Chapter 13

Federal Regulation of Animal Use

There is a debate as to what is the right of a mouse. Why are we wasting time in Washington with taking seriously this business?

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Federal Regulation of Animal Use

This chapter describes Federal law, as enacted and currently interpreted, that directly governs and regulates the acquisition and use of laboratory animals for research and testing. Federal laws and regulations governing the purchase, sale, handling, or transportation in commerce of animals for exhibition, domestic, or other purposes unrelated to research, testing, and education are not examined. Federal laws and regulations that have been interpreted to require testing with certain methodologies or protocols are considered in chapter 7, and appendix B describes regulations promulgated and guidelines issued by specific Federal agencies, pursuant to statutory authority, to regulate laboratory-animal use in required or sponsored research and testing.

FEDERAL LAWS AND REGULATIONS

Long before passage of the Laboratory Animal Welfare Act (Public Law 89-544) in 1966, Congress–following a trend against cruelty to animals that had manifested itself in some States throughout the 19th century-in 1873 passed the first Twenty-Eight Hour Law (Act of Mar. 3, 1873). Action was taken by the national legislature under its powers to regulate interstate commerce because of the toll exacted in animal flesh, literally, by inhumane conditions of rail transport for meat-producing livestock. The law barred confinement of livestock in rail cars for longer than 28 hours,

Continuing expressions of concern led to repeal of the original act and the passage in 1906 of the Twenty-Eight Hour Law still in effect today (45 U.S.C. 71-74). (In the intervening three decades, 22 States passed general anticruelty statutes (13).) Since enactment of the 1906 act preceded the rise of interstate motor traffic, its provisions regulating length of confinement and conditions of treat - ment during shipment do not apply to trucks (39). Similar concerns about needless suffering undergone by food-producing animals led Congress to pass the Humane Slaughter Act (public Law 85-765) in 1958, permitting slaughter only by "humane" means.

After 1966, concerns about animals led to Federal protection of:

- Horses, with the passage in 1970 of the Horse Protection Act (public Law 91-929), against an unesthetic physical practice on animals to produce a physical appearance aesthetically appealing to humans ("soring" the ankles to produce a high-stepping gait);
- marine mammals as a class (whales, porpoises, seals, and polar bears, for the most part), with the passage in 1972 of the Marine Mammal Protection Act (Public Law 92-522) against extinction or depletion from indiscriminate taking, including hunting, harassment, capture, and killing (permitted takings, including for subsistence and research purposes, must be accomplished humanely, with "the least degree of pain and suffering practicable to the animal"); and
- endangered and threatened species, with the passage in 1973 of the Endangered Species Act (Public Law 93-205), making it unlawful to buy, sell, or transport in interstate or foreign commerce any species found to be endangered and closely regulating commerce in any species threatened with extinction.

Thus, Congress has acted on several occasions over the past century to protect animals, both as individuals and as species (i.e., marine mammals and endangered species). The degree of commitment to protection of animals through proscription, regulation, and enforcement varied, with Congress exhibiting a tendency toward stricter controls beginning in the 1970s. Similarly, recent exercising of the constitutional authority of the Federal Government over interstate commerce seems to be based on interests broader than the welfare or treatment of individual animals -e.g., saving a species from extinction.

Congressional handling of humane treatment for experimental animals, discussed in this chapter, is an interesting mixture: It professes to protect the individual animal (e.g., the experimental subject), but it establishes classifications that favor some animals over others. It uses Federal authority over interstate commerce to regulate the procurement and housing of laboratory animals, but it does not use it to the same degree as for other animals in other circumstances. Though Congress has found less-than-humane treatment of laboratory animals to be worth exercising authority over interstate commerce in order to control, it has not judged the burden on commerce to be serious enough to preempt the regulatory field. By a cautious exercise of its power, Congress has acknowledged implicitly that there is some intrinsic public value in animal experimentation and that the uniqueness of the process of experimentation requires a deliberate approach, in order to achieve one policy objective without sacrificing the other.

The Laboratory Animal Welfare Act

The 1966 Act

Finding increasing evidence that dogs and cats owned as pets were being stolen by unscrupulous dealers, moved across State lines, and resold to research institutions to satisfy a demand for experimental subjects, Congress enacted the Laboratory Animal Welfare Act in 1966. The act sought to head off these abuses by requiring dealers and research facilities that handle, care for, treat, or transport certain animals "in commerce" to follow standards to be developed and issued by the U.S. Department of Agriculture (USDA). The purposes of the act were:

- to protect the owners of dogs and cats from theft of such pets;
- to prevent the use or sale of stolen dogs or cats for purposes of research or experimentation; and
- to establish humane standards for the treatment of dogs, cats, and certain other animals by animal dealers and medical research facilities.

"In commerce" meant interstate commerce between States, the District of Columbia, territories, and possessions; between points within a State, the District of Columbia, a territory, or a possession, but through an outside point; or within the District of Columbia, a territory, or possession. Thus, to be covered by the act a dealer or research facility would have to acquire, for a use covered by the act, a regulated animal that had moved, or at some point would move, "in commerce."

Although "animal" was defined to include nonhuman primates, guinea pigs, hamsters, and rabbits, recordkeeping requirements were restricted to dogs and cats. Humane treatment was required on the premises of animal dealers, in transit, and at research institutions. The act established a system for licensing dealers and registering research facilities, with monitoring by Federal regulators. The Secretary of Agriculture was vested with the power to promulgate and enforce standards for humane care, treatment, and housing of protected animals. The act provided for the suspension of the license of any dealer violating its provisions and, upon conviction, imprisonment of not more than 1 year and a fine of not more than $1,000. The law's reach extended to transportation of regulated animals by the supplier, but not by common carriers. The Secretary was authorized to cooperate with State and local officials to prevent theft of dogs and cats, apprehend pet thieves, and administer the previsions of the act. In addition, the Secretary was directed to establish rules for inspections of premises and of the required records of licensed dealers and registered research facilities, primarily to expedite the search for stolen pets.

As applied to research, the act's reach was short. Research facilities to be regulated were limited by definition to those that:

- used or intended to use dogs or cats in experiments, and
- either purchased them "in commerce" or received any Federal funds for research, tests, or experiments.

Covered facilities were required to register with the Secretary rather than be subject to more stringent licensure requirements. Research-animal suppliers were subject to the new law's requirements only if they bought, sold, or transported dogs or cats and if the dogs or cats supplied were used for research by the client institution. In other words, research facilities could continue to procure experimental animals from farms, munici-

pal pounds and shelters, and '(duly authorized agents of local governments, " rather than having to acquire animals only from licensed dealers. Research facilities were defined to include '(major research facilities and exclude the thousands of hospitals, clinics, and schools which use other animals for research and tests, " though research or experimentation included use of animals as teaching aids in educational institutions associated with major research facilities.

A specific and unequivocal exemption from newly devised standards for humane treatment for actual research activities was included. USDA jurisdiction over research activities was confined to care and treatment of research animals in an institution's holding facilities. The drafters of the bill were careful to point out that the exemption of research procedures was not to be compromised. The conference report stated the legislation's intent was (38):

> . . . to provide protection for the researcher in this matter by exempting from regulation all animals during actual research or experimentation, as opposed to the pre- and post-research treatment. It is not the intention of the committee to interfere in any way with research or experimentation . . . [T]he Secretary is not authorized to prescribe standards for the handling, care, or treatment of animals during actual research or experimentation by a research facility. The important determination of when an animal is in actual research so as to be exempt from regulations under the bill is left to the research facility, but such determination must be made in good faith.

Regarding the power to require regular record-keeping and to inspect premises to assure compliance, the committee intended:

> . . . that these inspectors will be employees of the U.S. Department of Agriculture. . . [and that] inspectors not be permitted to interfere with the carrying out of actual research or experimentation as determined by a research facility. . . [and] that inspection. . . be specifically limited to searches for lost and stolen pets by officers of the law (not owners themselves) and that legally constituted law enforcement authorities means agencies with general law enforcement authority and not those agencies whose law enforcement duties are limited to enforcing local animal regulations. It is not intended that this section be used by private citizens to harass or interfere in any way with the carrying out of research or experimentation. Such officers cannot inspect the animals when the animals are undergoing actual research or experimentation.

Unlike dealers, research facilities were subject only to civil penalties (a fine of up to $500 for each offense) for violation of the act.

In the Senate committee's report on its version of the bill leading to the act, comments from relevant executive agencies were included. The Departments of Commerce and the Treasury and the Federal Aviation Administration deferred to the views of USDA and the Department of Health, Education, and Welfare (DHEW). The Under Secretary of DHEW opposed licensure for research facilities and restrictions on procurement by them of experimental subjects from other than licensed sources. Noting that the agency charged with enforcing the new law would be USDA, the letter expressed support "for sound legislation to alleviate abuses which now exist in the transportation, purchase, sale, and handling of animals intended for use in research laboratories ." The Secretary of Agriculture responded as follows (38):

> This Department conducts programs in research related to animal production and animal diseases. In addition, it is charged with the administration of programs for the control and eradication of infectious, contagious, and communicable diseases of livestock and poultry; for the prevention of the introduction and dissemination [in] the United States of such diseases; and for the prevention of the exportation of diseased livestock and poultry. It also administers laws regarding the humane slaughter and treatment of livestock.
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> . . . There are many State laws covering [illicit traffic in family pets] and licensing requirements pertaining to dogs are common. Since the operating methods of people who steal family pets and the commercial aspects of the purchase and transfer of dogs and cats in commerce are not areas as to which this Department has expertise, we are unable to evaluate the effectiveness of existing State laws. In respect to animals, the functions of this Department relate basically to livestock and poultry, Accordingly, there is a question as to whether it would not be desirable that a law such as that in question be administered by a Fed-

> eral agency more directly concerned and having greater expertise with respect to the subject than this Department.

USDA estimated that administration of the act would cost approximately $2 million per year. It was authorized to assess "reasonable" fees for licenses issued. Judging that the exact cost was undeterminable, because it was not known how many new dealers would be licensed, Congress included a general authorization for appropriations (38).

1970 Amendments

Continued allegations of poor treatment of animals by unregulated parties and expressions of concern for experimental animals besides dogs and cats prompted Congress to pass the Animal Welfare Act of 1970 (Public Law 91-579) to cover a broader class of animals, including those exhibited to the public and sold at auction, and to regulate anyone engaged in those activities.

