

062
From: THE PRIVATE SECRETARY



HOME OFFICE
QUEEN ANNE'S GATE
LONDON SW1H 9AT

Dear Tim

T/S
12/5
MAY 1983

...
The Home Secretary thought the Prime Minister would like to have the enclosed copy of the White Paper on Scientific Procedures on Living Animals which will be published at 3.30 pm tomorrow.

I am sending copies of this letter to the Private Secretaries of all members of the Cabinet, the Attorney General, the Chief Whip and Sir Robert Armstrong.

Yours ever

Kain

MRS K PAPPAS

T Flesher Esq



Jo R

10 DOWNING STREET

From the Private Secretary

10 May 1983

The Prime Minister has now seen the Home Secretary's minute of 9 May about the proposed White Paper on Scientific Procedures on Living Animals. She has agreed that this should be published on Thursday 12 May.

(TIM FLESHER)

Colin Walters, Esq.,
Home Office.

CONFIDENTIAL

2



Prime Minister

JF

9/5

PRIME MINISTER

SCIENTIFIC PROCEDURES ON LIVING ANIMALS

Home Affairs Committee considered on 26 April my proposals for modernising the Cruelty to Animals Act 1876 and agreed that a White Paper setting out our proposals should be published, subject to further interdepartmental consultations on certain points of detail. These consultations have now been completed and I attach a text of the agreed draft of the White Paper.

There has been pressure for many years to modernise this legislation and improve the existing controls. We undertook to do so in our manifesto and I have been persistently questioned as to when we shall be in a position to honour this commitment. While the Council of Europe was drafting a Convention on this subject - in which we played a leading role - it would have been premature to come forward with proposals which might not have complied in all respects with the ultimate requirements of the European Convention. The drafting of the Convention has, however, now been completed and the way is clear for us to announce our own proposals.

These will in certain respects - notably in allowing no exception to the pain condition - go further than the minimum standards required by the European Convention (the Convention itself recognises that Member States may wish to adopt stricter controls). The proposals are not, however, likely to satisfy fully the more extreme opinion in the animal welfare movement. They would like to prevent animals used for research and testing suffering more than trivial pain except in relatively exceptional circumstances. I am satisfied, however, that such a restriction would impose unacceptable limitations on important research and safety testing.

The proposals mark an important and substantial step forward in the safeguards we provide for animals used in this work and I believe they will command general support from all but the more extreme sections of public opinion.

In the light of your decision on the date of the General Election, I have arranged, subject to your agreement, that the White Paper should be published this Thursday, 12 May.

I am copying this minute to the other members of the Cabinet, Sir Robert Armstrong and John Sparrow.

How
9
May 1983

CONFIDENTIAL

DRAFT WHITE PAPER

SCIENTIFIC PROCEDURES ON LIVING ANIMALS

INTRODUCTION AND SUMMARY

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

of its kind

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

3. We are determined to maintain and improve the protection of animals which has applied in this country for over a century. Our proposals are also all consistent with the Council of Europe Convention (Appendix B) now nearing completion. Article 4 of the Convention allows member States to adopt measures for the protection of animals going further than the minimum which the Convention requires. The Government's proposals do go further. But we are very glad to see agreement in Europe on common minimum standards. Not only will this provide protection to animals throughout Europe, it will also help to ensure that work we would not allow in this country is not simply undertaken abroad. The United Kingdom has a large pharmaceutical industry which makes a big contribution to

our balance of payments and employs 67,500 people. In devising new controls it is very important not to put industry at risk unnecessarily. One benefit of the European agreement, when it becomes effective, will be to minimise such a risk.

