

Chapter 16

Regulation of Animal Use in Selected Foreign Countries

One of the tests of a civilized society is its treatment of animals.

*Scientific Procedures on **Living Animals**, (Command 9521
British Home Office
May 1985*

We have come to the conclusion that the status of the dog in Western Society is such that it is desirable to minimize its use in the laboratory. Some 50 percent of Canadian households include a dog. These pets are regarded by most owners in an anthropomorphic way as being full members of the family. Clearly, such people are very receptive to emotional appeals to ban the use of animals-especially dogs like theirs-for research. Thus, it will probably be necessary to phase out the significant use of dogs if a major battle over the use of animals for research is to be avoided.

J.C. Russell and D.C. Secord
University of Alberta, Edmonton
Perspect. Biol. Med. 28:374-381, 1985

Possibly the most important feature of any legislation on behalf of laboratory animals is the acknowledgment that the ultimate responsibility for their welfare rests with society and not with the research community.

Anne Doncaster
Mississauga, Ontario
“Experiments on Animals—Review of
the Scientific Literature,” June 1982

CONTENTS

	<i>Page</i>
Australia +	359
Canada	360
Japan	362
Western Europe	363
Denmark + ,	363
Federal Republic of Germany	366
Netherlands ,	367
Norway , , ,	368
Sweden	369
Switzerland	371
United Kingdom	373
Summary and Conclusions	377
Chapter 16 References.	377

List of Tables

<i>Table No,</i>	<i>Page</i>
16-1. National Laws for the Protection of Animals in Selected European Countries	364
16-2. Comparison of the United Kingdom's Cruelty to Animals Act of 1876 and Proposed Amendments	374
16-3. Experiments by Species of Animal, 1977-84, United Kingdom.	375
16-4. Primary Purpose of Experiments, 1977-84, United Kingdom	376
16-5. Experiments by Type of Registered Facility, 1977-84, United Kingdom	376

Regulation of Animal Use in Selected Foreign Countries

The protections afforded animals vary greatly among countries, from almost complete disregard of animal welfare to the many cultural and legal protections provided in Western Europe and Canada. These protections are currently the subject of heated debate in many countries, particularly where animal protection is already significant. In 1985, for example, Switzerland's voters rejected a referendum that would have virtually banned the use of animals for experimental purposes. The use of the LD₅₀ in safety testing continues to be given careful scrutiny by Government and scientific organizations in Switzerland (73,76, 77) and the United Kingdom (4,67,69).

Actions taken in other countries are relevant to U.S. policies for several reasons. First, steps taken by trading partners can lead to political and economic pressures to take similar actions. Second, decreased use of animals abroad, particularly by multinational corporations, can lead to an increased use in the United States. Finally, the experiences of other countries can serve as instructive models, both for policies and for their effects.

This chapter describes the laws of Australia, Canada, Denmark, the Federal Republic of Germany, Japan, the Netherlands, Norway, Sweden, Switzerland, and the United Kingdom. The most common provisions are prohibitions against painful experiments without anesthesia unless anesthe-

sia would frustrate the purpose of the experiment; requirements for licensing or permitting of facilities, investigators, or experiments; limitations on animal use for education; and requirements for internal or external review of experiments by interdisciplinary committees. Two of the more unusual provisions are the protection of crustaceans (Norway) and of native nonvertebrates (the Netherlands).

The impact of these laws on the welfare of animals is affected by several factors other than the substantive requirements of the laws, including societal attitudes toward animals; training of scientists and technicians, both in techniques and in ethics; the composition and procedures of reviewing committees; and the vigor of animal welfare advocates. This chapter discusses the substantive and procedural aspects of these various laws and, where information was available, criticisms and comments on the effectiveness of the systems.

In addition to the array of national laws, there are international agreements—both in effect and proposed—that affect animal welfare. Among these, the Convention on International Trade in Endangered Species, bans on trade in primates, the Draft Convention of the Council of Europe, and the guidelines of the Council for International Organizations of Medical Sciences, are discussed in appendix E.

AUSTRALIA

In Australia, as in the United States, animal welfare is primarily a State concern. Each State has its own legislation and regulations for animal experimentation. At the Federal level, a select committee of the Australian Senate is in the early stages of an 18-month examination of animal welfare, and in 1985 the National Health and Medical Research Council revised its Code *of Practice* for experimental animals (41a).

Of the States, New South Wales has the most extensive laws. Its Prevention of Cruelty to Animals Act, passed in 1901 and amended many times, prohibits activities such as inflicting unnecessary pain; killing, mutilating, or poisoning; and failing to provide proper food, drink, shelter, or exercise. Experimentation is permitted only in the most humane manner available and pain must be alleviated. The most recent amendments, in 1979,

primarily served to make the act more specific. Two levels of cruelty were defined and penalties specified—aggravated cruelty, resulting in death or severe injury or disease (fined at about \$1,400 and/or 1 to 2 years imprisonment), and simple cruelty, resulting in pain or distress (fined at about \$700 and/or 6 months) (2).

In addition to the act's prohibitions, it requires that those performing surgery have certain scientific credentials or a license. Recognizing that credentials alone do not prevent cruelty, the Min-

ister for Local Government has the power to require those performing surgery as licensees to report the details of a procedure (1).

In 1985, the New South Wales Parliament passed legislation establishing an Animal Research Review Panel to oversee licensing of research institutions and animal suppliers. Each institution is required to establish its own review committee (56). These requirements make the laws of New South Wales quite similar in their comprehensiveness and approach to the laws existing in Western Europe.

CANADA

As in the United States and Australia, the Provinces have primary authority over animal use; national action is not taken unless there are inter-provincial or national concerns. Although Canada has no national legislation pertaining specifically to protecting laboratory animals, it has a comprehensive voluntary national system.

Three Provinces have legislation affecting laboratory animal use: Two deal primarily with procurement of unclaimed pound animals (8,9,10), while Ontario has a more comprehensive Animals for Research Act, amended in 1979 (6) and accompanied by regulations (i'). Many provisions of the Ontario law parallel the voluntary national program.

Although Canada is rather proud of its voluntary program, some Canadian animal protectionists are not satisfied. Vandalism and threats against an official have occurred at the University of British Columbia in Vancouver, the Clarke Institute of Psychiatry in Toronto has been firebombed, and protesters have campaigned against the use of pound animals at Dalhousie University (55).

Many years ago, scientists at the University of Alberta went further than their counterparts in other Provinces in protecting animal welfare. They employed a research veterinarian who upgraded their facilities to levels as high as animal hospitals and clinics, added various precautions against the use of stolen dogs, and established open communication with the press and the local community.

Another policy, certainly welcomed by dog enthusiasts, has been the gradual replacement of the dog with the small Yucatan pig for many kinds of experiments. Some Alberta researchers feel that animal protectionists have not been active in Alberta because of these initiatives (55).

Canada's voluntary national program is run by the Canadian Council on Animal Care (CCAC). The first step toward the creation of the CCAC was taken in 1963, when the Canadian Medical Research Council requested the National Research Council (of Canada) to investigate the procurement of experimental animals, the facilities for their care, and control of experiments. This request followed on the heels of the inauguration of the Canadian Society for Animal Care (which became the Canadian Association for Laboratory Animal Science, an organization similar to the American Association for Laboratory Animal Science).

After completing its investigation, the National Research Council recommended that institutions voluntarily assess and control animal experimentation through:

- animal care committees that would monitor care and use of experimental animals and ensure compliance with uniform standards;
- Provincial advisory boards to deal with procurement matters; and
- a national, independent advisory body to establish guiding principles and oversee their application and to advise Provincial governments.

These recommendations led to the formation of the CCAC in 1968 as a committee of the Association of Universities and Colleges of Canada (AUCC). CCAC is independent of governmental and direct university control and is funded by the Medical Research Council and the National Research Council. Its 20 members are drawn from various sectors: 8 from national associations of higher education (including the AUCC), 5 from departments of the Federal Government, 4 from national agencies providing research grants, 2 from the Canadian Federation of Humane Societies, and 1 from the Pharmaceutical Manufacturers Association of Canada. The members of the CCAC also participate informally in curriculum committees for institutions that educate animal care attendants and technicians and, together with the Canadian Association for Laboratory Animal Science, certify laboratory animal personnel at five skill levels (28, 50)(51)(52).

The CCAC has two executive officers: the Executive Director, responsible for standards and overall operation; and the Director of the Assessment Program, responsible for compliance with the voluntary program. They organize the CCAC's activities around the *Guide to the Care and Use of Experimental Animals*, a two-volume publication much like the *Guide for the Care and Use of Laboratory Animals* issued by the U.S. National Institutes of Health (NIH). The CCAC's *Guide*, provided at no charge to every researcher using animals, details standards for the care and use of animals in experiments for government, university, and pharmaceutical research institutions.

The most important requirement of the *Guide* is that a local institutional Animal Care Committee (ACC) be set up. Volume I lists the following general requirements for a facility's committee:

- It must consist of senior scientific personnel experienced with laboratory animals. An experienced veterinarian or a biological scientist should be a member of the ACC or retained as a consultant.
- It must be kept informed of all activities involving animals.
- It must establish procedures to ensure that in any experiment likely to result in pain, the animal is anesthetized or given analgesics except when it would interfere with the experiment.

