Federal regulation of experimental animal use in the United States of America

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Summary: The author outlines the regulation of animal experimentation in the United States of America (USA). Regulation in this field is at the developmental stage; issues are still being defined as public interest in animal welfare focuses on various aspects of animal science. Society continues to initiate regulations for animal experimentation in response to technological advances which were unknown when the first USA Federal legislation in this field (the Laboratory Animal Welfare Act) was signed in 1966. Under the sponsorship of animal welfare activists and, more recently, animal rights advocates, amendments to the 1966 law have increased the scope of Federal authority by extending both the number of species covered and the areas of care which are regulated. A greater awareness has evolved of the issues raised by animal experimentation, both among the general public and within the scientific communities. The importance of the Institutional Animal and Care Use Committees in research facilities is described, together with other factors which affect Federal legislation.

Government regulatory philosophy is also changing towards a participatory relationship between regulators and public interest groups. Various affiliations to global and regional organisations have heightened national awareness with regard to the perceived exploitation of animal species.

The author demonstrates clearly that the prevailing trend in the USA is towards expanded agreements which are jointly derived and implemented, and which will be instrumental in the search for resolutions. The author concludes that these resolutions will continue to revolve around the ethical need to respect the nature of animal species and the need for knowledge concerning both humans and animals which can help to extend and enhance the quality of life.


INTRODUCTION

The Federal regulation of animal experimentation in the United States of America (USA) is still in the emergent stage. The development of legislation in this field depends on the acknowledgement of a growing sentiment among the public that society has an ethical responsibility to consider the needs of animals which are used by man. In the USA, this still contends with a strong inclination within society to maintain freedom of scientific inquiry. The developmental pattern of Federal legislation to regulate the
welfare of animals in research reflects this dichotomy in public opinion. Animal welfare advocates have seized on moments of heightened public awareness with regard to a given issue to urge enactment of national legislation by Congress. This is the pattern which has prevailed over the past thirty years.

LEGISLATIVE HISTORY

LABORATORY ANIMAL WELFARE ACT OF 1966

The first legislation affecting animal experimentation in the USA illustrates the typical pattern of development. The Laboratory Animal Welfare Act (LAWA) of 1966 (3) remains the basis for governmental regulation of animals used in research. This legislation was enacted on a wave of public reaction to an article which appeared in Life magazine in 1965 (2). The article described, with photographs, the misadventures of a pet dog which had allegedly been stolen, sold, and ultimately acquired by a research facility. Congressional representatives received thousands of letters from outraged pet owners. The alleged theft of pets for use in research continues to create public concern and media coverage. The LAWA of 1966 covered dogs and cats bought or sold in inter-State commerce for purposes of experimentation. Many of the provisions of the 1966 Act are still in effect, while others have been expanded by legislative amendments. This first Federal legislation, administered by the United States Department of Agriculture (USD A) required the registration of research facilities and the licensing of dealers who bought, sold or used dogs or cats for purposes of research. Inherent to this requirement was mandatory identification and record-keeping of dogs and cats by dealers and research facilities. Four further species (rabbits, guinea-pigs, hamsters and non-human primates) were also covered by care and treatment standards, but only in those facilities which also used dogs or cats.

1970 Amendments

The enactment of the 1970 Amendments to the LAWA of 1966 – renamed the Animal Welfare Act (AWA) by the amendments – significantly affected the acquisition and use of experimental animals by research facilities. For the first time, Federal regulations were extended beyond animal holding facilities to standardize conditions in the research laboratory, provided that this did not disrupt or interfere with the experimental design of the research. The definition of the term “animal” was expanded to include all warm-blooded species. However, the Secretary of Agriculture was granted discretionary authority to limit the species covered (except the original six species). The initial implementation of this amended definition by the USDA excluded rats, mice, birds, domestic farm animals and marine mammals, due to the limitation on the availability of funds and other resources. Marine mammals were effectively excluded by the implementation of regulations contained in the 1972 Marine Mammal Protection Act. In 1989, domestic farm animals were also specifically removed from the list of excluded species in the regulatory definition of the term “animal”, but rats, mice and birds were still excluded from regulation. (A civil legal action filed in a District Court in the USA by the Animal Legal Defense Fund, et al., seeking immediate inclusion of rats, mice and birds, is still under litigation and is discussed below.)