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

5. The Government has a duty to safeguard the community from avoidable harm - and indeed tragedies - and to enable

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

6. The general principles which underlie the Council of Europe Convention and which the Government's proposals follow are:

- (1) The purpose for which experiments should be permitted should be clearly defined and limited;

- (2) Non-sentient alternatives to animals should be used whenever practicable;
- (3) The minimum number of animals should be used consistent with the objective;
- (4) Animals bred, supplied and used for experimental procedures should be cared for in accordance with the best standards of modern animal husbandry;
- (5) In the application of the controls the concept of pain should be applied in a wide sense;
- (6) The infliction of unnecessary pain should be avoided;
- (7) Appropriate measures should be taken to reduce pain and suffering;
- (8) There should continue to be control over the severity and duration of any pain which is unavoidable if the object of the procedure is to be achieved.

which are

7. The main changes from existing controls (summarised in Appendix C) to be made by the Government's proposals will be:

(1) Animal Procedures Committee

A new Committee, the Animal Procedures Committee, will be established by statute. It will replace the Home Secretary's present, non-statutory, Advisory Committee on Animal Experiments and will have wide powers to advise on questions of policy and procedure and on applications which the Home Secretary refers to it as giving rise to special concern. It will make an annual report which will be presented to Parliament.

(2) Inclusion of additional procedures

The basis of the 1876 Act is an experiment. This excludes a number of procedures such as

- (i) breeding for physical defects
- (ii) production of antisera
- (iii) passaging of tumours
- (iv) interference with the embryo and foetus

These will be brought under the new controls which will relate to procedures, a wider concept, and not as hitherto to experiments.

(3) Extension to animals being bred and supplied

Animals being bred for and supplied to laboratories do not at present benefit from any special control. The Government's proposals would extend appropriate controls to these animals. For the animals most commonly used in laboratories licensees will be required to use purpose-bred animals from registered suppliers only.

(4) Care of animals outside the period of the experiment

Strictly, the 1876 Act applies only to animals while they are under experiment. In practice the Home Secretary's inspectors have always been concerned with all aspects of laboratory accommodation and the care of animals in laboratories. The Government's proposals will give statutory effect to this practice.

(5) All work to require specific authorisation

Among the requirements of the European Convention, procedures will be permissible only if certain criteria are satisfied. For example there must be no other scientifically satisfactory method, not involving the

use of an animal, reasonably and practicably available; where there is a choice between procedures, those chosen should use the minimum number of animals, cause the least suffering and be most likely to provide satisfactory results. To give effect to these requirements it will be necessary for all work done under the new legislation to be specifically approved. The existing controls do not achieve that. We shall accordingly introduce a new system of project licensing which will provide a specific and positive control over the procedures that are undertaken. This will make it possible to apply extra stringent controls to procedures giving rise to special concern and such controls will be applied, for example, to applications for licences to test cosmetics.

(6) Anaesthetics and analgesics

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

(7) Use of animals for instructional purposes

Demonstrations are at present permitted under the 1876 Act only on fully anaesthetised animals - which are not allowed to recover - and only for students of medicine and allied sciences, including agriculture, at undergraduate level and above. We shall, in addition, allow demonstrations in other approved professional training courses, e.g. for potential technician licensees, but not in the education of schoolchildren or others at the same level.

Demonstrations on animals allowed to recover from anaesthesia may be allowed but only in exceptional circumstances and then only when the animal would not suffer more than trivial pain. Filmed material should be used whenever possible. Undergraduate students would be licensed

direct
to use animals only under/ supervision and only when
essential for them to acquire necessary knowledge.

- (8) Procedures for the acquisition of manual skills for
microsurgery

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

- after a procedure has been completed
(9) Animals will be allowed to survive/if they are
fit to do so.

- (10) The Inspectorate, which since 1876 has had a vital
part to play in raising standards and spreading the
best practice throughout the country, will continue in

/operation

CONFIDENTIAL

operation, will be strengthened, and will have new
and enhanced duties/ⁱⁿoperating the new controls.