- It is responsible for all training and qualifications of personnel who care for animals.
- If its members believe required procedures are not being followed and unnecessary pain is being experienced, it has the power to stop the procedure and to destroy the animal humanely if necessary to alleviate distress (11).

In 1983, an addendum to Volume I, *The Use of Animals in Psychology*, provided additional guidelines to those engaged in psychological research (13). Volume II of the *Guide*, published in 1984, provides information on selection, acquisition, use, and care of 22 distinct classes of laboratory animals (14).

In addition to the *Guide*, CCAC has also published *Ethics of Animal Experimentation*, a set of principles for "all those utilizing vertebrates in the conduct of research, teaching, or testing." These stress the importance of:

- exhausting all alternative methods before animal use is considered;
- using the best methods on the smallest number of appropriate animals required to obtain valid information;
- having a reasonable expectation that the study will contribute significantly to knowledge that may eventually improve the health or welfare of humans or animals;
- avoiding unnecessary pain and duress, both in intensity and duration;
- humanely destroying animals when severe pain cannot be alleviated;
- seeking humane end points;
- withholding food or water on a short-term basis only;
- avoiding physical restraints; and
- using anesthetics or analgesics for surgery or traumatic procedures (burning, freezing, fracturing) (12).

CCAC publications that do not necessarily promote animal welfare, but that are useful to experimenters, include *Canadian Suppliers of Laboratory Animals* (a detailed list of suppliers, with species, producers, and locations) and annual editions of *Research Animals in Canada* (comprehensive information, by species, on laboratory-animal resources available to researchers) (15).

Compliance with the various guides and principles and the functioning of the local ACCS are over-

seen by assessment panels chosen by the CCAC. The typical panel consists of three scientists, one representative appointed by the Canadian Federation of Humane Societies, and the Director of Assessments, acting ex officio. Panelists are selected, to the extent possible, for the fields of research at the institution to be assessed.

Institutions, contacted in advance, complete a questionnaire describing the local ACC, the research facilities, the animals used, and the personnel. After the facility has been inspected (for as long as 4 days in large institutions), the panel discusses its general findings with the ACC and reports in confidence to the principal official of the institution. If the panel is dissatisfied, a followup visit may be scheduled. Major assessments occur approximately every 2 years; minor ones, or reassessments, occur less frequently (15,23).

Identified problems that are widespread are solved at the national level. For example, inappropriate use of certain animals as models, poor surgical or anesthesia techniques, dated equipment, and poor husbandry led the CCAC's ad hoc Education Committee to issue the *Syllabus of the Basic Principles of Laboratory Animal Science* in 1983 (16). Several Canadian universities have used the syllabus in short courses in basic laboratory-animal science, and one university proposed that

such courses be mandatory for graduate students who may use animals during research (27).

Although there are no penalties in law or regulation for violating CCAC standards, an incentive for compliance has been provided by the Health Protection Branch of the Department of National Health and Welfare since 1975. It includes in its contracts with private sector institutions a requirement that the CCAC *Guide* be followed. All governmental departments with contracts involving animal experimentation have now adopted similar provisions, and a finding of noncompliance is grounds for terminating a contract (28,51).

Responding to increasing criticism from some quarters about CCAC's reliance on researchers to police themselves and to more frequent demands for Provincial legislation controlling research animal use, Canada's Minister of State for Science and Technology requested a review of CCAC's effectiveness in 1981. A special committee formed to conduct the review found that the CCAC has had considerable influence in eliminating those problems that led to its establishment and that it works effectively to produce further improvements. The site inspections involving the humane society and the facility upgrading were found to have resulted in Canadian animal care facilities now being among the best in the world (28).

JAPAN

The protections afforded animals in Japan are like those of Europe in their requirements for anesthetics and euthanasia, as well as in their concern, in particular, about dogs and cats. An interesting facet of the Japanese laws is that they combine the protection of animals with the responsibility of those possessing animals to protect other humans from them.

The principal law governing animal control and treatment in Japan (33) went into effect in 1974. Its purposes are to prevent cruelty to animals; to provide for appropriate treatment, taking natural habits into account; to engender a feeling of love for animals among people, thereby contributing to the development of respect for life and sentiments of friendship and peace; and to pro-

tect humans from any hazards to themselves or their property that could result from possession by others of domestic or laboratory animals. The law establishes a fine of up to \$1,400 for violations of the law or of standards implementing it (32, 33,34).

The law protects all mammals and birds, but it is apparently intended to apply to other species as well. It establishes several responsibilities relevant to research:

- Those possessing animals are responsible for their maintenance, health, safety, and control,
- Where an animal is used for education, experimental research, manufacture of biotics, or other scientific purposes, the animal is to

suffer the minimum pain possible within the limits imposed by these purposes.

- If an animal will not recover from a scientific procedure, the person who used the animal must immediately dispose of the animal by a method that causes it the minimum pain possible.

These responsibilities do not apply to education and research in livestock husbandry or breeding or to experiments for the purpose of observing animal's roles in an ecosystem (37).

The Prime Minister has issued three standards in implementing this law: Standards for the Keeping and Custody of Dogs and Cats (1975); Standards Relating to the Keeping and Custody of Animals for Exhibition, etc. (1976); and Standards Concerning the Raising, Custody, etc. of Animals in Experimental Use (1980) (37). The first two establish general requirements for adequate food, water, shelter, exercise, care, safety, and disease control for animal owners, custodians, and exhibitors. As the title indicates, the first standard applies to dogs and cats; the most recent standard covers other mammals, birds, and reptiles. Enforcement guidance for local authorities was also provided in 1980 (37), and a licensing system was established for facilities conducting experiments (35).

The law establishes a decentralized system for general administration and enforcement. Local authorities at various levels—prefectures, cities,

towns, villages, and wards—pass ordinances and establish custody and disposition programs. Prefectures, the largest units, can levy fees for custodial programs and can enlist the aid of animal protection societies. Such programs can also be granted subsidies by Cabinet Order (38).

An Animal Protection Council created by the Cabinet in 1974 (36) aids the Prime Minister at his request. Though the 15-member Council is advisory, the Prime Minister must consult with it before establishing, enlarging, or abolishing standards. The Council, together with the Government and the Japanese Science Council, recommended in 1980 that the Government establish guidelines for animal experimentation (39). The guidelines developed are quite like the NIH's Guide *for the Care and Use of Laboratory Animals*; they cover standards for housing, husbandry, veterinary care, handling during and after experimental procedures, anesthetics, euthanasia, and disposal (63).

In addition to these several publications on how to use animals, the Government has also published detailed information on licensed and regulated facilities, including statistics on experimental-animal use (75). According to this publication, mice accounted for 78 percent of total animal usage in 1980, while rats accounted for a little less than 17 percent. The total number of animals used has been declining from a peak in 1970 (13.6 million), though the use of hamsters, dogs, cats, and primates has increased (30).

WESTERN EUROPE

Throughout Western Europe, animals have legislative protections. The first such protections were anticruelty laws, many of which were passed in the late 19th century. Most anticruelty laws had only limited application to experiments, but in the last several decades, additional laws were passed to protect experimental animals, primarily from pain. This section describes the laws of seven of the more active countries. Table 16-1 compares the major provisions of these laws.

Denmark

The philosophy in Denmark, as in other Scandinavian countries, is that animal experiments are prohibited unless specifically allowed. This belief was first expressed by statute in 1953 (19). With amendments in 1977 (18), Denmark gave authority for all experiments involving animals to an Animal Experiment Board at the Ministry of Justice. This board has seven members who are doctors

Table 16-1.—National Laws for the Protection of Animals in Selected European Countries

Provisions	Denmark	Federal Republic of Germany	Netherlands	Norway	Sweden	Switzerland	United Kingdom
Species protected. . . .	Vertebrates	All animals	Vertebrates, native species	Vertebrates, crustaceans	Vertebrates	Vertebrates	Vertebrates
Distinctions among species	Should use lowest rank; dogs, cats, rabbits purpose-bred	Better to use invertebrates or cold-blooded vertebrates	Vertebrates better protected	Monkeys, dogs, cats better protected	Should use lowest rank; all purpose-bred	Should use lowest rank	Primates, dogs, cats, equidae preferred; no stray dogs
Alternatives must be used if available	Yes	Yes	Vertebrates	Yes	Alternatives promoted	Yes	Alternatives encouraged
Anesthetics, analgesics, or approval required for painful experiments	Except for minor or transient pain	If pain, suffering, or injury likely	If injury or pain likely	If pain is possible (unless Board approves)	Surgery on mammals unless committee approves	Slight pain or anxiety; if too painful, must forgo	Statute does not specify, but certificate may require
Educational uses	Higher education, technique	High school and above	University and vocational	Professional training	Allowed, but restricted	Not allowed	Some demonstration; not for practicing
Ban on animal use for more than one painful experiment.	All dogs, cats, monkeys; most experiments	No multiple surgeries on vertebrates	Rarely reused because of pain requirements	Only one experiment allowed per animal	Rarely reused because of pain requirements	Only reused if pain was slight	If anesthetized or because of pain requirements
License/permit for dealers, facilities, and investigators	All facilities, head investigators	Dealers, facilities, investigators	Dealers (dogs and cats), facilities	Investigators or facilities licensed	Breeders, facilities	Breeders, facilities	Facilities registered, investigators licensed
Review of experiments ., .	Most experiments need approval by national Board	Not needed; proposed that facility's animal welfare officer review	Head of institute reviews	Investigator or facility (licensee) review	Notification/application; tiered system	2 State committees review	Home Office and Advisory Committee
Administration	Centralized, government/nongovernment board; licensee is responsible	States enforce and administer (proposed that facilities have animal welfare officer)	Central enforcement and reporting: administration by institute	Central coordination, some functions delegated to licensees	Central coordination with oversight by facility head and committee	Central coordination, administered by States	Centralized, shared by Head Office, Advisory Committee, Royal Society
Animal welfare representation ...	3 nominees to national Board	Being considered	Not required, but facility reports are public	Not required	On all committees; being reconsidered	Members of national commission	Advisory Committee
Reporting	Annual report	In-house recordkeeping	Annual report	Annual report	Government recordkeeping	In-house recordkeeping	Annual report

SOURCE Office of Technology Assessment

or veterinarians. Members are nominated by various groups—two by the Medical, Agricultural, and Veterinarian Scientific Councils; one by the Public Health Authority; one by the Council for Industry; and three by associations for the protection of animals.