Other significant changes brought about by the 1970 Amendments were as follows:

– The requirement for adequate veterinary care was modified to specifically include the appropriate use of anaesthetics, analgesics, tranquillizers and other pain-relieving drugs.
Research facilities were required to report certain information to the USDA, including: the number of animals used (by species); whether pain-relieving drugs were administered, when appropriate; and a justification for causing pain, if such pain-relieving measures were not applied. The USDA was required to compile the data, together with other information on activities under the AWA, in an annual report to Congress. This report was made available to the public following release by Congress.

Prior to 1970, a research facility was not required to be registered under the AWA if experimental animals were purchased only from sources in the same State and no Federal research grants had been awarded to the facility. Similarly, dealers who did not sell animals across State borders were not required to be licensed. However, the 1970 Amendments to the AWA redefined the term “commerce” to include both intra-State and inter-State traffic in animals for research. Thus, the AWA was one of the first pieces of legislation in the USA to overcome the traditional resistance to Federal regulation of commercial activities within a State.

All commercial suppliers of animals for research purposes were required to be licensed.

In summary, the far-reaching effects of the 1970 Amendments to the AWA brought the majority of researchers and dealers under regulation and provided the legislative authority for regulation related to the welfare of all warm-blooded species. Other areas of animal welfare were also addressed in the 1970 Amendments, e.g. animals used for exhibition or for use as pets (at the wholesale level) were provided humane care and treatment. Implementation of legislation in the specific areas covered by these Amendments is still evolving. Recently, work has commenced on the development of species-specific standards for farm animals used for purposes of experimentation. However, to date no legislation covers rats, mice and birds.

1976 Amendments

The principal effect of the 1976 Amendments to the AWA was to extend coverage to commercial carriers (airlines, trucks) transporting animals for research as well as other specified purposes (i.e. for exhibition or for use as pets). These Amendments also covered intermediate handlers taking physical possession of animals during the course of transportation.

The sizes of primary enclosures for transportation were standardized, and regulations for ventilation, ambient temperature ranges and handling procedures were implemented. As a result, some carriers (primarily rail and truck) ceased transporting animals for the stated purposes. However, major air carriers instituted training programmes for cargo handling personnel which helped to minimize human handling errors.

1985 Amendments

The series of Amendments to the AWA which were passed by Congress in 1985 focused almost entirely on experimental animals. These Amendments provide the most detailed and encompassing regulations for the use of animals for biomedical research in the USA.

In some quarters of government, as well as the scientific community, these regulations were viewed as an invasion of the right to free scientific inquiry. On the other hand, some animal protection advocates had documented and highly publicized a few dramatic incidents of mistreatment and neglect of animals under experimentation.
This publicity raised awareness of the issues among the general public, and a mistrust of "what goes on behind closed laboratory doors" was implanted.

In essence, the 1985 Amendments require each research project to include a protocol providing an assurance that the humane treatment of animal subjects will be implemented, as far as possible. Implicitly, these Amendments raised for the first time, in the field of regulation, the question of the relative importance of a research project compared to the degree of pain and distress caused to the animal subjects. The following provisions contained in the Amendments were complex, and their impact cannot yet be fully assessed.

**Impact on research personnel**

For the first time, the provisions contained in the 1985 Amendments for the regulation of the responsibility for the care and use of research animals encompassed all levels of human interaction with these animals. Requirements were included for the research administrator, the principal investigator, the attending veterinarian, animal care technicians and members of an Institutional Animal and Care Use Committee (IACUC) (including a non-affiliated member to represent the public interest). The Congressional Committee which forged the outline of the 1985 Amendments incorporated into the legislation several requirements which structured this expanded responsibility of the scientific community for experimental animal care practices.

