Report on openness / Animal Procedures Committee.

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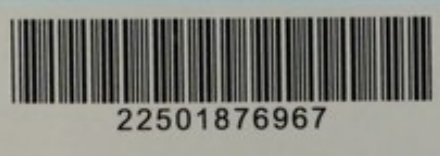
ANIMAL PROCEDURES COMMITTEE

REPORT ON OPENNESS

AUGUST 2001



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Introduction

1. The Government made a commitment in its 1997 election manifesto to legislate to ensure that the public would have a clear and statutory right of access to information held by the public sector. Freedom of Information is seen as an essential component of the Government's programme of constitutional reform. That programme aims to involve people more closely in the decisions which affect their lives. Giving people greater access to information is essential to that aim.

2. The Freedom of Information Act 2000 provides for the first time, that everyone will have the right of access to information held by bodies across the public sector. That Act recognises that openness cannot be completely unlimited. It therefore sets out a framework within which the right of access to information is balanced against the equally important rights to privacy and to confidentiality, and the Government's need for time and space in which to think and plan.

3. The Act achieves that by setting out a right of access and how it can be exercised, and then setting a number of conditions and exemptions from that right. The underlying principle is that information will be disclosed unless it is exempt information, and information is exempt if its disclosure would, or would be likely to, prejudice an interest, such as personal safety or commercial confidentiality. In most cases it will not be enough simply to say that there is an exemption. The Act also provides that for most exemptions the public authority holding requested information will also have to look at the balance of the public interest in maintaining that exemption or disclosing the information. If the authority concludes that there is no overriding public interest in withholding the information, it must disclose it.

4. The Act provides for the right of access to publicly held information to be enforceable. It establishes an Information Commissioner and an Information Tribunal with wide powers. The Commissioner will be able to require that information is provided in order to assess any complaints, and to require the disclosure of information where she considers the authority has depended inappropriately on an exemption or has wrongly assessed the test of the balance of public interest. Authorities and complainants will have a right of appeal to the Information Tribunal and government departments and some other public authorities will also be able to ask the Secretary of State to override the Commissioner's decision in respect of public interest disclosure.

5. The Freedom of Information Act will be introduced in stages but must be in effect for all public authorities by no later than 30 November 2005. The Government has said that it intends to bring it into effect for central Government departments and most Non-Departmental Public Bodies as early as possible. This is likely to be during 2002, although a firm date has not yet been announced. The provisions of the Act will then be applied to further tranches of the public sector by agreement with the Information Commissioner, but probably at 6-month intervals.

6. The Animals (Scientific Procedures) Act 1986 (the 1986 Act), requires the licensing of any experiment or other scientific procedure carried out on living, protected animals which may cause them pain, suffering, distress or lasting harm. Licences under the Act are issued by the Home Office on behalf of the Home Secretary. They may only be issued if the benefits outweigh the likely adverse effects to the animals

concerned. The Home Office's Animals (Scientific Procedures) Inspectorate examines all applications and provides professional advice on them. The Animal Procedures Committee (APC) provides the Home Secretary with advice, independent from the Home Office and its Inspectorate, about the legislation and his functions under it. The Committee consists of experts from a wide variety of backgrounds. There are currently 20 members.

7. Some relevant background information about UK animal experimentation can be obtained from the statistics for 1999. At the end of 1999 there were a total of 3,481 project licences in force. The severity levels were as follows :

Mild	1406	40.4%
Moderate	1861	53.5%
Substantial	66	1.9%
Unclassified*	148	4.2%
Total :	3481	

* (Unclassified = all procedures carried out under general anaesthesia from which the animal does not recover).

There were 21 Inspectors who undertook 2,730 inspections. 2,656,800 experiments were undertaken and the number of animals used was 2,570,000. (The discrepancy is because some animals are used in more than one procedure).

8. Section 24 of the 1986 Act relates specifically to the release of confidential information about animal procedures. It makes it an offence for anybody *'otherwise than for the purpose of discharging his functions under the Act'* to disclose information about animal procedures which the person who provided it has given in confidence. The future of this section of the Act is a key consideration in the debate on openness in animal procedures. If it continues in place without amendment, such information would be exempt from disclosure under the provisions of the Freedom of Information Act, which specifically exempts information disclosure of which is prohibited by or under any other enactment (section 44).

9. Much public concern has been expressed about what is perceived as the secrecy of the procedures for the licensing and conduct of animal procedures. Ten years after the implementation of the 1986 Act, the APC conducted a review of the operation of the Act, which was published in 1998 in the APC's Annual Report for 1997. In the course of that review the Committee recognised that it would be considering the practical implications of a balanced application of "*the principle of openness concerning the use of animals in scientific procedures*" and said that it would be investigating the subject more thoroughly. Some specific areas to be explored were identified.

   - Should details of licence applications be made available?

   - Should the annually published statistics provide additional information, such as data on the severity banding of projects and the level of adverse effects actually caused?

- Should more information about the benefits which accrue from research involving animals be published, and linked to animal usage and suffering?
- Should the annual statistics be revised to provide more information on the use of genetically-modified animals and harmful mutants? (The last area has been taken up as a separate task by the APC's Biotechnology Working Group).

The Committee decided to establish a working group to take forward an investigation of openness.

10. The APC Openness Working Group was formed in 1999. It recognised that in addition to the issues identified by the review it would need to carefully consider what advice, if any, it might put forward in relation to the retention, variation or repeal of section 24 of the 1986 Act. It decided as a first step to seek the views of interested individuals and bodies on the issues. A copy of the consultation letter which was sent out on 13 January 2000, is at Annex A (i). The members of the working group took account of their own knowledge and expertise, and that of the representatives who met with them, in the consideration of the large number of responses received (2,320). A statistical analysis of the responses is at Annex A (ii).

11. To inform the continuing discussions of the working group each member prepared commentaries based on the responses from five different groups of respondents: individual members of the public; animal welfare organisations; commercial institutions; individuals working in commercial institutions; and academics and academic institutions. These are recorded in Annex B. By recording those views the APC does not necessarily endorse them.

12. The working group also took account of the views of the Home Office Minister then responsible for animal procedures, Mr Mike O'Brien.

