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Report of the Animal Procedures Committee for 1987

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ANNUAL REPORT OF THE ANIMAL PROCEDURES COMMITTEE FOR 1987

Submitted to the Rt Hon Douglas Hurd MP, Secretary of State for the Home Department, and the Department of Health and Social Services, Northern Ireland; November 1988.

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MR J C BRICE MB BS FRCS
DR R W BRIMBLECOMBE PhD DSc FRCPath
MR H CARTER MRCVS
DR C R COID PhD FRCVS FRCPath FIBiol
PROFESSOR A D DAYAN BSc MB BS MD FRCPath FIBiol FRCP
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MR A G THOMSON *Secretary*

MEMBERSHIP OF THE ADVISORY COMMITTEE ON ANIMAL EXPERIMENTS AS AT 1 JANUARY 1987

PROFESSOR D G T WILLIAMS MA LLM *Chairman*
DR M BALLS MA DPhil
PROFESSOR D E BLACKMAN BA PhD FBPsS
MR J C BRICE MB BS FRCS
DR C R COID PhD FRCVS FRCPath FIBiol
PROFESSOR A D DAYAN MD MB BSc MRCP FRCPath
PROFESSOR THE REVD CANON G R DUNSTAN MA DD LLD FSA
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 PhD MD
DR J G G LEDINGHAM DM FRCP
DR B B Newbould BPharm FPS PhD MCPP
MR N SNODGRASS CBE BSc MRCVS

1 Introduction

Origins of the Committee

1.1. The Animal Procedures Committee was established on 1 April 1987. The Committee is a statutory body, appointed under the Animals (Scientific Procedures) Act 1986, sections 19 and 20 (reproduced at Appendix 1).

1.2. The 1986 Act makes new provision for the protection of animals used for experimental or other scientific purposes. It replaced and repealed the controls over experiments on animals contained in the Cruelty to Animals Act 1876.

1.3. A summary of the provisions of the 1986 Act, and the main changes for the system of control under the 1876 Act, is provided at Appendix 2.

1.4. Although the 1876 Act made no provision for an advisory committee, a committee of this sort had existed since 1913 following a Royal Commission, which between 1906 and 1912 reviewed the administration of controls over animals experiments under the 1876 Act, and recommended, *inter alia*, that independent advisers should be appointed to assist the Secretary of State in his responsibilities of licensing such experimentation. In 1980, that committee was reconstituted and renamed the Advisory Committee on Animal Experiments.

1.5. Experimentation on living animals has always provoked controversy. The existence of controls over such experiments, under the Cruelty to Animals Act 1876, did not prevent such controversy continuing. As well as pressure for such activities to be prohibited altogether, there was continuing pressure for changes to the system of controls. In 1981 the Advisory Committee on Animal Experiments reported to the Secretary of State on the framework of legislation which might replace the 1876 Act. In that report the committee recommended that any such new legislation to control animal experiments should make provision for the establishment of a statutory advisory committee. This proposal was incorporated in the Government's proposals for legislation (Cmnd 8883, May 1983 and Cmnd 9521, May 1985), and the Animals (Scientific Procedures) Act 1986 accordingly established the Animal Procedures Committee.

Composition of the Committee

1.6. Section 19 of the 1986 Act provides for the composition and appointment of the Committee. Certain minimum requirements must be fulfilled. 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 adequately 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 experiments on animals. The minimum size of the Committee is a Chairman and at least 12 other members.

Appointment of the Committee

1.7. It is appointed jointly by the Home Secretary (who is responsible for the administration of the Act in Great Britain) and the Department of Health and Social Services in Northern Ireland.

Functions of the Committee

1.8. Section 20 of the Act provides that the function 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 also refer matters to the Committee for consideration.

1.9. The central principle of the Act is that, since for the foreseeable future experiments on living animals will be necessary in order to promote and secure the well-being of the community and animals and to allow the development of medical and scientific knowledge, there must be rigorous controls to ensure that only work which is necessary and justified is allowed. To achieve this the Act requires any programme of work to be authorised through the project licence, and requires the Secretary of State to weigh the possible suffering of any animals which might be used in a programme of work against the benefits likely to accrue.

1.10. This concept of balance is reflected in the statutory provisions establishing the Committee. These require that in considering any matter the Committee must "have regard both to the legitimate requirements of science and industry and to the protection of animals against avoidable suffering and unnecessary use in scientific procedures". This has set the broad framework for the Committee's approach to its activities.

Initial approach of the Committee

1.11. Within this broad framework, the Committee's approach to its task has been governed by the following considerations:-

(i) we are conscious of the importance of ensuring that the system of control under the 1986 Act achieves and retains credibility. It must be seen both by researchers and by the general public as enabling the desired balance to be achieved between the needs of experimental animals and the needs of science, medicine and industry;

(ii) the first years of implementation of the new Act are in many ways the most crucial. All existing work is being reviewed against the standards required for licensing under the new Act and areas of work not hitherto requiring a licence but requiring to be licensed under the new Act are being brought into the licensing system. A very considerable volume of work is involved, for the Inspectorate and for the Home Office and a number of precedents of policy and of principle have of necessity to be set. The early years of operation of the new Act are therefore likely greatly to influence its manner of operation for many years to come. The Advisory Committee on Animal Experiments was fully consulted and involved in the consultations leading to the introduction of the Act, during its passage through Parliament and in the period immediately following Royal Assent as preparations were made for the implementation of the Act when it came into force on 1 January 1987. The Advisory Committee was consulted both on the principles of the new system of control as now enshrined in the Act and also on the more detailed issues of implementation of the Act. As mentioned above, we attached, and attach, considerable importance to the first years of operation of the new Act. The Home Office fully shares that view. We have therefore continued the practice established by the Advisory Committee of taking a

detailed and we hope constructive interest in the process of implementation of the new Act. We have received regular reports on the general progress of the phased implementation programme, have commented at the draft stage on a variety of documents relating to the detailed operation of the new licensing system and have made suggestions as to the conduct of particular aspects of the new system of controls;

(iii) the major change incorporated in the new system of control is the separation of assessment of the competence of individuals to carry out particular procedures and the assessment of the value of proposals for projects of work. These are separately licensed by personal licences and project licences. The system prevailing under the previous legislation ensured assessment of the competence of individuals but provided much less information about the work being carried out, its objectives and justification. We have therefore viewed the project licensing system, and particularly the weighing of animal suffering and likely benefit which is an integral part of it, as being of the utmost importance. As an essential part of this we have paid particular regard to the *reduction* in the number of animals used in projects, the *refinement* of experimental techniques so as to minimise animal suffering and the *replacement* of the use of animals by other methods of achieving the same ends;

(iv) the assessment of licence applications by the Home Secretary is very heavily dependent upon the work of the Animals (Scientific Procedures) Inspectorate. They inspect establishments where licensed work is carried out, often making unannounced visits, and make recommendations to the Secretary of State concerning licence and certificate applications. Recognising this central and crucial role of the Inspectorate, we have paid close attention to the resources provided for the Inspectorate;

(v) linked with this we have given attention to the complementary roles of the Inspectorate and the Committee as separate sources of advice to the Secretary of State. As the Advisory Committee on Animal Experiments did before us, we have been greatly assisted by the skilled advice the Inspectorate have provided for us on a wide range of matters, and have benefited from the presence of the Chief Inspector and Superintending Inspectors at our meetings. (In December 1987 the Committee and the Inspectorate held a joint meeting, which did much to foster these important links).

1.12. The Committee met six times during 1987 (and in addition, the Advisory Committee on Animal Experiments met twice during the year, in January and in March). The Committee also made two visits to establishments carrying out licensed work, as part of its consideration of the project licensing of cosmetics testing (paragraph 3.6 below).

