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Report of the ANIMAL PROCEDURES COMMITTEE FOR 1988

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Report of the Animal Procedures Committee for 1988

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PROFESSOR D G T WILLIAMS MA LLM *(Chairman)*

DR M BALLS MA DPhil

MR E BERNARD FIAT

MR J C BRICE MB BS FRCS

DR R W BRIMBLECOMBE PhD DSc FRCPath FIBiol

MR H CARTER MRCVS

DR C R COID PhD FRCVS FRCPath FIBiol

PROFESSOR A D DAYAN MD FRCP FRCPath FIBiol

PROFESSOR THE REVD CANON G R DUNSTAN MA DD LLD FSA

MR R EWBANK MVSc FIBiol MRCVS

MR T G FIELD-FISHER TD MA QC

DR J E HAMPSON BSc PhD

MR C HOLLANDS

SIR ANDREW HUXLEY OM FRS

PROFESSOR S M JENNETT MD PhD FRCP *(Glasg)*

DR J G G LEDINGHAM DM FRCP

DR B B NEWBOULD BPharm FPS PhD MCPP

PROFESSOR T R E PILKINGTON MD FRCP

PROFESSOR E J LAWSON SOULSBY MA PhD DVSM AM DSc MRCVS

PROFESSOR P H VENABLES BA PhD Hon DSc FBPsS

MR G H MARRIAGE *(Secretary)*

ANNUAL REPORT OF THE ANIMAL PROCEDURES COMMITTEE FOR 1988

Submitted to the Rt Hon Douglas Hurd CBE MP, Secretary of State for the Home Department, and the Department of Health and Social Services, Northern Ireland; July 1989.

1 Introduction

Origins of the Committee

1.1 The Animal Procedures Committee is a statutory body, appointed under sections 19 and 20 of the Animals (Scientific Procedures) Act 1986. It was established on 1 April 1987 and its first Annual Report (HC36) was published on 5 December 1988.

1.2 The Animals (Scientific Procedures) Act 1986 regulates 'any experimental or other scientific procedure applied to an animal which may have the effect of causing that animal pain, suffering, distress or lasting harm'. The Act came into effect on 1 January 1987 and its provisions are being progressively brought into force.

Composition of the Committee

1.3 Section 19 of the Act provides for the composition and appointment of the Committee. At least two thirds of the members, other than the Chairman, must be qualified medical practitioners or veterinary surgeons or qualified in a branch of biological science. There must be at least one member who is a barrister, solicitor, or advocate. The interests of animal welfare must also be represented in the membership of the Committee and at least half of the members other than the Chairman must be persons who neither hold, nor have held within the previous 6 years, a licence to carry out scientific procedures on animals. The minimum size of the Committee is a Chairman and at least 12 other members.

1.4 The membership of the Committee as at 31 December 1988 is shown on page iii. It remained unaltered throughout 1988 but five members reached their maximum period of appointment early in 1989. We should like to record our thanks to Mr Jason Brice, Dr Charles Coid, Mr Thomas Field-Fisher, Professor Gordon Dunstan and Professor Sheila Jennett for the valuable contributions they made to the work of the Committee and its predecessor, the Advisory Committee on Animal Experiments.

Functions of the Committee

1.5 Under section 21 of the Act, the duty of the Committee is to advise the Secretary of State on matters concerned with the Act and his functions under it. The Committee may itself select subjects for study and the Secretary of State may refer matters to the Committee for consideration.

Business of the Committee

1.6 The Committee met nine times during 1988, of which three were visits to establishments carrying out licensed work, as part of its review of psychological and behavioural research (4.13 below).

1.7 These are early days both for the Act, and for the Committee, so it is not surprising that visits by the Committee to establishments can be a source of concern. The purpose of the Committee's visits is simply to allow it to see at first hand certain kinds of scientific procedures, how these are carried out and the conditions in which the animals are housed. The Committee does not see its task as to second-guess the work of the Inspectorate in any way.

1.8 The Committee's concerns are the way the Act is being applied, so that its members are better informed and better placed to provide advice to the Secretary of State. The Committee has been very impressed by the care with which establishments have planned the visits which have been made and is grateful for the welcome which was extended to its members.

1.9 The Committee has also been gratified to note a number of positive changes which have been made at establishments which it has visited, particularly to the conditions in which animals are housed.