**Institutional Animal and Care Use Committees**

Each research facility was required to establish at least one Committee with the overall purpose of reviewing and assessing animal care and treatment for experimental purposes in the facility. This requirement parallels a guideline which is part of the Public Health Service policy on humane care and use of laboratory animals (14). These IACUCs provide an instrument of peer review without direct regulation of research. The Regulatory Enforcement and Animal Care (REAC) unit of the Animal and Plant Health Inspection Service (APHIS) of the USDA monitors the work of the IACUCs and enforces the requirements of the law through periodic unannounced inspections of facilities.

In reviewing research proposals, the IACUCs refer to the following criteria established in the 1985 Amendments:

1. Procedures involving animals must avoid or minimize discomfort, distress and pain to the animals.
2. The principal investigator must consider alternatives to procedures which may cause more than momentary or slight pain or distress to the animals, and must provide a written narrative description of the methods and sources (e.g. the Animal Welfare Information Center [AWIC]) which were used to determine that no alternatives were available.
3. The principal investigator must provide written assurance that the activities do not unnecessarily duplicate previous experiments.
4. Procedures which may cause more than momentary or slight pain or distress to the animals must satisfy the following requirements:
   - Such procedures must be performed with appropriate sedatives, analgesics or anaesthetics, unless withholding such agents is justified for scientific reasons, in writing, by the principal investigator. The procedure may only continue for the necessary period of time.
- The planning of such procedures must involve consultation with the attending veterinarian or his/her designated replacement.

- Such procedures must not involve the use of a paralytic without anaesthesia.

e) Animals which would otherwise experience severe or chronic pain or distress without the possibility of relief must be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure.

f) The living conditions of the animals must be appropriate for the species, in accordance with Part 3 of the USDA regulations (11), and must contribute to the health and comfort of the animals. The housing, feeding and non-medical care of the animals will be directed by the attending veterinarian or another scientist trained and experienced in the proper care, handling and use of the species being maintained or studied.

g) Medical care must be available for animals and provided, as necessary, by a qualified veterinarian.

h) Personnel conducting procedures on the species being maintained or studied must be appropriately qualified and trained in the relevant procedures.

i) Activities which involve surgery must include appropriate provision for pre-operative and post-operative care of the animals, in accordance with established veterinary medical and nursing practices. All survival surgery must be performed using aseptic procedures, including the use of surgical gloves, masks and sterile instruments. Major operative procedures on non-rodents may be conducted only in facilities which are intended for the purpose, and which are operated and maintained under aseptic conditions. Non-major operative procedures on non-rodents and all surgery on rodents do not require a dedicated facility; however, these must be performed using aseptic procedures.

j) No animal may be used in more than one major operative procedure from which it is allowed to recover, except under the following circumstances:

- a further operation is justified for scientific reasons, as attested in writing by the principal investigator

- the operation is required as part of routine veterinary procedure or to protect the health or well-being of the animal, as determined by the attending veterinarian

- in other special circumstances, as determined by the APHIS Administrator on an individual basis.

k) Methods of euthanasia must be in accordance with the definition of this term in the USDA regulations (11), unless a deviation from such methods is justified for scientific reasons, in writing, by the investigator and approved by the IACUC.

Some researchers (10) have suggested that research facilities should voluntarily invest IACUCs with the additional responsibility of assessing the worth or scientific merit of proposed research in relation to animal welfare issues. However, the AWA does not require IACUCs to fulfil such a role.