2 Implementation of the Animals (Scientific Procedures) Act 1986

General Progress

2.1. The Committee has received regular reports on the general progress of implementation of the new Act. During 1987, 6782 personal licences, 1278 project licences and 372 certificates of designation were issued under the Act in Great Britain. Of the project licences, 611 were in the mild severity category, 643 in the moderate category and 24 in the substantial category. In Northern Ireland, the number of personal licences was 337; project licences, 36; certificates of designation 11 and the severity bands of project licences issued were 6 mild, 28 moderate and 2 substantial.

Statutory requirements to issue guidance, codes of practice and statistics (Section 21 of the 1986 Act)

(a) *Guidance*

2.2. The 1986 Act provides only the statutory framework for a new system of controlling experiments on living animals. Of necessity the very great variety of detailed specific requirements necessary for a properly constructed licensing system were not set out in the legislation. The Secretary of State is responsible for the detailed arrangements, within the statutory framework.

2.3. Section 21(1) of the Act requires him to publish guidance as to how he proposes to exercise his power to grant licences and certificates under the Act and the conditions he proposes to include in such licenses and certificates.

2.4. The principal document setting out these arrangements is the *Home Office guidance note on the operation of the Animals (Scientific Procedures) Act 1986*, a draft of which was deposited in Parliament during the passage of the Act and which was the centrepiece of a package of information on the new Act and the arrangements for its implementation which the Home Office issued to all establishments carrying out licensed work in the autumn of 1986 so as to enable them to make proper arrangements, and where necessary to obtain the appropriate licences, prior to the coming into force of the new Act on 1 January 1987.

2.5. This is now being revised in the light of the experience of the first period of operation of the new Act so that it can be laid before Parliament in accordance with section 21(1) of the Act. The Advisory Committee on Animal Experiments was able to comment on this document at the early drafting stage and the Committee will in due course comment upon the revised version before it is laid in Parliament.

(b) *Codes of practice*

2.6. A statutory requirement contained in section 21(2) of the 1986 Act is that a code or codes of practices shall be issued by the Secretary of State as to the care of protected animals and their use for regulated procedures.

2.7. At the time of the passage of the 1986 Act a joint working party of the Royal Society and the Universities Federation for Animal Welfare (UFAW) had been

preparing guidelines on the care of laboratory animals used for scientific purposes. These guidelines — part of a much larger series covering a range of aspects of the use of experimental animals — were made public in July 1987. Because these sections of the guidelines cover much, though not all, of the likely subject matter for such a code of practice there has been close liaison (and some common membership) between the Home Office, the Advisory Committee, this Committee and the Royal Society/UFAW steering group during the preparation of the guidelines.

2.8. The Secretary of State is currently giving consideration to the adoption of a code of practice, to meet the statutory requirements, based upon the Royal Society/UFAW guidelines. The Committee will continue to be fully involved in the development of this subject, and will propose such changes as it considers necessary in the draft code of practice. Sections 2 and 3 of the Royal Society/UFAW guidelines do not directly deal with the subject of the control of pain and suffering. The Royal Society and UFAW intend however to cover this subject also and we are grateful to them for agreeing that this section of their guidelines will also be seen by the Committee in draft.

(c) *Statistics*

2.9. Section 21(7) of the 1986 Act requires the Secretary of State 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. Such statistics were published as to the use of animals under the 1876 Act.

2.10. The new Act brings under control a range of scientific and experimental procedures not hitherto controlled and extends protection to the fetal, larval and embryonic forms of animals from certain stages of development. Because of this, and because of a number of more detailed changes, it is likely that the recorded statistics for experiments under the new Act will for the first year show an increase by comparison with the statistics for 1986 or preceding years. We believe that it is most important that this phenomenon be properly and fully explained in the publication of the annual statistics for 1987 and we understand that the Home Office is making considerable efforts to achieve this as well as to improve the layout and extent of the information given in the statistical table, for example by giving a much more detailed breakdown of work involving non-human primates (see para. 4.6).

Other Guidance

(a) *Draize eye irritancy test*

2.11. The former Advisory Committee was fully consulted on guidance which the Secretary of State issued in February 1987 on the Draize eye irritancy test. A copy of the guidelines is at Appendix 3.

2.12. The eye is a most important and sensitive organ and it is therefore important that those who may be exposed to substances — whether in the home or at work — should not thereby incur the risk of eye damage. This requires that the possible irritant and corrosive affects of substances which may be encountered should be properly and rigorously assessed. Only by this means can harmful substances be identified, and appropriate labelling and other safety measures put into the effect where necessary.

2.13. The Draize test is an internationally recognised test for assessing the possible irritancy or corrosive effects of substances on the eye but has long been the subject of criticism and concern.

2.14. The aim of the guidelines on the conduct of the test is to ensure that

currently recognised best practice on the minimisation of any suffering involved in the conduct of this test be adopted by all those performing the test in this country, without sacrificing the acceptability of the results of such tests to other additional regulatory authorities.

2.15. In its consideration of the guidelines in draft the Advisory Committee gave careful consideration to the question of *in vitro* alternatives to the use of living animals for irritancy and corrosion testing. A number of such alternatives are in existence but none of them appeared to enable the use of living animals *to be avoided altogether* at least for the present.

2.16. The guidelines emphasise however ways in which the use of living animals can be minimised, by careful preliminary screening using *in vitro* methods and the use of a single animal where appropriate in preliminary *in vivo* testing.

2.17. These guidelines have been issued to licensees carrying out or proposing to carry out such work since February 1987.

2.18. The Committee considers that for so long as the use of living animals for eye testing remains a necessity, the guidelines on the conduct of such testing should ensure that the number of animals used for such testing, and the degree of any suffering involved, is kept to the minimum. But we shall keep the matter under review.

(b) *Neuromuscular blocking agents*

2.19. Neuromuscular blocking agents cause paralysis of voluntary muscles. An animal given such agents can be fully conscious and able to experience pain yet unable to move or indicate in some other way that it is experiencing pain. The 1986 Act prohibits the use of such agents as a substitute for an anaesthetic and requires that their use should be specifically authorised by the personal and project licences under which any such work is carried out. Because of the potential for animal suffering which could arise from any misuse of these agents, the Secretary of State has issued detailed guidelines on the circumstances in which the agents may be used and the precautions, for example for the maintenance of anaesthesia where involved, which must be taken by all licensees using the agents. The Animal Procedures Committee was actively involved in the preparation of these guidelines, a copy of which is at Appendix 4.

The role of the 'named veterinary surgeon'

2.20. In considering the implementation of the new Act the Committee examined the role of any named veterinary surgeon who also has responsibilities or connection with projects of work at the establishment for which he is the named veterinary surgeon.

2.21. The position of the named veterinary surgeon, together with that of the named person responsible for the day-to-day care of protected animals, are new features of the system of controls introduced by the Animals (Scientific Procedures) Act 1986. The system of controls places specific responsibilities for the welfare of animals on individual personal licensees and project licence holders, but the named veterinary surgeon and the named person responsible for day-to-day care are intended to provide further safeguards for the welfare of animals, with the ability to act independently to ensure the welfare of any animal at the establishment where they are appointed.

2.22. In the view of the Committee a named veterinary surgeon who was also a project licence holder at an establishment or a named veterinary surgeon who had a substantial interest, say as a personal licence holder, in the outcome of a particular project of work at his establishment might face a conflict of interest. To

guard against this we recommended that a named veterinary surgeon should not normally be able to act as such in respect of animals used under his project licence and that a named veterinary surgeon who has substantial interest in the outcome of a project of work at the establishment should seek a second opinion on matters relating to the welfare of animals under the project in question. We are pleased that the Secretary of State accepted this recommendation and that guidance to this effect was issued to establishments.

3 Casework

3.1. During the passage of the Act the Government took the view, with which the Advisory Committee on Animal Experiments agreed, that the new Act should not impose a blanket prohibition on any particular type of work but rather should seek rigorously to control all experimental and scientific work involving living animals, each proposal being considered on its merits.