Because there are fewer than 300 experimenters, most of whom are clustered in a handful of facilities, the Board is able to oversee all experiments. A permit must be obtained from the Board for most experiments, and its decisions cannot be appealed. The only exceptions to the requirement for approval are nutrition studies that will cause conditions similar to what might occur naturally, and experiments that cause only transient and minor pain, as in the taking of blood samples or skin biopsies, but even these procedures are subject to the statute's other requirements. In a change from the earlier statute, Government institutes must obtain permits for experiments, although licensing of individual investigators in certain positions and of facilities is still automatic. Those having permission to conduct experiments may delegate this authority to others, but they remain responsible for the experiment.

There are two other important changes in statutory law. First, the use of animals in experiments is forbidden if alternative methods, such as cell, tissue, or organ cultures, could achieve the same results. Second, in the area of education, animals may only be used in universities and other institutions of higher learning, and then only to train people in experimental techniques. One troublesome provision, carried over from the 1953 act, is that animals of the lowest possible "rank" must be used. One can infer from the special protections given dogs, cats, and monkeys that these are the highest species, but the statute does not specify how rank is to be determined. A recent ordinance requires that as of January 1, 1986, all dogs, cats, and rabbits be purpose-bred. The Animal Experiment Board is also studying the need for the LD₅₀ test, with decisions expected no earlier than mid-1986 (40).

The law requires the use of as few animals as possible and the prevention and alleviation of pain. Invasive (surgical) procedures and physically and chemically induced insults that might cause pain must be performed under anesthesia. The animal

involved must be killed before recovery unless the experimenter can assume that pain will not endure or unless the procedures require that the animal be kept alive. If the latter, the animal must be given pain relievers and special care. If it survives in an abnormal state, any suffering that results must be relieved to the extent possible. The abnormal condition must be corrected as soon as possible, or the animal must be destroyed humanely. If dogs, cats, and monkeys are not killed at the conclusion of experiments, reasons must be given; the exact details of destruction and disposal must be included (40). This is similar in effect to those statutes requiring that an animal be used in no more than one painful experiment.

Licensees must keep records and file a detailed annual report on numbers and species of animals used; type of euthanasia performed on dogs, cats, horses, ungulates, and nonhuman primates; and purposes of experiments. Since 1979, the Board has required reporting that is unique. Research institutions must distinguish between the total numbers used in experiments (Category A), and those used as controls and sacrificed for harvesting organs or some other purpose only indirectly related to the performance of an experiment (Category B). Categories are further subdivided to reflect the risk of pain and suffering:

- procedures of short duration performed not under anesthetic (Category A-1);
- procedures of longer duration, when the animal is not sacrificed while still anesthetized (Category A-2);
- procedures performed under anesthetic, when the procedure is of short (Category A-3-a) or long (Category A-3-b) duration;
- procedures to produce or test substances performed without anesthetic and not included in the following two categories (Category A-4);
- procedures involving the induction of pathogens or infection (Category A-5); and
- procedures involving the injection of other matter (Category A-6).

There has been a steady growth in the number of licensees in Denmark, from 159 in 1970, to 276 in 1983, some of which is due to broadening scope of licensing requirements. Animal use has been fairly steady, but Category A uses have grown. Mice and rats accounted for 91 percent of all po-

tentially painful experimental animal use in Denmark in 1983. Of those two species, 66 percent were used for toxicological testing. Nonhuman primates and companion animals (dogs and cats) were used in less than 0.25 percent of the total experiments. Most dogs and cats were used in longer term procedures under anesthetic, from which they recovered. In painful procedures, primates were used most often in long-term procedures under anesthetic, but 56 percent were used for purposes exempt from the law (40), that is, nutrition studies or experiments involving only minor or transient pain.

Federal Republic of Germany

West Germany's animal protection laws have been evolving since 1883, at which time anesthetics were required, if possible; experiments using animals could be done by trained persons only; the number of animals and amount of distress were to be minimized; and greater protection was afforded "higher" animals. Amendments in 1933 retained these requirements and added a licensing requirement for institutions using animals. In the 1972 Animal Protection Act, licenses were also required for individual scientists for each study (19).

The Parliament is considering new legislation that would create an ethics commission of scientists and animal protectionists that would review detailed applications for each project involving animals, require that each laboratory appoint an animal welfare officer, and require that the Government identify alternatives and promote their use. Finally, Parliament is also considering a special tax, probably 5 to 25 percent of costs, on animal experiments as a means of providing additional incentive to use alternatives (26,29).

Although the law is national, it is administered by the States (Lander). In enforcing the law, States can use sanctions ranging from stopping an experiment and seizing the animals or revoking a permit, to imposing penalties of about \$3,800 and up to 2 years' imprisonment (24).

The basic goal of the law is that no one shall be permitted to cause pain, suffering, or injury to animals without acceptable reasons. Other provisions require that vertebrates not be used when inver-

tebrates would suffice and that warm-blooded vertebrates not be used when cold-blooded ones would do. Further, experiments should be limited to the number absolutely necessary.

Those desiring a permit must be affiliated with a university or otherwise conducting research, and they must provide detailed information to the permitting authorities in the Lander documenting that:

- the desired results cannot be obtained by more humane methods;
- the experiment is necessary for the prevention, diagnosis, or cure of diseases in humans or other animals or serves scientific purposes;
- the director and deputy director of the experiment are reliable;
- the necessary equipment, facilities, supplies, and personnel are available; and
- proper care and medical treatment will be provided.

Permits may be restricted or revoked if requirements are not met by a specified time or if permit restrictions or regulations are not complied with. The permit contains the name of the director of the experiment and a deputy.

Unlike Denmark and other countries discussed in this chapter, educational uses are permitted at the high school level and a permit is not required. However, such activities must be reported to the authorities before they take place. Other experiments that do not require permits are those that fulfill governmental requirements and those used for diagnostic purposes.

Several restrictions pertain to pain. An animal should not endure pain, suffering, or harm if avoidable. Experiments on vertebrates may be performed only under anesthetic unless it is incompatible with the purpose of the research or the pain connected with the operation is less than the damage inflicted by anesthesia. A painful operation or treatment may be performed on an unanesthetized animal only once unless the purpose of the experiment cannot otherwise be achieved; the animal may be used for another experiment only if the second experiment does not involve pain, suffering, or harm. After an experiment, certain species must be presented immediately to a veterinarian, others to the experimenter, and killed painlessly if the animal can live only in great pain.

Animal experiments may be performed only by persons with the required professional knowledge in veterinary medicine, medicine, or biology. Surgery may only be performed by a certified veterinarian.

Detailed standards governing housing, care, and treatment of live vertebrates in experiments were published in 1977. The Federal Government has published a number of monographs and guidances for the use of the States and regulated facilities in interpreting the act in a variety of circumstances (25). In 1983, the German Veterinary Society issued *codex experiendi* providing advice and suggestions to investigators on the ethical use of experimental animals (26).

There are specific reporting requirements for regulated experiments. Each experiment for which permission was required must have a report on file that describes the purpose of the experiment, the number and types of animals used, and the nature and performance of the experiment. The reports must be signed both by experimenters and the director and retained for 3 years. Ownership histories must be kept for dogs and cats. Though no official national statistics are kept, the Ministry of Food, Agriculture, and Forestry estimates that approximately 7 million animals were used in experiments in West Germany in 1984 (71).

Netherlands

The Netherlands places a great deal of responsibility for animals' welfare on the head of the facility in which experiments are conducted. This oversight is coordinated by the Veterinary Chief Inspectorate of the Ministry of Public Health, who in 1984 began a major project in cooperation with five animal welfare organizations to identify potential alternatives to the use of animals in testing vaccines, serums, and other diagnostic methods. This report, and other initiatives, are expected to increase research on alternatives (53).