Training requirements

Another charge of the IACUCs involves ensuring that research personnel associated with the use of laboratory animals have certain competencies. These areas of competence are specified in the 1985 Amendments as follows:
a) Humane methods of animal maintenance and experimentation, including the following:
   - the basic needs of each species of animal
   - proper handling and care for the various species of animals used by the facility
   - proper pre-procedural and post-procedural care of animals
   - aseptic surgical methods and procedures.

b) The concept, availability and use of research or testing methods which limit the use of animals or minimize animal distress.

c) The proper use of anaesthetics, analgesics and tranquillizers for any species of animals used by the facility.

d) Methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility. No facility employee, Committee member or laboratory personnel may be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards contained in the AWA.

e) Use of available services (e.g. National Agricultural Library, National Library of Medicine) to provide the following information:
   - with regard to appropriate methods of animal care and use
   - alternatives to the use of live animals in research
   - information which could prevent unintended and unnecessary duplication of research involving animals
   - information with regard to the intent and requirements of the AWA.

An issue which has created some controversy among members of the scientific community is the requirement that personnel conducting procedures on the subject species must be trained and qualified in the relevant procedure. Generally, this will be the responsibility of the attending veterinarian, who must also provide the medical care (as needed) as well as direct the housing, feeding and non-medical care of experimental animals. This requirement may sometimes lead to a difference of opinion with regard to competencies among the various professional disciplines involved in biomedical research.

**Pain-relieving measures**

Another area specifically covered in the 1985 Amendments is the minimization and relief of pain or distress inflicted on animals in research. The following provisions were mandated:

a) application of procedures to avoid or minimize pain and distress

b) consideration of alternatives to procedures which inflict pain

c) planned administration of sedatives, analgesics or anaesthetics in painful or paralyzing procedures

d) painless euthanasia of surviving subjects which would otherwise experience acute or chronic pain or distress

e) provision of pre- and post-operative professional veterinary care, including the use of aseptic techniques

f) written justification for the use of an animal in more than one operative procedure
g) use of euthanasia methods in compliance with the regulatory standards – the American Veterinary Medical Association “Report of the Panel on Euthanasia” (1) is used as the guiding document.

Animal well-being

The 1985 Amendments call for the following highly controversial requirements:

a) promulgation of standards which “shall include minimum requirements for the exercise of dogs”

b) provision of a physical environment adequate to “promote the psychological well-being of primates” (6).

Relatively little published scientific evidence was available in the early 1980s to support the development of such standards. However, following the enactment of the 1985 Amendments, a body of research ensued which focused primarily on the environmental enhancement of non-human primates and, to a lesser extent, on the need of exercise requirements for dogs.

The first proposed rulemaking on these two issues was published in the Federal Register, and contained proposals for the specific design of housing and standards for the handling of animals. (After regulatory legislation is passed by Congress, there is a required legal process of publication of proposed rulemaking in the Federal Register, with a public comment period. The comments may necessitate modifying the proposals and republishing the revised version for additional public comment before final rules are published.) Thousands of comment letters were received, either in protest or approving the proposals. At the same time, under a conservative administration, a government-wide move for deregulation was under way. On these issues, the biomedical community launched an organized campaign to modify the proposed specific requirements. The protests from the scientific community cited the paucity of scientific evidence supporting such specific standards and the prohibitive costs of compliance. The proposed standards were modified and republished, but the controversy continued. Final rulemaking was accomplished in 1990. This final set of regulatory requirements focused largely on the required outcomes (i.e. performance standards for the subject animals). Research facilities were allowed a good deal of scope for professional judgement in how they produced these stated outcomes. For example, enclosures for non-human primates were required to provide enrichment experiences for the animal. This could be accomplished by providing mirrors, television, appropriate “furniture”, or other innovative methods or devices. The responsibility of assuring appropriate procedures and devices for environmental enrichment was placed with the attending veterinarian.