3.2. The Home Secretary nevertheless said that he would, for the foreseeable future, refer to the Animal Procedures Committee for advice all applications for project licences involving the following areas of work: training in the use of microsurgery, the testing of tobacco or tobacco products, and the testing of cosmetics including toiletry or perfumeries. This was in recognition of the particular controversy such work arouses; in the case of cosmetics and tobacco products because the nature of the product is not fully accepted by public opinion as sufficiently important to warrant the sacrifice of animal life in production or safety testing; and in the case of microsurgery techniques, because any use of animals for the acquisition of a manual skill had previously been prohibited under the Cruelty to Animals Act 1876 controls. The Committee attaches considerable importance to this area of its work and has been at pains to submit all such applications submitted to rigorous examination. In many of the applications for project licences which the Committee has considered it has recommended, and the Secretary of State has adopted, substantial modifications to the programme of work as described before the applicant has been authorised to proceed. These modifications have established precedents which have gone considerably wider than the particular procedures the applicants wished to undertake.

Training in microsurgery

3.3. During the period of this report the Committee has considered a number of applications for project licences to authorise the use of animals in order to enable the training of qualified surgeons wishing to acquire or maintain skills in the techniques of microsurgery. These applications have been of a high quality. It was quickly recognised that there were a number of common features of concern to the Committee and to the Home Office which needed to be covered in such applications. For example, the Committee is particularly concerned to ensure that there is normally a structured scheme of training . Such a scheme takes the student through the use of non-living material, instruction through video recordings etc., then of isolated tissues or cadavers; and only once proficiency had been demonstrated in the context of non-living material, progressing to the performance of procedures on anaesthetised rodents which are not allowed to recover consciousness. Home Office advice on these and other points of importance has been incorporated in a guidance note now issued to all those applying for project licences to authorise microsurgery training schemes, and this was scrutinised by the Committee in draft.

3.4. The Committee recognises that allowing the use of animals for the acquisition of skills in microsurgery is a development which has caused some concern. We have looked into the possibility of avoiding the use of living animals altogether for this work but we are satisfied that at present there are training needs in this important medical technique which cannot be met by the use of non-living materials and other non-animal techniques.

Tobacco

3.5. The Committee had not, during the period of this report, had referred to it any project licence application for work involving tobacco or tobacco products. (Its predecessor, the Advisory Committee, earlier in 1987 recommended approval of one project, for the exposure of breeding rats to cigarette smoke to obtain information about possible damage caused to the nervous systems of offspring *in utero* after requiring considerable modification to the experimental design). But, at the time of writing the Committee has had referred to it a project licence application for such work and the outcome of our consideration of the application and the general issue relating to the use of living animals for such work will be reported fully in the annual report for 1988.

Cosmetics

3.6. The Committee has spent a considerable amount of time on consideration of applications for project licences for the testing of cosmetics. The Committee visited two establishments where such work is carried out. Both establishments went to very considerable trouble to make our visits as informative and effective as possible and we should like to place on record our thanks for the considerable assistance which they gave us, not only in relation to matters relevant to their own application for a project licence but also for the extremely valuable information given to us on the general subject of cosmetics testing and the search for *in vitro* alternatives to the use of animals for this work.

3.7. We considered and recommended to the Secretary of State that he should grant two project licences for the testing of cosmetics. Further applications have been received and are being considered during the year 1988.

3.8. An important point of difficulty which emerged early on in the Committee's consideration of this subject relates to the definition of "cosmetics". The working definition is that given by the European Community, which is set out in Appendix 5 to this report. It is immediately apparent that whilst the term in popular use is normally assumed to signify beauty preparations such as lipstick etc. and perhaps perfumery, it in fact goes much wider and includes hygienic products like toothpastes and anti-dandruff shampoos which directly affect the health and welfare as well as the appearance of the individual, and protective products in industrial use such as barrier creams. A distinction also has to be drawn between the testing of the complete product, and the testing of individual ingredients used.

3.9. The term cosmetics, and the range of substances tested, thus extends much wider than substances for optional adornment with the corresponding difficulty, when trying to assess the merits of work on such products involving the use of living animals, in assessing the value of the products to be set against the suffering or use of animals. Cosmetics substances of *any* sort are applied to particularly sensitive areas of the body — the face, teeth etc. — and thus there is a particular requirement on manufacturers to ensure that such products are safe for use, use which may extend over many years on a daily basis. At least two members of the Committee are of the opinion that in no circumstances can the use of living animals to test any cosmetics product or ingredient for use in a cosmetic — whether for optional adornment or for toiletries or hygiene — be justified even if the procedures involved are only mild. The Committee as a whole however, whilst recognising the reasons for such an opinion, did not consider that the Secretary of State should be recommended not to grant project licences for such work.

3.10. However, the Committee recognises that the balance of likely benefit and likely cost in animal suffering for work involved in such products requires particularly careful scrutiny. We have therefore in each application considered paid particular attention to the detailed description of the conduct of the

individual tests described and the severity band for each test; we have looked closely for evidence that serious consideration has been given to the use of *in vitro* alternatives and a decision to use living animals for testing been made only where these are unavailable; and we have paid particular attention to the numbers and types of animals to be used and the use of single or small numbers of animals for initial screening tests to avoid the possibility of exposing large numbers of animals to any considerable degree of suffering.

3.11 Our visits to establishments carrying out this work and other information supplied to us have given us a clear picture of the considerable difficulties involved in producing satisfactory *in vitro* methods for testing. We have been impressed by the considerable attention given to this aspect of cosmetics testing by the companies we have visited and by the extensive work carried out, through literature searches, chemical analyses etc. to ensure that a decision to proceed with animal testing is only taken when absolutely necessary. The animal tests which are carried out are tests for mildness, not tests for severity. This is a difficult, but developing field and the Committee intends to take a close interest in future developments.

3.12. Our consideration of cosmetics testing so far has introduced us to the complexities and difficulties of safety testing; that is, not only the difficulties of moving away from the use of living animals for such testing; but the wide variety of hazardous or potentially hazardous contacts which have to be anticipated in the safety testing of any product, but particularly those such as cosmetics which are applied directly to the body or encountered in bulk form in the working life of those involved in their production. Conscious too of the moral difficulties surrounding the justification of using animals for testing cosmetics we have proceeded with caution.

3.13. A number of common requirements for cosmetics testing applications have been identified and incorporated in guidance notes on applications for cosmetics project licences which have been prepared by the Home Office and issued to those applying for them. We have also recommended to the Secretary of State, and he has accepted, that licences for such testing should be granted only on condition that the establishments concerned submit detailed information on the use of each procedure authorised, identifying separately toiletries (eg deodorants, toothpastes, bath products) and beauty preparations (eg make-up, lipstick and perfumery), for each year. We believe that the availability of detailed information of this sort, from a range of establishments, will enable the Committee in due course to carry out a thorough review of the subject so as better to advise the Secretary of State on the continuation of such work.

3.14. A related concern which has emerged from our consideration of this form of testing is that there is considerable variation in the requirements of different countries for testing of cosmetics (and many other substances) to be marketed in each country. The regulatory requirements can vary considerably, and in some instances the reason for a particular requirement, often involving extensive animal testing, can be difficult to ascertain. We believe that this is an important problem. We know that the Government recognises this and is taking such action as it can through participation in international regulatory bodies. This concern goes much wider than tests on cosmetics. Unfortunately it can be a slow and difficult process to secure incorporation of the latest techniques in the regulatory tests of materials and products. We shall continue to take a close interest in this area, both in respect of cosmetics and other materials and to encourage the Government to maintain its efforts to encourage the adoption of best practice.

4 Review of Psychological and Behavioural Research

4.1. The subject of the deliberate induction of stress in psychological and behavioural research has been a matter of public concern for some while. In 1983 the Secretary of State asked the Advisory Committee on Animal Experiments to look into this area of research, and to advise him whether it should continue and if so whether any further restrictions needed to be imposed. The Advisory Committee carried out a number of visits to establishments where such work was performed, between late 1983 and mid 1985 and also considered written material submitted on the subject. A draft report on the subject was prepared for the Advisory Committee in late 1985 and considered by the Committee.

