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HOME OFFICE

SCIENTIFIC PROCEDURES ON LIVING ANIMALS

Presented to Parliament by the Secretary of State for the Home Department, by Command of Her Majesty
May, 1983

LONDON
HER MAJESTY'S STATIONERY OFFICE
Reprinted 1984
£3.60 net

Cmnd. 8883

INTRODUCTION AND SUMMARY

1. In its Manifesto, the Government undertook to "update the legislation on experiments on living animals". This White Paper sets out the Government's proposals for new legislation which will be introduced as soon as Parliamentary time permits.

2. This will be the first legislation of its kind this century. It will repeal the Cruelty to Animals Act 1876 and bring in completely new controls which will give better protection to animals used in scientific procedures without prejudicing the benefits, to man and animal, which flow from the use of animals by scientists. Many of our proposals are modelled on the recommendations of the Home Secretary's Advisory Committee on Animal Experiments (reproduced at Appendix A).

3. We are determined to maintain and improve the protection of animals which has applied in this country for over a century. Our proposals are also all consistent with the Council of Europe Convention (Appendix B) now nearing completion. Article 4 of the Convention allows member States to adopt measures for the protection of animals going further than the minimum which the Convention requires. The Government's proposals do go further. But we are very glad to see agreement in Europe on common minimum standards. Not only will this provide protection to animals throughout Europe, it will also help to ensure that work we would not allow in this country is not simply undertaken abroad. The United Kingdom has a large pharmaceutical industry which makes a big contribution to our balance of payments and employs 67,500 people. In devising new controls it is very important not to put industry at risk unnecessarily. One benefit of the European agreement, when it becomes effective, will be to minimise such a risk.

4. When the 1876 Act was passed, animals were used mainly in surgical experiments. During the last century the biological sciences have greatly developed. The great majority of the experiments now controlled under the 1876 Act involve no operative procedure more severe than a simple inoculation or taking a blood sample. The 1876 Act controls have been adapted to meet needs which nobody could have foreseen a hundred years ago. This has been possible because from the outset successive Home Secretaries have interpreted the requirements of the legislation widely, and the scientific community has readily co-operated with them. But now we need a modern system to protect animals used in today's circumstances.

5. The Government has a duty to safeguard the community from avoidable harm—and indeed tragedies—and to enable science to continue to make progress in saving life and alleviating suffering. This duty obliges us to permit the use of animals in research and testing to continue. But the controls which have operated since 1876 to prevent animals so used from being exposed to avoidable or excessive suffering must be modernised so as to serve their purpose more effectively.

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concerned with all aspects of laboratory accommodation and the care of animals in laboratories. The Government's proposals will give statutory effect to this practice.

(5) *All work to require specific authorisation*. Under the requirements of the European Convention, procedures will be permissible only if certain criteria are satisfied. For example there must be no other scientifically satisfactory method, not involving the use of an animal, reasonably and practicably available; where there is a choice between procedures, those chosen should use the minimum number of animals, cause the least suffering and be most likely to provide satisfactory results. To give effect to these requirements it will be necessary for all work done under the new legislation to be specifically approved. The existing controls do not achieve that. We shall accordingly introduce a new system of project licensing which will provide a specific and positive control over the procedures that are undertaken. This will make it possible to apply extra stringent controls to procedures giving rise to special concern and such controls will be applied, for example, to applications for licences to test cosmetics.

(6) *Anaesthetics and analgesics*. The controls will implement the provisions of the Convention which draw attention to the desirability of the use of anaesthetics and analgesics where appropriate.

(7) *Use of animals for instructional purposes*. Demonstrations are at present permitted under the 1876 Act only on fully anaesthetised animals—which are not allowed to recover—and only for students of medicine and allied sciences, including agriculture, at undergraduate level and above. We shall, in addition, allow demonstrations in other approved professional training courses, e.g. for potential technician licensees, but not in the education of schoolchildren or others at the same level. Demonstrations on animals allowed to recover from anaesthesia may be allowed but only in exceptional circumstances and then only when the animal would not suffer more than trivial pain. Filmed material should be used whenever possible. Undergraduate students would be licensed to use animals only under direct supervision and only when essential for them to acquire necessary knowledge.

(8) *Procedures for the acquisition of manual skills for microsurgery*. The effect of the 1876 Act is to make it unlawful to use living animals for the purpose of acquiring manual skills for microsurgery. Surgeons seeking such skill must complete their training abroad, or undertake cumbersome work on decerebrate animals which may result in the use, and death, of a greater number of animals. Under our proposals such procedures would in future be permissible but only under anaesthetic and with a requirement to use analgesia whenever necessary.

(9) *Survival of animals after procedures.* Animals will be allowed to survive after a procedure has been completed if they are fit to do so.

(10) *The Inspectorate.* The Inspectorate, which since 1876 has had a vital part to play in raising standards and spreading the best practice throughout the country, will continue in operation, will be strengthened, and will have new and enhanced duties in operating the new controls.

8. The new controls will be a radical tightening up of existing protection for animals used in procedures. To go further, however, and prohibit entirely the use of animals if pain and suffering or lasting harm of more than a trivial kind is likely to result, would not be in the interest of man or animal. The advance of knowledge in medicine, veterinary science and agriculture has often only been possible and may only be possible through the use of animals for the purpose of research. Similarly, the public can only be protected from hazards, sometimes lethal, associated with products of all kinds, not only those which may be latent in modern drugs and medicines otherwise of great value and efficacy, by tests which may involve the use of animals. If we had not used animals in research in the past, the advances we have been able to make in understanding disease and improving methods of prevention and cure would have been slower and fewer. If we were not able to use animals for these purposes in the future, there is no doubt that this would put a brake on progress. The position is similar with the safety testing of medicines, vaccines and other products. If we could not use animals for these purposes we would either have to accept that the damage caused to individuals by the use of untested or inadequately tested substances would be likely to increase, or that somehow we would have to do without these substances. But they may often be of very great use and value; in human and veterinary medicine they may promise substantial improvements in the prevention and cure of diseases—some crippling or fatal—in man and animal. But our new controls will ensure that the greatest possible protection is given to the animals used.

9. In particular the pain condition, which prevents animals under experiment being subjected to pain which is both severe and enduring, will be continued and will not permit any exception. In this respect our controls will be stricter than those in the European Convention. It will also be a feature of the new controls that no animal should be subjected to a level of pain greater than is appropriate to the procedure in question.

10. The rest of this White Paper describes the Government's proposals in more detail.

Background to Government's proposals

11. The 1876 Act became law following the report of a Royal Commission (C.1397 of 1875). At that time the main use of animals for scientific work was surgical. The study of physiology and experimental sciences was progressing rapidly; and there was public apprehension about the course of these developments. A second Royal Commission, appointed in 1906, reported in 1912 (Cd. 6114). Its majority recommendations were accepted and implemented administratively. In the next 50 years the biological sciences developed more rapidly and on a broader front that ever before. In 1963 the Departmental Committee on Experiments on Animals, under the chairmanship of Sir Sydney Littlewood, was appointed. The Committee which

reported in 1965 (Cmnd. 2641) concluded that the 1876 Act had been generally effective but drew attention to the need to adapt it to modern scientific and technological requirements and made a number of recommendations for this purpose. Some of these have been adopted administratively. Those requiring legislation have not yet been implemented.

12. Since the Littlewood report a number of Bills on the subject of animal experimentation has been introduced in Parliament by Private Members and Private Peers. The most recent were Mr. Peter Fry's Protection of Animals (Scientific Purposes) Bill, introduced in 1979 but withdrawn before it completed its passage through the House of Commons Standing Committee, and the Earl of Halsbury's Laboratory Animals Protection Bill, also introduced in 1979, and referred to a Select Committee of the House of Lords. The Select Committee's valuable report (246 of 1980) includes a revised draft Bill which was passed by the House of Lords on two occasions but failed to make progress in the Commons. The Select Committee concluded (paragraph 43) that "There is no doubt that the Act has, by and large, been successfully applied by the Home Office Inspectorate to meet modern needs . . . However, all our witnesses consider the law to be in some ways unsatisfactory".