Immediately following the protracted rulemaking process, a legal action was filed against the USDA by the Animal Legal Defense Fund, et al. This action sought to force a return to more specific design standards. On 25 February 1993, a Federal judge of a District Court issued a decision in favour of the animal protection plaintiffs. The United States Department of Justice is currently appealing against the Court decision, on behalf of the USDA. Until all litigation is completed, USDA-REAC inspectors continue to make unannounced inspections of research facilities, to check for compliance with the performance standards described above. As with the functioning of the IACUCs, this approach relies on professional competence and judgement. Animal protection advocates claim that this system cannot be trusted at present.
Responsibility for the implementation of the AWA remains in the hands of the Secretary of Agriculture. This responsibility has been delegated to the Administrator of APHIS. Between 1966 and 1988, another APHIS regulatory unit, Veterinary Services, was responsible for ensuring the implementation of the AWA and compliance by regulated animal users. During the restructuring of APHIS in 1988, a new regulatory enforcement unit – REAC – was organized. The Regulatory Enforcement section has the responsibility of investigating, documenting and pursuing legal actions for non-compliance with any of the animal or plant health regulatory responsibilities of APHIS, including the AWA. The Animal Care section of the unit was given the regulatory authority for the AWA and related legislation. This authority includes responsibility for ensuring compliance with the AWA requirements by USDA registrants and licensees. The principal mechanism for monitoring compliance consists of periodic unannounced inspections of research facilities conducted currently by 52 trained Veterinary Medical Officers (VMOs) and of the premises of dealers by either VMOs or 31 trained Animal Care Inspectors (ACIs).

FACTORS INTERACTING WITH FEDERAL LEGISLATION

The American Association for the Accreditation of Laboratory Animal Care

During the 1960s, the laboratory animal science organizations of the biomedical community supported the establishment of a voluntary accreditation system for facilities using animals for research. The American Association for the Accreditation of Laboratory Animal Care (AAALAC) was founded in 1965 by fourteen scientific organizations, and continues to offer accreditation at research facilities which apply and which satisfy both the criteria in the Public Health Service Guide for the Care and Use of Laboratory Animals (12) and all USDA requirements under the AWA. Institutions which apply for accreditation receive an extensive inspection and evaluation by a team of several laboratory animal veterinarians who visit the site. Renewal of accreditation is based on subsequent inspections at three-year intervals. This programme has been conducted energetically and with the highest integrity, and an increasing number of research facilities are seeking accredited status. At present, the AAALAC accreditation does not affect the USDA inspection schedule. A request has been made that the number of USDA inspections be decreased for accredited institutions; this request is currently under consideration. Such self-regulatory programmes accord well with recent governmental initiatives. However, animal welfare interest groups are still wary of self-regulation. It is hoped that a level of trust is being built which will sustain the efficacy of such co-operation.

Animal Welfare Information Center

Another outcome of the 1985 Amendments was the establishment of the AWIC at the National Agriculture Library to provide a database of information regarding all animal research. The purpose of this database is to provide world-wide information to investigators, to aid compliance with the requirements on checking for alternatives to the use of animal models and to avoid unnecessary duplication of research. A small staff of six persons now performs a thorough task of maintaining this information.
Relationship between the USDA and the National Institutes of Health

A significant factor in the progress of regulating the experimental use of animals is the co-operative relationship between the USDA and the National Institutes of Health (NIH) of the United States Department of Health and Humane Services (HHS). The 1970 Amendments to the AWA mandated consultation between the relevant governmental agencies concerned with animal welfare issues. The wording of the 1985 Amendments strengthened this relationship. With regard to animal experimentation, the USDA/NIH relationship is instrumental in assuring compliance by any research facilities which use Federal funding for animal experimentation. This collegial relationship must continue to grow, with the characteristics of honesty and integrity which will assure moderate public opinion that the conflicting interests of animal welfare and freedom of inquiry are being acknowledged and considered.

International influences

At the same time that the LAWA of 1966 and the 1970 Amendments were being implemented in the USA, the Council of Europe undertook a programme of animal protection initiatives among its intergovernmental activities. One product of these initiatives was the “European Convention for the Protection of Vertebrates Used for Experimental and Other Scientific Purposes” in 1986. United States governmental officials have observed with keen interest the progress in the development and implementation of the recommendations included in this multi-nation agreement. At present, the focus of activity in the USA is on the full implementation of existing legislation and the development of co-operative regulatory arrangements with scientific and other public sector entities. However, governmental officials in the USA are very conscious of the significant role which multi-nation agreements will play as the exchange of scientific information and international trade expand. In the view of the author, the provisions of the Convention and the resulting legislation of Council of Europe member countries will lead the way to future multilateral agreements between the USA and European countries.