4.2. However, this time was close to the introduction of the new system of controls under the Animals (Scientific Procedures) Act 1986 and to the establishment of the Animal Procedures Committee. In view of this, the Advisory Committee on Animal Experiments having considered the draft report felt that it would be inappropriate for it to present a report on such a major and important subject so close to the establishment of the new Animal Procedures Committee and also without the benefit of assessing the impact of the new controls on the work in question.

4.3. Initial discussion by the Animal Procedures Committee elicited further details of work about which concern was felt and suggestions for the way in which the Committee might take up the remit. The matter was examined further by the Home Office during the course of 1987 and in 1988 the Committee has embarked upon a series of further visits to establishments to assist it in preparing a report for the Secretary of State. Further details of the Committee's consideration of this subject will be contained in the annual report for 1988.

Sponsorship of research

4.4. This report has already touched upon a number of areas of work in which the question of alternatives to the use of animals in scientific or experimental work has been considered. The refinement of experimental procedures to minimise suffering, and the reduction in the numbers of animals used, have also been important considerations in a variety of items of work considered by the Committee. The Animals (Scientific Procedures) Act 1986, Section 20(4) permits the Committee to promote research "relevant to its functions", and we are pleased that the Committee has had the opportunity actively to promote research into alternatives and the reduction of animal use and suffering in experimental and scientific procedures.

4.5. The Home Secretary has made available funds to enable research relevant to his functions under the 1986 Act to be funded and has asked the Committee to advise him on the proposals for research which might be supported using this money. The Committee has therefore appointed a Research Sub Committee which has considered and advised the Secretary of State on the areas of research which he might support (reduction, refinement and replacement) and the manner in which research proposals might be sought. The Secretary of State has accepted the Committee's recommendations and arrangements have been put in hand to seek and consider proposals for research support for which would start in the financial year 1988/1989. Further details of the progress of this activity by the Committee will be provided in the annual report for 1988.

Non-human primates

4.6. Another major item of work carried out by the Committee during 1987, at the request of the Secretary of State, has been consideration of the Secretary of State's proposed response to the report "The Use of Non-Human Primates as Laboratory Animals in Great Britain". The report was jointly published by the Fund for the Replacement of Animals in Medical Experiments and the Committee for the Reform of Animal Experimentation and endorsed by the British Veterinary Association and the Royal Society for the Prevention of Cruelty to Animals.

4.7. Whilst recognising that the new controls under the Animals (Scientific Procedures) Act 1986 would in all probability lead to improved conditions for non-human primates used for research, the report took as its starting point the special care and concern appropriate for non-human primates, many of them animals of considerable intelligence, and our nearest relatives. Accepting that a difficult balance must be struck between the need to use these animals in some medical and scientific research and their need for special care, as well as their increasing scarcity, the report suggested a number of specific measures to improve the care of the animals when used for laboratory purposes and to ensure that only where their use was absolutely necessary would such utilisation be permitted, and then only for the lowest possible order of species appropriate to the work.

4.8. The Committee endorsed the concern for non-human primates which had led to the issue of the joint report. We recommended that the Secretary of State accept and implement the majority of the recommendations in the report, though others we felt were adequately covered by the existing or envisaged controls and administrative arrangements. In particular the Committee endorsed the suggested requirement of a high level of proof that the use of non-human primates is necessary in any application for their use; the encouragement of use of non-human primates which have been bred in captivity, as opposed to wild caught animals, wherever possible; encouragement of the use of the lowest possible order of species non-human primates; notification to the Animal Procedures Committee of projects involving the use of non-human Hominoidea (ie the gibbon, the siamang, the orang-utan, the chimpanzee and the gorilla; any such projects are likely to be rare: no work is known to have been done on such animals for at least the last six years); and applications for any work involving non-human primates which includes any procedure in the substantial severity category. The Committee also emphasised the need, identified in the report, to ensure that the use of non-human primates is restricted to establishments which provide facilities of a very high standard for their husbandry and welfare; and for detailed statistics on the use of non-human primates to be available as part of the annual published statistics of procedures carried out under the 1986 Act. The Committee is pleased that the Secretary of State was able to accept all its recommendations as set out in Appendix 6.

Use of animals to obtain manual skills

4.9. As mentioned previously, the fact that the 1986 Act permits the use of living animals for the acquisition of manual skills, something which was not permitted under the previous controls, has been a matter of some concern and in recognition of that concern the Secretary of State has said that he will not, for the foreseeable future, permit the use of living animals for such purposes, except the use of terminally anaesthetised rodents for the training of qualified surgeons in microsurgery.

4.10. However, it has been put to us that the Secretary of State's restrictions on the use of living animals for the acquisition of basic manual skills (such as gavage) has prevented the establishment of systematic training courses for laboratory

technicians and others who may carry out regulated procedures on living animals as part of the conduct of work under the controls of the 1986 Act.

4.11. The Committee recognises the benefits to animals which might flow from systematic training courses in simple procedures where the final aim would be the performance of techniques on living animals. The Committee is also conscious of the public concern that animals might be viewed as simply another training device and thus exposed to increased suffering. This is a matter to which the Inspectorate is also giving further consideration.

Use of Animals in schools

4.12. It is against the Secretary of State's policy to permit regulated scientific procedures on living animals in schools. We strongly support that policy and have encouraged, through the Home Office, the Department of Education and Science to issue guidance to schools to make the position clear. We have commented on the Department of Education and Science's draft, and we hope the guidance will be issued shortly.

Handling of infringements

4.13. Another point about the administration of the Act which we considered (and which was also a concern of the Advisory Committee on Animal Experiments) is the handling of infringements. Infringements could vary considerably from a minor and unintentional breach of administrative requirements of the Home Office through a deliberate and major breach of the requirements of the legislation, for example the deliberate performance of painful work without licence authority, although past experience of the 1876 Act is that breaches of this kind are almost unknown.

4.14. The action to be taken in individual cases is not a matter for the Committee, but we have a legitimate concern in the general policy of how infringements should be dealt with. The great variety of circumstances of infringements requires in our view a careful selection of the appropriate response and administrative action, including where necessary reference of a case to the Crown Prosecution Service.

4.15. The range of administrative action available includes, for example, a letter of admonition only, in cases where it is clear that a minor infringement occurred inadvertently and that all concerned are fully conscious of the need to avoid such a mistake in future; to the imposition of additional special conditions on either the personal or project licence; a change in the holder of the project licence in a case where it was thought that he had been lax in exercising adequate control over those working under the authority of that licence; or in more extreme cases, the revocation of a personal or project licence, or indeed, the certificate of designation of an establishment as a place were scientific procedures may be carried out. Such revocation of a personal or project licence or certificate of designation could result in those concerned being deprived of their livelihood, so it should not be assumed that administrative action, though less severe than criminal prosecution, is painless or ineffective.

4.16. The Committee is concerned, however, that where appropriate, people who offend against the Act should be prosecuted. In 1986 the Advisory Committee on Animal Experiments made the following points to the Secretary of State:

> *"Administrative sanctions can no doubt be effective, but discretion to enforce the criminal law should not mean that it is never enforced in the courts.*

We accept that technical infringements of the law on the whole are best dealt with by means of administrative sanctions, up to and including the withdrawal of authority to carry out procedures on living animals. However, in the case of serious infringements where intentionally or through negligence an animal has been caused unnecessary suffering, or where there has been a conscious evasion of the legal controls, we see no reason in principle why the full force of the criminal law should not be applied. We are reassured that such grave breaches of the law are so few in number; but we should expect that this would make it all the more possible to isolate and deal appropriately with such cases without jeopardising the relationship of trust and co-operation between inspectors and licensees, whose importance to the effectiveness of the controls we readily acknowledge.