The amendments broadened the 1966 act's coverage beyond dogs, cats, monkeys, guinea pigs, hamsters, and rabbits to protect all warm-blooded animals as the Secretary of Agriculture may determine are being used for research, testing, experimentation, exhibition, or as pets. Excluded specifically from the new definition were horses not used for research and other livestock, poultry, and farm animals used for food or fiber production (7 U.S.C. ***2132@).*** The 1970 amendments define the word "animal" as:

> . . . any live or dead dog, cat, monkey (nonhuman primate animal), guinea pig, hamster, rabbit, or other such 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.

The act does not appear to give the Secretary the discretion to determine that a warm-blooded animal used for experimentation is not an "animal" for purposes of the act. The act gives the Secretary the authority to determine only whether or not a warm-blooded animal is being used or is intended for use for experimentation or another named purpose. If the warm-blooded animal is judged as being used in that way, it is an "animal" under the act's coverage (6).

In 1977, the Secretary promulgated regulations that specifically excluded rats, mice, birds, and horses and other farm animals from the definition of "animal" (9 CFR I. I(n),(o)). The introductory comments published by the Secretary upon issuing the regulation did not discuss the basis for this exclusion (42 FR 31022) (6).

The Secretary's 1977 regulatory exclusion of rats and mice from coverage by the act appears to be inconsistent with the language of the 1970 amendments. The exclusion of rats and mice from the definition of "animal" appears to frustrate the policy Congress sought to implement in 1970 and consequently to be beyond the Secretary's statutory authority (6).

The Secretary's enforcement powers over the expanded classes of licensees and registrants were broadened by adding to the definitions of "commerce" and "affecting commerce." These expanded concepts made it plain that the act extended to trade, traffic, commerce, and transportation among States and, further, that Congress considered any activity leading to the inhumane care of animals used for purposes of research, experimentation, exhibition, or held for sale as pets as constituting a burden, obstruction, or a substantial effect on the free flow of commerce. Penalties exacted against persons convicted of interfering with, assaulting, or killing Federal inspectors were increased, and the Secretary's authority to obtain adequate information to sustain administration was augmented by broadening discovery procedures. A new provision was added, establishing a legal agency relationship between a covered entity and any person acting for or employed by that entity, essentially to ensure that the Secretary could hold licensees and registrants to account for the acts, omissions, and failures of their agents or employees.

The definition of research facility was amended to include those using covered live animals, not just live dogs and cats, but the Secretary was given the authority to exempt institutions not intending to use live dogs or cats, unless other animals would be used in "substantial numbers." Regulation of covered research facilities was increased to require annual reporting and to add civil penalties for any refusal to obey a valid cease and desist order from the Secretary.

The amendments announced a commitment to the humane ethic that animals should be accorded the basic creature comforts of adequate housing, ample food and water, reasonable handling, decent sanitation, sufficient ventilation, shelter from extremes of weather and temperature, and adequate veterinary care, including the appropriate use of pain killing drugs. Besides adding handling to the basic categories of care, treatment, and transportation of covered animals, the standard of "adequate veterinary care" was broadened to include the appropriate use of anesthetic, analgesic, or tranquilizing drugs, when the use of such drugs is considered proper in the opinion of the attending veterinarian at a research facility.

The prohibition on interference with research was qualified in 1970 with a proviso that every covered research facility must show, at least annually, that professionally acceptable standards of animal care, treatment, and use are being followed by each research facility during actual research or experimentation. However, the intent regarding the continued prohibition on interference in experimentation itself was clear (35):

> . . . it is the intention of the committee that the Secretary neither directly nor indirectly in any manner interfere with or harass research facilities during the conduct of actual research or experimentation. The important determination of when an animal is in actual research is left to the research facility itself.

Similarly, the House Committee on Agriculture's report on this bill stated that the inspection section applies only to agencies with general law enforcement authority and is not intended to "be used by private citizens or law enforcement officers to harass research facilities and in no event shall such officers inspect the animals when the animals are undergoing actual research or experimentation ." In summarizing these provisions, the report said that "the research scientist still holds the key to the laboratory door. This committee and Congress, however, expect that the work that's done behind that laboratory door will be done with compassion and with care" (35).

The committee report included a letter from the USDA Under Secretary indicating the Department:

- was doing everything possible to carry out its assigned responsibilities under the act within the limitations of available resources of a fiscal year 1970 appropriation of $337)000;
- agreed with the objective of the legislation concerning the need for humane care and handling of laboratory animals during actual research and experimentation, but believed "that the Department of Health, Education, and Welfare is the appropriate agency to administer such an activity. We would expect to work with that Department to help assure consistency of standards and make other necessary arrangements to promote the objectives of both [laws]"; and
- suggested that regulating the humane care and handling of animals by exhibitors should be the responsibility of State and local agencies, rather than the Federal Government.

The committee's report, noting that license fee collections and appropriations in fiscal year 1971 were expected to total $376,600, projected that the responsibilities added by the 1970 amendments would increase related program costs by approximately $1.2 million annually. The report responded to research facilities' concerns that compliance with higher standards for adequate veterinary care would require substantial expenditures for new plants, equipment, and better trained personnel by urging "that adequate funds from Federal sources be made available for those research facilities which depend to a large extent on support derived from both State and Federal sources for laboratory facility improvements" (35).

1976 Amendments

Amendments to the Animal Welfare Act in 1976 (Public Law 94-279) enlarged its provisions to define more sharply and to simplify the regulation of animals treated inhumanely during transportation affecting interstate commerce and to combat ventures involving animal fighting. In brief, the amendments having an effect on experimentation:

- added a specific finding that activities or animals regulated by the act are in interstate and foreign commerce and do, in fact, burden or

substantially affect the free flow of commerce, making regulation necessary to relieve those burdens;

- reordered the statement of policy to reflect Congress' desire to:" 1) 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''—in that order;
- simplified the definition of "commerce" by eliminating the definition of "affecting commerce)" and substituting a definition of "State" (the conference committee resisted an attempt to narrow the definition of "commerce" by adopting a provision from the Senate-passed bill that would have done so with an amendment that retained the act inclusion of commerce between intrastate points but through a place outside the State);
- extended required "dealer" licensure by redefining "dealer" to include persons who negotiate the purchase or sale of protected animals for profit;
- broadened the definition of animal to correct a then-existing interpretation that hunting, security, and breeder dogs did not fall within the act's protection;
- required carriers and intermediate handlers of animals, not otherwise required to be licensed, to register with the Secretary;
- extended the agency relationship, recordkeeping, and other existing regulatory requirements to carriers and intermediate handlers;
- increased the Secretary's options for enforcement and collections by revising the section on penalties and appeals and by increasing the daily civil penalty for violation of cease and desist orders from $500 to $1,000 for all classes of regulated parties;
- extended to Federal research facilities the existing requirement to demonstrate at least annually that professionally acceptable standards governing the care, treatment, and use of animals are being followed; and
- required the Secretary to consult and cooperate with other Federal departments, agencies, or instrumentalities concerned with the welfare of research animals, where transportation or handling in commerce occurs.

USDA estimated that the enlarged responsibilities for establishment and enforcement of humane transportation standards and certification practices and the oversight of compliance by carriers and intermediate handlers would increase its annual operating costs by $565,000 in fiscal year 1977 and $385,000 per year thereafter. (The decline in required outlays in future years was attributed to a reduced need for training and orientation.)

The Congressional Budget Office (CBO) estimated a total startup cost in fiscal year 1977 of $968,000—some $570,000 for transport standards and certification enforcement and $398)000 for investigation of animal fighting ventures. That estimate projected a gradual increase in each segment of new enforcement outlays for 5 years, with total costs for these new responsibilities rising to $1,304,000 by fiscal year 1981. CBO questioned USDA's estimates of declining costs, pointing out that USDA had factored in neither anticipated higher salary costs in the future nor the total anticipated cost of enforcing the new Federal ban on animal fighting. Neither agency projected any offsetting increase in miscellaneous receipts, since newly covered carriers and intermediate handlers would not be required to become licensed. Reflecting uncertainty about the total costs of the new effort to regulate animal transport, House and Senate conferees agreed to remove the House-passed funding ceiling of $600,000 per year, though the annual ceiling for enforcing animal-fighting prohibitions was fixed at $400,000 (36).

1985 Amendments

With the enactment of the Food Security Act of 1985 (Public Law 99-198), Congress amended the Animal Welfare Act for the third time. The amendments, effective December 1986, strengthen standards for laboratory-animal care, increase enforcement of the Animal Welfare Act, provide for the dissemination of information to reduce unintended duplication of animal experiments, and mandate training for personnel who handle animals. For the first time, the Department of Health and Human Services is brought into the enforcement of the Animal Welfare Act, as the Secretary of Agri-

culture is directed to "consult with the Secretary of Health and Human Services prior to the issuance of regulations" under the act.

The statute requires the Secretary of Agriculture to issue minimum standards for all aspects of the veterinary care of animals, including standards for the exercise of dogs and a physical environment adequate to promote the psychological well-being of primates. The Secretary shall require that no animal be used in more than one major operative experiment from which it is allowed to recover, except in cases of scientific necessity or by determination of the Secretary.

Each research facility covered by the Animal Welfare Act—including Federal facilities—is required to appoint an institutional animal committee that includes at least one doctor of veterinary medicine and one member not affiliated with the facility. The latter is intended "to provide representation for general community interests in the proper care and treatment of animals." Any member of the committee revealing confidential information is subject to a fine of up to $10,000 and three years' imprisonment. The committee must inspect all animal study areas at least twice a year. USDA shall inspect each facility at least once a year, and each facility is required to report at least annually to USDA that the provisions of the act are being followed. (Committees in Federal facilities will report not to USDA, but to the head of the Federal entity.)

This provision for institutional animal committees, taken in concert with similar provisions in the Health Research Extension Act of 1985 (Public Law 99-158) and the **policy of the** Public Health Service (see app. C), brings the overwhelming majority of experimental-animal **users in the United States under the oversight of a structured, local review committee.**

USDA is directed to establish an information service at the National Agricultural Library (NAL). The service, in cooperation with the National Library of Medicine, shall provide information that could prevent the unintended duplication of animal experimentation, reduce or replace animal use, minimize animal pain or distress, and aid in the training of personnel involved with animals.