Animal rights extremism

Congress in the USA recently enacted the Animal Enterprises Protection Act of 1992 (5), making it a Federal offence to cause physical disruption to an animal enterprise resulting in more than US$10,000 economic damage or causing serious bodily injury or death to any person. In the same Act, the Attorney General and the Secretary of Agriculture were directed to undertake a joint study of the incidence of animal rights extremism and the effects on research and agriculture. To comply with this directive, USDA-APHIS co-operated with the Criminal Division of the Department of Justice which assumed the leading role in preparing the study. The findings were published in August 1993, as the “Report to Congress on the Extent and Effects of Domestic and International Terrorism on Animal Enterprises” (13).

The report covered the period from 1977 (when the first animal rights-related extremist act was reported) to June 1993. Of the 313 incidents documented, 43% targeted biomedical research facilities. Typical of the anecdotal data provided in this report is the following (13):

“In July 1989, without warning, the Animal Liberation Front activists illegally entered a laboratory and office at Texas Tech University’s Health Sciences Center in Lubbock, Texas. The laboratory was operated by Dr J. Orem, who was conducting research on sleeping disorders – including Sudden Infant Death Syndrome – and using
cats for experimentation. During the intrusion, laboratory equipment was damaged or disabled, slogans were spray-painted on the walls, and five adult research-conditioned cats were stolen. Immediately following the raid, an intense propaganda and harassment campaign focusing on Dr Orem's research ended. In traditional fashion, People for the Ethical Treatment of Animals held a news conference and issued a statement justifying the release of the cats.

"The cost of replacing the stolen cats, which had not yet been used in research, was estimated at $2,500. Repair and replacement costs were estimated as follows: facilities - $15,500; equipment - $31,800; and supplies - $6,200. It was also reported that, as a result of the incident, the laboratory facilities and equipment were fully or partially inactive for 45 weeks. In addition, it was estimated that the institution's cost of paying the research scientists and staff as well as maintaining the facilities and equipment during the inactive period ran into the hundreds of thousands of dollars. Ultimately, after the direct, collateral, and indirect consequences of the incident were considered, the total cost to the targeted institution was estimated at just over $1 million."

It is not unusual for a mainstream animal protection organization to announce the results of a raid by a clandestine group. While denying any participation in illegal activities, mainstream groups condone some activities, such as the release or kidnapping of animals. A number of media campaigns following such incidents have focused public opinion on certain issues, resulting in regulatory legislation.

In 1993, there was an upsurge in threats against individual researchers, their families and property. On 27 April 1993, the homes or automobiles of five NIH scientists living in the Maryland suburbs of Washington D.C. were vandalized (13). While such incidents are very disturbing, the economic impact to date has been relatively minor. Actions against private individuals or residences represented 14% of the total number documented in the August 1993 report (13). Nine persons have been convicted of acts in connection with animal rights extremism. In one of these cases, F.S. Trutt pleaded guilty to Federal charges of possessing explosives in January 1989. She had previously been arrested in Connecticut for placing a pipe bomb near the parking space of the President of the United States Surgical Corporation, which uses dogs for testing surgical materials.