The Animals (Scientific Procedures) Bill rightly makes provision for substantial penalties for the most serious offences involving animals used in scientific procedures. We are concerned that the new legislation will fail to command the respect it deserves, unless there is a willingness to bring its full force to bear when the circumstances warrant it. We appreciate that under the new legislation, as under the existing legislation, these decisions must be taken by the Director of Public Prosecutions and in the light of the facts of each individual case. But it is the hope of the Committee that the official procedures for dealing with serious infringements may be improved so that the possibility of prosecution is more vigorously explored. We believe this will be of particular importance for both the public credibility and the effectiveness of the new legislation now before Parliament, which has your Committee's full confidence and support."

The Secretary of State replied as follows:

"The difficulties of interpreting the 1878 Act, and the fact that the legislation is virtually untested in the courts, may well have played a part in the absence so far of any prosecution under the Act brought with the Secretary of State's assent. It would be wrong, however, to conclude that there has been a conscious or deliberate policy of avoiding the prosecution of offences involving unauthorised experiments on living animals. As members of the Committee will know, just such a prosecution was brought against a licensee in Scotland in 1978, but for technical reasons, under the Protection of Animals (Scotland) Act 1912 rather than under the 1876 Act. There is a full commitment to consider prosecution in the case of flagrant violations of the law.

Looking to the future, under the new legislation the Director of Public Prosecutions will have responsibility for scrutinising all possible prosecutions under the new Act, as well as under the Protection of Animals Act 1911 where an animals at a designated establishment is concerned. I would hope that with the tighter controls to be introduced and the extensive guidance and codes of practice which will be available to researchers, the number of inadvertent or careless infringements of the law will be substantially reduced. Where infringements are committed, there will be all the less excuse for them and we shall view them very seriously indeed. Decisions about possible proceedings under the new Act will also be made with the advantage of a clear and modern framework of law, avoiding many of the uncertainties and pitfalls which beset interpretation of the 1876 Act.

As I have said, each case must be considered on its merits, and the final judgments will be for the Director alone to make. For these reasons it would be wrong for me to undertake in advance that any particular line of policy will be followed. I hope, however, that what I have said will be seen as a firm assurance that the responsible authorities do not, and will not, avoid advancing criminal proceedings where they may be justified and in the public

interest. The majority of infringements are technical and I think that this is likely to remain the case. In a few cases more substantial neglect or irresponsibility is involved. At the most serious level, there are a very few instances of deliberate evasion of the law. I would certainly consider that an infringement of this kind would merit the most severe sanctions."

The present Committee entirely endorses the stand which its predecessor took. It welcomes the Secretary of State's observations on this matter, in which it will keep a close interest as the new controls take effect.

5 Forward Look

5.1. This report covers only 8 months of activity by the Animal Procedures Committee but they have been busy months, (as were the months of work by the Advisory Committee on Animal Experiments during the period leading up to and including the passage of the Animals (Scientific Procedures) Act 1986).

5.2. We have throughout been very conscious of the considerable expectations of the new Act, both by the general public and by the scientific community. Although it will take several years before the new system is fully in operation, we believe that a very good start has been made, that sensible administrative arrangements have been put in place and that thanks to the skilled work of the Animals (Scientific Procedures) Inspectorate, and the whole-hearted cooperation of licensees and establishments a rigorous and sophisticated system of effective control is developing.

5.3. As mentioned above, the Committee attaches the greatest importance to the period of phased implementation of the new controls. We shall continue to take a close interest in the progress of implementation, as well as continuing the examination of specific applications referred to us by the Secretary of State and examining the more general issues referred to us or which come to our attention.

5.4. We regard it as of the upmost importance to maintain close and effective liaison with the Animals (Scientific Procedures) Inspectorate.

5.5. In addition to the work already mentioned, much of which is continuing into 1988 and likely to continue into succeeding years, the Committee has given consideration to other areas of research involving animals which might in the future merit detailed scrutiny by the Committee.

5.6. One possible area indentified is that of licensed research in agriculture, particularly research directed towards increased yield from farm animals. Work is in hand to enable the Committee to give further consideration to this possibility during 1988 and, as a separate but related development, the Committee will during 1988 hold a joint meeting with the Farm Animal Welfare Council.

5.7. An appropriate note on which to end this report is one of guarded optimism. The Committee has been struck by the diligence and enthusiasm with which all concerned have turned to the task of operating the more detailed system of control which the 1986 Act has introduced. Some of the benefits of this activity go unobserved except perhaps by those closest to research. However, whether noticed or not, we believe that the emerging system of control will match the high expectations of Parliament and the public.

Appendix I

The Animal Procedures Committee.

19.—(1) There shall be a committee to be known as the Animal Procedures Committee.

(2) The Committee shall consist of a chairman and at least twelve other members appointed by the Secretary of State.

(3) Of the members other than the chairman—

(*a*) at least two-thirds shall be persons having such a qualification as is mentioned in subsection (4) below; and

(*b*) at least one shall be a barrister, solicitor or advocate,

but so that at least half of those members are persons who neither hold nor within the previous six years have held any licence under this Act or under the Cruelty to Animals Act 1876; and in making appointments to the Committee the Secretary of State shall have regard to the desirability of ensuring that the interests of animal welfare are adequately represented. 1876 c. 77.

(4) The qualifications referred to in subsection (3)(*a*) above are full registration as a medical practitioner, registration as a veterinary surgeon or qualifications or experience in a biological subject approved by the Secretary of State as relevant to the work of the Committee.

(5) Members of the Committee shall be appointed for such periods as the Secretary of State may determine but no such period shall exceed four years and no person shall be reappointed more than once.

(6) Any member may resign by notice in writing to the Secretary of State; and the chairman may by such a notice resign his office as such.

(7) The Secretary of State may terminate the appointment of a member if he is satisfied that—

(*a*) for a period of six months beginning not more than nine months previously he has, without the consent of the other members, failed to attend the meetings of the Committee;

(*b*) he is an undischarged bankrupt or has made an arrangement with his creditors;

(*c*) he is by reason of physical or mental illness, or for any other reason, incapable of carrying out his duties; or

(*d*) he has been convicted of such a criminal offence, or his conduct has been such, that it is not in the Secretary of State's opinion fitting that he should remain a member.

(8) The Secretary of State may make payments to the chairman by way of remuneration and make payments to him and the other members in respect of expenses incurred by them in the performance of their duties.

(9) The Secretary of State may also defray any other expenses of the Committee.

20.—(1) It shall be the duty of the Animal Procedures Committee to advise the Secretary of State on such matters concerned with this Act and his functions under it as the Committee may determine or as may be referred to the Committee by the Secretary of State. Functions of the Committee.

(2) In its consideration of any matter the Committee shall have regard both to the legitimate requirements of science and industry and to the protection of animals against avoidable suffering and unnecessary use in scientific procedures.

(3) The Committee may perform any of its functions by means of sub-committees and may co-opt as members of any sub-committee any persons considered by the Committee to be able to assist that sub-committee in its work.

(4) The Committee may promote research relevant to its functions and may obtain advice or assistance from other persons with knowledge or experience appearing to the Committee to be relevant to those functions.

(5) The Committee shall in each year make a report on its activities to the Secretary of State who shall lay copies of the report before Parliament.

Appendix II

ANIMALS (SCIENTIFIC PROCEDURES) ACT 1986

A SHORT GUIDE TO THE MAIN PROVISIONS OF THE ACT

Introduction

This is a short guide to the main provisions of the Animals (Scientific Procedures) Act 1986. This Act replaces the Cruelty to Animals Act 1876 with a new system of controls on scientific work on living animals, which you will find described in greater detail in the Home Office note "Guidance on the Operation of the Animals (Scientific Procedures) Act". Relevant sections of this Home Office Guidance Note are indicated, where appropriate, in the following paragraphs. If you work at a place which is registered with the Home Office, your Home Office Liaison Officer or Head of Department will have received copies of the Guidance Note.