The law requires research facilities to provide for scientists, animal technicians, and other personnel involved with animal care and treatment training on:

- the humane practice of animal maintenance and experimentation;
- methods that minimize or eliminate the use of animals or limit animal pain or distress;
- the utilization of the NAL information service; and
- the way to report deficiencies in animal care.

Current Provisions Governing Research

In addition to the provisions of the 1985 amendments, there are 14 key provisional of the Animal Welfare Act, as amended, that affect research facilities:

- Definition of "Research Facility. " The act defines "research facility" to cover 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 receives Federal funds for research, tests, or experiments. Exemptions may be granted where dogs or cats are not used, except where the Secretary determines that substantial numbers of other types of warm-blooded animals are used and the principal purpose of the entity covered is biomedical research or testing [7 U.S.C.A. 2132(e)]. For these to be a violation under this provision, it must be established that Federal jurisdiction extends to the particular facility—either that some connection exists between animals acquired or used and interstate commerce, or that Federal funding support is received for the contemplated research. Research facilities that receive no Federal support for experimental work and that either purchase animals

[1]Pertinent previsions of the act are discussed **in the order they appear in the** U.S. **Code, with cross-references where appropriate. All parenthetical references in this section are to current provisions of chapter 54 of** Title 7 of the Code, which can be found **in Title 7, "Agriculture,"** *U.S. Code Annotated,* **$52131-2152 (St. Paul, MN: West Publishing Co.), 1973 Edition (126-139) and 1984 Supplement (126-139).**

within their own State or maintain intramural breeding colonies are not "research facilities" under this definition.

- Registration Requirement. Research facilities not otherwise required to be licensed as a dealer or exhibitor are required to register with the Secretary [7 U.S.C.A. 2136]. Most U.S. research facilities covered by the act are thus required only to register, rather than to pay license fees and submit to more stringent compliance requirements and criminal penalties. A "dealer" is someone engaged in interstate trade of regulated animals for research, teaching, or exhibition, or for companion, hunting, breeding, or security purposes. '(Exhibitors" include carnivals, circuses, and zoos touching commerce in some way, excluding "retail pet stores, organizations sponsoring and all persons participating in State and county fairs, livestock shows, rodeos, purebred dog and cat shows, and any other fairs or exhibitions intended to advance agricultural arts and sciences)" as determined by the Secretary [7 U.S.C.A. 2132(h)],
- Acquisition of Dogs and Cats. Covered research facilities (including Federal agencies [7 U.S.C.A. **2138])** may not purchase dogs or cats from anyone other than a person holding a valid license, unless the seller is not required to be licensed by the act, or an operator of an auction sale [7 U.S.C.A. 2137], who may also need a license [7 U.S.C.A, 2142], Only dealers and exhibitors who meet the act's definitions for those activities, and auction sellers who sell dogs or cats "affecting commerce)" must be licensed.
- Responsibility for Employees and Agents. A principal-agent relationship between research facilities and their agents or employees concerning any "act, omission, or failure" is created by statute [7 U.S.C.A. 2139]. This provision creates a legal presumption that a covered research entity knows about, and is responsible for, transgressions of the act by its employees or authorized agents.
- Recordkeeping for Animals Research facilities must make and retain records only with respect to the purchase, sale, transportation, identification, and previous ownership of live dogs and cats [7 U.S.C.A. 2140].
- **Animal Marking Requirements.** Generally, the act requires that all animals delivered for transportation, transported, purchased, or sold, in commerce by a dealer or exhibitor be marked or identified as required by the Secretary. Research facilities need only mark or identify live dogs and cats (7 U.S.C.A. 2141].
- Compliance With Auction **Sale Rules.** Research facilities involved in purchase, handling, or sale of animals in commerce at auction sales must comply with humane standards and rec - ordkeeping requirements established by the Secretary to regulate those activities [7 U.S.C.A. 2142].
- Standards of Care and Treatment. The general grant of rulemaking authority to the Secretary for establishing minimum requirements for handling, housing, feeding, watering, sanitation, ventilation, shelter from extremes of weather and temperature, adequate veterinary care (including appropriate use of anesthetic, analgesic, or tranquilizing drugs, when such use would be proper in the opinion of the research facility's attending veterinarian), and separation of species when necessary may not be construed as authorizing the Secretary to promulgate rules, regulations, or orders with regard to design, outlines, guidelines, or performance of actual research or experimentation by a research facility as determined by such research facility. But the Secretary must require every facility to show annually that professionally acceptable standards governing animal care, treatment, and use, "including appropriate use of anesthetic, analgesic, and tranquilizing drugs, during experimentation are being followed by the research facility during actual research or experimentation" [7 U.S.C.A. 2143(a)].
- 'Animal Certification Requirements. Research facilities may not deliver for handling or transportation in commerce any dog, cat, or other designated animal without a certificate of inspection, executed by a licensed veterinarian not more than 10 days prior to delivery, for freedom from infectious diseases or physical abnormalities that would endanger the animal or other animals or endanger public health. The statute permits the Secre - tary by regulation to exempt from this require-

ment animals shipped to research facilities for purposes of research, testing, or experimentation requiring animals not eligible for such certification [7 U.S.C.A. 2143(b)].

- Minimum Age for Transport. Research facilities may receive dogs, cats, and other designated animals younger than the minimum age requirement for transportation in commerce established by the Secretary pursuant to the act [7 U.S.C.A. 2143(c)].
- Federal Facilities Federal agencies with laboratory-animal facilities are required to comply with regulations for humane treatment in commerce as they apply to nongovernmental research facilities [7 U.S.C.A. 2144].
- Inspections Research facilities are required to grant inspectors reasonable access to their places of business, facilities, animals, and records. Inspectors are empowered to confiscate or destroy in a humane manner any animal found to be suffering as a result of a failure to comply with the act, its regulations, or standards, if such animal is held by a research facility and is no longer required by such research facility to carry out the research, test, or experiment for which such animal has been utilized [7 U.S.C.A. 2146(a)]. Research facilities engaged in the purchase, handling, or sale of animals are also required to permit inspections by legally constituted law enforcement agencies in search of lost animals [7 U.S.C.A. 2147].
- Penalties, Hearings, and Appeals. For any violation of the act, its regulations, or standards, a research facility maybe assessed a civil penalty up to $2,500 for each day of noncompliance. Knowing failure to obey a cease and desist order can result in an additional penalty of $1,500 for each day of noncompliance. Research facilities are not subject to criminal penalties for violations [7 U.S.C.A. 2149(b), (c),(d)].
- **Annual Report to Congress.** Each March, the Secretary of Agriculture is required toreport to Congress the identification of all research facilities that are required or choose to be licensed, the nature of all investigations and inspections conducted and reports received, and the Secretary's suggestions for legislative changes to improve the administration of the act. The annual enforcement report cannot be released to non-Federal entities until it has been made public by a congressional committee [7 U.S.C.A. 2155].

Regulations

Congress intended that the broad statutory framework it had erected in the Animal Welfare Act be fleshed out to achieve the law's general objectives. USDA received common grants of discretionary power and ministerial duties, giving the Secretary both latitude to exercise judgment in enforcing the law and the obligation to execute a number of distinct duties.2

Responsibility for administration was delegated by the Secretary to the Administrator of the Animal and Plant Health Inspection Service (APHIS). Ministerial and enforcement duties are the province of the APHIS Deputy Administrator for Veterinary Services, and initial collection of records and supervision and assignment of inspectors are done by Veterinarians-in-Charge, based in APHIS's State offices in each of five geographic regions throughout the United States. Except for the Northeast region (served centrally by a Boston office), every State has an APHIS office, usually in the capital [7 CFR 371.2(a),(d); 9 CFR l.l(a)-(j)l. Inspectors known as Veterinary Services Representatives perform investigative tasks in consultation with an attending veterinarian or with a three-member committee employed by a registered research facility (one of whom must be a licensed veterinarian), which is responsible for evaluating the type and amount of anesthetic, analgesic, and tranquilizing drugs used on animals during actual research, testing, or experimentation where appropriate to relieve all unnecessary pain and distress in the subject animals [9 CFR l.l(ee)].

"Animal" includes '(any live or dead dog, cat, monkey (nonhuman primate mammal), guinea pig, hamster, rabbit, or any other warm-blooded animal, which is domesticated or raised in captivity or which normally can be found in the wild state,

[2]Pertinent provisions are discussed **in this section in the order in which they appear in the published regulations, with cross-references where appropriate. All parenthetical references are to Title 7, Part 371, and Title 9, Parts 1-4, of the U.S.** *Code of Federal Regulations* **(Washington,** DC: General Services **Administration, 1984).**

and is being used, or is intended for use, for research, testing, experimentation or exhibition purposes, or as a pet" [9 CFR I. I(n)]. By regulation, this definition excludes birds, rats, mice, and horses and other farm animals intended "for use as food or fiber, or livestock or. . . [for] improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber" [9 CFR 1.l(n),(o)l. The definition of "dog" is enlarged to include those used for hunting, security, or breeding purposes [9 CFR l.1(1)-(n),(q)]. The farm-animal exemption and expanded dog definition reflect changes in the act made in 1970 and 1976. The only warm-blooded animals, other than those specified in the act, that the Secretary has chosen to designate are marine mammals.

A research facility not otherwise required to be licensed must register with APHIS by completing a standard registration form and filing it with the office in the State of its principal place of business. The registrant receives a copy of the form and "applicable standards" from APHIS and is required to acknowledge their receipt and agree to comply with the standards by signing a form [9 CFR 2.25-2.26].

Each "reporting facility" (each segment of a registered facility using experimental animals and for which an attending veterinarian has responsibility, including departments, agencies, and instrumentalities of the United States) must file an annual report, signed by a legally responsible official, showing that professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, during actual research, testing, or experimentation, were followed by the facility. The report, due by December 1 and covering the preceding Federal fiscal year (Oct. l-Sept. 30), must include:

- the location of the facility where animals were used;
- common names and approximate numbers of animals on which research, experiments, or tests were conducted involving:
  (a) no pain, distress, or use of pain-relieving drugs;
  (b) accompanying pain or distress to the animals, for which appropriate anesthetic, analgesic, or tranquilizing drugs were used; and
  (c) pain or distress to the animals for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would adversely affect the procedures, results, or interpretation of the research, experiments, or tests and a brief statement explaining the reasons for the same (in all three cases, routine procedures—injections, tattooing, and blood sampling–need not be reported); and
- certification by the attending veterinarian or institutional committee that the type and amount of anesthetic, analgesic, and tranquilizing drugs used on animals during research, testing, or experimentation was appropriate to relive pain and distress for the subject animals (9 CFR 2.28).