13. In 1980 the Home Secretary invited his Advisory Committee on Animal Experiments to study the framework of legislation to replace the 1876 Act, with particular reference to the proposals before the Houses of Parliament and the Council of Europe. The Advisory Committee's report was published in 1981 and was welcomed by the Home Secretary as an especially important and informed contribution to discussion of the issues. The report agreed with the Select Committee's criticisms of the present law. In our view the report has admirably achieved its objective and we have modelled many of our proposals on those of the Advisory Committee.

14. A Council of Europe committee of experts began work in January 1978 on a draft Convention for the protection of animals used for experimental and other scientific purposes. That committee has now completed its work. It is hoped that the complete text of the Convention will shortly be submitted to the Committee of Ministers for approval, which would open the Convention for signature and ratification. The Government intends to sign and, when Parliamentary time can be found to implement the proposals in this White Paper, to ratify the Convention.

15. In March 1983 the British Veterinary Association, the Committee for the Reform of Animal Experimentation, and the Fund for the Replacement of Animals in Medical Experiments, jointly published proposals for new legislation. There is a large measure of agreement between their proposals and the Government's. The Government welcomes the contribution these bodies have made to this important public debate.

THE GOVERNMENT'S PROPOSALS

The Animal Procedures Committee

16. The Committee will be composed of a Chairman and not more than 12 members, two-thirds of whom will be drawn from medicine, veterinary science and other biological sciences. They will all be appointed in a personal capacity. The new Committee will continue to perform the general advisory function of the present Advisory Committee, considering such matters as may be referred to it by the Home Secretary including questions of policy, practice and procedure, trends in experimental and scientific work, the development of alternatives to animals in experiments and proposals for revision in the law. It will also have an enhanced role in advising on the administration of the new controls. The Home Secretary will be required to consult the Committee before prescribing the standard conditions to which all licences will be subject and before granting project licences in specified areas of work he regards as giving rise to special concern. He will specify proposals for testing cosmetics as such an area. In any application in such a specified area in which, exceptionally, the Home Secretary feels unable to accept the recommendation of the Committee he will be required, while observing considerations of confidentiality, to make public his reasons.

17. The Home Secretary will make available to the Committee information about the administration of the legislation, and such other facilities, as it needs to carry out its functions. Information provided to the Committee will be subject to the ordinary controls concerning disclosure. The Committee will make an annual report of its work to the Home Secretary, which will be presented to Parliament together with the annual statistics.

18. The functions of the Committee may make it necessary from time to time for it to seek additional expert advice. The Committee will be given power to seek such advice and, where necessary, to carry out its work through sub-committees.

The Inspectorate

19. The Home Secretary's Inspectorate, which is central to the present system of control and supervision of the use of animals in experiments, will be retained and strengthened. The inspectors will also assume the additional responsibilities necessary for regulating breeding and supplying establishments. Their duties will be:

(1) to advise the Home Secretary on all applications for personal and project licences; and for the registration of user, breeding and supplying establishments;

(2) to visit registered user establishments and other places at which the performance of procedures has been authorised, and registered breeding and supplying establishments, in order to ensure that the requirements of the legislation and of licences issued under it are being properly observed; that the animals are properly cared for; and that the conditions of registration of the establishments are being complied with; and

(3) to report irregularities to the Home Secretary.

20. The 1876 Act prescribes no qualifications for inspectors; it has been the practice since 1965 to appoint only persons with appropriate medical or veterinary qualifications. Under the new legislation the Home Secretary will continue this practice.

The Scope of the New Legislation

21. In accordance with Article 1.2(c) of the draft Convention, the new legislation will apply to any experimental or other scientific procedure which may cause the animal pain, suffering, distress or lasting harm, including any course of action intended to, or liable to, result in the birth (or hatching) of an animal in any such condition. Its scope will therefore be wider than that of the 1876 Act and will embrace some uses of animals such as the preparation of known antisera and the maintenance in animals of infectious organisms or tumours, which are not at present formally controlled but which may involve as much pain or discomfort as others at present subject to control. Decerebration of an animal (i.e. destruction of its brain) will be regarded as a procedure requiring authority in respect of all vertebrates, not solely as at present in mammals. Consequently, as the performance of procedures in schools is to be prohibited (see paragraph 41a below), the decerebration of frogs (including pithing) for teaching purposes in schools will no longer be permitted. The administration of an anaesthetic to an animal with a view to carrying out a procedure under the Bill will be regarded as part of that procedure. Non-experimental clinical veterinary or agricultural practice will be specifically excluded. In accordance with the draft Convention, methods accepted in modern practice as humane for killing or marking an animal will be outside the scope of control.

Animals to be Protected

22. The new legislation will apply to all living non-human vertebrates (i.e. all living animals of the Sub-phylum Vertebrata of the Phylum Chordata, excluding man, including the foetuses of mammals whether or not within the maternal tract; and including also, from the moment at which they are capable of leading an independent existence outside the egg or the maternal tract, as the case may be, the embryonic or larval young of members of other classes of the Sub-phylum Vertebrata). The protection afforded under the new legislation will be wider in scope than that afforded under the 1876 Act or by the draft Convention. It is, however, intended to continue to limit protection for the time being to vertebrate animals. This is in accordance with the scope of the 1876 Act and of the draft Convention. The Home Secretary will be empowered, however, to extend protection to other kinds of animals which he may consider at some future time should be brought within its scope in the light of new scientific knowledge about the degree to which they may experience pain.

23. The Government agrees with the Advisory Committee that the recent administrative practice of requiring special authority for the use of non-human primates should continue. The aim must be as high a level of protection as possible for all animals used for experimental and other scientific purposes. The choice of species of animal to be used in a procedure is an important consideration and is recognised as such in the draft Convention (Article 7).

Applicants for licences will therefore be required to justify their choice. These provisions will extend to all species safeguards comparable to the special protection which is conferred in the existing legislation only on cats, dogs and equidae (horses, asses and mules).

Pain

24. The 1876 Act applies only to experiments likely to cause "pain". There is, and can be, no definition of the term; nor has it been interpreted by the courts. For the purpose of deciding what experiments require licences, the Home Secretary's practice has been to interpret the concept of pain in animals in its widest possible sense as including disease, other disturbance of normal health, adverse change in physiology, discomfort and distress. The draft European Convention extends, subject to specific exceptions, to any experimental or other scientific procedure which "may cause pain, suffering, distress or lasting harm". New legislation will apply to all such procedures.

25. A standard condition placing an upper limit on the degree or duration of pain which may be caused in experiments on live animals has been imposed in all licences issued under the 1876 Act since 1887; and has been applied in its present form without exception since 1929. This, among its other provisions, requires the painless killing of the animal if it is suffering severe pain which is likely to endure. Article 9 of the draft European Convention provides that any procedure under which an animal may experience severe pain which is likely to endure may be permitted if it is specifically authorised and is of exceptional importance for meeting the essential needs of man or animal. The Convention also allows us, however, to adopt stricter controls than the minimum it requires. In all licences in the United Kingdom *we intend to continue unchanged the requirement* that, if at any time an animal is found to be suffering severe pain which is likely to endure, it shall at once be painlessly killed. In addition inspectors will continue to be empowered to direct the painless killing of any animal which appears to the inspector to be suffering considerable pain.

26. Moreover, the new system of control will ensure that in no procedure will the level of pain be permitted to exceed what is unavoidable to achieve the intended results. For this purpose licensees will be required to use anaesthetics and analgesics wherever appropriate.