2 Operation of the Animals (Scientific Procedures) Act 1986

General Progress

2.1 The Committee has received regular reports on the progress of implementation of the new Act. During 1988, 7,194 personal licences, 2,095 project licences and 18 Certificates of Designation were issued under the Act in Great Britain. Of the project licences, 850 were assessed as being of mild severity; 1,069 were assessed as being of moderate severity; and 44 were assessed as being of substantial severity. 132 project licences, where the work was with terminally anaesthetised or decerebrate animals, were unclassified. In Northern Ireland, the number of personal licences issued was 60; project licences, 37; and Certificates of Designation, 2. Of the project licences, 14 were assessed as being mild; 18 moderate; 3 substantial; and 2 unclassified.

2.2 We can take this opportunity to correct the figures given in our Annual Report for 1987, where the total number of project licences were shown as 1279. The correct figure was 1293; of which 570 were assessed as mild; 629 as moderate; 23 substantial; and 71 unclassified.

2.3 There were in total 2,860 project licences, 16,509 personal licences and 375 designated places in Great Britain on 31 December 1988.

Requirements to issue Guidance and Codes of Practice

2.4 Under section 21(1) of the Act, the Secretary of State is required to publish guidance as to how he proposes to exercise his powers to grant licences and certificates under the Act and the conditions he proposes to include in such licences and certificates.

2.5 The principal document setting out these arrangements is the *Home Office Guidance on the Operation of the Animals (Scientific Procedures) Act 1986*, a draft of which was deposited in Parliament during the passage of the Act. This document formed the centrepiece of a package of information on the Act and the arrangements for its implementation. The Home Office issued it to all establishments carrying out licensed work in the autumn of 1986 so as to enable proper arrangements to be made prior to the coming into force of the new Act on 1 January 1987.

2.6 Much of the content of this document was concerned with the transitional arrangements under which the 1986 Act progressively replaced the provisions of the Cruelty to Animals Act 1876. This transitional period is now almost at an end. By 31 December 1988, all the 375 establishments carrying out licensed work had Certificates of Designation under the 1986 Act, and over 90% of scientific procedures were covered by project licences issued under the 1986 Act. The Home Office guidance notes can now, therefore, be revised and, it is currently expected that, following consultation with the Committee, revised notes for guidance will be laid before Parliament in the autumn of 1989.

2.7 Under section 21(2) of the Act, the Secretary of State is required to issue Codes of Practice for the care of protected animals and their use for regulated procedures.

2.8 In July 1987, and only six months after the Act had come into force, the Royal Society and the Universities Federation for Animal Welfare (UFAW) published the first of a series of guidelines on the care of laboratory animals and their use for scientific purposes. This covered the housing and care of laboratory animals. It was recognised from the start that this document could form the basis for a Code of Practice issued by the Secretary of State under the Act.

2.9 This Code of Practice was finalised during 1988 and laid before Parliament on 7 February 1989 (HC 107). The Committee was fully consulted by the Secretary of State in accordance with section 21(3) of the Act about this Code and took the opportunity to comment upon the changes which were necessary to convert the Royal Society/UFAW guidelines into a Code of Practice. It is confident that the Code will command widespread support.

2.10 The Committee considers that the publication of this *Code of Practice for the Housing and Care of Animals used in Scientific Procedures* is an important part of the framework for the implementation of the Act. The Code specifies in some detail the conditions under which the animals should be kept and the space requirements set out in the Code match up to, and in some cases exceed, the requirements of the European Community Directive of 24 November 1986 (Council Directive 86/809/EEC on the *Approximation of Laws, Regulations and Administrative Provisions of the Member States regarding the Protection of Animals used for Experimental and other Scientific Purposes*) and the European Convention for the *Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes*.

2.11 Under section 21 of the Act, the failure of any person to comply with any provision of the Code, while not of itself rendering that person liable to criminal civil proceedings, is admissible in evidence in any proceedings about an infringement. The Code has, therefore, a formal status under the Act in comparison to the voluntary Guidelines on which it was based.

2.12 The Committee is considering which further Codes might be issued under the Act in due course.

Statistics

2.13 Under section 21(7) of the Act, the Secretary of State is required to publish and lay before Parliament such information as he considers appropriate with respect to the use of protected animals in the previous year for experimental and other scientific purposes. These statistics were published for a long time under the Cruelty to Animals Act 1876.

2.14 One of the features of the 1986 Act is that it brings under its control a range of scientific procedures which were not hitherto controlled and it also extends to cover foetal, larval and embryonic forms of animals from certain stages of development. It is, therefore, not surprising that the overall recorded statistics for *scientific procedures* in the first year of operation of the Act (Cm 515) showed an increase by comparison with statistics for *experiments* for 1986 or preceding years but the underlying trend continued the welcome, steady reduction in the number of experiments over a number of years.