Like most other West European countries, the Netherlands has had a general statute that protects animals from cruelty since the late 19th century. It prohibits causing pain, suffering, or injury to an animal, or withholding proper care without reasonable cause. It provides criminal penalties for violations, but it has not been necessary to use

them for animal experiments (21). A law governing trade in livestock confines trade in dogs and cats to licensed dealers, thus protecting pets (43), and an ordinance taking effect in 1986 requires that dogs, cats, and rabbits be purpose-bred (31). Finally, the Netherlands has a "protection of nature" law, which protects some invertebrate species—such as *Helix pomatia*, the Roman snail—and all native amphibians (42,44).

The Law for Experimental Animals, passed in 1976, established a comprehensive system for regulation of animal experimentation, including the filing of annual reports by all animal facilities with the Ministry of public Health (45). The law is based on general guidelines issued by the International Committee for Laboratory Animals, and became the Council of Europe's model for the Draft Convention on protection of laboratory animals (see app. E).

The law requires justification for all animal experiments on vertebrates that are likely to be injurious or cause significant pain or other distress. Experiments must benefit human or animal health or food, or science, and must be approved by the head of the institute where they are to be done. Statistics on registered experiments compiled by the Dutch Government indicate that from 1978 to 1983 about 20 percent of the experiments were related to the production of serums, vaccines, and other biological products; about 30 percent were related to toxicological and pharmaceutical research; less than 10 percent were related to the diagnosis of pregnancy or disease; and about 30 percent were related to the solution of a scientific problem (and the vast majority of these were related to medical research). Less than 2 percent were for training and education. These statistics also indicate that about one-third of the experiments were done because of legal requirements, and less than 10 percent were toxicity tests.

As do many other countries, the Netherlands does not permit painful experiments on vertebrates when alternatives are available, and requires anesthetics for more than negligible pain except where their use would frustrate the purpose of the experiment. Where severe and prolonged pain will likely result from the procedure, the animal must be humanely killed without recovering from anesthesia (45). Statistics for 1978-83 indicate that

some 20 to 30 percent of experiments do not require anesthetics (though the figure is steadily decreasing); that more than 10 percent of the animals are killed without treatment to obtain organs or blood; that about 10 percent of the operations end in euthanasia or slight pain; and that the greatest number of experiments producing significant pain are those involving pathogens, immunization, or toxic substances.

The Government entrusts most of the responsibility for administering the law to the head of the research enterprise to whom licenses are issued. The director of research need not be an expert, but he or she is responsible for appointing experts to ensure that:

- animal technicians involved in licensed experiments are qualified and accredited up to the level established by the Ministry;
- those engaged in animal experimentation cooperate in matters affecting the welfare of the subjects;
- research workers are qualified to perform assigned tasks; and
- the welfare of experimental animals is supervised by a qualified veterinary surgeon or equivalent professional.

From January 1986, licensed institutions are required to have an institutional ethics committee composed of persons of several disciplines, including ethics, who oversee all experiments (31).

Licensed institutions must keep records on experiments and care. They are further required to report research activities, including data on numbers of animals used by type and purpose. The information is available to the public.

The law also provides for establishment of a central veterinary inspectorate under the Ministry of Public Health, responsible for:

- **registering research** facilities, as of 1984 (22);
- periodically inspecting facilities conducting research;
- issuing regulations and guidelines governing laboratory animal housing; and
- regulating sources (breeders and suppliers) of laboratory animals.

In addition, the law also authorizes the appointment of an advisory committee of persons skilled

in animal experimentation, laboratory-animal science, and animal welfare to advise the Ministry. This committee includes two representatives of animal welfare organizations. The committee participates in the drafting of regulations and other aspects of implementing the 1976 law.

The Ministry of Public Health is the central enforcement agency for the 1976 law. It has the power to issue detailed regulations on laboratory-animal treatment and presides over them using teams of veterinary inspectors who supervise and advise research institutions. The director of the research facility is also expected to enforce standards of care and treatment.

Regulations require that investigators and technicians complete training in laboratory-animal principles and techniques (22), including a 20-day course that emphasizes animal well-being and the social and ethical aspects of animal use (53). A 4-year program for training animal technicians is also available.

Data compiled from the 1983 annual reports indicate that there are 71 licensed institutes (containing 387 distinct research departments); 2,118 investigators working directly with animals; 2,541 persons involved in animal care management; and 4,683 students taking classes involving animal experiments.

Indications of the commitment to protecting animals are the use of experimental review committees in 17 percent of the departments surveyed and the fact that in 19 of 71 establishments, methods had been introduced to replace animals in experiments, reduce the use of animals, or refine procedures (54). Furthermore, there has been a steady decline in the use of experimental animals over the reporting years, from 1.6 million in 1978 to 1.3 million in 1983. Of these, mice account for about 56 percent and rats, about 26 percent.

Norway

Norway requires more of people in their behavior toward animals than most other countries. The Welfare of Animals Act, passed in 1974 and in effect since 1977, even goes as far as requiring people encountering a domestic animal or tame reindeer in pain to come to its assistance or to call

the appropriate authority, and the act forbids the display of animals other than fish (46,47).

The act applies to vertebrates and crustaceans; it provides that animals shall be treated well and that due regard shall be given to their natural instincts and needs so that they are not in danger of being caused unnecessary suffering. Adequate care must be provided and many procedures can only be performed by a veterinarian or other highly qualified professional. Anesthetics must be used when there is reason to believe that a procedure may cause considerable suffering unless it would interfere with the purpose of the experiment, but such an experiment would require special permission from the National Experimental Animal Board. Experiments must be planned and carried out to avoid any unnecessary suffering, sometimes necessitating pilot studies. Destruction without delay is required where suffering after recovery will occur. Animals used in painful procedures without anesthetic may not be reused in further experiments.

The provisions of the act most applicable to research are its prohibitions on the use of live animals for educational purposes, except as a necessary part of professional training. It also requires permission to carry out biological tests on animals.

The purpose must be to diagnose animal or human disease, test a hypothesis, produce or control a product, or test medicines or other substances for effects. Such tests must not inflict greater suffering than is strictly necessary to achieve the purpose, and licensees are permitted to acquire and use local and general anesthetics for this purpose. Inspection authority is broad, and anyone "willfully or negligently" violating the act or authorized regulations is guilty of a misdemeanor, carrying penalties of a fine or imprisonment up to 6 months for the first offense, and up to a 1 year for subsequent offenses (47).

The Experimental Animal Board, first appointed under the statute by the Minister of Agriculture in 1976, has primary authority. Its five members issue and administer regulations on obtaining permission for experimentation on protected animals.

In 1985, the regulations were amended to provide that no experiment on a live animal can be carried out without the written consent of the in-

stitute's or organization's license holder. Copies of executed consent forms must be filed with the Board (20).

Sweden

Sweden's approach to experimental use of animals has much in common, both in substance and procedure, with that of the other countries of Western Europe surveyed here. For example, experiments involving pain or suffering receive greater scrutiny, anesthesia during painful experiments is generally required, and licenses are issued to facilities in which experiments are conducted. Its more unusual features are the close working relationships among scientists, technicians, and laypeople (most often animal welfare advocates) at all levels of review and the complex system of ethical review, which divides responsibilities among many organizations and committees.

The review procedures, which have evolved over many years, are being reevaluated by the Government. Matters being reconsidered include the extensive use of laypeople (who often disagree with other reviewers); the use of small subcommittees (which sometimes disagree with full committees); and the limited review given to experiments that cause little or no pain (which leaves their aim unexamined) (57). Sweden's active animal welfare representatives can be expected to vigorously oppose any changes that would decrease their input in the review process or that might reduce the protections provided to animals (17).

The first law pertaining to experimental use of animals, passed in 1944 (58), prohibited cruel treatment and governed care and transport of classes of animals. Painful experiments on animals were generally prohibited and experiments could be performed only in licensed institutions by persons with established qualifications for conducting such research (64). Furthermore, anesthetic was required where more than minor pain was produced, except where its use would frustrate the study's purpose (58).

Several ordinances and amendments were published between 1978 and 1982 (59,60,61). They added both substantive and procedural requirements. Experiments involving pain, suffering, or anxiety now have to be licensed by the National

Board of Agriculture (unless conducted by the Government). Vertebrates were ranked hierarchically, ranging from mammals to birds to reptiles to frogs to fish. The use of warm-blooded vertebrates in education at or below the secondary level became subject to approval, regardless of whether pain or suffering would occur. Animals used in laboratories now must be bred for that purpose, and dogs, cats, and rabbits must be marked and various records kept showing their origin. Most responsibility for the conduct of experiments is placed on individual licensees and heads of licensed institutions.

Several changes were also made in how experiments were to be reviewed. These changes were based on a voluntary system that began at the University of Uppsala. A Laboratory Animals Board, established by the National Medical Research Council in 1965, was called on in 1972 to help the Council review grant applications. Drawing from the considerable expertise of Karl-Johan Obrink, a professor of physiology at the University of Uppsala's medical school, and of Lars Wass, a representative of the National Board of Universities, guidelines were developed for both the organization and operation of an ethics committee.