Permissible Purposes

27. Under Article 2 of the draft European Convention a procedure may be performed on an animal for one or more of the following purposes only:

(a) (i) the avoidance or prevention of disease, ill-health or other abnormality, or their effects, in man, vertebrate or invertebrate animals or plants, including the production and the quality, efficacy and safety testing of drugs, substances or products;

(ii) the diagnosis or treatment of disease, ill-health or other abnormality, or their effects in man, vertebrate or invertebrate animals or plants;

(b) the assessment, detection, regulation or modification of physiological conditions in man, vertebrate and invertebrate animals or plants;
(c) the prolongation or saving of life of man, vertebrate or invertebrate animals or plants;
(d) the protection of the environment;
(e) the production and quality control of foodstuffs;
(f) the breeding of vertebrate or invertebrate animals;
(g) scientific research;
(h) education and training;
(i) forensic inquiries.

28. There is a good deal of overlap between these categories. The object in new legislation must be to achieve a proper balance between two public interests; on the one hand avoiding prejudice to work which is essential to the prevention or cure of human or animal disease, or important in extending knowledge, and on the other responding to public concern for the welfare of experimental animals. We believe that this can be done, on the basis of the permissible purposes listed above, modified where appropriate.

29. Procedures may be performed on animals for the purpose of testing substances and products for their potential to cause harm to man or the natural environment. Whilst recognising public concern over the use of animals in such tests, the Government has to take fully into account the equally valid concern of others that potentially harmful substances or products are recognised before they are placed on the market. Tests to evaluate these products will continue to be permissible and controlled. Similarly, suitable provision will be made for procedures to be permitted in accordance with the purposes specified in paragraph 27(b), (c), (e), (f) and (i) above. As regards 27(d), it is proposed to provide that experiments intended for the protection of the natural environment, in circumstances where otherwise the health or welfare of man or animal would suffer—e.g. testing rivers for pollution—should be permitted.

30. The testing of cosmetics on animals is a particularly controversial area and, in the Government's view, should be subject to specially stringent controls. The new proposals will, therefore, require that all applications for project licences for the testing of cosmetics should be referred to the new Animal Procedures Committee. The Government will also seek to ensure in international negotiations that no such testing is required beyond what is absolutely essential.

31. Although the number of tests of cosmetics is relatively very small (in 1981 there were fewer than 25,000 experiments to test cosmetics and toiletries, or around half of one per cent. of the total number) many members of the public are understandably concerned that animals should be used for the safety testing of a new lipstick or deodorant. The Government has, therefore, considered whether it should go further and prohibit the use of animals for testing of cosmetics altogether or, alternatively, restrict the types of tests which

should be permitted. It considers neither to be feasible. It is difficult to define what is strictly a cosmetic when substances may simultaneously be of medical or other therapeutic value. Such testing may also be required to comply with statutory or other requirements to protect both users and those concerned with their production.

32. Scientific research is included in the Convention's list of permissible purposes (paragraph 27(g) above) to cover research which may not fall under any of the other headings but ought to be undertaken. Research with no immediately clear application has led to many of the greatest practical advances. Such research will be allowed but it will be subject to all the safeguards we shall provide for the protection of animals used in procedures, and in particular those concerned with the purpose which it is hoped to achieve.

33. Demonstrations will be allowed, as at present, for students of medical and allied sciences including agriculture, at undergraduate level and above. In addition, such demonstrations will be allowed in future in other approved professional training courses, e.g. for potential technician licensees, but not in the education of schoolchildren or others at the same level. It is not proposed to retain the present restriction allowing only demonstrations on fully anaesthetised animals which are not allowed to recover. There may be occasions when particular demonstrations might be justifiably performed on animals which might subsequently be allowed to recover from anaesthesia, but only when they would not suffer more than trivial pain.

34. The present total prohibition on the experimental use of animals for the acquisition of manual skill has resulted in some surgeons seeking skill in the important field of micro-surgery having to go abroad to complete their training. The prohibition will be modified to meet this and future developments by empowering the Home Secretary to authorise procedures to acquire a special and specific skill in which, in his view, it is necessary to use animals. Provision will also be made, subject to appropriate restrictions, for the performance of procedures for the purposes of making films for educational purposes. Such films may often permit the further use of animals to be avoided.

The Licensing System

35. The system of licensing is a fundamental feature of the control of the use of animals. Whilst the existing arrangements are satisfactory as regards the persons licensed, they are less so as regards the work undertaken. Under the existing law a licence, without more, is valid only for work on fully anaesthetised animals. In relation to such work, however, unless the licensee is subject to a limiting condition*, the licensee needs no further authority and may move on from project to project, provided anaesthesia is used throughout. Work in which the animals are not under anaesthetic for part or all of the time is allowed only if appropriate certificates are issued, signed both by professors of medicine and by presidents of learned institutions, to the effect

* Such a condition is normally imposed to restrict work of this kind to licensees who are experienced and highly qualified.

that the purpose of the experiment could not be achieved if the animals had to be anaesthetised throughout. The Home Secretary has power to disallow certificates in whole or in part. In practice certificates are rarely disallowed except for technical reasons and the Advisory Committee is consulted before work is disallowed on the merits. Moreover, those certificates are usually drafted in terms which are capable of permitting a series of projects to be undertaken without further authority having to be obtained. This system of control is no longer satisfactory. We accordingly propose to introduce a substantially improved system of licensing which will enable the various objectives of the new controls to be effectively achieved. Our proposals have much in common with those of one of the two schemes proposed by the Advisory Committee (Appendix A, paragraphs 5 to 7). Provision will be made for two kinds of licence: personal licences and project licences. The Home Secretary will be empowered to attach to these licences any conditions which he may think expedient.

Personal Licences

36. Each person performing a procedure on an animal will continue to need to be individually licensed. It will not be lawful to grant a personal licence to a person under the age of 18. Otherwise the qualifications required of an applicant will, as now, be a matter for the discretion of the Home Secretary who will be empowered to license persons whom he considers suitable and competent. In granting licences he will exercise his power to attach conditions to them to limit the kind of work the particular licensee is authorised to undertake to that which the Home Secretary considers is within the competence and experience of the applicant. In appropriate cases a personal licence will be granted subject to the requirement that the holder works only under the general or direct supervision of another licensee. Direct supervision will always be required when undergraduate students are licensed.

Project Licences

37. Project licences will be a new feature of the system. It will not be necessary for every licensee to be granted a project licence for the work on which he is engaged. Such licences will be needed only by the licensee who has overall responsibility for the project and will cover all other licensees engaged on it. It will not, however, be lawful for a licensee to undertake work involving the use of living animals unless a valid project licence is in existence authorising that work. The definition of a project will vary considerably according to the kind of work in question. The work carried out by an individual research student designed to obtain the answer to a specific question and lasting for only a few months could constitute a project. Equally, toxicity evaluation of more or less broadly defined types of substances carried out over a period of years could also constitute a single project, even if the substance being tested varies throughout the period. Applicants for project licences will be required to provide sufficient information about the nature of the project and its purposes as will enable the Home Secretary to judge whether it satisfies the criteria of purpose and other requirements.

Sponsorship

38. An application for a personal licence will have to be supported by a senior licensee with personal knowledge of the applicant. An application for a project licence will have to be countersigned by a professor in a relevant discipline or some other person in authority knowledgeable in the proposed area of work and acceptable to the Home Secretary. This sponsor will be asked to express his opinion as to whether:

(a) the project is likely to achieve the declared purpose;

(b) any alternative non-sentient method would satisfactorily and reliably achieve the purpose:

(c) the type of animals which it is proposed to use is appropriate; and

(d) the applicant's proposed use of anaesthesia or analgesia is adequate.

39. Licences will be valid for a fixed period which will either be stated on their face or determined by regulations.

Student Licensing

40. The Government has considered proposals, including those by the Advisory Committee, that students should not be required to hold an individual licence for work under the direct supervision of a senior licensee if limited, for example, to the performance of procedures on animals which are anaesthetised throughout and killed before recovering consciousness. We do not consider that the administrative advantages are a sufficient reason for departing from the general principle that each person should be individually licensed and should bear personal responsibility for the animals he uses.