The main provisions of the new Act will come into operation on 1 January 1987. However, some current licences, certificates and registrations authorised under the 1876 Act will continue to be valid for a limited period after the new Act comes into force. It is therefore important that you also read the Home Office leaflet "Summary of Transitional Arrangements", distributed with this guide, which describes in detail how the new controls are to be implemented.

Scope of the Act

The new Act provides for the licensing of experimental and other scientific procedures carried out on "protected animals", which may cause pain, suffering, distress or lasting harm. Such work is referred to in the Act as a "regulated procedure". "Protected animals" are defined in the Act as all living vertebrate animals except man and the definition extends to foetal, larval or embryonic forms which have reached specified stages in their development (see Home Office Guidance Note, paragraphs 3-6). Under the Act an animal is regarded as "living" until the cessation of circulation or destruction of its brain, so procedures carried out on decerebrate animals are subject to the controls.

All work currently authorised by the 1876 Act will be subject to the new controls. In addition, some work not previously controlled *will* have to be licensed under the new Act. Such work includes, in particular, some breeding of animals with genetic defects; production of antisera and other blood products; the maintenance and passage of tumours and parasites; and the administration for a scientific purpose of an anaesthetic, analgesic, tranquiliser or other drug to dull perception. Killing an animal requires licence authority in certain circumstances (see Home Office Guidance Note, paragraph 9 and Annex A).

The controls do *not* extend to procedures applied to animals in the course of recognised veterinary, agricultural, or animal husbandry practice; and there are certain other exceptions (see paragraphs 7, 8 and 10 of the Home Office Guidance Note).

Personal and Project Licences

Two kinds of licence are required for all scientific work controlled by the Act. The person applying the regulated procedures must hold a *personal licence*. But in addition the procedures must be part of a programme of work authorised by a *project licence*. *No* work may be done unless the *procedures*, the *animals* used, and the *place* where the work is done, are specifically authorised in both personal and project licences.

The *personal* licence is the Home Secretary's endorsement of the holder's competence and suitability to carry out specified procedures on specified animals. Applicants, who must be over 18, will be required to give details of their

qualifications, training and experience; and those who have not previously held a Home Office licence will need the endorsement of a sponsor (normally someone in a senior position at the applicant's place of work). For further details about personal licences see paragraphs 28-38 of the Home Office Guidance Note, which also contains a specimen application form (Annex J).

A *project licence* will be granted where the Home Secretary considers that the use of live animals in a programme of work for a purpose permitted by the Act is justified, and the methods proposed appropriate. In deciding whether and on what terms to authorise the project he is required to weigh the likely adverse effects on the animals used against the benefit likely to accrue from the work. He must also be satisfied that the applicant has adequately considered the feasibility of using alternative methods not involving live animals. The holder of a project licence must be someone who undertakes overall responsibility for the scientific direction and control of the work. This will generally be the senior personal licensee engaged on the project. For further details about project licences, see paragraphs 39-67 of the Home Office Guidance Note, which also contains a specimen application form (Annex I).

Designation of Premises

Except where otherwise authorised in a project licence, any place where work is carried out under the Act (including places currently registered inder the 1876 Act) must be designated as a scientific procedure establishment, by a certificate issued by the Home Secretary. In addition, establishments which breed certain types of animal (mouse, rat, guinea-pig, hamster, rabbit, dog, cat amd primate) for use in scientific procedures ('breeding establishments'), and establishments which obtain such animals from elsewhere and supply them to laboratories ('supplying establishments'), must also be designated by a certificate. All designated establishments will be inspected by the Home Office Inspectorate, and will be required to nominate a person to be responsible for the day-to-day care of animals, and a veterinary surgeon to be available to advise on their health and welfare. These arrangements will be brought into effect over a period of time. For the timetable, please refer to the leaflet "Summary of Transitional Arrangements". The Home Office Guidance Note contains further details about certificates of designation (paragraphs 68-79) and a specimen application form (Annex K).

Fees

The Act empowers the Home Secretary to charge fees to the holders of certificates of designated establishments. Paragraph 73 of the Home Office Guidance Note gives details of the system of charging.

Assessment of Applications

All applications for authority under the Act will be considered by the Home Office Inspectorate, who will recommend whether and on what terms the application should be granted. The Home Secretary may also seek the opinion of an external assessor on part or all of an application, if he thinks it necessary, for example because the area of research is highly specialised or the techniques involved novel. The assessor will be an expert from an invited panel covering the main branches of the biological sciences. The applicant will always be informed if it is proposed to consult an assessor. The final decision about any application for authority under the Act rests with the Home Secretary.

Applications may also be referred for advice to the Animal Procedures Committee. All project licence applications for work on cosmetics will be referred to the Committee and, for the present, applications for project licences for work on conscious animals involving tobacco products and also for training in microsurgery (see also paragraphs 59-61 of the Home Office Guidance Note).

Conditions of Licences and Certificates

The Home Secretary may attach appropriate conditions to any personal licence, any project licence, or any certificate designating an establishment as a scientific procedure, breeding or supplying establishment. The standard conditions to be included in personal and project licences, and certificates of designation, are set out in Annexes C to G of the Home Office Guidance Note.

Certain conditions are referred to in the Act itself, in particular conditions attached to all personal licences requiring precautions to be taken to prevent or minimise suffering by animals used in procedures, and requiring any animal in severe pain or severe distress which cannot be alleviated to be immediately humanely killed. Also, when section 7 of the Act (designation of breeding and supplying establishments) is brought into force, conditions will be attached to all project licences regulating the source of animals used in work under the Act. Special restrictions will apply to the source of cats and dogs.

Representations against Refusal of Applications, etc.

A person whose application for authority under the Act is refused, or whose licence or certificate is to be revoked or varied other than at his own request, has the right to make representations to an independent legally qualified adviser appointed by the Home Secretary. The adviser will consider any representations made and the Home Secretary will take into account the adviser's views before reaching a final decision. The system is described in greater detail in paragraphs 83-84 of the Guidance Note.

Additional Controls

The Act contains a number of additional controls which are described in more detail in the Home Office Guidance Note. These include restrictions on the use of animals in more then one series of procedures (paragraph 16 and Annex H), a requirement to kill an animal suffering at the conclusion of a series of procedures (paragraph 17), and restrictions on the use of neuro-muscular blocking agents (paragraph 19). Other controls prohibit the performance of procedures as an exhibition to the general public or for live showing on television; empower an Inspector to require the destruction of an animal which he considers to be suffering excessively; and penalise the provision of false information in support of an application, and the improper disclosure of information obtained in confidence by a person exercising functions under the Act.

The Inspectorate

The Act gives statutory recognition to the Home Office Inspectorate and describes the Inspectors' duties. Inspectors will hold either medical or veterinary qualifications. They will be available to give advice and assistance to licensees and other personnel.

The Animal Procedures Committee

The Act establishes an advisory body, the Animal Procedures Committee which will replace the present Advisory Committee on Animal Experiments and will have the duty of advising the Home Secretary on matters concerned with the operation of the controls in the Act. The Act prescribes the composition of the Committee. The Committee is required in its consideration of any matter to have regard both to the legitimate requirements of science and industry and to the protection of animals against avoidable suffering and unnecessary use in scientific procedures.

Guidance, Codes of Practice and Statistics

The Act requires the Home Secretary to publish and lay before Parliament guidance on the operations of the controls, codes of practice as to the care and accommodation of animals and their use in scientific procedures, and annual statistics. Additional guidance on matters to do with the use of animals in procedures will be issued from time to time.

Offences and Penalties

The offences created by the Act, and the penalties they attract, are described in paragraphs 11-25 of the Home Office Guidance Note.