Methodology

13. The working group met for the first time on 17 November 1999. Its initial membership was three members of the APC: Professor Christopher Atterwill (Director of Biosciences, Huntingdon Life Sciences Ltd) (chair), Mr Mike Baker (UK Director, International Fund for Animal Welfare) and Mr Robert McCracken (a barrister). The consultation period ended on 10 March 2000 (Annex A). Because of the large number of responses which were received it was decided to increase the membership of the working group by two further members of the APC: Professor Grahame Bulfield (Director and Chief Executive, Roslin Institute) and Professor David Clark (Honorary Senior Research Fellow, University of Kent) joined the working group on 17 March.

14. Each member of the working group was provided with copies of all the written responses which were received. In addition, they were provided with several statistical breakdowns of the responses (see Annex A (ii)). Meetings of the Working Group took place on 17 November 1999, and in 2000 on 30 May, 13 June, 26 July, 25 September, 23 October and 20 and 27 November. At some of these meetings the working group was assisted by visiting specialists: representatives from Glaxo-Wellcome, the Police National Public Order Intelligence Unit and the Home Office Freedom of Information Unit attended our meeting on 26 July. Two other Home Office officials attended the working group's meeting of 25 September: a superintending inspector of the Animals

Scientific Procedures Inspectorate and the head of the Animals Licensing Section of the Animals, Bye Laws and Coroners Unit. The Chief Inspector of the Animals Scientific Procedures Inspectorate attended the working group's meeting of 20 November. The working group was grateful to all of them for their helpful contributions to the understanding of the issues.

Discussion

15. After assessing all the responses to the consultation exercise the working group realised that there were large bodies of opinion which were at either end of the spectrum of thinking about openness in relation to the 1986 Act. The first of these, comprising animal welfare organisations and many individual members of the public, saw the only way forward as one of total openness, with full retrospective disclosure and the repeal, rather than adaptation of section 24. At the other end of the spectrum were those – from the private and public sectors - using animals in regulated procedures. They were very concerned about any increase in openness. This was for a variety of reasons, the predominant one being personal security. Others included commercial confidentiality; the erosion of the UK research base; and the concern that increased availability of information might delay the preparation and processing of applications.

16. It is recognised that institutions have already been required to provide an increased degree of openness through the Ethical Review Process (ERP), introduced from 1 April 1999. Additional openness is provided by the mandatory presence in the ERP of independent lay members. It is felt by some that the integration of the ERP within the licensing framework has already placed an increased burden on the institutions operating the process, which should be noted.

17. The working group noted that the Home Office and the APC itself have made some progress towards openness by setting up pages on the web. The web addresses are www.apc.gov.uk; www.homeoffice.gov.uk/dob/abcu; www.homeoffice.gov.uk/dob/aspi .

18. Annex C contains the Home Office Circular letter of 1 April 1998 introducing the Ethical Review Process and the text of a reply to a Parliamentary Question announcing a review.

19. From the results of the consultation exercise the Working Group tried to come to a pragmatic balance between the undoubted sincere and deeply held concerns of the public about animal welfare and openness and the equally deeply held concerns of industry and academia. The responses from the public and from welfare organisations saw wider openness as a means to increase the accountability of this controversial aspect of life making it more open to public scrutiny. But the working group also took into account the concerns of industry and academia: concerns about personal security; commercial confidentiality; an increase in the regulatory administrative burden; and the fear that work involving animals would move abroad to the detriment both of animal welfare and the UK's commercial advantage. That might be caused both by enhanced openness and by increased regulation.

Statutory implications

20. The Working Group considered an analysis of the Freedom of Information regimes in other countries – Australia, New Zealand, Eire, the Netherlands, the United States and Canada - prepared by the then Home Office Freedom of Information Unit as part of the consultation on the FOI Bill in 1999. Since none of these countries has a similar system of licensing of animal experiments to that of the UK the conclusions that can be drawn from this analysis are limited.

21. The Working Group noted that Part II of the Freedom of Information Act 2000 sets out the principal exemptions from the duty to disclose requested information. That Act can be viewed at www.hmso.gov.uk/acts/acts2000/20000036 . The most relevant sections include:

- section 41 (Information provided in confidence). This exemption relates to information which a public authority has received under the common law duty of confidentiality and whose disclosure would constitute an actionable breach of confidence; and

- section 43 (Commercial interests). Information is exempt if it constitutes a trade secret or its disclosure would, or would be likely to, prejudice the commercial interest of any person;

22. The Committee noted that other parts of the 2000 Act qualify the way in which the exemptions operate, and in particular that each of the exemptions identified above is subject to a public interest duty of disclosure, except in respect of the exemptions for information received under a common law duty of confidence (section 41). Such a test is already inherent in the determination of the duty of confidentiality.

23. As already noted, section 24 of the 1986 Act prohibits the disclosure of any information received in confidence. The Freedom of Information Act 2000 makes provision for such statutory bars to be repealed or amended by Order for the purpose of removing or relaxing the prohibition (section 75). The working group noted from its consultations with the Animal (Scientific Procedures) Inspectorate and with the Animal Procedures Section of ABCU that appreciable extra demands would be placed on them if any change to section 24 of the 1986 Act were to be made retrospective. The working group was also very aware that all information contained in Project Licence Applications has been given up to now on the understanding by the applicants that all such information was given in confidence.

24. A key feature of the Freedom of Information Act 2000 is the requirement on each public authority to adopt and maintain a publication scheme. A scheme must set out the information which the authority proposes to publish pro-actively and must be approved by the Information Commissioner. Such a scheme provides an opportunity for the Home Office to actively place in the public domain that information in relation to experimentation on animals which it believes should be readily available and will assist in minimising the disruption to the Animals (Scientific Procedures) Inspectorate and ABCU which might otherwise arise from their obligations under the Freedom of Information Act.

25. The Committee concluded that it is likely that there will be a need to vary section 24 of the 1986 Act; that there should be no blanket exemptions on the duty to disclose information; and that any publication scheme which the Home Office might develop would need to reflect the spirit of openness.

Other considerations

26. The Working Group considered the recommendations proposed in some of the responses to the consultation exercise for improving the openness of licensing procedures. The research and development process for new chemicals and medicines within life sciences [1]is a complex one, and one that is generally poorly understood by the public. Within that process, however, there are points besides the licensing process where we considered that increased openness could be applied.