2.15 We were most impressed by the format and layout of the statistics for 1987 and the care taken to generate a set of statistics which was comparable with those which would have been produced under earlier legislation. We know of no other country in the world which produces such detailed statistics about experiments involving living animals and we welcome the development this year of certain novel cross tabulations alongside the customary tables.

3 Casework

3.1 In our Annual Report last year, we explained why certain types of project licence applications, e.g. for micro-surgery training; the testing or use of tobacco and tobacco products; and cosmetics testing; are examined by the Committee at the request of the Secretary of State, in recognition of the public controversy which such work can arouse. We described also our approach to the handling of such casework and the issues involved. This report describes how we applied and developed that approach during 1988.

Training in Micro-Surgery

3.2 During 1988, the Committee considered three applications for project licences to authorise the use of terminally anaesthetised rats in order to enable the training of qualified surgeons wishing to acquire or maintain skills in the techniques of micro-surgery. As we made clear in para 3.3 of our Report last year, before being allowed to perform any procedures on living animals, trainees must have demonstrated their competence through work with inanimate material or human tissue (generally placentae). All three applications conformed with the current Home Office guidance and were found acceptable.

3.3 In addition, the Secretary of State referred to the Committee for advice an application from a veterinary surgeon for a personal licence to attend an approved micro-surgery training course, as the exemption of micro-surgery from the ban on acquisition of manual skills (see para 4.18) had been made primarily with the benefit of human beings in mind. The Committee considered that there was no objection in principle to extending this benefit to animals and the licence was issued. The fact that our advice was sought on this and a wide range of other matters is welcome confirmation that the Secretary of State fully accepts the role of the Committee and its remit.

Tobacco

3.4 One project licence for work involving tobacco was referred to the Committee in 1988. This was for work intended to produce safer tobacco products.

3.5 The Committee feels that it cannot recommend the issue of a project licence under the Act for such work unless the benefits likely to accrue as a result of the programme of work clearly outweigh the likely adverse effect on the animals concerned.

3.6 A number of members of the Committee expressed the strong view that work involving tobacco products could not be justified on moral grounds, however good the science and the prospect of achieving the objective. In their view, so-called safer tobacco products only served to encourage people to use them, when the emphasis should be quite the reverse. There was no social benefit.

3.7 However, it is a difficult issue whether moral considerations of this kind fall unambiguously within the Committee's terms of reference and there is a moral argument for supporting research which might lead to safer products and, therefore, better health for the considerable number of people who continue to smoke despite the risks, as well as for passive smokers.

3.8 With the applicant's agreement, the application was referred to the Independent Scientific Committee on Smoking and Health (Froggatt Committee) of the Department of Health, which is looking into matters related to smoking and health, for background information and current thinking on the prospects for safer tobacco products. The Froggatt Committee's response was received early in 1989 and the application was subsequently withdrawn.

Cosmetics

3.9 In our 1987 report we set out fully the Committee's approach to consideration of applications for project licences for the testing of cosmetics. It is worth repeating that the definition of cosmetics is that adopted by the European Community in its Cosmetic Directive 76/786/EEC which was reproduced in Appendix V of our report last year. This goes much wider than purely decorative products like lipsticks and includes hygienic products like soaps, toothpastes and shampoos, as well as preparations to combat skin complaints and barrier creams to protect workers in industry.

3.10 All these products are used by many people every day and it is essential they are safe to use and safe to produce. Cosmetic products and their ingredients are commonly tested to demonstrate lack of toxicity under appropriate conditions. A need to examine new ingredients and formulations must be assessed in relation to national and international legal and regulatory requirements. The Committee concluded last year that, in the interests of safety, there should be no blanket ban on the testing of cosmetics or their ingredients. However, we recognise that weighing the balance of likely benefit against the adverse effects on the animals involved in such testing requires particular care because of the complex issues involved.

3.11 In 1988, we recommended the issue of four project licences on the same conditions as the two issued in 1987 and conforming with the Home Office Guidance. One of these conditions is that the establishments concerned should submit detailed information on the use of each procedure authorised, identifying separately toiletries and beauty preparations for each year. This information will enable the Committee to carry out a thorough review of the subject in due course so as to be in a better position to advise the Secretary of State about the continuation of such work. The first such report will be received by the Committee during 1989.