Conclusion

If you think you may need the authority of a licence or certificate under the Act, or you would like to know more about the Act and how it may affect you, you are advised to contact the Home Office Inspector for your establishment. If you are unsure whom to contact, the Home Office Liaison Officer or senior licensee in your Department will be able to advise you, or you may write to:-

E Division
Room 976
Home Office
50 Queen Anne's Gate
LONDON SW1H 9AT

and your letter will be passed to the Inspector who will then contact you. *Remember:* the accompanying leaflet "Summary of Transitional Arrangements" and the Home Office Guidance Note contain important additional information, and you should consult them before contacting the Inspector or submitting any application under the new Act.

September 1986

Appendix III

HOME OFFICE GUIDELINES ON EYE IRRITATION/CORROSION TESTS ('DRAIZE' EYE TEST) – FEBRUARY 1987

Introduction

The aim of these Guidelines is to reduce the risk of suffering in eye irritancy studies. They concern everybody who is involved in using animals (the animal most frequently used is the rabbit) for eye irritancy/corrosion tests whether non-statutory or based on standard protocols, for example, the OECD Guidelines for Testing of Chemicals No 405 – Acute Eye Irritation/Corrosion (adopted 12 May 1981).

Initial Considerations

Before applying a substance to the eye, licensees must ensure that its physical and chemical properties are not such that a severe adverse reaction could be predicted. For example, substances which yield solutions with a pH of 2 or less, or 11.5 or greater should not be tested, neither should known corrosive substances or those with a high oxidation or reduction potential. Substances which in a dermal study appear to be corrosive or severe skin irritants should not be tested in the eye.

In vitro pre-screening tests are advisable and will become mandatory when such tests have been properly validated. At present, the isolated perfused eye test appears to be very useful, and substances giving positive effects *in vitro* indicative of a severe reaction *in vivo* should not, without good scientific justification and specific approval of the Secretary of State, be used in a Draize eye test.

Licensees must first test substances in the eye of a single animal before the main test and allow at least 24 hours for any damage to become apparent. This will avoid unnecessary testing of substances which cause severe ocular effects.

Dosage Reduction and Dilution

Test doses should be minimised where severe irritancy is likely. Consideration should be given to using doses one-tenth of those in the OECD Guideline. In the case of pesticides, bath gels and shampoos, dilutions should always be tested before the original concentrated formulation. In the case of shampoos, it may be sufficient just to compare diluted material with a reference material. In the case of aerosols, direct spraying into the eye (as for example, recommended in the OECD Guidelines) should not be used; instead the aerosol material should be collected in a container for subsequent application to the eye.

Inspection

Animals must be inspected more frequently than the fixed time points for scoring given in standard guidelines. They should be examined at least twice during the first hour after administration of the test material to the eye, at least twice during the remainder of the first 24 hour period and more frequently if warranted by the

circumstances. Thereafter they must be examined at least once per day. Consideration should be given to the use of systemic analgesics in appropriate circumstances, and prompt action must be taken to deal with animals showing severe effects (as described below).

Withdrawal from Study

An animal must be withdrawn immediately from the study and humanely killed if at any time it shows (a) very severe ocular damage (eg sloughing and ulceration of conjunctival membrane; corneal perforation; blood or pus in the anterior chamber,); or, (b) blood stained or purulent discharge; or, (c) significant corneal ulceration.

Additionally, careful consideration must be given to responses based on the standard Draize scale. Any animal showing maximal effects on this scale — (ie absence of a light reflect (iridial response level II) or corneal opacity (grade IV) without evidence of recovery within 24 hours or maximal conjunctival inflammation (swelling grade IV, together with vascular change grade III)) — without evidence of recovery within 48 hours, should be withdrawn from the study and killed humanely.

Personal licences issued under the Animals (Scientific Procedures) Act 1986 include a termination condition requiring that animals in severe pain, or severe distress which cannot be alleviated, should be immediately and painlessly killed by approved methods. At any time if an Inspector considers that an animal is undergoing excessive suffering, he may require it to be immediately killed. The following general signs are considered particularly relevant: maintained vocalisation; hunched posture; abnormal quiteness; marked photophobia; regular rubbing of the eye; or failure to eat or drink.

(Licencees are reminded that the pain condition 3(a) and (b) inserted in all licences issued under the Cruelty to Animals Act 1876 must always be strictly observed while such licences are still in force.).

Incorporation in Procedures

Licencees should include humane considerations including those described above in written protocols and standard operating procedures.

Departure from these Guidelines

In the unlikely event that there is a need to depart from the standards outlined in these Guidelines, the Secretary of State must be consulted beforehand through the Home Office Inspector and give approval. In drawing up any such proposal full consideration must be given to the need to make adequate use of systemic analgesics and/or sedatives, extended pre-screening, and appropriate dilution of test material.

February 1987

REFERENCES

Draize, J.H., Woodard, G. and Calvery, HO. Methods for the study of irritation and toxicity of substances applied topically to the skin and mucous membranes. J Pharmacology and Experimental Therapeutics 82, 377 – 390 (1944).

OECD Guidelines for the Testing of Chemicals. No 405 – acute eye/irritation/corrosion – 12 May 1981.

FED REG. 1973, vol 38, No 187, section 1500.42, page 27,109: "Test for eye irritants".

Appendix IV

HOME OFFICE GUIDELINES ON THE USE OF NEUROMUSCULAR BLOCKING AGENTS

Introduction

1. In section 17 of the Animals (Scientific Procedures) Act 1986 it states that "no person shall in the course of a regulated procedure:-

(a) use any neuromuscular blocking agent unless expressly authorised to do so by the personal and project licences under which the procedure is carried out; or
(b) use any such agent instead of an anaesthetic."

To do so would constitute an offence under the Act. But should a person be able to show that he reasonably believed after making due enquiry that he had appropriate authority, he would not be guilty of the offence in (a) above.

2. Curare and other agents that block neuromuscular transmission are used to abolish muscle tone during anaesthesia in man and animals. Special care is necessary when such pharmacological compounds are used systemically because they specifically block neuromuscular transmission causing paralysis, yet have no significant central effects and will not therefore induce analgesia, unconsciousness or even sedation.

3. Neuromuscular blocking agents must not be used without an adequate level of anaesthesia and analgesia. If administered to a conscious animal they would not prevent it feeling pain and the animal would be in a helpless state of paralysis. Unless the dose is small, the animal would not survive without mechanical ventilation because of paralysis of the respiratory muscles.

4. Neuromuscular blocking agents may be classified according to their action at the motor endplate:-

(a) depolarising – including suxamethonium. These agents depolarise the motor endplate causing muscle fasciculation and then prevent further, normal, depolarisation;
(b) non-depolarising – including tubocurarine, gallamine, alcuronium, pancuronium, atracurium and vecuronium. These agents occupy motor endplate receptors and prevent normal depolarisation. Their effects can be antagonised by anti-cholinesterase compounds.

5. There are other naturally occurring biological compounds, such as venoms (eg Black Widow Spider) and toxins (eg Clostridium botulinum toxin) which, when used systemically, block neuromuscular transmission. There are also other agents (eg neomycin, high concentrations of magnesium ions) which have non-specific effects at the motor endplate. Such agents are not used clinically as neuromuscular blockers, and neither is it intended that they should be used instead of an anaesthetic. They will not be regarded specifically as neuromuscular blocking agents for the purposes of the Animals (Scientific Procedures) Act 1986; however, they must not be administered to living animals for an experimental or other scientific purpose unless authorised by a project licence.

Licensing Requirements

6. PERSONAL LICENCE. Applicants will have to provide evidence that by their training, qualifications and experience they are conversant with current anaesthetic techniques in the animal species with which they propose to work and they they understand the use of neuromuscular blocking agents as set out in this note for guidance. They will normally be required to have witnessed the use of these agents and to be familiar with the procedures for achieving and maintaining anaesthesia under such regimes. Where a licensee has been given permission to use neuromuscular blocking agents for the first time, he/she will, unless specifically exempted by the Home Secretary, be required to give the Inspector 48 hours' notice of the performance of any procedure using these agents; this restriction may be extended to further occasions if the Inspector considers it appropriate.