27. Apart from the issue of openness in regard to licensing procedures, we also considered the wider issue of openness in the public and private sectors. Openness might be furthered by:

- an increase in the publication of data derived from animal experimentation, whether positive or negative;
- an increased transparency of the Inspectorate's activities in the form of enhanced publication of statistics and reports;
- educating the public about the research and development process within the Life Science industries;
- increasing the public's knowledge about the Life Science industries by encouraging visits to establishments by responsible members of the public and by a programme of attendance by industry representatives to local groups and schools etc.

28. Some actions which could be taken by the industries themselves include:

- an increase in the visibility of industry to the general public; and
- a clarification of the research and development process to welfare organisations and the wider public by a process of education.

Actions that could be taken by the Home Office include :

- an increase in transparency in the APC and the Inspectorate. We go into further detail about this below.

Recommendations

Introduction

[1] Life Sciences are those areas of science covering biological research involving animal or human health. They have traditionally been referred to as the pharmaceutical and toxicology industries.

29. After careful consideration, we have concluded that total openness, as supported by a number of individuals' and animal protection organisations' responses, is not practical chiefly because of concerns in relation to personal security, but also because of issues of commercial confidentiality. Our aim however, has been to recommend measures which will lead to the greatest degree of openness compatible with those concerns. To achieve any increase in openness, however, some prior change will in our view be required to section 24 of the 1986 Act. Recommendation 1 therefore addresses that issue. Recommendations 2 and 3 set out our proposals for revisions to project licence applications, and to the publication of results of experiments. We consider these to be the most important of our recommendations.

Recommendation 1: amendment to section 24

30. Repeal or relaxation of the prohibition in section 24 of the 1986 Act on the disclosure of information relating to animal experimentation should be considered as a necessary step of giving effect to the recommendations for greater openness described in this report. Any changes agreed should not be retrospective.

Recommendation 2: the Project Licence Application form

31. We recommend that the Project Licence Application form should require a summary of the procedures to be undertaken, and that this summary should be comprehensive and detailed enough to provide a reader with a clear indication of the costs and benefits of the project. Such a summary would be perhaps a maximum of two pages, and would be written in language appropriate to the general reader. We recommend that such a summary should include:-

- Key objectives and possible benefits of the project;
- Reasons for the need to use animals; what alternatives have been considered; and why these are not appropriate;
- Reasons for the choice of species and strains;
- Numbers of animals to be used and kept for the specific project;
- What will happen to the animals as a result of the project - a synopsis of the main adverse effects covering the lifetime experience of the animal; including factors such as source, husbandry, procedures and their effects, and eventual fate of the animal;
- Estimated level of the severity of the project;
- Specific measures to minimise adverse effects and improve welfare, including both husbandry and procedures; and
- How the applicant has weighed the costs against the benefits to judge whether the use of animals is justified.

The summary of procedures should be proactively published as part of the Home Office's publication scheme.

32. The Committee recognised that there were advantages and disadvantages to whether a summary of a licence application should be made public at the stage when an application was received by the Home Office, or later, at the stage when a licence was granted. If the application were made public at the earlier stage:

- it would give members of the public time to comment before a licence was granted, so that they could seek to influence the decision making process;
- animal protection organisations might be able to refer to possible alternative procedures which had not been considered; and
- sight of applications which were ultimately turned down would allow the public to see that the licensing process was sufficiently rigorous.

33. On the other hand, it was also suggested that making an application public before the licence had been granted had disadvantages:

- It might hamper the iterative process of discussion which goes on between the Home Office and applicants;
- It was also noted that as applications are progressively developed by that iterative process, more than one version of a changing application would have to be made public; and that
- until a licence is granted, the procedure has not been subject to an exercise of governmental judgement, and therefore should not be made public.

34. The Committee hopes that when the Home Office considers the stage at which a summary of a project licence application should be made public, the advantages and disadvantages of both options will be taken into consideration.

Recommendation 3: Publication of results

35. Positive outcomes of experiments are usually published in open scientific literature, but projects which yield no useful results, or fail to prove a project or principle ("negative results") are seldom written up - this is true, in particular, of basic medical research. Failure to publish such results could lead to unnecessary repetition of animal experimentation.

36. Mechanisms for making available information on both positive and negative research outcomes would differ depending on whether the research was basic medical research or commercial research. One possible mechanism for disseminating information on basic medical research could be to record on the ABCU website the results achieved or an explanation of why the project was abandoned. The effort this would entail should not be underestimated and would contribute little to academic progress. Another possibility would be to publish interim reports on grant-funded research. In the commercial sector, the position is not simple. Negative results are rarely published, and for reasons of commercial secrecy even positive results are not published until a patent application has been lodged. If a new medicine fails to reach the market neither

positive nor negative results may ever be published. In such circumstances the process of assessing the release of any information will involve commercial lawyers more than scientists, and it will be a lengthy, complex and iterative procedure. Because of these problems, we recommend that a more detailed investigation of a workable process should be undertaken.

37. The Committee recognised that this was a particularly difficult and complicated area. However, the development of a satisfactory system could result in a reduction of nugatory experiments and the Committee urges the Home Office to commission further examination of possible mechanisms for publishing negative results. Publication should form a part of the Home Office publication scheme.

Recommendation 4: increased openness regarding infringements

38. Summaries of major infringements are considered in an anonymised form by the APC, and discussed at Committee meetings. In the case of a more serious infringement a detailed anonymised account is supplied. We believe that information of this kind should be more widely available and we would be willing to publish this material as an appendix to our annual report.

Recommendation 5: increased openness in reporting of statistics and the work of the Animal (Scientific Procedures) Inspectorate

39. Annually, a statistical report on animal experimentation is published, available from HMSO. We recommend that the usefulness of the information in that report should be improved. For example, it should include numbers of animals kept for experimentation in addition to the existing statistics, which detail only numbers of animals actually used in experiments. We also recommend that the report should include fuller details of the severity of experiments. This would assist the public to come to an informed view.

40. Although an annual statistical report is produced, there is no annual report of other areas of the work of the Animal (Scientific Procedures) Inspectors. We recommend that such an annual report should be produced, which might cover areas such as visits to establishments; the results, number and type of licences processed; and the outcome of research renewal applications. That report should be published as part of the Home Office publication scheme.