Applications for Project Licences for Education and Training

41. Article 25.3 of the draft European Convention provides that procedures for the purpose of education and training should be permitted only if their objective cannot be achieved by effective audio-visual or any other suitable methods or combination of methods. This will be met by requiring applicants for project licences for this purpose to certify that the objective could not effectively be achieved by such means.

42. At present such procedures, when they involve pain or distress to the animal, are permissible, insofar as they are permissible at all, only in registered places. It is not proposed that any significant extension of the categories of registered places should be made. Since decerebration will in future be a controlled procedure, permissible only in a registered place, and since licences will be issued only to persons aged 18 or over, it will not be possible under the new proposals for living animals to be used in schools, in potentially painful scientific procedures for educational purposes, whether in demonstrations—for which project licences would in any event not be issued in such circumstances—or by schoolchildren themselves or others at the same level.

Requirement to Kill Animals after Use

43. The requirement of the 1876 Act to kill all animals used in experiments in which the animal recovers from anaesthesia has proved unsatisfactory. When the Act was passed, and most experiments involved major surgery, this may have been necessary. Today many surgical experiments are of such a kind that an animal can make a complete and satisfactory recovery. In other experiments, anaesthesia may be used not because it is necessary to prevent pain but to assist the experimenter by immobilising the animal. It will be a requirement in new legislation that an animal should be humanely killed at the end of a procedure only if it is likely to suffer adverse effects or has suffered lasting harm. It will sometimes be clear at the outset that it is appropriate to make it a specific requirement of the project licence that the animals must be killed when the procedure is completed.

Curare and Other Muscle Relaxants

44. The use of curare and agents having similar effects will be prohibited except with the consent of the Home Secretary.

User Establishments

45. Except with the specific authority of the Home Secretary (which is intended to cover necessary field work—see paragraph 47) authorised procedures will be permitted to be performed only at establishments which he considers suitable for approval and registration. He will be empowered to attach conditions, whether general or particular, to certificates of registration. Conditions will be attached in all cases to secure that:

(1) a named person or persons will have day to day responsibility for ensuring that the conditions are fulfilled;

(2) a veterinary surgeon, either from the staff of the establishment, retained part time, or available to be called in at all necessary times, will be responsible for advice on animal health and welfare;

(3) adequate staff must be available for the care of the animals used, or kept for use, in procedures;

(4) adequate care and accommodation must be maintained appropriate to the particular animals; and

(5) environmental conditions must be checked daily.

46. It is not expected that there will be any significant increase in the number of establishments registered for the performance of controlled procedures. Those establishments where procedures are carried out which are not covered by the 1876 Act but will be covered by the new proposals (see paragraphs 7(2) and 21 above) will need to be registered if they are not registered already. The additional number, however, is likely to be small.

47. The Home Secretary will have power to authorise the performance of procedures other than at a registered establishment, for example, in a field or wood, where necessary.

Breeding and Supplying Establishments

48. There are at present no controls over the breeding and supply of animals for use in experiments, except for the prohibition in the Dogs Act 1906 on the disposal by the police of stray dogs for use in experiments. The Government intends to introduce such controls in accordance with the provisions of the draft European Convention. This will require the registration and inspection of all establishments which breed and supply animals intended for use in experimental and other scientific procedures; for such establishments to provide their animals with certain standards of care and accommodation; and for recording various details of all such animals, particularly in respect of cats and dogs.

Source of Animals

49. There will be a requirement that all animals used in procedures must be obtained from a registered breeding or supplying establishment. The Home Secretary will be empowered to make general or specific exemptions from this requirement. General exemptions will be made by means of regulations in the case of animals such as horses, asses, mules, cows, sheep and goats which are at present usually obtained from farms. General exemptions for the use of poultry and fish obtained from commercial breeders may also be necessary. Particular exemptions will be allowed administratively, for example, to cover the use of animals taken from the wild when such animals and their environment are the subject of the experiment. In all cases, however, in which animals are supplied under the terms of a general or specific exemption the conditions imposed on the user establishment will require records to be kept enabling the precise source of the animal to be identified. The use of dogs or cats found straying will not be permitted.

Other Provisions

Statistics

50. The Home Secretary will publish annual statistics about the use of live animals in procedures which are subject to the provisions of the Bill. These will include information about the number and species of animals used, the purpose of their use, and the extent to which it was required by national or foreign legislation.

Offences and Penalties

51. It will be an offence to perform or take part in performing a procedure without authority on a live animal which may cause pain, suffering, distress or lasting harm; knowingly to aid and abet the performance of an unauthorised procedure; and knowingly to provide false information in an application for a licence or for registration. Provision would be included to make unlawful unauthorised disclosure of confidential information. Other offences might be needed to provide appropriate sanctions to make aspects of the controls, e.g. in respect of establishments breeding and supplying animals,

effective. All offences will be triable summarily but the 6 months time-limit on their institution will be modified to provide that proceedings may be taken within 6 months from the date on which the evidence comes to light but not later than 3 years from the commission of the offence. Penalties for offences will be in line with those available for offences under the Protection of Animals Act 1911.

52. To safeguard licensees from vexatious prosecutions, the consent of the Director of Public Prosecutions will be required for the prosecution of a licensee. At present the Home Secretary's consent to such prosecutions is necessary but it is no longer considered appropriate to involve the Home Secretary in any aspect of the prosecution process.

Territorial Extent

53. The proposals will apply to Great Britain and, with appropriate modifications, to Northern Ireland, where responsibility rests with the Department of Health and Social Services.

Financial and Manpower Implications

54. In accordance with the Government's objective of keeping the burden on resources to a minimum, the aim will be to ensure that the new arrangements can be introduced without unnecessary cost. Since the introduction of controls over the breeding and supply of animals for use in procedures is likely to lead to some increase in costs, consideration will be given to the feasibility of introducing these controls over a period of time. A small increase in the Home Office staff involved, mainly to strengthen the Inspectorate, will be necessary. Fees will be payable for licences and for registration.

CONCLUSION

55. The Government believes that the proposals in this White Paper will provide continued and extended protection of animals from avoidable suffering while permitting their use in the proper interests of man and animal. They will enable the Government to ratify the European Convention. The Government intends to introduce legislation on these lines as soon as the Parliamentary timetable allows.

56. The Government would welcome any written comments on the proposals which should be sent to the Home Office, E4 Division, Queen Anne's Gate, London SW1H 9AT by 12 August 1983.

REPORT OF THE ADVISORY COMMITTEE ON THE FRAMEWORK OF NEW LEGISLATION TO REPLACE THE CRUELTY TO ANIMALS ACT 1876

SUMMARY OF MAIN RECOMMENDATIONS

1. New legislation should extend to all animals of the species of the Sub-phylum Vertebrata of the Phylum Chordata, including the foetuses of mammals and the embryonic or larval young of members of other Classes (whether oviparous or viviparous) that have attained such a stage of development that they are capable of a discrete existence outside the egg of maternal tract.

2. The Bill should apply to any experimental or other scientific use of an animal which causes, or is expected to cause, anything more than momentary pain or suffering.

3. The Secretary of State should be empowered to issue licences only for certain purposes.

4. With the exception of work involving students, the present system of licensing individual persons should be continued.

5. Two alternative licensing schemes are put forward for consideration. The details of either scheme should be applied administratively. Applicants under either scheme should be required to provide a justification for the work proposed and evidence of competence to perform the work.

6. All applications should be supported by a sponsor, usually a senior person at the applicant's place of work.

7. Certain applications should be supported by a referee in addition to a sponsor. The referee would be concerned with evaluation of the proposed work. The Home Office should maintain and publish a list of referees to whom they would send appropriate applications.

8. Undergraduate students should not generally be individually licensed and should work under the direction of a supervisor holding a licence for teaching purposes.