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

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

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

Background to Government's proposals

11. The 1876 Act became law following the report of a Royal Commission (C.1397 of 1875). At that time the main use of animals for scientific work was surgical; the study of physiology and experimental sciences was progressing rapidly; and there was public apprehension about the course of these developments. A second Royal Commission, appointed in 1906, reported in 1912 (Cd 6114). Its majority recommendations were accepted and implemented administratively. In the next 50 years the biological sciences developed more rapidly and on a broader front than ever before. In 1963 the Departmental Committee on Experiments on Animals, under the chairmanship of Sir Sydney Littlewood, was appointed. The Committee which reported in 1965 (Cmnd 2641) concluded that the 1876 Act had been generally effective but drew attention to the need to adapt it to modern scientific and technological requirements and made a number of recommendations for this purpose. Some of these have been adopted administratively. Those requiring legislation have not yet been implemented.

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

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

14. A Council of Europe committee of experts began work in January 1978 on a draft Convention for the protection of animals used for experimental and other scientific purposes. That committee has now completed its work. It is hoped that the complete text of the Convention will shortly be submitted to the Committee of

Ministers for approval, which would open the Convention for signature and ratification. The Government intends to sign and, when Parliamentary time can be found to implement the proposals in this White Paper, to ratify the Convention.

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

THE GOVERNMENT'S PROPOSALS

The Animal Procedures Committee

16. The Committee will be composed of a Chairman and not more than 12 members, two-thirds of whom will be drawn from medicine, veterinary science and other biological sciences. They will all be appointed in a personal capacity. The new Committee will continue to perform the general advisory function of the present Advisory Committee, considering such matters as may be referred to it by the Home Secretary including questions of policy, practice and procedure, trends in experimental and scientific work, the development of alternatives to animals in experiments and proposals for revision in the law. It will also have an enhanced role in advising on the administration of the new controls. The Home Secretary will be required to consult the Committee before prescribing the standard conditions to which all licences will be subject and before

/granting

granting project licences in specified areas of work he regards as giving rise to special concern. He will specify proposals for testing cosmetics as such an area. In any application in such a specified area in which, exceptionally, the Home Secretary felt unable to accept the recommendation of the Committee he will be required, while observing considerations of confidentiality, to make public his reasons.

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

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

The Inspectorate

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

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

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

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

The Scope of the New Legislation

21. In accordance with Article 1.2(c) of the draft Convention, the new legislation will apply to any experimental or other scientific procedure which may cause the animal pain, suffering, distress or lasting harm, including any course of action intended to, or liable to, result in the birth ^(or hatching) of an animal in any such condition. Its scope will therefore be wider than that of the 1876 Act and will embrace some uses of animals such as the preparation of known anti-sera and the maintenance in animals of infectious organisms or tumours, which are not at present formally controlled but which may involve as much pain or discomfort as others at present subject to control. Decerebration of an animal (ie destruction of its brain) will be regarded as a procedure requiring authority in respect of all vertebrates, not solely as at present in mammals. Consequently,

CONFIDENTIAL

as the performance of procedures in schools is to be prohibited (see paragraph 4a below), the decerebration of frogs (including pithing) for teaching purposes in schools will no longer be permitted. The administration of ^{an} anaesthetic to an animal with a view to carrying out a procedure under the Bill will be regarded as part of that procedure. Non-experimental clinical veterinary or agricultural practice will be specifically excluded. In accordance with the draft Convention, methods accepted as humane for in modern practice / killing or marking an animal will be outside the scope of control.

Animals to be Protected

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

23. The Government agrees with the Advisory Committee that the recent administrative practice of requiring special authority for the use of non-human primates should continue. The aim must be as high a level of protection as possible for all animals used for experimental and other scientific purposes. The choice of species of animal to be used in a procedure is an important consideration and is recognised as such in the draft Convention (Article 7). Applicants for licences will therefore be required to justify their choice. These provisions will extend to all species safeguards comparable to the special protection which is conferred in the existing legislation only on cats, dogs and equidae (horses, asses and mules).