Other recommendations

41. The Committee agreed other recommendations. They are for the Committee itself to pursue, rather than the Home Office.

Recommendation 6: additional voluntary openness

42. To assist public debate the Life Science institutions should be encouraged to open their facilities to the responsible public.

Recommendation 7: APC involvement in special investigations

43. We note that APC minutes are placed on the APC website. In the same way,

where the APC discusses a report by an APC working group carrying out a "quality assurance audit" of an investigation by the Inspectorate, that discussion, the report of the audit working group and the Inspectorate report should all be made available on the web, suitably anonymised. This change should be acknowledged in the Home Office publication scheme.

Recommendation 8: APC interaction with other bodies

44. The APC should have a programme of regular interaction with other committees, representative bodies and pressure groups in the UK and overseas. This would be for two purposes: to educate and inform members of the APC; and to achieve a mutual and reciprocal educational and information process with other relevant influential bodies. In the UK this would include bodies such as the House of Lords select committee on animal experimentation, the Agriculture and Environment Biotechnology Commission (AEBC), the United Kingdom Xenotransplantation Interim Regulatory Authority (UKXIRA), and representatives of users and animal protection organisations. The aim of international co-operation would be to contribute towards the development of international Freedom of Information legislation relating to animal experimentation, especially within the European Union.

Conclusion

45. The Committee recognised that because of the widely differing and sincerely held opinions of the respondents to our consultation exercise, the application of increased openness to the issue of animal experimentation was a difficult one. We hope that this report will assist the Home Secretary to formulate a policy which will address the needs of all sides of this debate.

Consultation letter
Openness and Animal Procedures

ANNEX A (i)

Room 978, 50 Queen Anne's Gate
London SW1H 9AT
0207 273 2915 or 2770
apc.secretariat@homeoffice.gsi.gov.uk

13 January 2000

Dear reader

Consultation Paper on Openness and Animal Procedures

This paper seeks your views on the application of openness to the use of animals in scientific experiments or other procedures.

We will use the responses which we receive to advise the Government on this issue as the current Freedom of Information Bill goes through Parliament and thereafter.

2. The paper begins with some background information. We then set out the issues, and some options for change. We welcome comment on all of this. But you may find it helpful to focus on the alternatives which are set out in paragraph 21.

Background – Government policy on openness

3. The Government is committed to a radical change in people's ability to participate in public decision making and the exercise of the State's powers. Its policy is based on:

> ***The assumption that information should be released except where disclosure would not be in the public interest***
>
> *Government Background Paper to the Freedom of Information Bill*

Background – the legislation

4. The Animals (Scientific Procedures) Act 1986 requires the licensing of any experiment or other scientific procedure carried out on living, protected animals which may cause them pain, suffering, distress or lasting harm.

5. Licences under the Act are issued by the Home Office on behalf of the Home Secretary. They may only be issued if the benefits outweigh the likely adverse effects to the animals concerned. No reasonably practicable alternative not involving animals must be available. The Home Office's Animals (Scientific Procedures) Inspectorate examines all applications and provides professional advice on them.

6. Section 24 of the 1986 Act relates specifically to the release of confidential information about animal procedures. It makes it an offence for anybody *'otherwise than for the purpose of discharging his functions under the Act'* to disclose information about animal procedures which the person who provided it has given in confidence. The future of this section of the Act is a key consideration in the debate on openness in animal procedures.

Background – the Animal Procedures Committee

7. The Animal Procedures Committee (APC) provides the Home Secretary with advice, independent from the Home Office and its Inspectorate, about the legislation and his functions under it. The Committee consists of experts from a wide variety of backgrounds.

8. By law, the APC must take account of *both* the legitimate requirements of science and industry *and* the protection of animals against avoidable suffering and unnecessary use in scientific procedures.

Applying the Government's new approach on openness to animal procedures

9. Much public concern has been expressed about what is perceived as the secrecy of the procedures for the licensing and conduct of animal procedures.

The reasons for animal procedures

10. Many people believe that animal experimentation is necessary to benefit mankind

- by researching causes and treatments for diseases
- by performing risk assessments on new medicines
- by testing new and existing products to minimise harm to humans.
- and cannot be replaced by non-animal alternatives.

11. It is nonetheless agreed that animal welfare is a matter of very great concern, and the Animals (Scientific Procedures) Act seeks to ensure that, as well as being justified by the balance of benefits and burdens, all experimentation is subject to principles of reduction, refinement and replacement.

The Case for Greater Openness

12. Some feel, however, that

- repetitive or otherwise unjustifiable work is authorised
- licensing conditions do not ensure that animals live as far as possible in conditions which respect their nature
- licensing conditions do not ensure that the procedures involve the minimum of suffering
- compliance with licensing conditions, such as those relating to living conditions and conduct of procedures, is not adequately enforced
- such breaches of conditions as do come to light are not viewed by the authorities sufficiently seriously
- no effective mechanism exists to ensure that the potential benefits derived from the harm inflicted are actually realised.

13. Those who have the above concerns tend to feel that greater public access to information about the operation of the system and treatment of animals would make possible more effective public scrutiny. Such scrutiny would lead to worthwhile improvements for affected animals. At

present even members of the APC have access only to the most limited amounts of information.

14. Others who argue in favour of greater openness take a different line. Their argument is that there are no serious defects in the current arrangements for the welfare of animals used in experiments, and that the problem lies in the public's (mistaken) perception that there are. Every reassurance from or about the Home Office's Inspectorate is met with the response that 21 Inspectors cannot begin adequately to protect the animals involved in two million procedures a year. Those who support this argument are, however, unable to present the information which would justify their position because of the current restrictions on access to information about animal procedures.

The Case against Greater Openness

15. An argument against greater openness would be that, whatever criticisms may have been justified in the past, the present system and culture ensures that the welfare of laboratory animals is properly attended to in contemporary scientific practice.

16. Researchers and toxicologists should not have to face public criticism or even physical assault just for doing their important jobs. Commercial organisations should not have to make available information which might cause them patent problems or would save their competitors from the trouble of doing research for themselves.