Research facilities must observe certain requirements for maintaining identification of dogs and cats either received from or consigned for delivery into commerce. Live dogs and cats so consigned must bear either the original tag or tattoo, or a tag, tattoo, or collar supplied by the facility, that identifies each animal by description or number [9 CFR 2.50e)].

Records on acquired dogs or cats must be kept and maintained to disclose the name and address of the person from whom the animal was acquired; the official tag number or tattoo; a description of each live dog or cat, including species, sex, date of birth or approximate age, color and distinctive markings, and breed or type; and the number assigned to the animal by the facility.

Facilities that transport, sell, or otherwise dispose of a live dog or cat must maintain on forms furnished by APHIS, in addition to the above information, the name and address of the person into whose custody the animal is delivered, the date of delivery, and the method and identification of mode of transportation.

Research facilities may not destroy or dispose of required records without the written consent of APHIS, and records must be held for longer where necessary to comply with any other Federal, State, or local law (9 CFR 2.100). Research

facilities (like dealers, exhibitors, and auction operators) must open their records to APHIS requests for information and inspections related to the act's enforcement as well as their facilities, during ordinary business hours, and they must be willing to have the facility's name published in a periodic list of registered facilities (9 CFR 2.126-2.127). They must also open their premises to inspection by police or legally constituted law enforcement agencies with general law enforcement authority (other than agents whose sole authority is to enforce local animal regulations) for inspections for missing animals, where the authority provides a description of the animal and the owner's name and address and agrees to abide by institutional policies concerning spread of disease and animal escape, but such searches cannot be extended to animals undergoing actual research or experimentation, as determined by the facility (9 CFR 2. 128).

An APHIS inspector can act to confiscate and destroy an animal found to be suffering as a result of a research facility's failure to comply with the act, its regulations, or its standards only:

- if the animal suffering through such failure is no longer required to carry out the research, test, or experiment for which it has been utilized;
- if the inspector has made a reasonable effort to notify the facility and request that the responsible condition be corrected or appropriate veterinary care be given, and the facility refuses to comply; or
- if the inspector is unable to locate or notify a representative of the facility, in which case a local law enforcement officer may be contacted to accompany the inspector to the premises to either provide veterinary care or confiscate and destroy the suffering animal.

Costs of care or destruction are to be borne by the violator facility. If the animal to be destroyed is an endangered species, the Deputy Administrator is required to consult with the Department of the Interior and the International Union for the Conservation of Nature and Natural Resources [9 CFR 2.129].

Research facilities are required to comply with detailed standards for humane care and treatment, except that nothing in the rules, regulations, or standards may affect or interfere with the design, outlines, guidelines, or performances of actual research or experimentation by a research facility as determined by such research facility (9 CFR 2.100(a)).

Part 3 of the regulations details specific standards for humane care and treatment according to category of defined animal—dogs and cats, guinea pigs and hamsters, rabbits, nonhuman primates, marine mammals, and warm-blooded animals other than the above species-under three headings:

- Facilities and Operating Standards (general, indoor, and outdoor facilities and primary enclosures);
- Animal Health and Husbandry Standards (feeding, watering, sanitation, employees, classification and separation, and veterinary care); and
- Transportation Standards (consignment to carriers and intermediate handlers, primary enclosures used for transport, primary conveyances [motor vehicle, rail, air, and marine], food and water requirements, care in transit, terminal facilities, and handling).

Although specific environmental requirements differ by category of defined animal, the pattern of each set of standards is quite similar. The primary difference with respect to research facilities pertains to the veterinary care standards for each animal, which contain the following common provisions: "Programs of disease control and prevention, euthanasia, and adequate veterinary care must be established and maintained under the supervision and assistance of a doctor of veterinary medicine. " Specifically, research facilities must:

- include the appropriate use of anesthetic, analgesic, or tranquilizing drugs in their programs of veterinary care, when such use would be proper in the opinion of the attending veterinarian. The use of these three classes of drugs shall be in accordance with the currently accepted veterinary medical practice, as cited in appropriate professional journals or reference guides, which shall produce in the individual subject animal a high level of tranquilization, anesthesia, or analgesia consistent with the protocol or design of the experiment;

- provide guidelines and consultation to research personnel regarding type and amount of the three classes of drugs recommended as being appropriate for each species of animal, through the animal care committee or attending veterinarian; and
- assure that the use of the three classes of drugs effectively minimizes the pain and discomfort of the animals while under experimentation [9 CFR 3.10, 3.34, 3.59, 3.84, 3.110, 3.134].

Few petitions for changes in existing regulations have been made. No person or organization has used the formal rulemaking process to seek to add any classes of warm-blooded animals. In 1982, the Humane Society of the United States filed a petition for rulemaking and collateral relief that, among other things, sought definitions of the terms '(pain," "distress," and "routine procedures" and a requirement that research facilities explain in adequate detail why pain-relieving drugs are withheld from animals used in experiments acknowledged to cause pain and distress (12).

In summary, USDA's approach has been literal and cautious with regard to research facilities. This position can be traced to two influences. First, both the act itself and its legislative history make clear Congress' desire to avoid any entanglement in the actual conduct of research. Second, both the legislative and executive commitments of funds and personnel for enforcement have never lived up to the expectations of those who believe the primary mission of the existing law to be the prevention or alleviation of experimental-animal suffering.

Enforcement

The responsibilities of APHIS in enforcing the Animal Welfare Act fall into three main categories:

- . making, implementing, and enforcing policies and rules for national and international programs to protect the health of US. livestock and poultry resources, assuring quality and safety of veterinary biologics, and providing for the welfare and humane treatment of certain animals;
- cooperating and providing technical assistance to State and local governments regarding international quarantines and exotic animal disease programs; and
- providing professional development and training for **APHIS** personnel and training for foreign visitors in veterinary service programs.

Nineteen public laws outline APHIS's duties in the first area, including the Animal Welfare Act, the Horse Protection Act, and the Twenty-Eight Hour Law (49 FR 26674). By far, the most time- and resource-consuming APHIS objective is protecting domestic plants and livestock from diseases and pests, Of 841 pages in the ***code of Federal Regulations*** on **APHIS** duties and programs, only **100** are devoted to animal welfare activities under the relevant acts (7 CFR 1984 ed. 371.2). Port-of-entry inspections by APHIS seek to prevent the introduction of insects, plant diseases, nematodes, and animal pests and diseases harmful to crops and crop products. Plant exports are controlled through a certification system administered by APHIS, and cooperative programs with States are conducted to eradicate domestically established plant pests.

The APHIS mission, then, is traditionally bound to certification, inspection, and cooperative assistance programs that govern agricultural activities, devoted almost exclusively to protecting plants and animals used to produce food and fiber.

The APHIS Assistant Deputy Administrator for Animal Health Programs, under the Deputy Administrator for Veterinary Services, is responsible for directing enforcement activities through four regional offices, located in Scotia, NY; Tampa, FL; Englewood, CO; and Fort Worth, TX (50 FR 31341). (Prior to 1985, five regional offices existed but this was changed in response to a review of APHIS activities by the General Accounting Office (GAO).) Licensing, registration, and inspection of all regulated entities-dealers, exhibitors, research facilities, carriers, intermediate handlers, and auction sales—are handled by a field force directed by Veterinarians-in-Charge in the APHIS offices in 45 State capitals. Field officials conducting animal welfare work include veterinary medical officers, compliance officers, and animal technicians. Six veterinarians trained in laboratory-animal husbandry procedures coordinate animal welfare activities among the four regions (43), APHIS has 286 Veterinary Medical Officers (inspectors), who spend approximately 6 percent of their time inspecting research facilities (25).

Table 13-I summarizes funding and staff support dedicated to animal welfare activities, compared with the total APHIS budget and equivalent staff-years, for Federal fiscal years 1980-85. As a percentage of the total budget for APHIS activities, animal welfare has consistently constituted less than 2 percent.

Animal welfare appropriations have remained virtually constant since fiscal year 1982, despite gradual reductions in APHIS's overall budget. (Some of the decline in regular appropriations can be traced to increases in fees collected for a variety of activities, though program-specific reductions have occurred (4),) The total number of staff-years spent on APHIS activities (calculated from work -years available from authorized positions for which general appropriations are made) declined steadily from fiscal year 1980 through fiscal year 1985. That decline is reflected proportionately in animal welfare activities, but the percentage of staff -years devoted to those activities has remained constant and, as a percentage of the total staff time, is slightly higher than that of appropriated funds.

As of March 1985, a total of 1,286 research facilities had registered with APHIS as using covered animals, as having acquired them in commerce, or as receiving related Federal funding support. Sixty-four percent of the principal registered research facilities (RRFs) are located in just 10 populous States (California, New York, Pennsylvania, Ohio, Massachusetts, New Jersey, Texas, Illinois, Michigan, and Florida; see table 13-2); most facilities are close to urban centers. These numbers are for the principal registrants only, not the total number of research sites. A university campus system, for example, is only required to register once under the act, though it may have a number of sites where research or tests are performed. The location of licensees (dealers and exhibitors), other registrants (carriers and intermediate handlers), and violators of the act animal-fighting prohibition may not, of course, exhibit a similar distribution. Given APHIS's traditional and overarching duties to protect food-and fiber-producing plants and animals as well as the Animal Welfare Act's exemption from coverage of most agricultural research, it seems that not even the major share of animal welfare enforcement resources could be targeted toward monitoring the care and treatment of experimental animals.