Project Licence Application For Postgraduate Education in Mammalian Physiology

3.12 The Secretary of State sought the Committee's advice on a project licence application for the education of post-graduates in mammalian physiology which had as its objective the reversal of the decline in undergraduate teaching in systems physiology. The application had been referred to an independent assessor who expressed the opinion that the project was justified both in terms of that objective and the use of dogs for the purpose.

3.13 The Committee noted that many students of physiology do not handle animals as part of their courses and that there was a serious lack of this kind of teaching. Although there was some concern about the proposed use of terminally anaesthetised dogs, the Committee recognised that much physiological knowledge had been derived from them and that the applicants were known to be experienced in handling dogs. The educational objectives of the course were accepted as valid and did not breach the Home Secretary's policy of prohibiting such work when the aim was to acquire manual skills. The Committee therefore concluded that the issue of this project licence was justified and recommended accordingly.

4 Other Work of the Committee

Research to Reduce, Refine or Replace Animal Procedures

4.1 We described in paragraphs 4.4 and 4.5 of our report for 1987 the arrangements we had put in hand to establish a Research Sub-Committee to help us to advise the Home Secretary, at his invitation, on the priorities for research and to assist him in evaluating proposals.

4.2 The Research Sub-Committee was formed under the Chairmanship of Dr John Ledingham, with Dr Charles Coid, Mr Clive Hollands and Sir Andrew Huxley as members. An Inspector acted as adviser and the Home Office provided the Secretariat.

4.3 The Sub-Committee met eight times between 1 October 1987 and 31 December 1988. The first four meetings were devoted to drawing up simple and workable arrangements for handling proposals for research and drafting the terms of the advertisement inviting applications. These were agreed by the main Committee and the terms of the advertisement are reproduced as an appendix. The subsequent meetings were held to consider the applications which were received, to decide which ones to refer to external assessors and, in the light of the assessors' comments, to recommend which applications should be supported and rank them in order of priority.

4.4 124 applications were received. 23 were selected for referral to independent expert assessors; ten reached the final shortlist on the basis of the assessor's report; eight were recommended for funding; and four are being funded.

4.5 The applications were grouped under eight general headings as follows:

Theme	*Number of Applications*	*Referred to Assessors*	*Number Funded*
Topical and other toxicity or toxicological work	18	3	1
Focussed alternatives to regulatory tests, including Draize eye test, pyrogens and vaccines	14	10	3
Education, databanks and computing	13	2	0
Pain assessment and use of analgesics	12	3	0
The housing of animals	11	3	0
Metabolism, liver cells, enzymes and hepatotoxicity	8	0	0
Antibodies: their production and clinical use	5	5	0
Miscellaneous	43	2	0

4.6 In addition all five of the projects on the production and clinical use of antibodies have been referred to an expert assessor with the request that he provides position reports on this subject. Only then will the Sub-Committee consider whether to fund any of these research applications.

4.7 The selection criteria applied by the Sub-Committee were as follows:

Proposals must clearly address the objectives of the scheme and offer real prospects of benefit to laboratory animals, i.e. contribute significantly and readily to the ***reduction, refinement*** *or* ***replacement*** *of the use of living animals and be relevant to a recognised area of concern.*

These criteria have to be satisfied before consideration is given to the scientific merit of the proposal, i.e. the quality of the proposal, including the reliability of the methodology and the prospect of results within a reasonable time; and the standing of the applicant.

Only proposals which satisfy all the criteria are referred to independent expert assessors for further evaluation. Final decisions are based on the assessors' reports and relevance to areas of concern.

4.8 The application of these criteria produced the result set out below and as announced in a Parliamentary Question for Written Answer on Monday 6 March in reply to Mr Robin Corbett MP (Col 383).

Dr P A Botham & Dr G J A Oliver, ICI Central Toxicology Laboratory 'Validation of the enucleated eye model'.

Dr A F Bristow & Dr S Poole, National Institute for Biological Standards and Control 'Assay of pyrogens measuring lymphokine production in vitro'.

Dr A Robinson, Public Health Laboratory Service 'Alternative potency tests for cellular pertussis'.

Dr R M Stagg, now at Department of Agriculture and Fisheries, Scotland 'Fish cell culture for toxicity assessment'.

Funding of Research

4.9 The total funds available to support the work recommended by the Research Sub-Committee were £60,000 and, in the event, £70,000 was allocated in grants. There was additional expenditure of about £8,000 as the result of assessors' fees, advertising, commissioning an investigation into antibody production as well as supporting international work on acute toxicity testing aimed at further reducing the need for formal LD50 or LC50 tests.