17. The public has no need to know more because there is nothing to which any reasonable person would object if he or she became aware of it.

The Animal Procedures Committee

18. The Animal Procedures Committee indicated in its Annual Report for 1997 that it would be considering the practical implications of a balanced application of "*the principle of openness concerning the use of animals in scientific procedures*". The Committee advised the Home Office's Freedom of Information Unit in 1999 that "*the overall presumption should be that information provided to the Home Office in the course of licensing scientific procedures on animals is disclosable on demand*"

19. It is important that it advise the Home Secretary early in 2000 as new legislation is being considered by Parliament. The APC Openness Working Group seeks the views of interested individuals and bodies on the issues.

20. We invite respondents to consider particularly the practical issues involved in a balanced application of the principle of openness in relation to:

- details of licence applications
- contents of the Inspectorate files
- Inspectorate advice to the Home Secretary
- Results of research
- Compliance monitoring and enforcement
- Proceedings of the Animal Procedures Committee
- Local Ethical Review Processes (LERPs)

- Application of alternative methodologies and compliance with principles of reduction, refinement and replacement

21. Respondents may find it convenient to express views on the following possibilities:

OPTION A: Full information is made available about all the above matters

This would provide the fullest benefits which access to information can offer. It might, however, expose individuals to risk of public criticism or attack. It might also prejudice the financial interests of commercial organisations whose trade secrets were revealed.

OPTION B: Full information is made available about all the above matters with the exception (on demonstration by affected persons of prejudice from disclosure outweighing public interest in disclosure) of information revealing:

the identity and addresses of individuals

This would protect individuals from attack but would otherwise have the same benefits and disadvantages as Option A.

OPTION C: Full information is made available about all the above matters with the exception of information (on demonstration by affected persons of prejudice from disclosure outweighing public interest in disclosure) revealing:

the identity and addresses of individuals or
potentially patentable material before it is made public through the patent process or
information about investigations into non compliance before completion thereof.

This would protect individuals from public criticism or attack and commercial organisations from financial loss through exposure of trade secrets but achieve only some of the benefits of openness.

OPTION D: Full information is made available about all the above matters with the exception of information (on demonstration by affected persons of prejudice from disclosure outweighing public interest in disclosure) revealing:

the identity and addresses of individuals or
potentially patentable material before it is made public through the patent process, and any other strategic research and development information of commercial value to competitors; or
compliance monitoring and enforcement

This would avoid emotive exploitation for publicity of unusual occurrences but would provide fewer of the benefits of openness than Option C.

OPTION E: Full information is made available except in relation to matters which have been the subject of a requirement from affected persons for confidentiality

This would provide maximum protection for individuals and commercial organisations. It would provide few, if any, of the benefits of openness.

22. We suggest that in replying to us you focus on what is desirable *in principle*. We are

considering the legal feasibility of, and mechanisms for achieving, these objectives separately.

Your reply

23. Comments on the above issues and options should be sent to APC 'Openness', Room 978, Home Office, 50 Queen Anne's Gate, London SW1H 9AT so as to arrive by Friday 10 March 2000. Or you can if you prefer e-mail us by that date at apc.secretariat@homeoffice.gsi.gov.uk. Again please mark your e-mail reply 'openness'.

24. We attach a pro-forma sheet which you might wish to use for your reply. You do not need to use this sheet to reply to us, but if you do please briefly fill out the information at the top of the form and tick off which of the options A to E (as described in paragraph 21) you prefer.

25. We will, if asked, disclose the content of responses to this letter and the identities of respondents. Please let us know if you would prefer us not to disclose your name and address.

CHRIS BONE
Secretary

A statistical analysis of responses

There were 2,320 responses to the consultation exercise.

Table 1, and figure 1(a), profile the spread of responses across four categories of respondent: institutions, individuals, pharmaceutical organisations and welfare organisations. These show that the greatest number of responses – over 1,000 - was from individuals, followed by responses from institutions and pharmaceutical organisations (700 and 500 respectively), with a small number of responses from animal welfare organisations. It was apparent that many responses from individuals were on pro-formas provided by interest groups such as the BUAV. Some bodies such as the Medical Research Council had also provided stock letters for members' use. We made no negative value judgements about the use of these methods of response.

Table 1 and figure 1(b) also define the breakdown of those responses across the various options proposed in the consultation exercise. In addition to the options A to E given in the consultation exercise, we decided to use two more categories. Option X denotes those responses which specified more than one option. Option Y denotes those responses which did not specify an option.

Figure 1 (a – e) shows that individual respondents overwhelmingly chose options A or B (total or almost complete openness). Pharmaceutical organisations had a marginal preference for option D, but with many opting for option E.

Table 2 and figure 2(a to e) give a further breakdown of responses from institutions and pharmaceutical organisations. This indicates the spread of responses between individuals in those organisations and those of management. Not surprisingly, the higher number of responses came from individuals.

Of the other institutions (research facilities, universities and government institutions) depicted by the figures in table 1(type 1), there was a majority opting for option Y (no given option preferred). However, there was also a fairly even spread over options C, D and E, indicating a body of opinion favouring a certain degree of openness.

A further breakdown between individual opinion and management opinion in the institutions and in the pharmaceutical industry, is depicted in table 2 and figure 2 (e). This confirmed that the majority of individual opinion in the Institutions (research, university, government), favoured none of the options offered, but did offer some preference across options C, D and E (a certain degree of openness). Which in many ways reflected individual opinion in the pharmaceutical / CRO sector who preferred options D and E. Management opinion in the institutions also favoured no option, as did management opinion in the pharmaceutical / CRO sector.

TABLE 1

RESPONSES ON OPENNESS CONSULTATION PAPER

Total combined responses.