As the most widely used experimental subjects—mice and rats—have been excluded by USDA regulation from the act's coverage (9 CFR l.l(n),(o)), current regulations probably do not affect a substantial percentage of animals used for experimental purposes. This can be tested in a crude way by comparing the 1984 Directory of Toxicology Laboratories, compiled by ***Chemical Times and Trends (CT&T),*** with APHIS's 1984 List of Registered Research Facilities. Sixty-eight of 112 testing facilities, or 61 percent, listed in the CT&T directory also appear by name in the APHIS registration list; 39 percent are not registered. This implies no wrongdoing on the part of unregistered toxicity testing labs, since they may not fall under any of the definitional requirements for compliance with the act. The number of unregistered facilities is conservative, however; for purposes of comparison, it was assumed that all university-affiliated testing sites are covered by the parent institution's principal registration and that any nonuniversity lab whose name approximates that of another registrant is also covered. If rats and

Table 13.1 .- Requests for Appropriations, Actual Appropriations, and Staff-Years, USDA Animal and Plant Health Inspection Service, Fiscal Years 1980-85

	1980	1981	1982	1963	1984	1985
Total appropriation, APHIS[a] (in thousands)	$249,098	$282,385	$281,967	$275,115	$263,238	$267,558
Executive request, Animal Welfare (in thousands)	$ 3,594	$ 4,355	$ 4,402	$ 1,509	$ 1,568	$ 3,655
Total appropriation, Animal Welfare[a] (in thousands)	$ 4,128	$ 4,291	**$ 4,882**	**$ 4,886**	**$ 4,865**	**$ 4,865**
Proportion (percent) of total appropriation	1.7	1.5	1.7	1.8	1.9	1.8
Total staff-years, APHIS[b]	5,286	5,099	5,069	4,637	4,416	4,440
Staff-years, Animal Welfare Act enforcement	150	137	137	120	119	120
Proportion (percent) of total	2.8	2.7	2.7	2.6	2.7	2.7

[a]All appropriations are actual (excluding pay supplementals).
[b]Staff-years are calculated from available work-years for authorized positions (appropriated funds only). All figures are actual, except for fiscal year 19S5, which is projected.

SOURCE: Office of Technology Assessment.

Table 13-2.—Distribution of Research Facilities, by State, Registered With USDA/APHIS Under the Animal Welfare Act

State/jurisdiction	Number of registered research facilities	Percent of total	Rank out of 52
Alabama	12	*0.9*	24
Alaska		0.1	51
Arizona	;	0.7	34
Arkansas	3	0.2	46
California	175	13.6	1
Colorado	25	1.9	13
Connecticut	17	1.3	22
Delaware	8	0.6	36
District of Columbia	8	0.6	37
Florida	47	3.7	10
Georgia	12	0.9	25
Hawaii	4	0.3	41
Idaho		0.3	42
Illinois	63	4.9	8
Indiana	21	1.6	15
Iowa	11	0.9	27
Kansas	18		19
Kentucky	6	.05	38
Louisiana	12	0,9	26
Maine	11	0.9	28
Maryland	33	2.6	11
Massachusetts	69	5.4	5
Michigan	49	3.8	9
Minnesota	19	1.5	16
Mississippi	3	0.2	47
Missouri	27	2.1	12
Montana	3	0.2	48
Nebraska	10	0.8	31
Nevada	1	0.1	52
New Hampshire	4	0.3	43
New Jersey	68	5.3	6
New Mexico	11	0.9	29
New York	120	9.3	2
North Carolina	19	1.5	17
North Dakota	3	0.2	49
Ohio	72	5.6	4
Oklahoma	13	1.0	23
Oregon	18	1.4	20
Pennsylvania	90	7.0	3
Puerto Rico	10	0.8	32
Rhode Island	9	0.7	35
South Carolina	5	0.4	39
South Dakota	2	0.2	50
Tennessee	11	0.9	30
Texas	67	5.2	7
Utah	10	0.8	33
Vermont		0.3	44
Virginia	23	1.8	14
Washington	18	1.4	21
West Virginia	5	0.4	40
Wisconsin	19	1.5	18
Wyoming	4	0,3	45
Total	1,286	100	

SOURCE: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, *Animal Welfare: List of Registered Facilities,* Fiscal Year 1985.

mice used in testing and testing-related research merit the same coverage as other warm-blooded animals, and if inhumane treatment of such anireals that are not part of interstate commerce is as much a burden on oraffects commerce as much as the animals that are part of such commerce this disparity assumes greater legislative and regulatory significance.

Table 13-summarizes annual registration and reporting activity as recorded by APHIS for fiscal years 1978-83. The total number of licensees and registrants covered by the act-all classes of regulated parties, from dealers through intermediate handlers-decreased slightly, and the total at the close of fiscal year 1983 remained smaller than in 1978. Increases in the number of RRFs over the preceding year occurred in 4 of the 6 years. The number of registered research facilities classified as "inactive" by APHIS (i.e., reporting no use of regulated animals for 2 consecutive years) has risen steadily but it remains below 7 percent of the total. As a class, RRFs rose from 15.8 percent of the total in fiscal 1978 to 19.3 percent in fiscal year 1983, due mainly to a simultaneous decrease in the number of licensed dealers.

APHIS indicated in its 1981 and 1982 Annual Enforcement Reports that the failure of qualified research facilities to register and report was a significant enforcement problem and stated that it "currently had no effective system for detecting research facilities that use laboratory animals without being registered." During 1981, one research facility was prosecuted for failure to register, resulting in registration and entry of a cease and desist order by an administrative law judge (41). Three cases were filed against registrants who had failed to report in 1981; in one case, a fine of $1,000 was assessed, the first time a research facility had been fined for failure to report (41,42).

A number of reports are late or not filed by actively registered research facilities either through inattention, ignorance of the law, lack of penalties with sufficient deterrent value, some incompatibility between the calendar or fiscal years of facilities and the established Federal fiscal year for reporting, the inability of APHIS to analyze and compile all reports to meet the congressionally

Table 13-3.—Licensing, Registration, and Reporting Activity of Registered Research Facilities Under the Animal Welfare Act, Fiscal Years 1978.83

	1978	1979	1980	1981	1982	1983
Total licensees/registrants	6,902	6,389	6,585	6,492	6,297	6,447
Licensed dealers	4,501	3,982	3,886	3,664	3,439	3,490
Exhibitors:						
Licensed	924	978	1,101	1,168	1,237	1,266
Registered	313	239	170	130	106	101
intermediate handlers/carriers	66	139	274	312	339	346
Registered Research Facilities (RRFs)						
Active	1,057	1,051	1,092	1,169	1,113	1,166
Inactive [a]	35	—	62	49	63	78
New RRFs added	—	—	71	—	43	70
RRFs asproportion of total percent)	16	17	18	19	19	19
Reports received from RRFs	1,092	NA	1,061	1,111	968	1,127
Active	1,072	1,061	857	919	885	1,005
Negative [c]	—	169	138	143	73	73
Late or no report filed[d]	20	NA	66	49*	10	49

[a]Means no reported use of regulated animals for two consecutive years.
[b]Excludes reports from Federal facilities.
[c]Means no use of regulated animals during reporting year.
[d]Means no Annual Report received by December 1 of reporting year for inclusion in APHIS' Animal Welfare Enforcement Report to Congress for that year
[e]Last reporting year for which late or no filings could be calculated from information given in Annual Animal Welfare Enforcement Report. Later figures supplied by APHIS.
NA = Not available.

SOURCE: Office of Technology Assessment

established deadline for annual enforcement reports, or some combination of all these factors.

The method used by APHIS for monitoring compliance with the act's and its own standards is "regular,unannounced'' inspections of licensee and registrant premises. For research facilities, the most important standard is that adequate veterinary care or, more particularly, "professionally acceptable standards" of relief of pain and distress are observed during and after experimentation, except where administration of anesthetics or pain relievers would interfere with the purpose of the experiment. Major inspections are characterized as:

- **recurring compliance inspections,** performed to "spot-check" active licensees and registrants for continued compliance with established standards;
- inspections to **investigate complaints** of noncompliance or substandard treatment;
- **status searches,** undertaken to determine whether a business (principally potential dealers) should be licensed; and
- inspections to investigate apparent violations that have come to the attention of inspectors (43).

Though a multi-sited facility may be required to register only as a single entity, obviously all sites where covered animals are held must be inspected on a regular basis if standards are to be enforced adequately. The precise number of sites of animal use in experimentation in the United States is unknown; it likely falls between 5,000 and 10,000.

In 1985, GAO completed a study for the Chairman of the Subcommittee on Agriculture, Rural Development and Related Agencies, Senate Committee on Appropriations, on USDA activities under the Animal Welfare Act. GAO focused on:

- the training and guidance given to USDA's inspectors;
- how USDA schedules its inspections of licensees and registrants and the frequency of those inspections; and
- the followup action USDA takes when inspectors find unsatisfactory conditions (32).

GAO reviewed animal welfare inspection activities at the APHIS area offices in California, Iowa, Kansas, Missouri, New York, and Texas. These offices accounted for 45 percent of the 19,473 recurring compliance inspections made in fiscal year 1982.

Regarding the training and guidance of inspectors, GAO found that 57 out of 73 inspectors had attended formal training courses. However, 43 of the 57 had received no training in recent years. The last training course for the 17 inspectors in Texas was given in 1979.

Although USDA personnel and planning documents state that four inspections a year per site is desirable, GAO found that the 3,379 sites in the six States were inspected, on the average, 1.7 times during fiscal year 1983. In California and New York, each site averaged 0.7 inspections per year. Between 6.4 percent (in Kansas) and 51.7 percent (in California) of the registered facilities in a given State were not inspected at all during fiscal year 1983.

When looking at followup action taken by USDA for unsatisfactory conditions, GAO reviewed inspection reports of 114 sites where major deficiencies were found. In general, GAO found that the APHIS offices complied with the Service's policy and met the timeframe goals for the various steps in the process. Only 17 of the 114 sites did not follow the prescribed procedure.

While conducting the review, GAO noted some additional matters affecting the APHIS Animal Welfare Program. First, there was no specified program or procedure to oversee the quality of inspections. Three of the six States surveyed did not have any program for monitoring inspection quality. Second, GAO found inconsistencies in the reporting of inspections. Finally, GAO found that funding of inspections for 1983 had been based on 1982 work levels rather than on estimates of current potential workloads and the severity of expected problems.

USDA is subject to the provisions of the Freedom of Information Act (FOIA) (public Law 90-23), a Federal law that generally requires most Federal agencies to release to interested persons information in its possession, unless it is classified or meets one of the other exceptions established by Congress and interpreted by the courts. Congress, concerned about the potential for "harassment" of research facilities through the use and publication of their required inspection forms and reports, specified in the final sentence of Section 25 of the 1966 Animal Welfare Act that USDA could not release any such information (except to other agencies) "unless and until it [was] made public by an appropriate'' congressional committee (Public Law 89-544).