4.10 The Committee was pleased to be able to start its work in supporting research into alternatives and the reduction of animal use and suffering in experimental and scientific procedures. But it has been greatly disappointed by the funds which have been made available for this purpose.

4.11 During the passage of the Act, although the Government made it clear that they did not see the Home Office as becoming a major research funder, we had gained the impression that the Government saw research into **reduction, refinement** and **replacement** as an important component of the work of the Animal Procedures Committee. Viewed in this light, the £60,000 available for 1988/89 and even the £120,000 potentially available for 1989/1990 are, in our view, inadequate in relation to the objectives of the scheme and represent a disappointing return for all the work in assessing and evaluating the research applications which we received. We therefore remain of the view that the Government should seek to make a much more substantial sum available for this purpose.

Future Work

4.12 The Research Sub-Committee is awaiting advice, which is hoped will become available early in 1989, on the prospects of commissioned research, possibly in the areas of pain recognition and relief; antibody production and use; and the production and testing of vaccines.

Review of Psychological and Behavioural Research

4.13 In Paragraphs 4.1 to 4.3 of our previous report, we described the background to the Committee's consideration of the subject of the deliberate induction of stress in psychological and behavioural research. During 1988, we made further visits to three establishments where psychological or behavioural research is carried out. At the time of preparing this report, the Committee was reviewing what further enquiries, if any, it needed to make before offering advice to the Secretary of State.

Non-Human Primates

4.14 The Committee's report for 1987 contained a detailed account (paras 4.6 to 4.8) of the consideration which we had given to the special needs of non-human primates and of the procedures which had been agreed for the Committee to be able to monitor their use in regulated procedures.

4.15 In accordance with these procedures we were notified of a project licence application for work of substantial severity involving non-human primates to investigate the value of new treatments in preventing graft rejection following organ transplant.

4.16 The application was referred to an expert assessor for an opinion, in particular because the licence contained a requirement for a bilateral nephrectomy (removal of both kidneys). The Committee recommended the granting of this licence, subject to certain modifications to take account of the concerns expressed by the Committee and the points raised by the assessor (who confirmed that bilateral nephrectomy was essential), and with a special condition for the licensee to report progress at certain stages of the programme of work.

4.17 The Committee has on a number of occasions expressed concern about the design and sizes of cages and the environment in which non-human primates are kept. We are pleased to report that the Inspectorate conducted a survey of primate accommodation towards the end of 1988. This will provide a base line against which to measure progress towards the standards set out in the new Code of Practice within a realistic, but not too extended, timescale. The Committee will take a close interest in the progress that is made on this.

Use of Animals to Obtain Manual Skills

4.18 In our last Annual Report, we mentioned that, in view of the potential benefit to animals, it might be worthwhile exploring the possibility of slightly relaxing the restriction on the use of living animals for the acquisition of basic manual skills to facilitate systematic training courses for laboratory technicians and others who may carry out procedures on living animals under the Act. We are seeking the views of interested bodies and whether there is any evidence that the absence of "hands on" training is harmful to animals and leads to increased suffering and unnecessary use of animals due to a lack of practical experience in the proper performance of routine procedures. The Inspectorate is also giving the matter further consideration. We will report any developments in a future Annual Report.

Use of Animals in Schools

4.19 For reasons which were outside the Committee's control, there was a long delay before the Department of Education and Science's memorandum to schools mentioned in para 4.12 of our previous report, was issued as *Administrative Memorandum 1/89: Animals and Plants in Schools: Legal Aspects* on 9 February 1989. This promulgated the Secretary of State's policy not to permit regulated procedures in schools. The Committee had sight of the final draft memorandum late in the year and, following its representations, certain changes were effected.

Joint Meeting with the Farm Animal Welfare Council (FAWC)

4.20 On 5 May 1988, a joint meeting was held with the Farm Animal Welfare Council, which was represented by members of its Research and Development Group.

4.21 The two Committees have a number of shared concerns and interests, like the extent and nature of controls which are exercised over transgenic breeding and the borderline between work subject to the Animals (Scientific Procedures) Act 1986 and that which is classified as recognised veterinary, agricultural or animal husbandry practice and is therefore exempt from the Act by virtue of section 2(8). We agreed that there was a need for the two committees to keep closely in touch and exchange information on matters of mutual interest, especially when the Committee considers work under the Act for agricultural purposes. In due course, the Committee will consider a paper setting out the agricultural work which is covered by the Act, and that which is not, although it is recognised that it is not a clear-cut line, especially in animal husbandry.