In response to the Board's request for a system through which the Council Administration could determine automatically whether a grant application involving the use of animals ought to be referred for ethical review, Obrink and Wass proposed a scale of expected discomfort. Experiments causing little or no discomfort received little, if any, review, with other experiments receiving scrutiny in proportion to the pain they would cause. (This is not so different from other European systems—pain normally triggers review, and the reviewers would most likely take the degree of expected pain into account.) Other key provisions of the guidelines include:

- Members of the committee would be within easy reach of anyone planning animal work, even if the committee were large.
- The committee would be composed of animal technicians and laypeople, as well as researchers.
- The day-to-day work of the committee would be performed by ad hoc subcommittees, formed after submission of an investigator's

proposal to a member of the parent committee.

- Experimentation could begin immediately upon approval of an experiment by the subcommittee.
- To protect an investigator's privacy, the committee and subcommittees would be voluntary only and would have no legal or administrative authority.
- Discussion between investigators and subcommittee members would promote increased awareness of research ethics.

The prototype committee consisted of 30 individuals, mostly investigators. Meetings were held frequently and applications were reviewed in full committee, with investigators present to discuss experiments and answer questions.

With the election of a new National Government in 1976, the Minister of Agriculture decided that the Uppsala system, with minor modifications, should be introduced throughout the country and incorporated into the National Board of Agriculture's regular system of experimental control. It was in place by 1979.

As the laws have become more comprehensive, their administration has become more complex. The National Board of Agriculture has the broadest range of responsibilities. In addition to its involvement with the ethical committees and the Board for Laboratory Animals, it oversees government laboratories that use animals, approves plans for new facilities for animals, conducts inspections, oversees breeding and transportation of animals, provides a variety of forms needed for review and recordkeeping, and keeps journals of experiments that have been approved (59,60).

The 1979 laws gave certain enforcement and administrative functions to the County Public Health Committee, with consultation and direction with the National Board of Agriculture. Operating somewhat independently of the National Board of Agriculture is the Swedish Laboratory Animals Board (referred to as CFN in Sweden). It has members nominated by Government (including the National Board of Agriculture), universities, the Swedish Medical Research Council, and the Swedish Natural Science Research Council. The Board, most recently the subject of a 1982 statute,

is now charged with promoting cooperation between scientists, technicians, and animal welfare organizations; planning for long-term improvements in conditions for laboratory animals; promoting the development of alternatives, which it also funds; reviewing the work of ethical committees; and working toward the efficient use of animals by promoting cooperation among animal users (58).

The 1982 statute also required the establishment of six ethical committees, one in each university region. The requirements were based on the prototype committee developed in Uppsala. These committees, overseen by the National Board of Agriculture, advise and consult on individual experiments and report to their County's Public Health Committee. They have equal numbers of scientists, animal technicians, and laypeople.

The Central Veterinary Board of the National Board of Agriculture solicits nominees for review committees from each of six Regional Boards of Higher Education (that consist of university and political officials) and major animal welfare groups. Nominees are of three kinds: researchers, technicians, and laypeople. The animal welfare organizations nominate laypeople only. From the nominations submitted, the Board appoints six regional ethical committees, designating a chair and vice chair; six regional subcommittees for secret projects; and one special committee for military research. The special military-research group and the regional subcommittees for secret research were created to protect national defense interests and pharmaceutical trade secrets.

Although full committees meet at least twice annually, day-today application review is conducted by subcommittees, consisting of equal numbers of researchers, technicians, and laypeople. The technicians and laypeople are chosen from mandatory rotation lists, to avoid exclusion of any represented interest, and each subcommittee must have at least three members.

The applicant completes a one-page form, stating the objective of the research project; describing the experiment, with an emphasis on the use and disposition of the animals and the number of animals of different species that will be used; and describing what the investigator plans to do to al-

leviate and abbreviate suffering. When the subcommittee meets with the applicant, it may suggest improvements in the description of the procedure, modifications to the procedure itself, or a reduction in the number of animals used. If the subcommittee agrees to the applicant's proposal, it forwards a signed form to the central authority.

If an applicant or a subcommittee member disagrees with the decision of a subcommittee, the application is referred to the full committee, which can call a session to review appeals. All subcommittee decisions are discussed by the full committee at its regular meetings. A permit, valid for up to 3 years, is all that is needed to begin work. Re-review is required only if an investigator plans to conduct experiments more severe than those for which approval was granted.

Precise data on numbers of animals used for various kinds of procedures are not available. Reporting is only done in conjunction with the application process, although certain records must be submitted and others must be kept.

The time required to obtain a decision varies from region to region. Two contributing factors have been identified: difficulty in scheduling meetings, and some applicants' inability to use simple language, thus requiring extra time for clarification. To help remedy the lag problem, the 1982 ordinance required a subcommittee to reach a decision within 3 weeks of receipt of the application.

The 1982 ordinance also abolished the requirement that experiments be grouped into the traditional discomfort categories, thus eliminating needless discussion. Obrink, the architect of the voluntary review mechanisms, has expressed worry over the system's potential, with increasing regulatory emphasis, to become bureaucratized to the point where it sacrifices the objectives of ethical review for the sake of control (5,48,49).

Switzerland

Switzerland has probably gone further to protect animals than any other country and recently came to the brink of going even further. In 1985, Swiss voters were presented with a constitutional amendment that read: "The vivisection of vertebrates as well as all cruel animal experimentation shall be forbidden in Switzerland." The proposal

was rejected by a two-to-one margin. This law would have had a major impact on the three large pharmaceutical firms with facilities in Switzerland. Another, less restrictive referendum is being readied for Swiss voters, but may be 4 years away from a vote (74).

The Swiss antivivisection movement has become particularly active, if not violent in recent years. Research facilities have been broken into, scientists sued, and untrue or overstated stories publicized (for example, that vaccines had no part in fighting infectious diseases) (72).

Swiss scientists have not fought controls, and some have pointed out the benefits to good science—more attention is given to planning and scientists have greater incentives to keep abreast. Of course, there are also disadvantages to science—senior scientists must spend time answering simple questions and there can be delays of 4 to 6 weeks for licensing an experiment.

An indication of the importance of animal welfare to the Swiss is the fact that animal protection is addressed in the Constitution, which recognizes the necessity for and utility of humane treatment of animals. Controls on animal experimentation in Switzerland are found in the Federal Law of 1978 Regarding the Protection of Animals (as amended by the Ordinance of 1981 Regarding the Protection of Animals).

In response to antivivisectionist pressures, additional guidelines were developed in 1981 by the Swiss Academies of Medical Sciences and of Sciences. These have been adopted by government, industry, and academia. Under the guidelines, a permanent committee was set up to review animal experiments, and stringent requirements were set up for experiments involving severe pain—if the experiment cannot be modified to reduce pain, it must be forgone. Under the statute, any experiment that could cause pain to a protected animal or that would adversely affect its well-being must be licensed, whether conducted by government or by private institutions. Even where pain is not significant, licensing authorities must be satisfied that the expected benefits of the proposed experiment outweigh the adverse effects on experimental animals. Furthermore, animals that have suffered more than minor pain or anxiety may not be re-used (62).

Licenses are issued to individual investigators for each experiment or series of related experiments. Licenses to perform experiments are issued by the cantons, or Swiss States. Special commissions must determine whether all legal requirements and qualifications are met before a license is issued. Thus, the commission must verify, in each instance, whether the proposed experiment:

- is essential in order to achieve the objective of the experiment, or whether alternative approaches are possible;
- is sound from a methodological point of view;
- can be performed with a lower order of species than the one proposed; and
- can be modified to reduce the number of animals to be used.

The conditions under which experimental animals are to be kept and used are specified in the law, setting standards for accommodations of differing species, by size and weight, and prescribing care. Animal caretakers must demonstrate their competency by passing a Federal examination. Records of licensed experiments must be kept for a minimum of 2 years after the experiment ends, and they must be available for inspection by local authorities (77).

Most licensed experiments in Switzerland are conducted by large pharmaceutical companies (74), with some work done by Government and universities. In addition, a few private institutes do testing and research. The experiments' purposes fall into four major categories: research and development (87 percent); production and quality assurance (12 percent); teaching (1 percent); and diagnostics (less than 1 percent).

According to the Swiss Government, the three pharmaceutical companies used 36 percent fewer animals in 1983 than in 1976; the decrease between 1981 and 1983 averaged 23 percent for all species, with the largest categorical decreases occurring in the use of mice (26 percent) and rabbits (25 percent). The authorities believe this indicates a general trend toward reduced animal use, since the firms involved account for about two-thirds of all experimental-animal use; one governmental representative has said the decline was hastened by the implementation of the 1981 ordinance (77).

United Kingdom

The United Kingdom has been a pioneer in the protection of experimental animals. The Cruelty to Animals Act, passed in 1876 (68), was the most protective statute of its kind for many decades. Although the act has not been amended, the protections afforded animals have continued to expand through administrative actions of the Home office and by voluntary actions by institutions and individuals (69).

As in other parts of Western Europe, animal welfare advocates have been actively campaigning for more protective laws. Unlike many other countries, some of these groups have also made major scientific contributions to the development of alternatives. The most active of these scientifically, the Fund for the Replacement of Animals in Medical Experiments, was recently given over \$200,000 by the Government to fund research on alternatives.