Requests for information under FOIA have increased steadily since fiscal year 1979. Humane groups have usually made about half the petitions for information. In fiscal 1978, they accounted for 53 of 98 requests—54 percent (40). For fiscal years 1981-83, the proportions were 50,53, and 52 percent (41,42,43). The highest numbers of documents released were in fiscal year 1981 and calendar year 1984, which coincided with renewed lobbying for amendments to strengthen the Animal Welfare Act or for new legislation increasing the Federal regulatory presence in research. No data are available on the proportion of requests for research facility records for prior years, but 1984 records show that 58 percent of total requests concerned research facilities, 62 percent of all documents released affected research, and 50 percent of all regulated parties affected were registered research facilities. The Animal Welfare Institute, a Washington, DC, organization interested in the act application to research, entered most of the requests affecting such institutions (19). Documents most often requested are copies of inspection reports, reporting forms, records, and forms used to apply for licenses or registrations (43).

Litigation

No cases can be found where a Federal court has had to interpret the provisions of the Animal Welfare Act requiring humane care and treatment of research animals. Though some State courts have considered the act's provisions when interpreting the effect of other laws (see ch. 14), their decisions cannot affect the constitutionality of a Federal law's application under the Federal Constitution. In the only case where the U S. Supreme Court considered any of the act's provisions, "exemplary" language in the 1970 amendments extending judicial enforcement powers to the Federal district courts was cited to sustain review jurisdiction asserted under another, similar provision in Federal law (14),

Three Federal appeals courts have had occasion to examine the language of the act, though none

of the cases involved registered research facilities (11,21,27). One case is nevertheless germane because it is the only time the courts have had to examine the language and the intent of Congress in passing the act, In a 1976 decision denying a professional dog-and-pony-show owner's claim that he was not covered by the act, the U .S. Court of Appeals for the District of Columbia indicated the likelihood of a favorable judicial response to attacks on the act and of a liberal interpretation of the legislation. Quoting from the House report, the Court stated that (11):

> As the evolution of the Animal Welfare Act manifests, Congress has chosen a cautious approach to regulation in this area, increasing governmental intervention as the national interest seemed to warrant. . . . From the small beginning in 1966--confined to a few animals, and only when they were devoted to research purposes—the present legislation further, though still modestly, "implement[s] a statutory mandate that small helpless creatures deserve the care and protection of a strong and enlightened public." We perceive nothing in the Constitution outlawing this commendable "effort to demonstrate America's humanity to lesser creatures. "

The U.S. Supreme Court refused to review the decision (11). Thus, the case's value rests in using it to support the notion that the highest court refused to disturb a lower court's decision upholding the reasonableness of Congress' effort to protect animals from inhumane treatment, including in research. The D.C. Federal appeals court has cited provisions of the act on three other occasions, once in support of judicial review of the delegated powers of the Secretary of Agriculture (29) and twice without comment (1,28).

At the district court level (the Federal system's usual courts of first resort, or '(trial" courts), several cases have been brought in which the act's provisions have been raised (3,5,9, 10), but no court has fully considered or decided any case invoking the act against a research facility.

A review of reported and unreported cases involving the Animal Welfare Act indicates that what - ever case law has been developed bears little relation to the act's regulation of research activities. This can be traced to a single major factor. Congress–very deliberately, it appears, fearing harassment of research facilities—gave no party other than APHIS any statutory right to enforce the act or regulations promulgated pursuant to it. The degree of circumspection toward research evident in Congress' consideration of the act and its amendments must be seen as an obstacle to private enforcement of its standards through the courts, since at least one Federal court has held that humane groups have standing to sue on behalf of animals under another law enacted for humane objectives, the Marine Mammal Protection Act (2). Lack of standing—i.e., proof to a court that a claimant's stake in the accomplishment of the policy objectives of a statute is significant and the effect on the claimant's interests is real if those objectives are frustrated (see ch. 14)—makes it impossible to attain enforcement of laws from the bench.

The Health Research Extension Act of 1985

In 1985, Congress amended the Public Health Service Act (Public Law 78-184) by enacting the Health Research Extension Act of 1985 (Public Law 99-158), which contained provisions for the care and treatment of animals in research funded by the Public Health Service (PHS), including the National Institutes of Health (NIH). The act provided statutory authority for and recognition of certain elements of the PHS Policy ***on Humane Care and Use of Laboratory Animals by Awardee Institutions (see*** app. C).

The act also contained provisions for the development of alternative research methods. Thus, the concept of alternatives to animal use was explicitly described for the first time in Federal law in 1985. (The concept of alternatives first appeared in Federal law earlier in 1985, in fact. Public Law 99-129, The Health Professions Educational Assistance Amendments of 1985, also mentions the development of curriculum for veterinary students on alternatives to the use of animals. It is described in ch. 12.)

Care and Treatment of Animals in Research

The act requires that each entity receiving PHS support for research with animals establish a committee to monitor care and treatment of animals

used in research. These committees shall consist of at least three members, of which one must be a veterinarian and one an individual having no association with the institution. The act thus specifies more modest requirements for the committees than does the PHS policy. The PHS policy requires a minimum of five committee members, and the veterinarian must have training or experience in laboratory-animal science or medicine.

The animal care committees are responsible for: 1) reviewing at least semiannually the care and treatment of animals in all animal study areas and facilities for compliance with NIH guidelines, 2) keeping appropriate records of such reviews, and 3) certifying to NIH that such reviews have been conducted. In requiring a minimum of two inspections per year, the law is more stringent than the PHS policy, which requires at least one per year.

The act requires applicants for NIH funds to file assurances with NIH indicating both that the applicant will meet the NIH guidelines for the care and treatment of animals and that the applicant's institution has an animal care committee. Applicants must also assure NIH of the availability of instruction at their institutions in the humane practices of animal care and in research methods that minimize the use of animals and limit animal distress. All applications for NIH funds must include a statement of the reasons for using animals in the research. If NIH determines that a research entity is not meeting the guidelines, and if no action is taken after notification of the noncompliance, the act provides that the NIH Director shall suspend or revoke funding.

Research on Alternatives

The act directs NIH to establish a plan for research into methods of biomedical and behavioral experimentation that do not require the use of animals, that reduce the number of animals used, or that produce less pain and distress than methods currently in use. NIH is further directed to develop plans for evaluating the validity and reliability of such methods, proceeding with development of methods found to be valid and reliable, and training scientists in the use of such methods. The law instructs NIH to disseminate information to investigators about alternative methods that are found to be valid and reliable, and to establish an internal coordinating committee (made up of the directors of each NIH institute) to assist in developing the NIH plan, which must be prepared by October 1, 1986. With the creation in 1985 of the Biological Models and Materials Resources Section (see ch. 12), NIH appears poised to respond to this legislative mandate.

Other Federal Laws and Regulations

Beyond the Federal laws and regulations that either directly require or have been interpreted to require the use of certain animals in testing or research and guidelines adopted pursuant to general statutory authority, several other Federal laws and regulations establish duties for research facilities concerning the acquisition and general care of animals used for experimentation.

Good Laboratory Practices

In the 1970s, concern at the Food and Drug Administration (FDA) about faulty toxicological data based on animals, generated both internally and externally (18), led to the promulgation of regulations requiring all regulated parties conducting nonclinical laboratory studies that test for safety or effectiveness to conduct, keep records about, and permit audits on all such tests in a specified manner. In 1978, FDA adopted Good Laboratory Practices (GLP) rules (43 FR 59986) and began a laboratory audit and inspection program. In 1984, FDA published a notice proposing some changes in these regulations primarily to streamline recordkeeping, data storage and retrieval, and reporting practice (49 FR 43530). Further action may occur in early 1986,

Drawing on the FDA experience and mindful of its responsibility to collect and analyze substantial amounts of testing data for approval of new chemicals and registration of pesticides, the Environmental Protection Agency (EPA) defined its own approach to GLPs (44FR 27362). In 1978, EPA executed a Memorandum of Understanding to permit FDA to inspect toxicity testing labs and audit pesticide data submitted in support of registration applications (43 FR 14124). After much consideration—and the discovery by FDA of the submission of hundreds of fraudulent test results by one in-

dependent laboratory (22)–in 1983 EPA issued its own final GLP rules for its toxic substances control (48 FR 53922) and pesticides (48 **FR** 53946) programs.

The GLPs for FDA and EPA are similar. Both address all areas of laboratory operations, delineating requirements for the establishment of a Quality Assurance Unit to conduct periodic internal inspections and keep records for audit and reporting purposes; Standard Operating procedures (SOPS) for all aspects of each study and for all phases of laboratory maintenance; a formal mechanism for evaluation and approval of study protocols and their amendments; and inclusion in reports of data in sufficient detail to support conclusions drawn from them. FDA performs four kinds of inspections in US. toxicology labs (8):

- GLP **compliance,** including examination of an ongoing study as well as a completed study (once every 2 years);
- **data audit** as needed, to verify that information submitted to the agency accurately reflects the raw data;
- **directed,** when prompted by questionable data, an informer's tip, etc.; and
- **followup,** to observe for correction of previously discovered deficiencies.

Inspections are conducted by investigators, who visit each facility and are given access to all parts of the premises where covered studies are performed and to all pertinent personnel and documentation. The Final Report and a more detailed Establishment Inspection Report are prepared after an audit is concluded; both can be obtained under FOIA. One (or more) of three sanctions can be imposed in cases of noncompliance: refusal to consider a study in support of an application; disqualification of the testing facility; or, in cases of alleged fraud, recommendation for criminal prosecution.

Provisions relating to care and housing of test animals are identical in both agencies' GLP rules. Both regulations provide that, where animals are housed, "facilities shall exist for the collection and disposal of all animal waste and refuse or for safe sanitary storage of waste before removal from the testing facility. Disposal facilities shall be so provided and operated as to minimize vermin infestation, odors, disease hazards, and environmental contamination. " Finally, each GLP has a full section on animal care, specifying SOPS for housing, feeding, handling, and care, with additional standards on separation, disease control and treatment, identification, sanitation, feed and water inspection, bedding, and pest control (21 CFR 1984 ed. 58.43,58.45,58.49, 58.90; 40 CFR 1984ed. 792.17, 792.43, 792.45, 792.90).

One chemical-industry representative summarized the benefits and problems of GLPs as follows:

- Benefits:
  1) promotion of good science through good documentation;
  2) credibility–''clean bill of health"; and
  3) self-assurance through knowledge-reducing chances of mistakes due to ignorance or use of shortcuts.
- Problems:
  1) duplication—possibility of six distinct audits in the animal care operation—FDA, EPA, USDA/APHIS, American Association for the Accreditation of Laboratory Animal Care (if accredited), State, and internal Quality Assurance Unit;
  2) adversarial climate—"guilty until proven innocent";
  3) confidentiality and accessibility—inadvertent disclosure of confidential business information or compromise of client confidentiality;
  4) time and cost—in larger facilities, single audits may occupy several hours per day for several weeks (7).