Pain

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

25. A standard condition placing an upper limit on the degree or duration of pain which may be caused in experiments on live animals has been imposed in all licences issued under the 1876 Act since 1887; and has been applied in its present form without exception since 1929. This, among its other provisions, requires the

painless killing of the animal if it is suffering severe pain which is likely to endure. Article 9 of the draft European Convention provides that any procedure under which an animal may experience severe pain which is likely to endure may be permitted if it is specifically authorised and is of exceptional importance for meeting the essential needs of man or animal. The Convention also allows us, however, to adopt stricter controls than the minimum it requires. In all licences in the United Kingdom we intend to continue unchanged the requirement that, if at any time an animal is found to be suffering severe pain which is likely to endure, it shall at once be painlessly killed. In addition inspectors will continue to be empowered to direct the painless killing of any animal which appears to the inspector to be suffering considerable pain.

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

Permissible Purposes

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

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

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

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

29. Procedures may be performed on animals for the purpose of testing substances and products for their potential to cause harm to man or the natural environment. Whilst recognising public concern over the use of animals in such tests, the Government has to take fully into account the equally valid concern of others that potentially harmful substances or products are recognised before

/they

they are placed on the market. Tests to evaluate these products will continue to be permissible and controlled. Similarly, suitable provision will be made for procedures to be permitted in accordance with the purposes specified in paragraph 27 (b) (c)(e) (f) and (i) above. As regards 27 (d), it is proposed to provide that experiments intended for the protection of the natural environment, in circumstances where otherwise the health or welfare of man or animal would suffer - e.g. testing rivers for pollution - should be permitted.

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

31. Although the number of tests of cosmetics is relatively very small (in 1981 there were fewer than 25,000 experiments to test cosmetics and toiletries, or around half of one per cent of the total number) many members of the public are understandably concerned that animals should be used for the safety testing of a new lipstick or deodorant. The Government has, therefore, considered whether it should go further and prohibit the use of animals for testing of cosmetics altogether or, alternatively, restrict the types of tests which should be permitted. It considers neither to be feasible. It is difficult to define what is strictly a cosmetic when substances may simultaneously be of medical or other therapeutic value. Such testing may also be required to comply with statutory or other requirements to protect both users and those concerned with their production. 17

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

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

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

use of animals to be avoided.

The Licensing System

35. The system of licensing is a fundamental feature of the control of the use of animals. Whilst the existing arrangements are satisfactory as regards the persons licensed, they are less so as regards the work undertaken. Under the existing law a licence, without more, is valid only for work on fully anaesthetised animals. In relation to such work, however, unless the licensee is subject to a limiting condition*, the licensee needs no further authority and may move on from project to project, provided anaesthesia is used throughout. Work in which the animals are not under anaesthetic for part or all of the time is allowed only if appropriate certificates are issued, signed both by professors of medicine and by presidents of learned institutions, to the effect that the purpose of the experiment could not be achieved if the animals had to be anaesthetised throughout. The Home Secretary has power to disallow certificates in whole or in part. In practice certificates are rarely disallowed except for technical reasons and the Advisory Committee is consulted before work is disallowed on the merits. Moreover, those certificates are usually drafted in terms which are capable of permitting a series of projects to be undertaken without further authority having to be obtained. This system of control is no longer satisfactory. We accordingly propose to introduce a substantially improved system of licensing which will enable the various objectives of the new controls to be effectively achieved. Our proposals have much in common with those of one of the two schemes proposed by the Advisory Committee (Appendix A, paragraphs 5 to 7). Provision will be made for two kinds of licence: personal licences and project licences. The Home Secretary will be empowered to attach to these licences any

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

conditions which he may think expedient.

Personal Licences

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

Project Licences

37. Project licences will be a new feature of the system. It will not be necessary for every licensee to be granted a project licence for the work on which he is engaged. Such licences will be needed only by the licensee who has overall responsibility for the project and will cover all other licensees engaged on it. It will not, however, be lawful for a licensee to undertake work involving the use of living animals unless a valid project licence is in existence authorising that work. The definition of a project will vary considerably according to the kind of work in question. The work carried out by an individual research student designed to obtain the answer to a specific question and lasting for only a few months could constitute a project. Equally, toxicity evaluation

of more or less broadly defined types of substances carried out over a period of years could also constitute a single project, even if the substance being tested varies throughout the period. Applicants for project licences will be required to provide sufficient information about the nature of the project and its purposes as will enable the Home Secretary to judge whether it satisfies the criteria of purpose and other requirements.