**CURRENT DIRECTIONS**

Legislation covering several areas included in the 1985 Amendments is still under development. Together with other Government bodies, REAC as a unit of USDA is participating in the initiatives of the present USA Administration, outlined by Vice President A. Gore in his "National Performance Review" (8). This review contains several recommendations which could have an influence on Federal regulation of animal experimentation:

- REG 02: to encourage more innovative approaches to regulation
- REG 03: to encourage consensus-based rulemaking
- REG 04: to enhance public awareness and participation
- REG 05: to streamline agency rulemaking procedures
- REG 07: to rank risks and engage in "anticipatory" regulatory planning
- REG 08: to improve regulatory science
- REG 10: to provide better training and incentives for regulators.
In April 1990, the USDA advised the public of its intent to begin regulating farm animals used for non-agricultural research under the authority of the AWA (4). USDA inspection of farm animals commenced in June 1990 using the standards and other requirements which applied to the more exotic species. More specific guidelines are now under development. At this stage, opportunities are being provided for the concerned public to identify issues and make recommendations to be considered during the rulemaking process. One such opportunity was a USDA-sponsored open forum for the public held in Oklahoma City, Oklahoma, from 28 to 29 September 1993. At this forum, four main subject areas were discussed in separate workshops: agricultural exemptions; agricultural vs. non-agricultural environments; well-being of farm animals; and special considerations for major operative procedures. The recommendations as reported by the respective Workshop Chairpersons have been printed and are available, on request, to concerned individuals and groups.

Another area of interest is the interaction of USDA with IACUCs. Further in-service training is under way for USDA inspectors who monitor the functioning of IACUCs in registered research facilities. The scope of regulation for animal welfare issues demands careful allocation of the available resources. Regulating officials value the functioning of self-regulation and compliance as represented by IACUCs. The future direction of experimental animal regulations depends heavily on the integrity and effectiveness of the IACUCs.

Furthermore, IACUCs are representative of the thrust advocated by the present Government in the USA. In an address to the United States Animal Health Association (USAHA), T. Medley (Acting Associate Administrator, APHIS) expressed this intent succinctly, advocating a regulatory system “that poses the least possible burden on society, while fulfilling society’s needs” (9). REAC has been proactive in developing performance standards based on flexible criteria which satisfy the objectives of the law. The outcome of the litigation mentioned above in the discussion of the 1985 Amendments will obviously have legal implications for such a future course of action.

CONCLUSION

The developments in regulation of experimental animal use in the USA, described above, span a generation of scientists, public interest groups and regulators. When deliberations were under way for the LAWA of 1966, very few scientists did not view the codification of animal care standards for research as an unwarranted interference by unqualified outsiders. Over the years, this current of opinion has shifted. In a blend of conscience and pragmatism, the majority of scientists have at least acknowledged public demands for humane measures in animal research and for accountability to assure adherence to humane practices. In the USA, there continues to be an effort to sustain good faith and leave as much regulatory power as possible in the hands of the scientific community. At the present time, these efforts stand at a crossroads. If research institutions can develop and maintain honest and effective structures and processes for assuring compliance with animal care standards, more areas of self-regulation can be developed. On the other hand, if these structures and processes are ineffective or deliberately misleading, there will be a public reaction which will make co-operative arrangements less likely. The knowledge that the investigators now entering the research field fully recognise their responsibility to animal subjects provides hope that a positive direction will be taken from the current crossroads.
In 1993, in a published address, I.J.H. Duncan of the University of Guelph, Canada, acknowledged the ethical responsibility of humanity to reduce suffering among animals, stating: “I think that we can do it. But we will only do it reasonably and rationally and defensibly if first we carefully gather the scientific evidence” (7).

In an ideal situation, this would surely be correct. However, in reality, there are sections of the public interested in animal welfare which are distrustful of science and scientific evidence. Regulation of animal use in research will therefore continue to represent a compromise between demonstrable physiological and behavioural phenomena and less objective but strongly-held public views. Scientists themselves are in the best position to bridge the gap between the two positions. When scientists can honestly communicate the efforts of research to reduce pain and distress among animal subjects, moderate public opinion will respond. Such communication can help to forge a resolution of two societal imperatives which are currently opposed: the responsibility of reducing suffering among animals, and the need to seek answers to biomedical questions.

RÉGLEMENTATION FÉDÉRALE SUR L’EXPÉRIMENTATION ANIMALE AUX ÉTATS-UNIS D’AMÉRIQUE. – D. Schwindaman.