Noting that the GLP compliance record has been good, the commentator suggests that some duplication can be avoided by instituting a self-audit compliance program, using the ***Guide for the Care and Use of Laboratory*** *Animals* of the National Institutes of Health (47).

If consideration is given to broadening USDA's enforcement of the Animal Welfare Act to reach more testing facilities that may not now be covered—either by extending coverage to include rodents beyond only hamsters and guinea pigs or by increasing covered facilities compliance duties—the problems of cost and duplication assume more significance. One indication of the cost of increas-

ing an animal facility's compliance duties comes from a study commissioned by **EPA** to estimate the compliance costs for its new **GLPs.** That study concluded that additional costs to industrial laboratories would be $15 million ($80,000 per laboratory for 185 laboratories) (48 FR 53946).

Military Research and Training

In 1973, Congress prohibited the use of dogs for research and development of chemical or biological weapons (public Law 93-365). At that time, Senate and House conferees stated that they did not support the use of dogs for research on chemical or biological agents whose only function was to destroy life. They believed it essential, however, that research to improve and save human and animal lives be continued, including establishing immunologic levels, occupational safety hazard levels, and other "vital medical research designed to improve and save lives."

Continued concern about this issue prompted a request for a GAO investigation of the U.S. Army's Edgewood Arsenal (Edgewood, NJ). The Comptroller General reported that the Army had complied with the restriction in fiscal year 1975 and, further, that compliance would continue. He responded to congressional concern about APHIS's lack of jurisdiction to inspect Federal facilities with the finding that, although dogs being used in toxic exposure research were treated well during experimental procedures, their housing facilities were deficient and needed physical improvements. He stated that legislation would be required to accomplish that purpose (33). Meanwhile, to implement the new restrictions, the Secretary of Defense issued three policy documents, in 1976 (44), 1982 (46), and 1984 (44), defining the types of investigations in which animals could be used.

In 1983, publicity about the use of dogs and pigs at the Uniformed Services University of Health Sciences (Bethesda, MD) to train military surgeons to treat wounds led to prohibitions on the expenditure of Department of Defense (DOD) funds in fiscal years 1984 and 1985 (Public Law 98-473) for the training of surgical personnel in treating weapon-produced wounds in dogs and cats (26). The Assistant Secretary of Defense for Health Affairs issued a memorandum in 1984 that explained the reach of the new limitation and superseded old policy directives (45):

> . . . effective October 1, 1983, dogs or cats will not be purchased or otherwise used for the purpose of training Department of Defense students or other personnel in surgical or other medical treatment of wounds produced by any type of weapon. In addition, the standards of such training with respect to the treatment of animals shall adhere to the Federal Animal Welfare Law and to those prevailing in the civilian medical community.

Current DOD policies and their effect on intramural and extramural defense research are examined in more detail in appendix B.

Animal welfare groups have expressed dissatisfaction about substitution of other animals for dogs and cats in ballistics training, and pressure on Congress to prohibit animals' use in this type of research is expected to continue (15).

Endangered Species, Public Health, and Import Legislation

Research facilities that plan to import, take, or otherwise use nonhuman primates or other animals protected by national or international laws and agreements must comply with provisions found in several laws. Besides prohibiting or controlling acquisition of some types of animals, these laws and agreements generally require, at a minimum, a permit or authorization from one or more Federal agencies. Relevant legislation includes:

- Section 7 of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 et seq.), and regulations administered by the Research Division of the Fish and Wildlife Service [50 CFR 10-24];
- Public Health Service Act regulations governing importation of nonhuman primates, both to control the spread of animal-borne disease (42 U.S.C. 264; 42 **CFR** 71) and for use in producing and testing viral vaccines (42 U.S.C. *262;* 21 CFR 620 et seq.);
- the Airline Deregulation Act of 1978 and the Tariff Schedules of the Civil Aeronautics Board;
- Convention on International Trade in Endangered Species of Wild Fauna and Flora Treaty of 1973 [see app, E); and
- certificates of need for importing rhesus monkeys (a 1955 agreement between the United States and India, resulting in the Indian Rhesus Monkey Certification Program).

AGENCY GUIDELINES AND ACTIVITIES

Besides providing general assurances to USDA that intramural research activities involving warm-blooded animals meet the general requirements of the Animal Welfare Act, various Federal agencies have adopted general animal use guidelines or have taken steps to review relevant intramural and extramural policies. Most policies are confined to measures governing humane care and treatment of animals in testing and research-establishment of standards, review, and enforcement. Some policies mention the actual conduct of experimentation.

The Public Health Service Policy

Pursuant to a delegation of authority from the Secretary of the Department of Health and Human Services (DHHS), NIH is responsible for implementing the public Health Service ***Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions*** (PHS Manual, chs. 1 through 43). Each institution that receives Federal support from PHS for research involving live vertebrate animals is subject to the policy, including agencies of the PHS itself (NIH; FDA; the Alcohol, Drug Abuse, and Mental Health Administration; the Centers for Disease Control; and the Health Resources and Services Administration). Provisions of the PHS policy, revised in 1985, are discussed in detail in chapter 15 and the policy is reproduced in appendix C.

Interagency Activities

Governmentwide Standards

Representatives from 14 Federal entities[3] involved in animal use sit on the Interagency Research Animal Committee (IRAC) formed in recognition of the need for an interagency committee knowledgeable about the use, care, and welfare of research animals.

[3]USDA, Department of Defense, DHHS, Department of Energy, Department of State, Departmentof the Interior, EPA, the National Aeronautics and Space Administration, the National Science Foundation, and the Veterans' Administration. Components of the Public Health Service within DHHS that are represented on the committee include the Alcohol, Drug Abuse, and Mental Health Administration; the Centers for Disease Control; FDA; NIH; and the Office of International Health.

Staffed and sponsored by NIH, IRAC was established by the Assistant Secretary of Health in 1983 as an outgrowth of the Interagency Primate Steering Committee that had been established within NIH in 1974 to assure both short- and long-term supplies of primates critical to biomedical research, testing, and vaccine development programs (48).

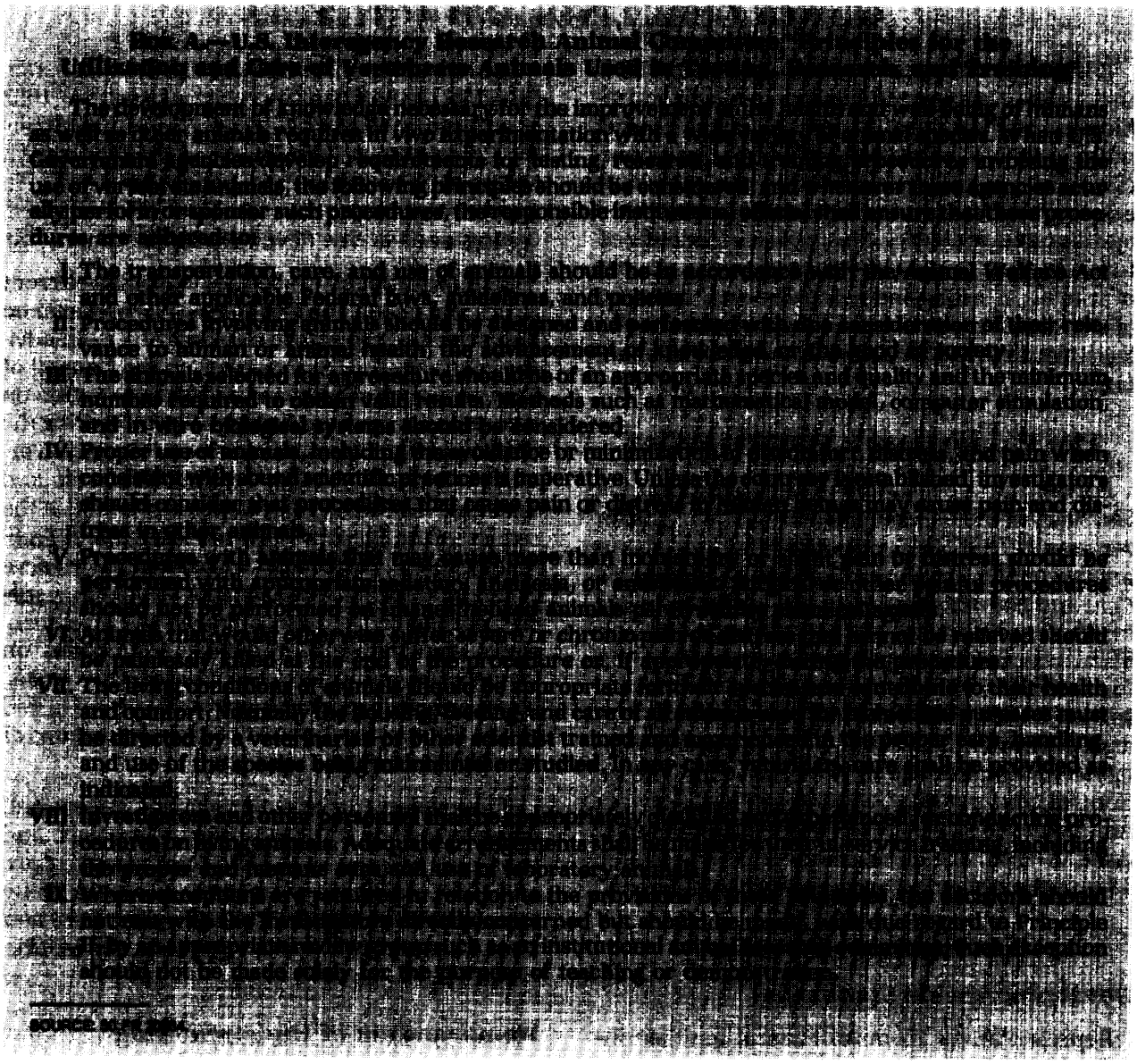
Along with regular meetings to discuss current issues and needs, the Committee has undertaken two principal projects to date: serving in an advisory capacity to U.S. observers to the Council of Europe, which considered a draft convention on laboratory-animal use (see app. E), and writing the "Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training" (see box A). Developed and issued at the request of the Executive Office of Science and Technology Policy, the principles are intended to serve as a model for Federal agencies developing specific policies on the use of animals. The IRAC principles incorporate nine distinct injunctions on proper care and treatment of research animals, based primarily on similar principles promulgated by the Council for International Organizations of Medical Science (see app. E).