9. The Secretary of State should be empowered to attach conditions to licences. Certain standard conditions, including a "termination condition", should be included in all licences.

10. Licences should be granted for 5 years or such shorter period as may be determined by the Secretary of State.

11. There should be a procedure for representations by aggrieved applicants. Representations should be considered in the first instance by the Advisory Committee.

12. A licensing sub-committee of the full Advisory Committee should be established to advise the Secretary of State on individual cases.

13. A "termination" condition should be applied administratively to every licence. Such a condition should not be incorporated in terms in the body of the Bill.

14. The controls over the use of muscle relaxants should be continued and extended, but solely by administrative means.

15. The existing requirement that an animal that has been anaesthetised must always be killed at the end of the experiment should be modified.

16. The re-use of an animal should be permitted, provided that on the second occasion it is fully anaesthetised throughout and humanely destroyed before it recovers from the effect of the anaesthetic.

17. The re-use of an animal in further recovery work should be permitted only in certain circumstances and with the approval of the Home Office Inspectorate.

18. Applicants for licences should be required to confirm that they have considered and rejected the availability of alternatives.

19. Special protection should be afforded to primates by administrative means.

20. The Bill should not be interwoven into the other general protection of animals legislation and should be independent.

21. Establishments breeding animals expressly for experimental and other scientific uses should be registered by the Home Office and made subject to inspection.

22. Establishments supplying animals should be registered by the Home Office and made subject to inspection.

23. So far as possible, new controls should prevent stolen pets and stray animals from finding their way into laboratories.

24. The Home Office Inspectorate should continue on lines broadly similar to the present.

25. Provision should be made for the establishment of a statutory Advisory Committee.

DRAFT CONVENTION FOR THE PROTECTION OF VERTEBRATE ANIMALS USED FOR EXPERIMENTAL AND OTHER SCIENTIFIC PURPOSES

PREAMBLE

The member States of the Council of Europe, signatory hereto,

Conscious that the aim of the Council of Europe is to achieve a greater unity between its members and that it wishes to co-operate with other States in the protection of live animals used for experimental and other scientific purposes;

Accepting that man in his quest for knowledge, health and safety has a need to use animals where there is a reasonable expectation that the result will be to extend knowledge or be to the overall benefit of man or animal, just as he uses them for food, clothing and as beasts of burden;

But recognising that man has a moral obligation to respect all animals and to exercise due consideration for their capacity for suffering and memory;

Desirous to limit wherever practicable the use of animals for experimental and other scientific purposes, in particular by seeking alternative methods to replace the use of animals;

And considering that it is desirable to adopt common provisions in order to protect animals used in those procedures which may possibly cause pain, suffering, distress or lasting harm and to ensure that where unavoidable they shall be kept to minimum,

Have agreed as follows:

PART I—GENERAL PRINCIPLES

Article 1

1. This Convention applies to any animal being used or intended for use in any experimemtal or other scientific procedure where that procedure may cause pain, suffering, distress or lasting harm. It does not apply to any non-experimental agricultural or clinical veterinary practice.

2. In this Convention:
   (*a*) "*animal*", unless otherwise qualified, means any live non-human vertebrate, including free-living larval and/or reproducing larval forms, but excluding other foetal or embryonic forms;
   (*b*) "*intended for use*" means bred or kept for the purpose of sale, disposal or use in any experimental or other scientific procedure;
   (*c*) "*procedure*" means any experimental or other scientific use of an animal which may cause it pain, suffering, distress or lasting harm, including any course of action intended to, or liable to, result in the birth of an animal in any such condition, but excluding the least painful methods accepted in modern practice (ie "humane" methods) of killing or marking an animal; a procedure starts when an animal is first prepared for use and ends when no further observations are to be made for that procedure; the elimination of pain, suffering, distress or lasting harm by the successful use of anaesthesia or analgesia or other methods does not place the use of an animal outside the scope of this definition.

(*d*) "*competent person*" means any person who is considered by a Contracting Party to be competent in its territory to perform the relevant function described in this Convention;

(*e*) "*responsible authority*" means, in the territory concerned, the Contracting Party or any other authority, body or person designated for the relevant purpose by that Contracting Party;

(*f*) "*establishment*" means any installation, building, group of buildings or other premises and may include a place which is not wholly enclosed or covered and mobile facilities;

(*g*) "*breeding establishment*" means an establishment where animals are bred with a view to their use in procedures;

(*h*) "*supplying establishment*" means an establishment, other than a breeding establishment, from which animals are supplied with a view to their use in procedures;

(*i*) "*user establishment*" means an establishment where animals are used for procedures;

(*j*) "*humane method of killing*" means the killing of an animal with a minimum of physical and mental suffering appropriate to the species.

Article 2

A procedure may be performed on an animal for one or more of the following purposes only and subject to the restrictions laid down in this Convention:

(*a*) (i) the avoidance or prevention of disease, ill-health or other abnormality, or their effects, in man, vertebrate or invertebrate animals or plants, including the production and the quality, efficacy and safety testing of drugs, substances or products;

(ii) the diagnosis or treatment of disease, ill-health or other abnormality, or their effects, in man, vertebrate or invertebrate animals or plants;

(*b*) the assessment, detection, regulation or modification of physiological conditions in man, vertebrate and invertebrate animals or plants;

(*c*) the prolongation or saving of life of man, vertebrate or invertebrate animals or plants;

(*d*) the protection of the environment;

(*e*) the production and quality control of foodstuffs;

(*f*) the breeding of vertebrate or invertebrate animals;

(*g*) scientific research;

(*h*) education and training;

(*i*) forensic inquiries.

Article 3

Each Contracting Party shall undertake, as soon as possible and in any case within a period of five years from the date of entry into force of the present Convention in respect of that Party, to take all necessary steps to give effect to the provisions of this Convention and to ensure an effective system of control and supervision.

Article 4

No provision in this Convention shall effect the liberty of the Contracting Parties to adopt stricter measures for the protection of animals used in procedures or for the control and restriction of the use of animals for procedures.

PART II—GENERAL CARE AND ACCOMMODATION

Article 5

1. Any animal being used or intended for use in a procedure shall be provided with accommodation, an environment, at least a minimum freedom of movement, food, water and care all appropriate to its health and well-being. Any restriction on the extent to which the animal can satisfy its physiological and ethological needs shall be limited as far as practicable.

2. The environmental conditions in which animals are bred, kept or used must be checked daily.

3. The well-being and state of health of animals shall be observed sufficiently closely and frequently to prevent avoidable suffering.

4. Each Contracting Party shall determine arrangements to ensure that any defect or suffering discovered is corrected as quickly as possible.

PART III—CONDUCT OF PROCEDURE

Article 6

1. A procedure shall not be performed if another scientifically satisfactory method, not entailing the use of an animal, is reasonably and practicably available.

2. Each Contracting Party should seek to take such steps as it deems appropriate to encourage, if possible, scientific research into the development of methods which could provide the same information as that obtained in procedures.

Article 7

When a procedure has to be performed, the choice of species shall be carefully considered and, where required, be explained to the responsible authority; in a choice between procedures, those should be selected which use the minimum number of animals, cause the least pain, suffering, distress or lasting harm and which are most likely to provide satisfactory results.

Article 8

All procedures shall be performed under general or local anaesthesia or analgesia or by other methods designed effectively to eliminate as far as practicable pain, suffering, distress or lasting harm, applied throughout the procedure unless the methods are judged to be more distressing for the animal than the procedure used or they are incompatible with the aim of the procedure. If such methods are incompatible with the aim of the procedure it must be declared to or authorised by the responsible authority.

Article 9

Where it is planned to subject an animal to a procedure in which it will or may experience severe pain which is likely to endure that procedure must be specifically declared to or specifically authorised by the responsible authority; authorisation shall be refused if the responsible authority judges that the procedure is not of exceptional importance for meeting the essential needs of man or animal including the solution of scientific problems.