Type	Option A	Option B	Option C	Option D	Option E	Option X More than one option	Option Y No Option chosen	Total
1	5	24	118	131	160	26	260	724
2	407	583	17	5	21	9	30	1072
3	Nil	Nil	22	256	187	1	32	498
4	9	9	1	1	Nil	Nil	6	26
Total	421	616	158	393	368	36	328	2320

Notes 1. Institutional (Research/University/Government) responses
2. Individual Responses
3. Pharmaceutical/CRO responses
4. Animal Welfare Groups

TABLE 2

RESPONSES ON OPENNESS CONSULTATION PAPER

Responses from Institutions and Commercial Companies

Type	Option A	Option B	Option C	Option D	Option E	Option X More than one option	Option Y No Option chosen	Total
1a	5	20	106	119	154	18	224	646
1b	Nil	4	12	12	6	8	36	78
2a	Nil	Nil	22	254	181	1	21	479
2b	Nil	Nil	Nil	2	6	Nil	11	19
Total	5	24	140	387	347	27	292	1222

Notes: 1a Institutional (Research/University/Government) individual responses
1b Institutional (Research/University/Government) on behalf of Dean, Certificate Holder/ Manager responses
2a Pharmaceutical/CRO individual responses
2b. Pharmaceutical/CRO on behalf of Dean, Certificate Holder/ Manager responses

Figure 1 (a)

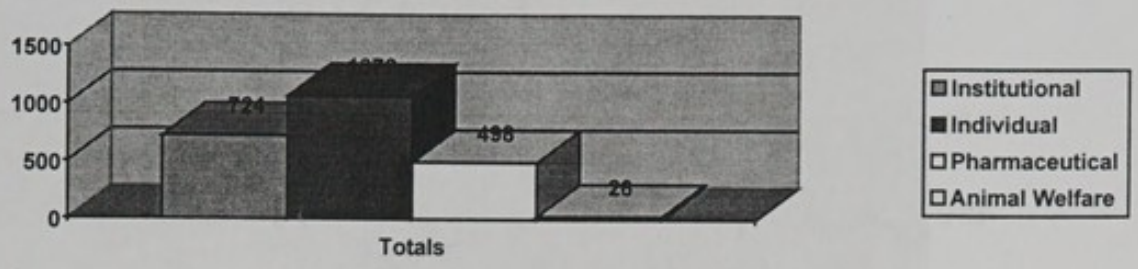


Figure 1 (b)

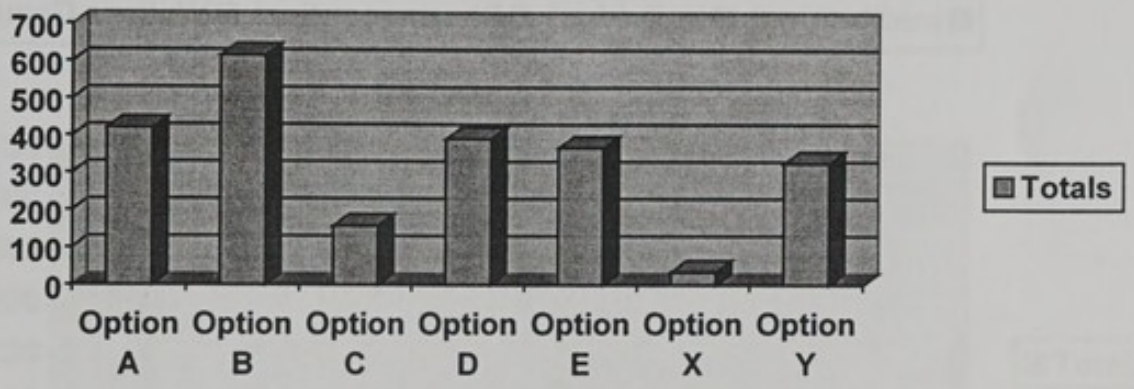


Figure 1 (c)

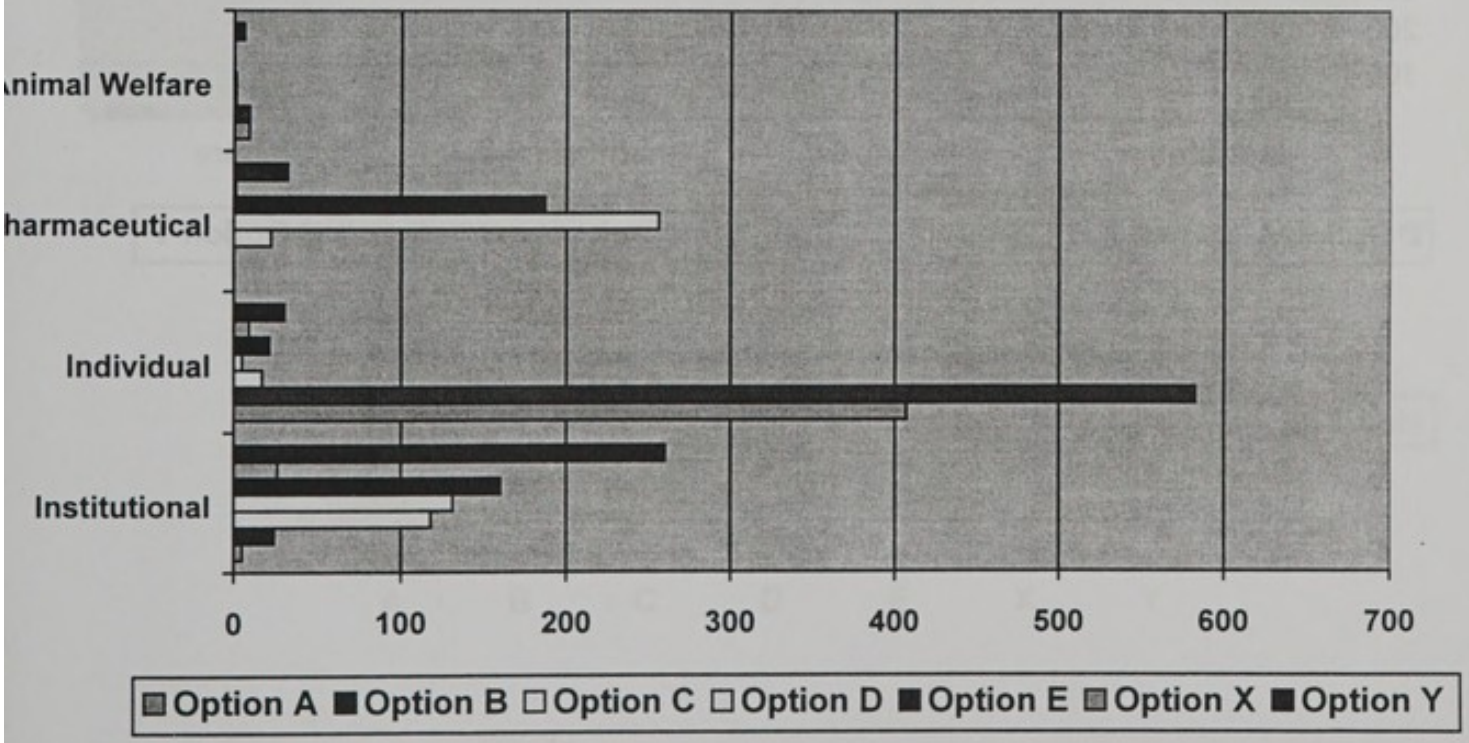


Figure 1 (d)