Contributing to the debate over how the act should be changed, the British Veterinary Association, the Committee for the Reform of Animal Experimentation, and the Fund for the Replacement of Animals in Medical Experiments made recommendations that became the basis for a 1983 White Paper by the Home Office. Several items in that paper provoked considerable debate, leading to the 1985 White Paper Scientific **Procedures on Live Animals** (70). This was presented by the Home Office to the Parliament in May 1985 and recommends substantial amendments to the 1876 Act, some of which would codify current practice. The 1876 act (as it is currently practiced) and the proposed legislation are summarized and compared in table 16-2.

Other acts that bear on these activities include the Dogs Act of 1906 and the Theft Act of 1968 (as amended by the Criminal Theft Act of 1977), which address the problem of stolen pets. Experiments regulated by the Cruelty to Animals Act are excluded specifically from the reaches of the Protection of Animals Act of 1911, the Protection of Animals (Scotland) Act of 1912, the Protection of Animals (Anesthetics) Act of 1954 (65), and the Protection of Animals (Anesthetics) Act of 1964 (66).

A basic philosophy of the act is that experiments should be permitted if they lead to new knowledge, but the use of animals to develop manual skills is not permitted. (Demonstrations—another educational use—are permitted, however, if the animal is anesthetized and does not recover.) In permitting the development of new knowledge, the authorities, as in many other countries, will not try to predict which experiments will result in useful knowledge or practical applications.

Control over experiments occurs in three ways: through the granting of licenses to experimenters, through the registration of facilities where experiments take place, and through the appointment of government inspectors. Although responsibility rests with the Home Office, assistance is provided by an Advisory Committee with representation by animal welfare organizations. In addition, many institutions have established their own informal review procedures (3).

The Secretary of State approves and registers every place for the performance of experiments or for the purpose of instruction, imposes conditions on licenses, and revokes licenses for cause. The Secretary may require reports, appoint inspectors, and require inspections. Most licenses are issued with one or more certificates. Certificates may be given for the period and series of experiments the persons signing the certificate may think expedient. There are six kinds of certificates, based on species use, pain, and the use of anesthetic,

A practical approach to the assessment of pain, suggested by a Royal Commission appointed in 1906, is that it would be unreasonable to impose greater restrictions on the infliction of pain for the advancement of knowledge than those imposed by public opinion in the pursuit of sport, in carrying out such operations as castration and spaying, or in the destruction of rabbits, rats, and other vermin (41).

The United Kingdom is able to compile detailed, accurate statistics on animal use through its reporting requirements as well as the through the issuance of licenses and certificates. Each licensee (except those who have no experiments to report for a given year) must submit an annual report for as many of each of the following reporting cate-

Table 16-2.—Comparison of the United Kingdom's Cruelty to Animals Act of 1876 and Proposed Amendments

Provision	Current law	Proposed amendments
Animals protected	All living vertebrates; additional protection for nonhuman primates, dogs, cats, and equidae	All living vertebrates, fetuses of mammals, embryonic or larval young of other species at specified stages, (would also add authority over breeding of animals with potentially disabling genetic defects; would allow the Home Secretary to protect invertebrates; would require justification of all species choices)
Permissible purposes	Advance new discovery of knowledge or lead to longer life, less suffering	Adopts permissible purposes of European Convention (Article 2) (see app. E), encompassing many procedures rather than experiments (e.g., production of serums, maintaining tumors or pathogens); Secretary must balance the severity (pain) against the purpose
Licensing system	Any person Home Secretary allows: difficult to alter issued license; restrictions must be specified	Personal license would only allow specified techniques and species; project license for each experiment, specifying purpose of work, species, number of animals, techniques; Secretary must answer to Parliament for balance of severity and purpose (Secretary must publish guidelines for the decision criteria)
Severity	No statutory limit on pain, but may be limited in certificates; pain may be severe or enduring, not both	An animal in severe pain or distress would have to be killed immediately and painlessly; severity would encompass pain, distress, suffering, morbidity, and mortality and would be tailored to each project license; would require licensees to minimize severity wherever possible; would broaden inspector's power to kill humanely
Assessors	No mechanism to assess integrity or competence for personal license	Senior licensee with personal knowledge of applicant and applicant's abilities would certify applicant's competence; Home Office would continue to issue license
Registering facilities	Most facilities for experiments are registered; most breeders and suppliers are not	All facilities would be registered; Secretary would have power to set standards for staffing, care, and accommodation; facilities would name person responsible for day-to-day care and outside veterinarian must be called for problems; breeders and suppliers would register
Fees	None	Registered facilities, based on number of procedures
Source of animals	Only stray dogs protected (Dog Act)	All animals purpose-bred in registered establishments (except for farm animals and animals taken from the wild); recordkeeping on source and disposal
Reuse of animals	Only anesthetized animals must be killed	Reuse would require Secretary's permission, and only if the animal has returned to normal
Killing of animals when procedure ends	Only if animal is in severe pain or was anesthetized	Not required to kill animals at the end of a procedure; if certified fit, surviving wild animals may be returned to the wild, farm animals to a farm, and certain domestic animals may be offered to private homes
Use of animals to attain manual skill	Not permitted unless decerebrated	Secretary would authorize for special, specific skills such as microsurgery on anesthetized animals
Use of alternatives	Encouraged but not required	License would not be issued until Secretary was convinced that alternatives were not suitable and that no further refinements or reductions could be made
Use for education and training	Only anesthetized animals that are killed before recovery for university lectures	Would be extended to allow other nonrecovery training for approved professional courses; would permit recovery if animal suffers only trivial pain or distress under exceptional circumstances, decerebration would become a licensed procedure and no longer permitted in schools
Advisory Committee	Not required, but has existed since 1912, with lay members since 1979	Would require Animal Procedures Committee, with lay members (including animal welfare advocates), doctors, veterinarians, and biologists; no more than half of the Committee would be licensees; would advise Secretary on procedures, standards, trends, licensing, and revisions of the law
Codes of practice	Voluntary codes are often used	Secretary would issue guidelines and codes of practice on animal husbandry and would give guidance on recognizing and alleviating stress and pain
Offenses and penalties	Experimenting without a license; 6 months and \$3,000	Performing, aiding, or abetting performance of a procedure without authority; providing false information; disclosing information obtained in confidence; 2 years and an unlimited fine
Records	All licensees keep records of experiments	Same

SOURCE: Office of Technology Assessment.

gories as apply. (The number of distinct entry codes for each list subclassification is given in brackets.)

- anesthetic (none, for part of experiment, or entire experiment) [3];
- types of vertebrates (mammals—rodents, rabbits, primates, carnivores, ungulates, and others—birds, reptiles, amphibians, and fish) [16];
- neoplasia [4];
- infection and immunology [41];
- primary purpose (to study body function or structure, to develop or study the various products or chemicals, to develop transplant techniques) [15];

- toxicity tests [6];
- experiments in response to domestic or foreign legislation [14]; and
- use of particular painful techniques (such as eye irritation) [141].

These annual reports are compiled in detailed reports. Several tables from the 1984 report are included here. Table 16-3 shows the frequency with which various species are used in the United Kingdom, table 16-4 shows the primary purpose of the experiments, and table 16-5 shows the registered institutions performing experiments. These tables represent only highlights of the considerable data available.

Table 16-3.—Experiments by Species of Animal, 1977=84, United Kingdom

Year	Species of animal (thousands of experimental animals used)							
	Mouse	Rat	Guinea pig	Other rodent	Rabbit	Primate	Cat	Dog
1977	3,234.9	1,073.0	187.7	38.7	191.8	9.0	8.5	14.3
1978	3,168.5	1,062.6	193.4	39.4	199.2	7.2	7.9	13.7
1979	2,901.3	994.8	165.7	37.2	187.0	6.4	7.5	12.0
1980	2,780.7	957.9	188.6	36.4	181.5	5.2	6.8	11.5
1981	2,616.9	908.6	159.1	35.0	176.0	6.2	8.0	13.5
1982	2,442.7	932.3	154.7	36.8	165.0		7.3	13.1
1983	2,070.2	878.4	144.7	36.2	160.0	5.6	7.5	13.9
1984	1,903.8	888.0	141.7	36.5	156.0	6.0	6.4	14.4
Year	Species of animal (thousands of experimental animals used)							Total ^a
	Other carnivore	Horse, donkey, or crossbred	Other ungulate	Other mammal	Bird	Reptile or amphibian	Fish	
1977	2.2	0.5	31.9	3.0	344.3	7.2	157.5	5,385.6 ^b
1978	2.7	0.6	36.0	2.6	314.3	6.6	140.6	5,195.4
1979	2.2	0.6	36.5	2.4	241.4	7.6	117.4	4,719.9
1980	1.3	0.5	33.4	2.6	211.6	7.8	175.5	4,579.5
1981	2.3	0.4	35.4	1.8	194.2	8.6	178.9	4,344.8
1982	1.9	0.5	33.6	2.7	251.8	7.8	165.8	4,221.8
1983	1.8	0.6	36.4	3.0	132.6	18.2	115.2	3,624.2
1984	1.7	0.6	33.1	2.7	155.0	8.1	143.2	3,497.3

^aColumns do not add up to total due to rounding.

^bIncludes 81.3 thousand experimental animals that could not be classified.