Article 10

During a procedure, an animal used shall remain subject to the provisions of Article 5 except where those provisions are incompatible with the object of the procedure.

Article 11

1. At the end of any procedure it shall be decided whether the animal shall be kept alive or killed by a humane method, subject to the condition that it shall not be kept alive if, even though it has been restored to normal health in all other respects, it is likely to remain in lasting pain or distress.

2. The decisions referred to in paragraph 1 of this Article shall be taken by a competent person, in particular a veterinarian, or the person who is responsible for, or has performed, the procedure.

3. Where at the end of a procedure:

(*a*) an animal is to be kept alive, it shall receive the care appropriate to its state of health and be placed under the supervision of a veterinarian or other competent person and shall be kept under conditions conforming to the requirements of Article 5. The conditions laid down in this sub-paragraph may, however, be waived where, in the opinion of a veterinarian, the animal would not suffer as a consequence of such exemption;

(*b*) an animal is not to be kept alive or cannot benefit from the provisions of Article 5 for its well-being, it shall be killed by a humane method as soon as possible.

4. No animal which has been used in a procedure entailing severe or enduring pain or suffering, irrespective of whether an anaesthetic or an analgesic was employed, shall be used in a further procedure unless it has returned to good health and well-being, and either:

(*a*) the further procedure is one in which the animal is subject throughout to general anaesthesia from which it is not allowed to recover; or

(*b*) the further procedure will involve minor interventions only.

Article 12

Notwithstanding the other provisions of this Convention, where it is necessary for the legitimate purposes of the procedure, the responsible authority may allow animals concerned to be set free provided that it is satisfied that the maximum practicable care has been taken to safeguard the animal's well-being. Procedures that involve setting the animal free shall not be permitted solely for educational or training purposes.

PART IV—AUTHORISATION

Article 13

The procedures referred to in Article 2 may be carried out on animals only by persons authorised, or under the direct responsibility of a person authorised, or if the experimental or other scientific project concerned is authorised in accordance with the provisions of national legislation. Authorisation shall be granted only to persons deemed to be competent by the responsible authority.

PART V—BREEDING OR SUPPLYING ESTABLISHMENTS

Article 14

Breeding and supplying establishments shall be registered with the responsible authority and shall comply with the requirements of Article 5.

Article 15

The registration provided for in Article 14 shall specify the person in charge of the establishment, who shall be comptent to administer or arrange for suitable care for animals of the species bred or kept in the establishment.

Article 16

1. Arrangements shall be made at breeding establishments to record, in respect of any animals bred there, the number and species of such animals leaving, the dates they leave and the name and address of the recipient.

2. Arrangements shall be made at supplying establishments to record the number and species of such animals entering and leaving, the dates of these movements, and from whom the animals concerned were acquired and the name and address of the recipient.

3. Each responsible authority shall prescribe the records which are to be kept and made available to it by the person in charge of the establishments mentioned in paragraphs 1 and 2 of this Article; such records shall be kept for a minimum of three years from the date of the last entry.

Article 17

1. Each dog and cat in an establishment shall be individually and permanently marked in the least painful practicable manner before it is weaned.

2. Where an unmarked dog or cat is taken into an establishment for the first time after it has been weaned it shall be so marked as soon as possible.

3. Where a dog or cat is transferred from one establishment to another before it is weaned and it is not practicable so to mark it beforehand, a full documentary record, specifying in particular its mother, must be maintained until it can be so marked.

4. Particulars of the identity and origin of each dog or cat shall be entered in the records of all establishments.

PART VI—USER ESTABLISHMENTS

Article 18

User establishments shall be registered with or otherwise approved by the responsible authority and shall comply with the conditions laid down in Article 5.

Article 19

Provisions shall be made at user establishments for installations and equipment appropriate for the species of animals used and the performance of the procedures conducted there, the design, construction and functioning of which shall be such as to ensure that the procedures are performed as effectively as practicable, with the object of obtaining consistent results with the minimum number of animals and the minimun degree of pain, suffering, distress or lasting harm.

Article 20

In user establishments:

(*a*) The person or persons who are administratively responsible for the care of the animals and the functioning of the equipment shall be identified;

(*b*) Sufficient trained staff shall be provided;

(*c*) Adequate arrangements shall be made for the provision of veterinary advice and treatment.

Article 21

In user establishments only animals supplied from breeding or supplying establishments shall be used, with such exceptions as may be allowed for particular reasons by each Contracting Party.

Article 22

1. Animals of the species listed below which are for use in procedures shall originate from or be acquired directly from registered breeding establishments, unless a general or special exemption has been obtained under arrangements to be determined by the Contracting Party:

Mouse	*Mus musculus*
Rat	*Rattus norvegicus*
Guinea Pig	*Cavia porcellus*
Golden Hamster	*Mesocricetus auratus*
Rabbit	*Oryctolagus cuniculus*
Dog	*Canis familiaris*
Cat	*Felis catus*
Quail	*Coturnix coturnix*

2. Each Contracting Party undertakes to add species, in particular of the order of primates, to this list as soon as there is a reasonable prospect of a sufficient supply of purpose-bred animals of the species concerned.

3. Straying animals of a domesticated species shall not be used in procedures. A general exemption made under the conditions of paragraph 1 of this Article may not extend to stray dogs and cats.

Article 23

Procedures may, where authorised by the responsible authority, be conducted outside user establishments.

Article 24

Arrangements shall be made at user establishments to maintain records and make them available as required by the responsible authority. In particular, these records shall be sufficient to meet the requirements of Article 27 and, in addition, show the number and species of all animals acquired, from whom they were acquired and their date of arrival.

PART VII—EDUCATION AND TRAINING

Article 25

1. Procedures carried out for the purpose of training or further training for professions or other occupations, including the care of animals being used or intended for use in procedures, must be notified to the responsible authority prior to the authorisation of the curriculum or their introduction in the course and shall be carried out by or under the supervision of a competent person, who will be responsible for ensuring that procedures concerned comply with national legislation under the terms of this Convention.

2. Procedures shall not be permitted in secondary schools or other institutions of education and training of equivalent or lower level except where the course of education or training concerned is specifically directed to preparing for a career involving the performance of procedures or the treatment or care of animals and the procedures entail no severe or enduring pain or severe or enduring suffering.

3. Procedures referred to in paragraphs 1 and 2 of this Article shall be restricted to the minimum measures absolutely necessary for the purpose of the education or training concerned and be permitted only if their objective cannot be achieved by comparably effective audio-visual or any other suitable methods.

Article 26

Persons who carry out procedures, or take part in procedures, or take care of animals used for procedures, including duties of a supervisory nature, shall have adquate education and training.

PART VIII—STATISTICAL INFORMATION

Article 27

1. Each Contracting Party shall collect statistical information on the use of animals in procedures and this information shall where lawful be made available to the public.

2. Information shall be collected in respected of:

(*a*) the number and kinds of animals used in procedures;

(*b*) the number of animals in selected categories used in procedures directly concerned with medicine and in teaching and learning;

(*c*) the number of animals in selected categories used in procedures for the protection of man and his environment;

(*d*) the number of animals in selected categories used in procedures required by legislation.

Article 28

1. Subject to requirements of national legislation relating to secrecy and confidentiality each Contracting Party shall each year communicate to the Secretary General of the Council of Europe information in respect of the items mentioned in paragraph 2 of Article 27.

2. The Secretary General of the Council of Europe shall publish the statistical information received from the Contracting Parties in respect of the items mentioned in paragraph 2 of Article 27.

3. Each Contracting Party is invited to communicate to the Secretary General of the Council of Europe the address of its national authority from which information about more comprehensive national statistics may be obtained on request. Such addresses will be contained in the publications of statistics made by the Secretary General of the Council of Europe.

PART IX—RECOGNITION OF PROCEDURES CARRIED OUT IN THE TERRITORY OF ANOTHER CONTRACTING PARTY

Article 29

1. In order to avoid unnecessary repetition of procedures for the purposes of satisfying national legislation on health and safety each Contracting Party shall, where practicable, recognise the results of procedures carried out in the territory of another Contracting Party.