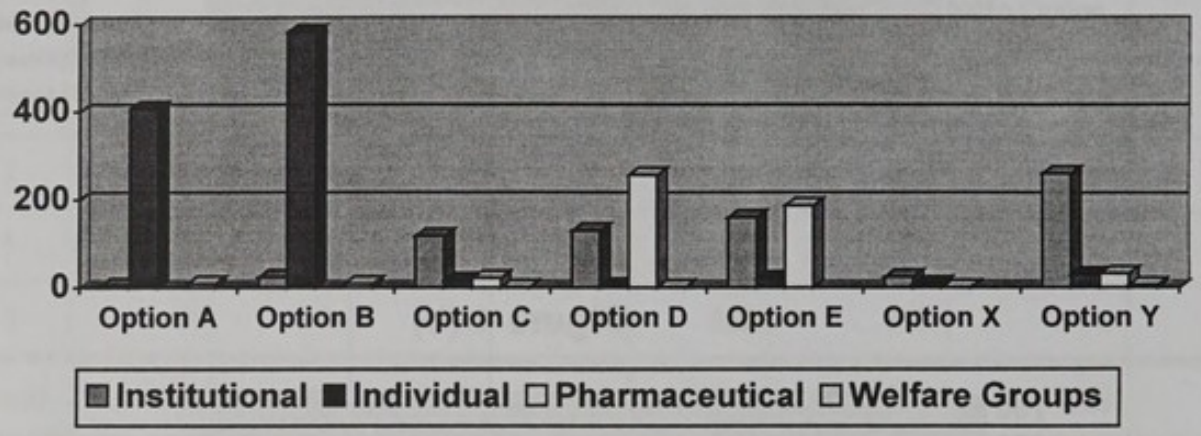


Figure 1 (e)

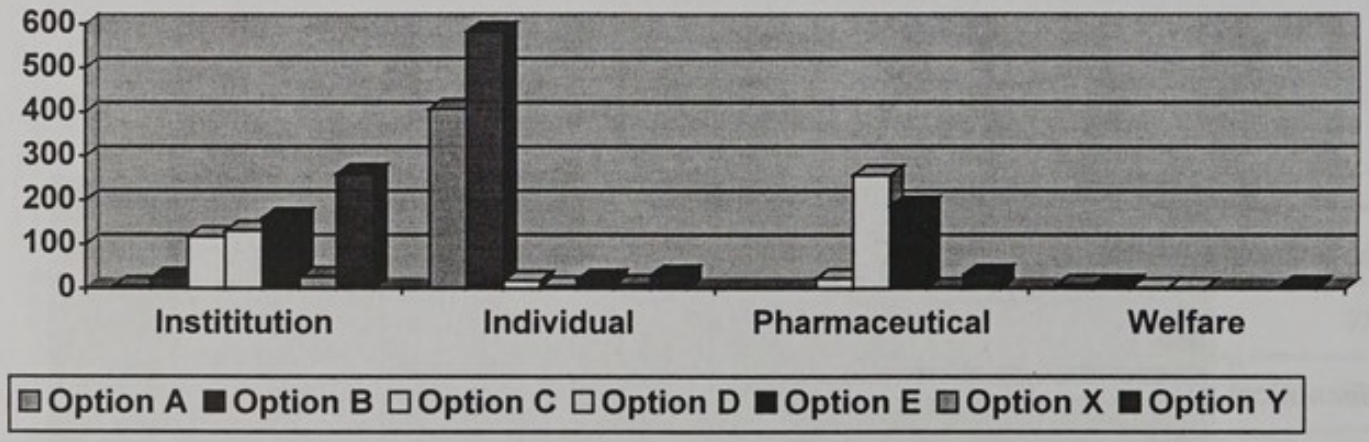


Figure 2 (a)