SOURCE: U.K. Home Office, Secretary of State, *Statistics of Experiments on Living Animals: Great Britain, 1984* (London: Her Majesty's Stationery Office, 1985).

Table 16-4.—Primary Purpose of Experiments, 1977-84, United Kingdom
(thousands of experimental animals used)

Year	To study normal or abnormal body structure or function	To select, develop, or study the use, etc., of medical, dental, and veterinary products and appliances	To develop transplant techniques	To select, develop, or study the use, hazards, or safety of				
				Plant pesticides including fungicides	Herbicides or substances modifying plant growth	Substances used in industry	Substances used in the household	Cosmetics and toiletries
1977	1,266.0	2,932.6	22.5	35.8	20.3	81.6	18.8	24.6
1978	1,164.8	2,925.7	16.2	50.4	18.8	88.0	14.9	28.2
1979	1,051.7	2,680.8	25.4	34.1	24.0	75.3	18.5	30.5
1980	909.3	2,680.1	14.7	40.1	17.5	80.4	13.8	31.3
1981	1,119.2	2,403.0	14.6	30.6	12.9	69.2	14.3	24.4
1982	997.0	2,373.0	15.2	33.0	15.1	66.2	13.9	18.9
1983	875.2	2,039.9	12.6	35.4	17.9	59.1	17.2	18.0
1984	824.8	1,915.7	15.0	46.7	18.1	64.5	12.9	17.5

To select, develop, or study the use, hazards, or safety of							
Food additives	Tobacco and its substitutes	Plants or animals and their toxins	General environmental pollutants	To demonstrate known facts	Other purposes	More than one purpose	Total ^a
1977	39.3	15.2	4.2	60.4	2.7	676.8	83.4
1978	42.5	2.7	2.7	70.4	2.6	709.8	57.6
1979	27.7	4.6	3.3	33.6	1.8	600.5	108.1
1980	21.3	1.9	3.3	40.9	1.7	635.9	87.2
1981	20.2	2.3	2.7	45.8	1.9	519.4	64.3
1982	20.1	3.2	5.9	27.3	1.6	562.5	68.9
1983	14.1	2.7	4.8	34.4	1.6	444.9	46.4
1984	12.0	2.2	5.8	31.8	1.1	453.1	76.0

^aColumns may not add up due to rounding.

^bIncludes 81.3 thousand experimental animals that could not be classified.

SOURCE: U.K. Home Office, Secretary of State, *Statistics of Experiments on Living Animals: Great Britain, 1984* (London: Her Majesty's Stationery Office, 1985).

Table 16-5.-Experiments by Type of Registered Facility, 1977-84, United Kingdom

Type of registered place ^a	1977	1978	1979	1982	1983	1984
(thousands of experimental animals used)						
Public health laboratories ^b	37.8	41.8	120.6	106.7	117.0	106.4
Universities (including medical schools).	875.5	927.4	975.9	895.3	847.6	813.6
Polytechnics	32.9	46.7	38.4	37.7	34.9	29.5
Quasi-autonomous nongovernmental organizations.	316.4	280.6	255.7	274.6	242.8	268.9
National health service hospitals (excluding medical schools).	180.5	157.4	147.7	159.4	154.3	144.2
Government departments	323.9	273.5	163.7	169.8	174.0	154.0
Nonprofitmaking organizations.	858.3	779.5	614.0	546.9	507.0	512.3
Commercial concerns	2,760.4	2,688.6	2,403.8	2,389.0	2,267.2	2,192.9
Total ^c	5,385.6 ^d	5,195.4	4,719.9	4,579.5	4,344.8	4,221.8

^aRecorded on the basis of the registered place that the licensees regard as their main place of work at the time the returns were issued. A licensee may have commenced experiments at more than one registered place during the year.

^bThe differences between 1978 and 1979 are partly because some establishments were reclassified from one type of registered place to another.

^cColumns may not add up due to rounding.

^dIncludes 81.3 thousand experimental animals that could not be classified.

SOURCE: U.K. Home Office, Secretary of State, *Statistics of Experiments on Living Animals: Great Britain, 1984* (London: Her Majesty's Stationery Office, 1985).

SUMMARY AND CONCLUSIONS

Most of the countries examined for this assessment have laws far more protective of experimental animals than those in the United States. Despite these protections, animal welfare advocates have been applying considerable pressure for even stronger laws, and many countries, including Australia, Switzerland, West Germany, and the United Kingdom, are considering major changes.

Many of the laws have similar requirements. Almost all require anesthetics or analgesics for painful experiments unless these would frustrate the purpose of the experiment. Switzerland goes so far as to require that certain experiments be forgone because they are too painful. Some countries balance the importance of the experiment and the level of pain it would cause before giving approval.

Several countries require euthanasia after a painful experiment is finished; some require destruction of an animal even when it is no longer in pain, rather than allowing it to be reused. Euthanasia requirements sometimes apply only to certain animals, such as dogs, cats, and monkeys. These species are also preferred in other ways, such as requiring that lower animals be substituted for them wherever possible.

Many countries encourage the use of alternatives, and Denmark, West Germany, the Nether-

lands, Norway, and Sweden require that non-animal alternatives be used if they are available. Sweden and the United Kingdom have provided funding for the development of alternatives, and West Germany is considering doing so. Many countries restrict educational uses of animals to professional or vocational training, and Switzerland prohibits even this.

All West European countries reviewed for this assessment require that facilities that use experimental animals be licensed. Some also license dealers, breeders, or experimenters. Many also require that individual experiments be approved, some by Government authorities, some by committees. Such committees, except in Sweden and the United Kingdom, do not require lay representatives, although Switzerland and Denmark have such representatives on national advisory boards. The use of ethics committees within the facilities that use animals is growing; their use is presently most well developed in Canada and Sweden,

The experiences of these selected countries can serve as useful models for various protections that are being considered in the United States. However, in trying to apply them, it is necessary to consider the size of a country, and perhaps more importantly, those cultural considerations that affect compliance with the laws.

CHAPTER 16 REFERENCES

1. Australia, Prevention of Cruelty to Animals Act Regulations, New South Wales Government Gazette, No. 68, May 24, 1929.
2. Australia, Prevention of Cruelty to Animals Act Regulations, New South Wales Government Gazette, No. 200, 1979.
3. Balls, M., Chairman of the Trustees, Fund for the Replacement of Animals in Medical Experiments, Nottingham, England, personal communication, March 1985.
4. Balls, M., Ridden, R.J., and Worden, A.N. (eds.), *Animals and Alternatives in Toxicity Testing* (New York: Academic Press, 1983).
5. Barany, E., "The Swedish System of Ethical Committees in the Laboratory Animals Field," *Conquest* 172:10-15, March 1983.
6. Canada, Animals for Research Act of 1970, Revised Statutes of Ontario, 1:103-117, 1980.
7. Canada, Animals for Research Act, Revised Regulations of Ontario, 1980, Regulations 16 and 18, 1:79-98, 1980.
8. Canada, Dog Control and Procurement Regulations for the Treatment of Animals, Alberta Regulation 33-72, November 1972.
9. Canada, the Universities Act of 1966, Province of Alberta, Section 50.