2. To that end the Contracting Parties agree, where each of them judges it practicable and lawful, to render each other mutual assistance, in particular by furnishing information on their legislation and administrative practice relating to the requirements for procedures to be carried out in support of submissions for registration of products, as well as factual information on procedures carried out in their territory and on authorisation or any other administrative particulars pertaining to these procedures.

PART X—FINAL PROVISIONS

Article 30

This Convention shall be open for signature by the member States of the Council of Europe and by the [European Economic Community]*. It is subject to ratification, acceptance or approval. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.

Article 31

1. This Convention shall enter into force on the first day of the month following the expiration of a period of six months after the date on which four member States of the Council of Europe have expressed their consent to be bound by the Convention in accordance with the provisions of Article 30.

2. In respect of a Signatory Party which subsequently expresses its consent to be bound by it, the Convention shall enter into force on the first day of the month following the expiration of a period of six months after the date of the deposit of the instrument of ratification, acceptance or approval.

Article 32

1. After the entry into force of this Convention, the Committee of Ministers of the Council of Europe may invite any State not a member of the Council to accede to this Convention, by a decision taken by the majority provided for in Article 20 d. of the Statute of the Council of Europe and by the unanimous vote of the representatives of the Contracting States entitled to sit on the Committee.

2. In respect of any acceding State, the Convention shall enter into force on the first day of the month following the expiration of a period of six months after the date of deposit of the instrument of accession with the Secretary General of the Council of Europe.

Article 33

1. Any [State]* may, at the time of signature or when depositing its instrument of ratification, acceptance, approval or accession, make one or more reservations. No reservations may, however, be made in respect of Articles 1–14 or Articles 18–20.

2. Any [Contracting State]* which has made a reservation under the preceding paragraph may wholly or partly withdraw it by means of a notification addressed to the Secretary General of the Council of Europe. The withdrawal shall take effect on the date of receipt of such notification by the Secretary General.

3. A Party which has made a reservation in respect of a provision of this Convention may not claim the application of that provision by any other Party; it may, however, if its reservation is partial or conditional, claim the application of that provision in so far as it has itself accepted it.

Article 34

1. Any [State]* may at the time of signature or when depositing its instrument of ratification, acceptance, approval or accession, specify the territory or territories to which this Convention shall apply.

2. Any [State]* may at any later date, by a declaration addressed to the Secretary General of the Council of Europe, extend the application of this Convention to any other territory specified in the declaration. In respect of such territory the Convention shall enter into force on the first day of the month following the expiration of a period of six months after the date or receipt of such declaration by the Secretary General.

3. Any declaration made under the two preceding paragraphs may, in respect of any territory specified in such declaration, be withdrawn by a notification addressed to the Secretary General. The withdrawal shall become effective on the first day of the month following the expiration of a period of six months after the date of receipt of such notification by the Secretary General.

Article 35

1. Any Party may at any time denounce this Convention by means of a notification addressed to the Secretary General of the Council of Europe.

2. Such denunciation shall become effective on the first day of the month following the expiration of a period of six months after the date of receipt of the notification by the Secretary General.

Article 36

The Secretary General of the Council of Europe shall notify the member States of the Council* and any State which has acceded to this Convention of:

(*a*) any signature;

(*b*) the deposit of any instrument of ratification, acceptance, approval or accession;

(*c*) any date of entry into force of this Convention in accordance with Articles 31, 32 and 34;

(*d*) any other act, notification or communication relating to this Convention.

Done at....., the.....,
in English and French, both texts being equally authentic, in a single copy which shall be deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall transmit certified copies to each member State of the Council of Europe* and to any State invited to accede to this Convention.

*There may be provision for the European Economic Community to accede to the Convention.

EXISTING CONTROLS

General Prohibition

1. Section 2 of the 1876 Act prohibits the performance on a living animal of an experiment calculated to give pain except subject to the restrictions imposed by the Act.

Statutory Restrictions and Exceptions

2. These restrictions are of two kinds. Some are absolute. The remainder may be relaxed if certain certificates are submitted and not disallowed (see paragraphs 10-15 below). The absolute restrictions are as follows:

(i) the experiment must be performed with a view to the advancement by new discovery of physiological knowledge or of knowledge which will be useful for saving or prolonging life or alleviating suffering (section 3(1)) (but see also paragraph 3 below);

(ii) the experiment must be performed by a person holding a licence granted by the Secretary of State (section 3(2));

(iii) the experiment must not be performed for the purpose of attaining manual skill (section 3(6));

(iv) curare must not be used as an anaesthetic (section 4);

(v) experiments on living animals must not be exhibited to the general public, whether admitted on payment or free of charge (section 6).

3. The Act contains a proviso which permits the first of the above restrictions to be relaxed if a certificate is submitted to the effect that the experiment is absolutely necessary to test a former discovery (section 3, proviso (4)). However, it is doubtful whether the concept of a test in such circumstances as distinct from an experiment is valid: the purpose of such a test would be substantially the same as that of the original work. There is no record of certificates under this provision ever having been used.

4. The restrictions which may be relaxed are as follows:

(i) the animal must be under the influence of an anaesthetic strong enough to prevent its feeling pain throughout the experiment (section 3 (3)). This restriction is removed if a certificate is given to the effect that insensibility cannot be produced without necessarily frustrating the object of the experiment (section 3, proviso (2)). (A standard condition is however attached to all such licences prohibiting any operative procedure more severe than a simple inoculation or superficial venesection.) The restriction is modified by the certificate mentioned in (ii) below;

(ii) if pain is likely to continue after the effect of the anaesthetic has ceased, or if any serious injury has been inflicted, the animal must be killed before it recovers consciousness (section 3 (4)). This restriction

is relaxed if a certificate is given to the effect that its observance would necessarily frustrate the object of the experiment, provided the animal is killed as soon as that object has been attained (section 3, proviso (3)). (A standard condition is attached to every such licence imposing further restrictions on the performance of experiments authorised by such a certificate; the operative procedures must be performed under full anaesthetic and full antiseptic precautions must be taken);

(iii) no experiment may be performed as an illustration of lectures in medical schools, hospitals, colleges or elsewhere (section 3 (5)); unless a certificate is given that the proposed experiments are absolutely necessary for the purpose of instructing the persons to whom such lectures are given with a view to their acquiring physiological knowledge or knowledge which will be useful to them for saving or prolonging life or alleviating suffering (section 3, proviso (1)). (A standard condition requires that the animal must be painlessly killed at the end of the experiment);

(iv) no experiment may be performed without anaesthetics on a dog or cat unless a certificate is given that the object of the experiment will be necessarily frustrated unless performed on an animal similar in constitution and habits to a cat or dog and that no other animal is available (section 5);

(v) no experiment may be performed on any horse, ass or mule unless a certificate is given to the effect that the object of the experiment will be necessarily frustrated unless performed on a horse, ass or mule and that no other animal is available (section 5).

Licensing

5. The requirement for persons performing experiments to hold a licence (see para 2 (ii) above) is complemented by the power conferred on the Secretary of State to grant such licences (section 8). (This power is also conferred on a High Court judge in relation to any criminal case in which he is satisfied that it is in the interests of criminal justice to make such an experiment (section 12). It is believed that this judicial power has been used only twice, once before the turn of the century.) The power is discretionary but in exercising his discretion the Secretary of State is required to have regard to the qualifications of the applicant to perform experiments on living animals. The duration of the licence is also at the discretion of the Secretary of State and power is expressly given him to revoke a licence.

6. The Act gives the Secretary of State power to attach conditions to licences but this power is limited in certain general ways: the conditions must be such as the Secretary of State may think expedient for the purpose of the better carrying into effect the objects of the Act and must not be inconsistent with the provisions of the Act. Only one matter of substance is specified in the Act as the subject of a condition: namely, a provision that the place in which any experiment is to be performed is to be registered (section 7). (This specification is without prejudice to the generality of the power to impose conditions relating to other matters provided they satisfy the general purposes such conditions must serve.)