Résumé : L’auteur expose, dans ses grandes lignes, la réglementation applicable à l’expérimentation animale aux États-Unis d’Amérique. La réglementation dans ce domaine n’en est encore qu’à ses débuts ; bien des questions restent à approfondir, d’autant plus que l’intérêt suscité par le bien-être des animaux concerne plusieurs aspects de la science animale. De nouveaux textes réglementaires sont toujours à l’étude en réponse aux progrès technologiques que la première législation fédérale des États-Unis d’Amérique en la matière (Laboratory Animal Welfare Act), signée en 1966, ne pouvait prévoir. Les associations de protection des animaux et, plus récemment, les groupes de défense des droits des animaux, sont ainsi à l’origine des amendements apportés à la loi de 1966 élargissant les compétences des autorités fédérales, le nombre des espèces et les domaines soumis à la réglementation. L’expérimentation animale préoccupe de plus en plus le public et la communauté scientifique. L’auteur décrit le rôle des Institutional Animal and Care Use Committees dans les établissements de recherche, ainsi que d’autres facteurs intéressant la législation fédérale.

L’attitude des pouvoirs publics en matière de législation évolue également dans le sens d’une plus grande concertation entre le législateur et les associations. Les organisations régionales et internationales ont renforcé la sensibilité nationale vis-à-vis de ce qui est perçu comme une exploitation des espèces animales.

L’auteur démontre clairement que la tendance aux États-Unis d’Amérique est à la recherche de solutions consensuelles dans le cadre d’accords élargis. Ces solutions devraient continuer, selon lui, à concilier l’obligation morale de respecter l’intégrité des espèces animales et la nécessité de mieux connaître l’homme et l’animal en vue d’améliorer la qualité de la vie.
REGLAMENTACIÓN FEDERAL SOBRE EXPERIMENTACIÓN ANIMAL EN LOS ESTADOS UNIDOS DE AMÉRICA. – D. Schwindaman.

Resumen: El autor expone las características generales de la reglamentación sobre experimentación animal en los Estados Unidos de América. Esta reglamentación está en pleno desarrollo y es necesario todavía avanzar en cuanto a la definición y solución de muchos problemas; además, la preocupación por la protección animal se vincula con varios aspectos de la ciencia animal. El progreso tecnológico lleva así necesariamente a preparar nuevos textos reglamentarios, que no podían preverse en ocasión de la primera legislación federal al respecto, llamada Laboratory Animal Welfare Act, que data de 1966. Las sociedades protectoras de animales y, más recientemente, las diversas asociaciones defensoras de los derechos de los animales han propuesto y obtenido actualizaciones de esta ley en el sentido de una ampliación de la competencia de las autoridades federales a través de un incremento del número de especies y de los ámbitos de experimentación a los cuales se refiere la reglamentación. La experimentación animal es cada vez más un tema de preocupación del gran público y de la comunidad científica; el autor se refiere a la importancia que han adquirido los Institutional Animal and Care Use Committees en los institutos de investigación, junto con otros factores que inciden en la legislación federal.

La actitud de las autoridades oficiales responsables de la reglamentación también ha ido cambiando en este sentido, en dirección de una mayor concertación entre el legislador y las asociaciones interesadas. Y tanto las organizaciones regionales como las internacionales han contribuido a sensibilizar a la opinión pública acerca de lo que se percibe como una explotación de los animales.

El autor demuestra claramente que la tendencia general en Estados Unidos es actualmente la búsqueda de soluciones a través de acuerdos que integren un amplio consenso tanto a nivel de su implementación como de su instrumentación. Sostiene, como conclusión, que estas soluciones seguirán contando con los imperativos éticos relativos al respeto de la integridad de las especies animales, así como con la necesidad de ampliar los conocimientos sobre el hombre y los animales con vistas al mejoramiento de la calidad de vida.

REFERENCES


