982 and 1983 were evaluated. Generally, it was found that great disparities existed among the different sources. No single data source presents an accurate count of the number of laboratory animals used in the United States since not one includes all potential users. In addition, it is impossible to compare data among sources due to the inadequacy of information on survey and data collection methodologies, definitions, areas of use, reporting requirements, and the inability to justify completeness of the data.

In a comparative analysis of data sources, it was found that the most useful data were the APHIS data sheets completed by every institution that uses laboratory species regulated under the Animal Welfare Act, APHIS requires that registered institutions report all use of dogs, cats, guinea pigs, hamsters, rabbits, and nonhuman primates. Even with this requirement, though, it seems that APHIS does not receive animal-use information from all possible users. The data from these forms were found to be more accurate than the Animal Welfare Enforcement Report, a summary submitted annually by APHIS to Congress. This report usually neglects 10 to 20 percent of the annual reports (those submitted late, usually after December 31) and so underestimates the actual number of dogs, cats, guinea pigs, hamsters, rabbits, and nonhuman primates used.

For fiscal years 1982 and 1983, the numbers of these kinds of animals used, according to the APHIS data sheets, are shown in table 3-7. For other laboratory species —mice, rats, birds, amphibians, and fish-the ability to obtain accurate estimates of the number used is impaired by a lack of reliable data sources. The best estimates are that 100,000 to 500,000 birds, 100,000 to 500,000 amphibians, 2.5 million to 4.0 million fish, and 12,2 million to 15.25 million rats and mice were used. (Animal use in medical and veterinary education is estimated to beat least 53,000 animals per year and is discussed in ch. 9.) Total animal use in the United States, therefore, is estimated as between 17 million and 22 million a year.

The great discrepancies in data sources meant no trends could be observed overtime and among different types of institution. Even within the APHIS data for six kinds of animals, no clear trends

Table 3-7.–Animai Use Reported to the U.S. Department of Agriculture, 1982 and 1983

	Number used	Number used
Animal	in 1982	in 1983
Dogs	194,667	182,425
Cats	59,961	55,346
Hamsters	417,267	454,479
Rabbits	547,312	509,052
Guinea pigs	497,860	521,237
Nonhuman primates	54,565	59,336
Total	. 1,771,832	1,781,875

^aTotals do not include rats or mice, two species that together represent the majority of animals used.

SOURCE: Office of Technology Assessment.

were found. Indeed, the most important finding was that no accurate source exists on the numbers of animals used annually in the United States. A stratified random sample of all possible user institutions done with a correct statistical analysis would probably be the best way to estimate laboratory-animal use in the United States.

In the Federal Government, six departments and four agencies use animals for intramural research and testing. These investigative efforts range from uncovering new knowledge that will lead to better health (within the National Institutes of Health), to evaluating hazardous substances in consumer products (within the Consumer Product Safety Commission's Directorate for Health Sciences), to protecting the health of American astronauts (within the National Aeronautic and Space Administration's Life Sciences Division).

OTA used the APHIS Annual Report of Research Facility forms to track animal use within the Federal Government itself by department (and by division within departments) and by species. In this way, it was possible to identify what portion of the estimated 17 million to 22 million animals used yearly were used within Federal facilities. In 1983, the Federal Government used at least 1.6 million animals, largely rats and mice. Ninety-six percent of the 1.6 million animals were used by DOD, DHHS, and the VA. Of the total, about 9 percent were dogs, cats, hamsters, rabbits, guinea pigs, and nonhuman primates.

The APHIS forms require that all experiments be categorized as: 1) involving no pain or distress; 2) involving appropriate anesthetic, analgesic, or tranquilizer drugs to avoid pain or distress; or 3) involving pain or distress without administration of appropriate anesthetic, analgesic, or tranquilizer drugs. Sixty-three percent of the animals used within Federal departments and agencies were in the experimental situation categorized as involving no pain or distress while 32 percent were given drugs and only 5 percent experienced pain or distress.

The APHIS reporting system lacks clear definitions and uniform reporting, If accurate data are to be obtained, the forms must be revised and better explanations of how to complete them must be provided.

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