Registration of Premises

7. Section 7 of the Act enables the Secretary of State to include in a licence a condition restricting any experiment under the licence to a place registered in such manner as the Secretary of State may direct. The Act does not make it mandatory for such a condition to be imposed but it is the almost invariable practice to include such a condition in every licence.

8. It is however mandatory provision in section 7 of the Act that any place where experiments are performed for the purpose of instruction must be *approved* by the Secretary of State and registered.

9. There is power to issue general or special directions from time to time as to the manner of registration. If has not proved necessary to exercise this power.

Certification

10. As described in paragraph 4 above, the relaxation of those restrictions in the Act which are not absolute depends in each case on the giving of a certificate to the effect that the relaxation is necessary if the object of the experiment is not to be frustrated. The provisions relating to certificates are set out in section 11 of the Act. They must be signed by two senior scientists namely one of the following and one of the professors mentioned in paragraph 11 below:

The President of the Royal Society;

The President of the Royal Society of Edinburgh;

The President of the Royal Irish Academy;

The Presidents of the Royal College of Surgeons in London, Edinburgh or Dublin;

The Presidents of the Royal Colleges of Physicians in London, Edinburgh or Dublin;

The President of the General Medical Council;

The President of the Royal Faculty of Physicians and Surgeons, Glasgow;

The President of the Royal College of Veterinary Surgeons; or

The President of the Royal Veterinary College London (in respect only of experiments performed under anaesthetic and designed to advance by new discovery veterinary science).

11. In addition to signature by one of the Presidents the certificate must be signed by a professor of physiology, medicine, anatomy, medical jurisprudence, materia medica or surgery in a university in Great Britain or Ireland or in University College, London, or in any college in Great Britain or Ireland incorporated by Royal Charter. (The references to Ireland now relate only to Northern Ireland.)

12. A copy of the certificate must be forwarded to the Secretary of State and does not, under the Act itself, become effective until a week after having been so forwarded. In practice this control is further extended by one of the

standard conditions which provides that no certificate shall take effect until the applicant has been notified that he may proceed. This gives the Secretary of State the opportunity to consider whether or not to exercise the power conferred on him to disallow or suspend any certificate.

Inspection

13. Section 10 of the 1876 Act provides that:

> "The Secretary of State shall cause all registered places to be from time to time visited by inspectors for the purpose of securing a compliance with the provisions of this Act and the Secretary of State may. . .appoint any special inspectors. . .as he may think fit, either permanently or temporarily".

14. Although the Act speaks of the purpose of inspection as being the visiting of registered places to secure "a compliance with the provisions" of the Act, the functions of the present day Inspectorate extend more widely.

Annual Statistics

15. The Act gives the Secretary of State power to direct any person performing experiments under the Act to make reports on the results of such experiments. These reports must be in such form, with such details and at such times as may be required (section 9). Under this provision licensees are required to submit copies of all publications reporting the results of their experiments and in addition make an annual statistical return. The latter forms the basis of the Return of Statistics of Experiments on Living Animals which is made to Parliament every year and published.

Licences and Certificates

16. Applications for licences must be submitted by the applicant on the appropriate form direct to the Home Office. Certificates, on the other hand, are given by the statutory signatories and the appropriate form must therefore be submitted by the applicant in turn to both the President of the learned society in question and the professor in the appropriate discipline. Since the greatest numbers of scientists working on experimental animals tend to be concentrated in the larger establishments of research or pharmaceutical production, it is often the practice for their applications to be submitted by the head of a department on behalf of his junior staff.

17. If the documents are technically in order they are then examined by a member of the Cruelty to Animals Inspectorate who recommends whether or not the Secretary of State should issue a licence or allow the certificate of certificates. The inspector may also recommend that particular conditions be imposed.

18. In considering an application for a licence and the imposition of conditions the qualifications of the licensee, his experience and his competence for the work proposed are taken into account. The Act does not specify any minimum academic or scientific qualifications for the holder of a licence.

The inspectors base their recommendations on their personal assessments of the suitability of the applicant, having regard not only to the information included in the papers but also to their personal knowledge of an establishment and of the staff in a department, particularly its head—and, often, in the light of a personal interview with the applicant. If an inspector is in doubt as to whether a licence should be granted he may recommend that the case be submitted to the Advisory Committee (see paragraph 22 below).

The Pain Condition

19. The most important condition attached to a licence is known as the "pain condition". Work done under the authority of a licence without any certificate is subject to the requirements of the Act that the experiments must be performed under full anaesthesia throughout and the animal killed before recovering from the anaesthetic if pain is likely to be suffered after recovery or if any serious injury has been inflicted on the animal. But work under licence alone now accounts for only a small proportion of the total number of all animals experimented on each year. The great majority of experiments are performed under the additional authority of a certificate in which the animal is conscious for all or part of the time. Accordingly, the pain condition imposes on the licensee the obligation to kill the animal painlessly if at any time it is found to be suffering pain which is severe *or* likely to endure *and* the main object of the experiment has been achieved; or, if the animal is found to be suffering pain which is severe *and* likely to endure, it must be painlessly killed whether or not the main object of the experiment has been achieved. In addition the inspectors are given power to direct the painless killing of an animal if at any time it is found to be suffering considerable pain.

20. Additional special conditions are imposed whenever warranted. One such condition is designed for applicants with limited qualifications or competence; in such cases the inspector may recommend that the licence be granted subject to the general or direct supervision of a senior licensee in the applicant's laboratory. Other examples of special conditions are the exclusion of the eye from a general authority to administer substances or a requirement that the licensee should submit a special report after a certain amount of experimental work has been done.

Advisory Committee

21. The inspectors' recommendations are based on their professional knowledge and experience but in cases where an inspector has doubt of any kind as to the recommendation he should make, he may recommend that the case be submitted to the Home Secretary's Advisory Committee. The Advisory Committee was established in 1913 to advise on individual cases of special difficulty but in recent years it has considered some more general issues which have become controversial—namely the "smoking beagles" issue and the use of the "LD 50 test" which was the subject of a report published in 1979. In 1979 the Committee was reconstituted with wider terms of reference as "the Advisory Committee on Animal Experiments". It was formerly known as "the Advisory Committee on the Administration of the Cruelty to Animals Act 1876".

Inspection

22. There are a chief inspector, two superintending inspectors and twelve other inspectors based in London and outstations at Shrewsbury, Swindon, Harrogate and Cupar (Scotland). All inspectors have medical or veterinary qualifications.

23. In addition to advising the Secretary of State on applications for authority under the Act to do experimental work and on the suitability of premises to be registered for the performance of experiments the inspectors spend a large part of their time visiting registered places and ensuring that licensees observe the law and the conditions attached to their licences. Such visits may be announced or unannounced. Inspectors do not have a statutory right of entry to any registered place but there has been no recorded instance of an inspector's being refused admission to a laboratory. This is not surprising, for it would be a simple matter for the Secretary of State to take action against any laboratory refusing to co-operate with an inspector.

24. Each visit of inspection is reported in writing to the chief inspector and any matters requiring attention are referred to the appropriate staff for action. If a licensee is found to have exceeded the authority of his licence, he may, according to the seriousness of the matter, be given an informal or formal warning or the papers may be referred to the Director of Public Prosecutions who will advise whether or not the infringement is so serious as to warrant a prosecution. If conditions in a laboratory are found to be such as to prejudice the welfare of the animals under experiment there, a letter of warning can be sent to those responsible and, if conditions do not improve, the Home Secretary can remove the laboratory from the list of places at which licences are made available.

Printed in the UK for HMSO, Dd.901883, C4, 10/84, 5673, 4592.

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ISBN 0 10 188830 9