10. Canada, Urban Municipalities Act of 1970, Province of Saskatchewan, Section 177.
11. Canadian Council on Animal Care, *Animal Care Committees: Recommended Terms of Reference and Guidelines* (Ottawa, Ont., Canada: 1980).
12. Canadian Council on Animal Care, *Ethics of Animal Experimentation* (Ottawa, Ont., Canada: 1981).
13. Canadian Council on Animal Care, *Guide to the Care and Use of Experimental Animals*, Vol. I (Ottawa, Ont., Canada: 1980).
14. Canadian Council on Animal Care, *Guide to the Care and Use of Experimental Animals*, Vol. II (Ottawa, Ont., Canada: 1984).
15. Canadian Council on Animal Care, *Research Animals in Canada* (Ottawa, Ont., Canada: 1984).
16. Canadian Council on Animal Care, *Syllabus of the Basic Principles of Laboratory Animal Science* (Ottawa, Ont., Canada: 1984).
17. Carlsson, B., Nordic Society Against Painful Experiments on Animals, comments in discussion at Second CFN Symposium, *The Ethics of Animal Experimentation*, Stockholm, Sweden, Aug. 12-14, 1985.
18. Denmark, Statute No. 220 of May 18, 1977, on Animal Experiments, and Ordinance No. 106 of 1954, on the Maintenance and Submission of Records on the Use of Animals for Biological and Medical Research, in *Forsøgsdyr og Dyreforsøg*, Svendsen, P., and Hau, J., 1982.
19. Denmark, Statute No. 93, "On the Use of Animals for Biological and Medical Research," 1954.
20. Erichsen, S., National Institute of Public Health, Experimental Animal Board Member, Oslo, Norway, personal communication, January 1985.
21. Esling, R., "European Animal Experimentation Law," *Animals in Research: New Perspectives in Animal Experimentation*, D. Sperlinger (ed.) (New York: John Wiley & Sons, 1981).
22. Evers, T., Attache for Health and Environment Protection, Royal Netherlands Embassy, Washington, DC, personal communications, February and November 1984.
23. Farstad, M., Science and Agricultural Counselor, Embassy of Sweden, Washington, DC, personal communication, October 1984.
24. Federal Republic of Germany, Animal Protection Act of July 24, 1972, Sartorius Band 1, Verfassung und Verwaltungsgesetze, 873, 1-12, Ergänzungslieferung März (1982).
25. Federal Republic of Germany, Federal Ministry of Food, Agriculture, and Forestry, *List of Regulations Affecting the Conduct of Animal Experiments*, BML No. 321-3520-1/1 (Bonn: Oct. 17, 1984).
26. Federal Republic of Germany, Federal Ministry of Food, Agriculture, and Forestry, *Proposal to the Cabinet for Amendments to the Animal Protection Act of July 24, 1972* (Bonn: November 1984).
27. Flowers, F., *Educating the Scientist in Research Animal Care* (Ottawa, Ont., Canada: Canadian Council on Animal Care, 1984).
28. Flowers, F., "Research Animal Care in Canada: Its Control and Regulation," *The Role of Animals in Biomedical Research*, *Ann. N.Y. Acad. Sci.* **406**: 144-149, 1983.
29. Gärtner, K., "100 Years of Regulations for Animal Welfare and for Animal Experimentation in Germany—Effects and Reasons," presented at Second CFN Symposium, *The Ethics of Animal Experimentation*, Stockholm, Sweden, Aug. 12-14, 1985.
30. Ikkaia, S., Second Secretary, Embassy of Japan, Washington, DC, personal communication, December 1984.
31. Jansen, Veterinary Officer of Public Health, Veterinair Hooftinspectie, The Netherlands, personal communication, October 1985.
32. Japan, Prime Minister's Office, Deputy Chief Secretary for General Affairs, *Circular: On the Enforcement of the Law Concerning the Protection and Control of Animals*, Sōkan, No. 60, Feb. 12, 1974.
33. Japan, Law Concerning the Protection and Control of Animals, Law No. 105, Oct. 1, 1973.
34. Japan, Enforcement Order, Law Concerning the Protection and Control of Animals, Cabinet Order No. 107, Apr. 7, 1975.
35. Japan, Prime Minister's Office, The Law and Related Standards for the Protection of Animals, Tokyo, Japan, 1982.
36. Japan, Order Concerning the Animal Protection Council, Cabinet Order No. 104, Apr. 11, 1974.
37. Japan, Prime Minister's Office, *Standards Concerning the Raising, Custody, etc. of Animals in Experimental Use*, Notification No. 6, Mar. 27, 1980.
38. Japan Experimental Animal Research Association, "Law Concerning the Protection and Control of Animals (Law No. 105), October 1, 1973," *Jikken Dobutsu* 31(3):221-231, 1982.
39. Japan Science Council, *On the Adoption of Guidelines for Animal Experimentation*, 80th General Meeting, Nov. 5, 1980.
40. Kjaersgaard, C., Chairman, The Permanent State Board for the Supervision of Use of Animals for Experiments, Copenhagen, Denmark, personal communication, January 1985.
41. Lane-Petter, W., et al., *The Welfare of Laboratory Animals: Legal, Scientific, and Humane Requirements* (Hertfordshire, England: Universities' Federation for Animal Welfare, 1977).
- 41a. National Health and Medical Research Council, *Code of Practice for the Care and Use of Animals for Experimental Purposes* (Canberra, Australia: Australian Government Publishing Service, 1985).
42. Netherlands, Decree of May 24, 1972, *Staatsblad* 311.

43. Netherlands, Law of Jan. 25, 1961, Staatsblad 19.
44. Netherlands, Law of Jan. 8, 1975, Staatsblad 48.
45. Netherlands, Law of Jan. 12, 1977, Staatsblad 67.
46. Norway, Regulation of Dec. 22, 1977, on Biological Experiments with Animals, 1977 Norsk Lovtidend, Avd. I, 1188-1192.
47. Norway, Statute No. 73 of Dec. 20, 1974, on Protection of Animals, Sections 20-22, Norges Lover, 1685-1981, at 2301-2306, 1982.
48. Öbrink, K., "Swedish Law of Laboratory Animals," *Scientists Center for Laboratory Animal Welfare Newsletter* 4(1): 1-3 and 4(2):5, 1982.
49. Öbrink, K., "Are Regulations to Protect Experimental Animals Adequate?" *Research Ethics*, K. Berg and K. Trany (eds.) (New York: Alan R. Liss, Inc., 1983).
50. Rowsell, H., Executive Director, Canadian Council on Animal Care, Ottawa, Ont., Canada, personal communications, April and November 1984 and March 1985.
51. Rowsell, H., *The Animal in Research: Perspective on Voluntary Control* (Ottawa, Ont., Canada: Canadian Council on Animal Care, 1984).
52. Rowsell, H., "The Voluntary Control Program of the Canadian Council on Animal Care," *J. Med. Primatol.* 9:5-8, 1980.
53. Rozemond, H., Veterinary Officer of Public Health, Veterinaire Hoofdinfectie, The Netherlands, personal communication, March 1985.
54. Rozemond, H., *Statistics of Animal Experimentation in the Netherlands: 1982* (Leischendam, The Netherlands: Veterinary Head Inspectorate, 1983).
55. Russell, J. C., and Secord, D. C., "Holy Dogs and the Laboratory: Some Canadian Experiences With Animal Research," *Perspect. Biol. Med.* 28:374-381, 1985.
56. Shewart, K., Minister for Local Government of New South Wales, Sydney, Australia, personal communication, Mar. 29, 1985.
57. Skogland, E., General Veterinary Division, National Board of Agriculture of Sweden, in discussion at Second CFN Symposium, *The Ethics of Animal Experimentation*, Stockholm, Sweden, Aug. 12-14, 1985.
58. Sweden, Ordinance No. 554 of 1982 on Amendment (and Republication) of the Ordinance on Use of Animals for Scientific Purposes, etc. (1979:286), 1982 Svensk Forfattningssamling, No. 554.
59. Sweden, Ordinance No. 29 of 1979, "The Ordinance of the National Board of Agriculture of Animal Breeding for Scientific Purpose, etc." (LSFS 1979:29).
60. Sweden, Ordinance No. 30 of 1979, "The Ordinance of the National Board of Agriculture of Keeping Journals etc. When Using Animals for Scientific Purpose" (LSFS: 1979:30).
61. Sweden, Statute No. 979 of 1978, "Statute on Alteration in the Animal Protection Act of 1944" (SFS 1978:979).
62. Switzerland, Federal Law of March 9, 1978, Regarding the Protection of Animals, RO 1981 :562-571, as amended by the Ordinance of May 27, 1981, Regarding the Protection of Animals, RO 1981:572-598.
63. Tajima, Y., "History of the Development of Laboratory Animal Science in Japan," *Jikken Dobutsu* 33(1):1-23, 1984.
64. Trolle, I., *Animal Experiments* (Stockholm, Sweden: Robert Larson, 1971).
65. [J. K., The Protection of Animals (Anesthetics) Act 1954, 2 & 3 Elizabeth II, ch. 46, *Halsbury's Statutes of England*, 3d ed., vol. 2, 1966.
66. U. K., The Protection of Animals (Anesthetics) Act 1964, ch. 39, *Halsbury's Statutes of England*, 3d ed., vol. 2, 1964.
67. U.K. Department of Health and Social Security, Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment, *Guidelines for the Testing of Chemicals for Toxicity*, Report on Health and Social Subjects 27 (London: Her Majesty's Stationery Office, 1982).
68. U.K. Home Office, Veterinary Inspectorate, *Notes for Guidance in Completing Forms of Application Under the Cruelty to Animals Act, 1876* (London: 1971).
69. U.K. Home Office, Advisory Committee on the Administration of the Cruelty to Animals Act, 1876, *Report on the LD₅₀ Test to the Secretary of State* (London, 1979).
70. U.K. Home Office, *Scientific Procedures on Living Animals* Command 9521 (London: Her Majesty's Stationery Office, 1985).
71. Voetz, D., Federal Ministry of Food, Agriculture, and Forestry, Federal Republic of Germany, Bonn, West Germany, personal communication, November 1984.
72. Weibel, E. R., "Man's Relation to Experimental Animals. Modern Times—The Present Situation in Switzerland," at the Second CFN Symposium, *The Ethics of Animal Experimentation*, Stockholm, Sweden, Aug. 12-14, 1985.
73. Weihe, w., "problems of Alternatives to Animal Experiments," *Fortschritte der Medizin* 100:2162-2168, 1982.
74. Weihe, w., "Regulation of Animal Experimentation—The International Experience: Switzerland," presented at the Second CFN Symposium, *The Ethics of Animal Experimentation*, Stockholm, Sweden, Aug. 12-14, 1985.
75. Yokoyama, A., *Handbook on Experimental Animals* (Tokyo: Yokendo, 1983).

76. Zbinden, G., and Flury-Roversi, M., "Significance of the LD₅₀ Test for the Toxicological Evaluation of Chemical Substances," *Arch. Toxicol.* 47:77-99, 1981.
77. Zobrist, S., Attache for Science and Technology, Embassy of Switzerland, Washington, DC, personal communications, October 1984 and December 1985.