Sponsorship

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

- a. the project is likely to achieve the declared purpose;
- b. any alternative non-sentient method would satisfactorily and reliably achieve the purpose:

/c

- c. the type of animals which it is proposed to use is appropriate; and
- d. the applicant's proposed use of anaesthesia or analgesia is adequate.

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

Student Licensing

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

Applications for Project Licences for Education and Training

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

41a. At present such procedures, when they involve pain or distress to the animal, are permissible, insofar as they are permissible at all, only in registered places. It is not proposed that any significant extension of the categories of registered places should be made. Since decerebration will in future be a controlled procedure, permissible only in a registered place, and since licences will be issued only to persons aged 18 or over, it will not be possible under the new proposals for living animals to be used in schools, in potentially painful scientific procedures for educational purposes, whether in demonstrations - for which project licences would in any event not be issued in such circumstances - or by schoolchildren themselves.

/Requirement

Requirement to Kill Animals after Use

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

Curare and Other Muscle Relaxants

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

User Establishments

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

- (1) a named person or persons will have day to day responsibility for ensuring that the conditions are fulfilled;
- (2) a veterinary surgeon, either from the staff of the establishment, retained part time, or available to be called in at all necessary times, will be responsible for advice on animal health and welfare;
- (3) adequate staff must be available for the care of the animals used, or kept for use, in procedures;
- (4) adequate care and accommodation must be maintained appropriate to the particular animals; and
- (5) environmental conditions must be checked daily.

44a. It is not expected that there will be any significant increase in the number of establishments registered for the performance of controlled procedures. Those establishments where procedures are carried out which are not covered by the 1876 Act but will be covered by the new proposals (see paragraphs 7(2) and 21 above) will need to be registered if they are not registered already. The additional number, however, is likely to be small. Other than in exceptional circumstances, e.g. where a building may be used for more than one purpose, the Home Secretary will not be prepared to register buildings such as, for example, schools for the purpose of the new proposals.

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

Breeding and Supplying Establishments

46. There are at present no controls over the breeding and supply

of animals for use in experiments, except for the prohibition in the Dogs Act 1906 on the disposal by the police of stray dogs for use in experiments. The Government intends to introduce such controls in accordance with the provisions of the draft European Convention. This will require the registration and inspection of all establishments which breed and supply animals intended for use in experimental and other scientific procedures; for such establishments to provide their animals with certain standards of care and accommodation; and for recording various details of all such animals, particularly in respect of cats and dogs.

Source of animals

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

Other Provisions

Statistics

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

Offences and Penalties

49. It will be an offence to perform or take part, without authority, in performing a procedure on a live animal which may cause pain, suffering, distress or lasting harm; knowingly to aid and abet the performance of an unauthorised procedure; and knowingly to provide false information in an application for a licence or for registration. Provision would be included to make unlawful unauthorised disclosure of confidential information. Other offences might be needed to provide appropriate sanctions to make aspects of the controls, e.g. in respect of establishments breeding and supplying animals, effective. All offences will be triable summarily but the 6 months time-limit on their institution will be modified to provide that proceedings may be taken within 6 months from the date on which the evidence comes to light but not later than 3 years from the commission of the offence. Penalties for offences will be in line with those available for offences under the Protection of Animals Act 1911.

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

Territorial Extent

51. The proposals will apply to Great Britain and, with appropriate modifications, to Northern Ireland.

Financial and Manpower Implications

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

will be payable for licences and for registration.

CONCLUSION

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

54. The Government would welcome any written comments on the proposals which should be sent to the Home Office, E4 Division, Queen Anne's Gate, London SW1H 9AT by [3 months from the date of publication].