These statements on establishment, review, and enforcement of standards of humane care and treatment are part of the NIH ***Guide for the Care and Use of Laboratory Animals*** and are explicitly endorsed in the PHS ***Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions (47).***

Memorandum of Understanding

In 1983, APHIS, NIH, and FDA executed a Memorandum of Understanding and agreed to exchange information on animal welfare concerns and compliance with policies. Each has appointed liaison officers to serve on a standing committee to meet at least annually. Specifically, APHIS, NIH, and FDA have agreed to:

- share information contained in the registry/inventory/listing of establishments that fall under the purview of each;
- send to one another, each quarter, a listing of establishments that have been inspected



or site-visited, to be used to avoid redundant evaluations;
- share information on significant adverse findings concerning animal care and welfare revealed by inspections or site visits and on followup actions taken;
- inform each other of evidence of serious noncompliance with required standards or policies for care and use of laboratory animals (including defective assurances of compliance with PHS policies) in establishments that fall under the authority of each agency;
- request from each other comments and advice on regulatory or policy proposals involving animal care and welfare under consideration; and
- provide to each other resource persons for scientific seminars, speeches, and workshops.

The agreement remains in effect indefinitely, may be modified by mutual consent, and may be ter-

minated by any agency on 90-day advance written notice to the other two agencies (37).

Specific Agency Activities

Six departments and four agencies within the Federal Government do intramural research involving animals. At least 1.6 million animals were used by these branches for such research during fiscal year 1983 (see ch. 3). In addition, extramural research is conducted by many of these departments, Two departments, Commerce and Transportation, conduct almost all research extramurally and so have no specific policy regulating animal use other than the PHS policy (1 7,23). For a detailed discussion of the regulation of animal use within Federal departments and agencies, see appendix B.

CRITICISMS OF THE PRESENT SYSTEM OF FEDERAL REGULATION

The operation of the Animal Welfare Act, as applied to research, has been criticized since its passage. In addition to obvious shortcomings—lack of coverage for actual research practices and inadequate resources for enforcement-critics have questioned the presumption that researchers know best how to care for experimental animals (20,49) and the choice of APHIS as the primary enforcement agency (16,24). Complex recordkeeping requirements imposed on APHIS inspectors and other field enforcement staff have been decried; the process of noting, investigating, and evaluating violations for prosecution, and the attendant rights of suspected violators that can result in delay in disposition of cases, are viewed by some as too cumbersome and bureaucratic (20). Some question the expertise and the will of APHIS, pointing out its traditional reluctance to accept broader responsibilities under the act. Indeed, USDA remains opposed to its further extension (34,37). A 1982 review of the APHIS reporting system by the Humane Society of the United States concluded that the present system, as it is administered (24):

> . . . fails to achieve its primary statutory objective: it does not provide APHIS with information sufficient to demonstrate that researchers have used pain-relieving drugs "appropriately" and in accordance with "professionally acceptable standards.'' The chief reasons for this failing are: 1) regulations and guidelines do not define "pain" or "distress, " 2) regulations and guidelines do not adequately define "routine procedures, " and 3) regulations and guidelines do not require meaningful explanations for the withholding of pain-relieving drugs in procedures acknowledged to cause pain.
>
> The Reporting System, as presently administered, for the same reasons also fails to achieve a secondary—but nonetheless important —objective: it does not generate reliable and meaningful information to the public about the use of animals in research.

Humane groups have used the Freedom of Information Act with increasing frequency to obtain copies of inspection and annual reports in attempts to demonstrate their claims that the system does not work. Members of the research community opposed to the act extension defend existing practices as adequate (16,34)37).

Could the Secretary of Agriculture require greater proof that "professionally acceptable" standards of care are being followed, require more detailed explanations of the use and withholding of anesthetics and pain relievers, and more effectively audit annual reports? The law permits such greater discretion. Several competing factors, however, are worth noting. First, consistent with Congress' enumerated powers to spend and to regulate interstate commerce, the objectives for the regulation of research are more limited than is often admitted by the critics. The remarks of congressional sponsors of the first bills, in the record of debates on the 1966 conference report, recognize that only a fraction of research animals would be covered (30) and that the new act was "nothing more than a very small first step toward the elimination of cruelty, mistreatment, and abuse of laboratory animals ." The absolute power that remained with the experimenter to determine the nature of experimentation prompted the remark that "animals that are under research or experimentation for sev-

eral years will have absolutely no protection under this law" (31). Subsequent amendments added more specific requirements but left the intra-research exemption undisturbed, retaining a post-hoc, audit-style enforcement system.

Second, creating an agency whose sole purpose is to regulate experimentation, or infusing more authority and funds into APHIS, are options that Congress has not chosen to exercise, even in the face of a lukewarm commitment to enforcement by existing executive agencies. Third, these choices have not been made because a consensus on the preferable mode and extent of control has never been apparent. Some regulation advocates, it appears, will settle for some degree of tinkering with the act; others will not rest until research on animals is done away with (27). Those differences have strong roots and are likely to persist.

There are important statutory and regulatory considerations regarding any attempt to modify existing law in order to effect replacements, reductions, or refinements of animal use. Statutory changes would reflect judgments on:

- whether the jurisdiction of enforcing agencies should be expanded to enforcement of adequate care, treatment, and use standards during actual conduct of experimentation;
- whether the scheme of regulation of experimentation should be scaled to a higher level of compliance responsibility, as is now the case for dealers and exhibitors;
- whether penalties for violations of research standards should be enacted that are commensurate with those assessed against other regulated parties;
- whether voluntary assurances or simple certifications of compliance are adequate;
- whether coverage of existing classes of animals is statutorily adequate to achieve even existing policy objectives; and
- whether proposed changes take into account the operation of other, overlapping laws that have different policy objectives.

Regulatory changes would involve judgments of:

- **whether** existing enforcement agencies are appropriate (and willing) to continue to fulfill current responsibilities and assume others;
- whether enforcement agencies should be given increased discretion in formulating and enforcing professionally acceptable standards of care, handling, treatment, and use of research animals;
- whether additional requirements for research regulation will be susceptible to consistent interpretation by inspection and enforcement agents in the field, in light of existing availability of training resources and aids for field inspectors; and
- whether efficient assignment of funds and enforcement resources on a state-to-state basis is likely to occur.

In addition, statutory or regulatory change would reflect a judgment of:

- whether funds authorized and appropriated will be adequate in relation to contemplated enforcement duties;
- whether regulated research institutions have sufficient financial resources and institutional and independent veterinary resources to effect meaningful compliance with a strengthened law, while avoiding any compromise of research or testing objectives; and
- whether strengthening existing laws will promote resolution of or enhance differences between the research and animal welfare communities.

Finally, the Animal Welfare Act is often criticized—inappropriately—for excluding mice and rats from its coverage. In fact, the act, as amended in 1970, covers all warm-blooded animals that the Secretary of Agriculture determines are being used or intended for use in research or for another named purpose. The Secretary does not appear to have the discretion to determine whether or not mice and rats are warm-blooded animals, only whether or not they are used in research. No amendment to the act is therefore necessary to bring mice and rats under its scope. The exclusion of mice and rats (and birds) from the definition of "animal" by USDA regulation in 1977 (9 CFR 1.1 (n),(o)) appears to frustrate the intent of Congress and to be beyond the Secretary of Agriculture's statutory authority (6).

SUMMARY AND CONCLUSIONS

The Animal Welfare Act and its amendments represent a cautious and deliberate attempt by Congress to improve care and treatment of research animals. Initially, the act was designed to regulate interstate traffic in dogs and cats used for research, with the goal of halting the use of stolen pets. This was accomplished by requiring Federal licenses for dealers, requiring research facilities to register, and instituting inspection and recordkeeping requirements for both. Enforcement responsibility was vested in the Animal and Plant Health Inspection Service of the U.S. Department of Agriculture, an agency not aligned with traditional, nonagricultural research interests. Three times the act was amended; twice the amendments extended interstate regulation to exhibition, transportation, and auction sales of covered animals (which, as enforced, now includes dogs, cats, rabbits, hamsters, guinea pigs, and nonhuman primates), The oversight of animal use by committees at every research facility was mandated in the most recent amendments.

A legislative reluctance to invade the actual conduct of research is clear. The Secretary of Agriculture is forbidden to enact any regulation that could be so construed. The closest the law comes is to require the Secretary to establish and enforce standards for care and treatment of experimental animals outside the laboratory door, and to require covered research facilities to certify that professionally acceptable standards of care, treatment, and use are being followed in the laboratory, including "appropriate" use of anesthetics and pain relievers, except when their use would interfere with experimental objectives. In addition, large classes of experimental animals—principally mice and rats—are not covered by the act as it is currently enforced by the Department of Agriculture, and the law's provisions remain weighted toward traffic in pet species. Since interstate regulation constitutionally requires some connection to interstate commerce, research institutions that use animals protected by the act but that receive no Federal funds and that maintain their own breeding colonies cannot be regulated. To date, there has been no significant judicial test of the provisions regulating research.

The Health Research Extension Act of 1985 amended the Public Health Service Act with provisions for the care and treatment of animals in PHS-funded research. The 1985 act also contained provisions for the development of alternatives to research methods using animals.

In addition to the Animal Welfare Act and the Health Research Extension Act of 1985, there is regulation of the use of laboratory animals at the Federal agency level. The Interagency Research Animal Committee was formed to provide a knowledgeable source about all vertebrate animal use in testing, research, and training within the Federal Government. It has developed the U.S. Government's "Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training" at the request of the Executive Office of Science and Technology Policy. The IRAC principles are endorsed by the Public Health Service, are part of the widely used NIH Guide ***for the Care and Use of Laboratory Animals,*** and are used by some Federal agencies in their own policies on animal use.

Six Federal departments and four Federal agencies conduct animal experimentation within Federal facilities (see app. B). Only the Departments of Commerce and Transportation, which use few animals, have no specific guidelines. The other entities all have some type of policy for such intramural research. In general, the more research conducted by an agency, the more extensive are its animal care guidelines. In addition, departments in which animal treatment has been targeted by animal welfare groups or spotlighted by the media tend to have more substantive guidelines.

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