4.22 As far as the Act is concerned, the fundamental test is the aim of the procedure; if it is for an experimental or other scientific purpose it needs to be licensed. The difficult issue to decide is when such a procedure is no longer considered experimental and has become a recognised veterinary, agricultural or husbandry practice. It is particularly topical in the case of transgenic animals. The Home Office view, which we fully support, is that where there is still doubt, the animals should remain under the protection of, and the procedures should be controlled by, the Act. However, there are certain legal and ethical questions which require further consideration.

4.23 Professor John Webster has been nominated to represent FAWC, when necessary, at discussions in the Animal Procedures Committee. One member of the Committee, Mr Clive Hollands, is also a member of FAWC.

Confidentiality of Test Data

4.24 The Committee considered a law report in The Times of 2 January 1988 on the case of Regina v Licensing Authority, *ex parte* Smith Kline & French Laboratories Ltd about the confidentiality of test data on pharmaceutical products. We were initially concerned about the implications of the judgement which could lead to more animal tests than might otherwise be necessary. It was agreed that the Committee's concern should be made known to the Department of Health and the Ministry of Agriculture, Fisheries and Food, pending an appeal. We were notified later in the year that the appeals to the Court of Appeal and the House of Lords subsequently failed. The Committee will be looking at the implications of these judgements.

5 Forward Look

5.1 This report covers only the second year since the Animal Procedures Committee succeeded the Advisory Committee on Animal Experiments. It has been a busy period during which we have built on, and developed, some of the work set out in our first report. We have taken further close interest in the continued progress towards implementation of the new system of controls introduced by the Act. The Inspectorate is expert in regulating the work of licensees and ensuring that scientific procedures are carried out with minimum suffering and that animals involved in scientific procedures are properly housed and cared for.

5.2 Although the provisions of the Act began to come into force in 1987, the changeover to the new and full controls of project licensing was not complete until the early part of 1989. It is gratifying that the transition from the Cruelty to Animals Act 1876 was completed according to schedule and that the new, more rigorous, system of controls is now in place. There remains only the designation and control of establishments which breed and supply animals for use in scientific procedures and this is expected to be done by January 1990. The full impact of the new Act has, therefore, yet to be felt.

5.3 In 1989, we look forward to being consulted on the arrangements for bringing into force, from 1 January 1990, the provisions under section 7 of the Act for designating establishments which breed and supply the most common species of laboratory animals; to being consulted on the revision of the draft Home Office Guidance on the Operation of the Act which will be laid before Parliament; to the effect of the introduction of the Code of Practice on the Housing and Care of Animals used in Scientific Procedures; and to supporting further research to reduce the use and severity of use of animals involved in scientific procedures.

5.4 Research and testing involving living animals have long raised difficult issues of both a moral and a practical kind. In the Animals (Scientific Procedures) Act 1986, this country has an up-to-date and sound legislative framework for regulating and controlling all scientific procedures involving living animals. The Committee is conscious of its responsibility for advising the Home Secretary, and contributing towards the continuing debate about how animal procedures should be controlled and regulated.

Appendix

Advertisement for research applications (see para 4.3).

ANIMALS (SCIENTIFIC PROCEDURES) ACT 1986

Research to reduce the number and severity of experiments on living animals

Suitably qualified persons or groups working in the UK are invited to apply for Home Office grants to support research which could lead to the reduction, refinement or replacement of the use of living animals for experimental or other scientific purposes. The sum of £100,000 has been allocated for this purpose in the first year and grants may be awarded for periods up to 3 years.

The Home Secretary has asked the Animal Procedures Committee to advise him on the priorities for such research and to assist him in the evaluation of proposals.

Areas which might attract support include the validation and acceptance of in vitro techniques, housing of laboratory animals, pain recognition and relief, and the refinement of tests so as to require fewer animals and/or less severe procedures.

In addition to examination by the Animal Procedures Committee, all the acceptable proposals will be subject to evaluation by independent expert assessors, who will also assist in monitoring the progress of work which is supported.

Application forms and further details may be obtained from the Home Office, E Division, 50 Queen Anne's Gate, London SW1H 9AT.

Completed applications on this occasion must be received in the Home Office by 21st April 1988. Funds permitting, further applications may be invited in 6 months time.

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