7. PROJECT LICENCE. Applicants who wish to use neuromuscular blocking agents in their project will have to:-

(a) justify their use;
(b) provide details of the anaesthetic regime and the methods available to ventilate the lungs; and
(c) provide details of the methods used to assist in monitoring the depth of anaesthesia.

8. These personal and project licence requirements do *not* apply to the use of such blocking agents during licensed work performed on decerebrate animals.

The Administration of Neuromuscular Blocking Agents

9. Full neuromuscular blockade will not be allowed in conscious, unanaesthetised animals.

10. The following are minimum requirements for the use of neuromuscular blocking agents administered to living animals under all circumstances whether or not it is intended that the animal should recover from anaesthesia.

(a) They must be used in conjunction with an established anaesthetic regime known to produce a stable level of anaesthesia for the duration of neuromuscular blockade in the species of animal used. Suitable provision must be made to ensure that the correct level of anaesthesia is always maintained.
(b) They must be administered by an experienced licensee who is competent in animal anaesthesia and aware of the actions and interactions of the compounds to be used during the effective period of that particular anaesthetic. The licensee must be aware of the need to ensure that the termination condition — condition 4 of the personal licence — is observed at all times. Care should be taken in procedures in which autonomic function is blocked because this will interfere with the normal cardiovascular response during light anaesthesia.
(c) An emergency routine should be agreed in advance to cater for hazardous events such as power failure (which could interrupt the operation of mechanical ventilators and infusion pumps for example). The aim must be to ensure that in such circumstances the interests of the animal are safeguarded.

11. Where animals are lightly anaesthetised with shorter acting agents administered by inhalation or by injection or they are expected to recover from anaesthesia, further special conditions apply.

(a) Animals should be attended at all times; this includes the recovery period until there is no risk that there could be a return to neuromuscular paralysis. Where surgical intervention is involved a second person must be present at all times to ensure the maintenance of anaesthesia.

(b) In lengthy procedures (greater than 8 hours) additional personal licensees with authority to use neuromuscular blocking agents must be available to provide assistance and take over responsibility in the event of fatigue.

(c) There should be continuous monitoring of heart rate and/or blood pressure, so as to indicate any lightening of the level of anaesthesia which may require prompt action. It may sometimes be appropriate to assess the depth of anaesthesia by continuous recording of the electroencephalogram, provided the recording is not invalidated by agents such as atropine, or by a rise in carbon dioxide tension which should be measured and maintained within the normal range.

(d) Access to a vein should be maintained at all times for prompt administration of a narcotic or anaesthetic agent in the event of return to consciousness. Adequate reserves of anaesthetic agents must be available.

(e) Facilities should be available to measure and maintain body temperature.

(f) In the case of animals allowed to recover from anaesthesia, appropriate compounds (eg neostigmine) should be used to reverse any residual neuromuscular blockade brought about by non-depolarising agents and an assessment should be made of neuromuscular function before return of consciousness is allowed to occur. If a depolarising agent is used the full effects must have worn off before the return of consciousness.

12. Any proposed exceptions to the requirements in paragraphs 10 and 11 above should always be referred to and agreed with the Inspector in advance.

13. The conditions specified in paragraphs 10 and 11 above do *not* apply to work performed on decerebrate animals.

April 1988

Appendix V

COSMETIC DIRECTIVE 76/768/EEC

Article 1

1. A 'cosmetic product' means any substance or preparation intended for placing in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or principally to cleaning them, perfuming them or protecting them in order to keep them in good condition, change their appearance or correct body odours.

2. The products to be considered as cosmetic products within the meaning of this definition are listed in Annex I.

3. Cosmetic products containing one of the substances listed in Annex V and cosmetic products containing colouring agents other than those referred to in Annexes III and IV and which are not intended to come into contact with the mucous membranes are excluded from the scope of this Directive. Member States may take such measures as they deem necessary with regard to these products.

Article 2

Cosmetic products put on the market within the Community must not be liable to cause damage to human health when they are applied under normal conditions of use.

Article 3

Member States shall take all necessary measures to ensure that only cosmetic products which conform to the provisions of this Directive and its Annexes may be put on the market.

An Annex VI shall be added, listing the substances which may be used as preservatives in the manufacture of cosmetic products under the conditions set out in the said Annex and in the preamble thereto.

Annex VII is added. It lists the ultra-violet filters which may be included in cosmetic products under the conditions laid down therein.

Appendix VI

THE USE OF NON-HUMAN PRIMATES AS LABORATORY ANIMALS

Home Secretary announces decision

The Home Secretary, the Rt Hon Douglas Hurd CBE MP, today announced his decision on the report on "The Use of Non-Human Primates as Laboratory Animals in Great Britain". The report was jointly published by the Fund for Replacement of Animals in Medical Experiments and the Committee for the Reform of Animal Experimentation and endorsed by the British Veterinary Association.

In answer to a Parliamentary Question from Greg Knight MP (Derby North), Mr Hurd said:

"I have completed my consideration of this helpful document. In doing so I have been much helped by the Animal Procedures Committee which has, at my request, made a detailed examination of the report and the proposals in it.

"I entirely share the concern for non-human primates which underlies the report. There is a difficult balance to strike between the need to use these animals in some medical and scientific research, and the special care that is needed in looking after them and their increasing scarcity. This joint initiative by the Fund for the Replacement of Animals in Medical Experiments, the Committee for the Reform of Animal Experimentation and the British Veterinary Association has provided a most helpful opportunity to consider in detail the way in which the new controls under the Animals (Scientific Procedures) Act 1986 may be used to strike this balance correctly. I am pleased to say that I am able to accept many of the recommendations made in the report. The following is a summary of the resultant action which has been taken or is now in hand.

(i) The Home Office is to explore the possibility of encouraging certain establishments where non-human primates are used for scientific or experimental purposes to set up a special course or courses for the benefit of licensees and others who work with non-human primates used for experimentation.

(ii) A detailed breakdown of the use of non-human primates, using a classification scheme suggested in the report will be included in the annual published statistics of procedures carried out under the 1986 Act.

(iii) In examining project licence applications which propose the use of endangered non-human primate species a high level of proof that the use of such species is necessary will be required for the application to be successful.

(iv) Establishments will be encouraged, wherever practicable, to use non-human primates which have been bred in captivity, as opposed to wild-caught animals.

(v) Establishments will be encouraged to ensure that the lowest possible order of species is used.

(vi) The Animal Procedures Committee will be notified of all projects where the use of non-human Hominoidea (the gibbon, siamang, the orang-utan, the chimpanzee and the gorilla) is proposed. The Committee will have the opportunity, if it wishes, to examine any such application, and to advise me of its views on the application.

(vii) When the controls of the 1986 Act are extended to cover establishments which breed or supply non-human primates such establishments will be required to keep lifetime records for all non-human primates bred at breeding establishments, and for all wild-caught non-human primates lifetime records from the date of importation will be required. Similar records are already required at establishments where non-human primates are used for scientific or experimental purposes authorised under the 1986 Act.

(viii) Particularly close scrutiny will be given to all project licence applications which include proposals to keep primates in isolation.

(ix) The Animal Procedures Committee will be notified of all applications for work involving non-human primates which includes any procedure in the substantial severity category. The Committee will have the opportunity to examine any such application and ot advise me of its views on the application.

The particular importance of safeguarding non-human primates is recognised in the 1986 Act, section 5(6) of which specifies that a project licence authorising the use of non-human primates (or cats, dogs or equidae) may not be granted unless it is established that animals of no other species are suitable for the purposes of the programme to be specified in the licence or that it is not practicable to obtain animals of any other species that are suitable for those purposes. In addition, we shall do everything possible to ensure that the use of non-human primates is restricted to establishments which provide facilities of a very high standard for their husbandry and welfare.

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