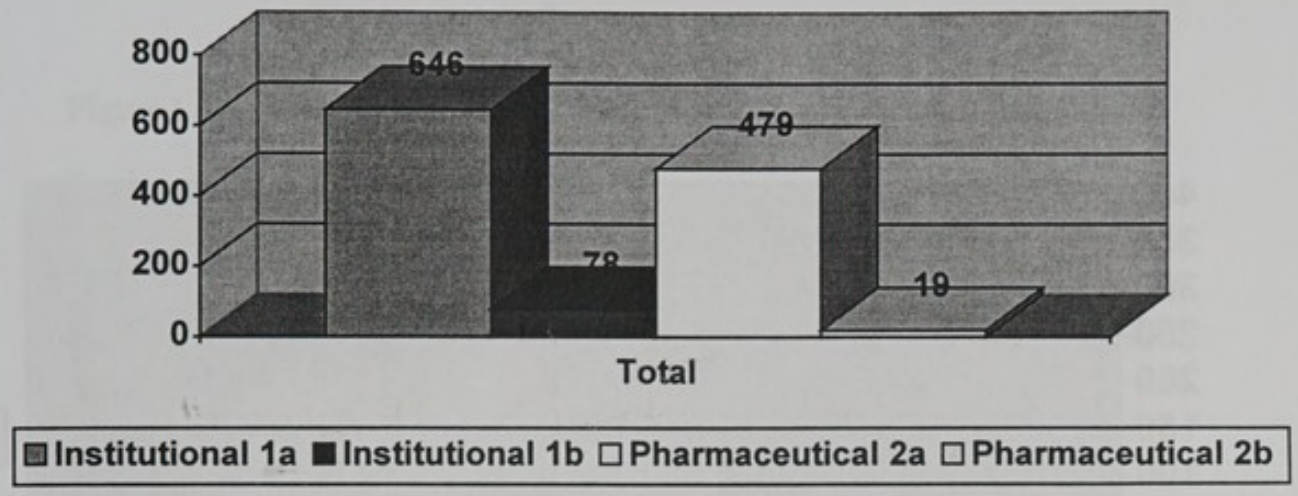
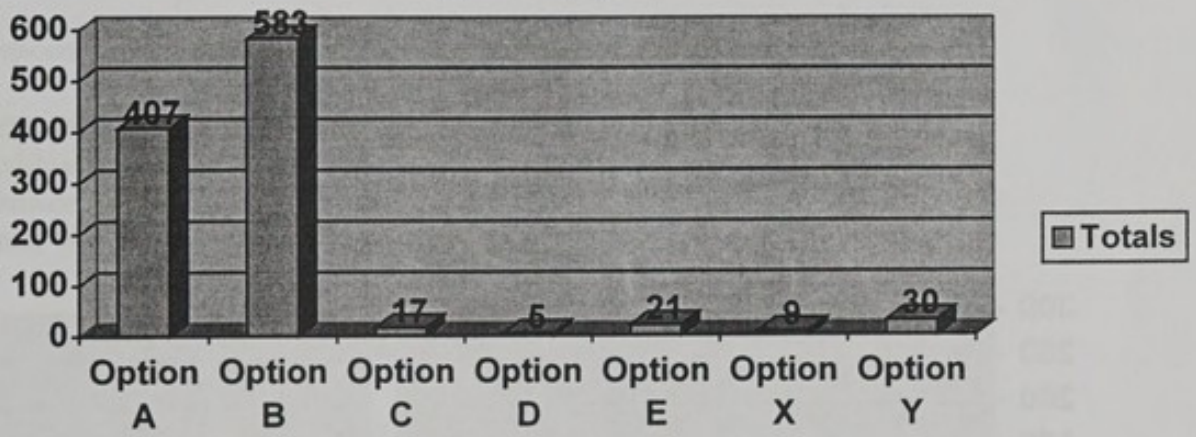


Figure 2 (b)



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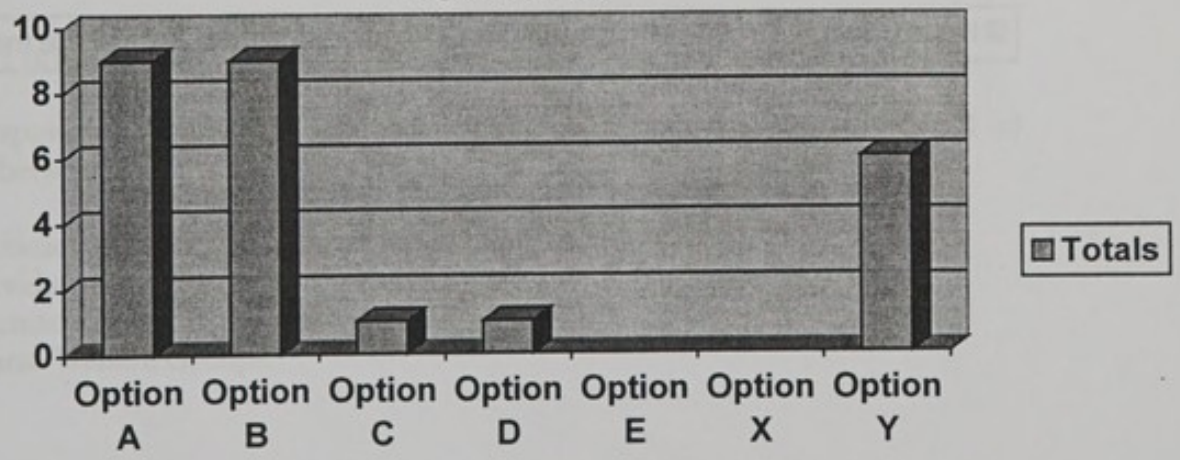

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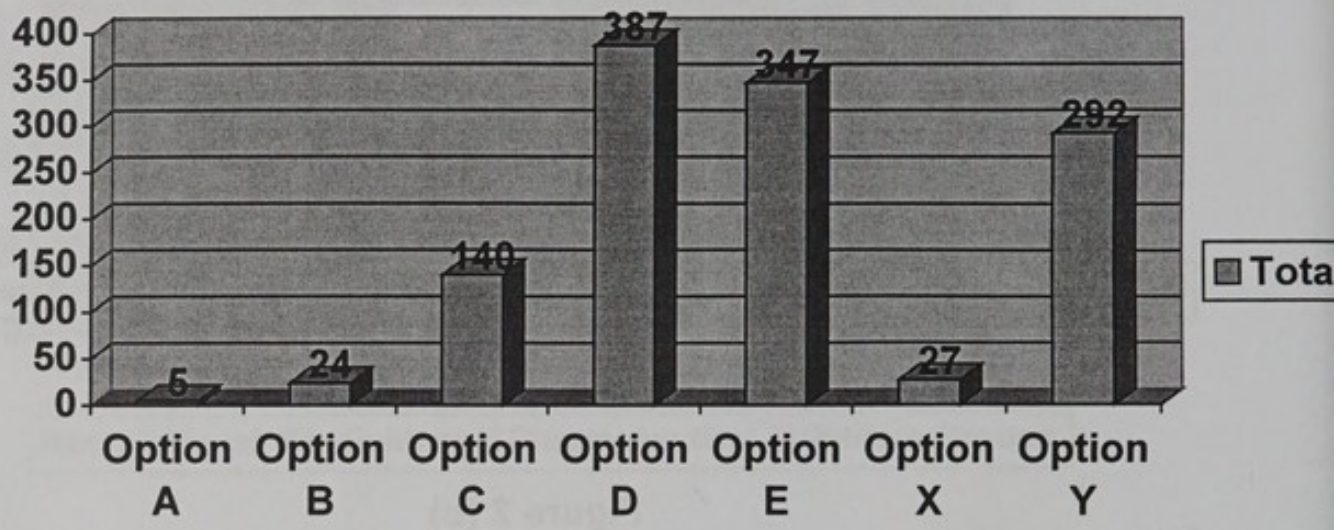

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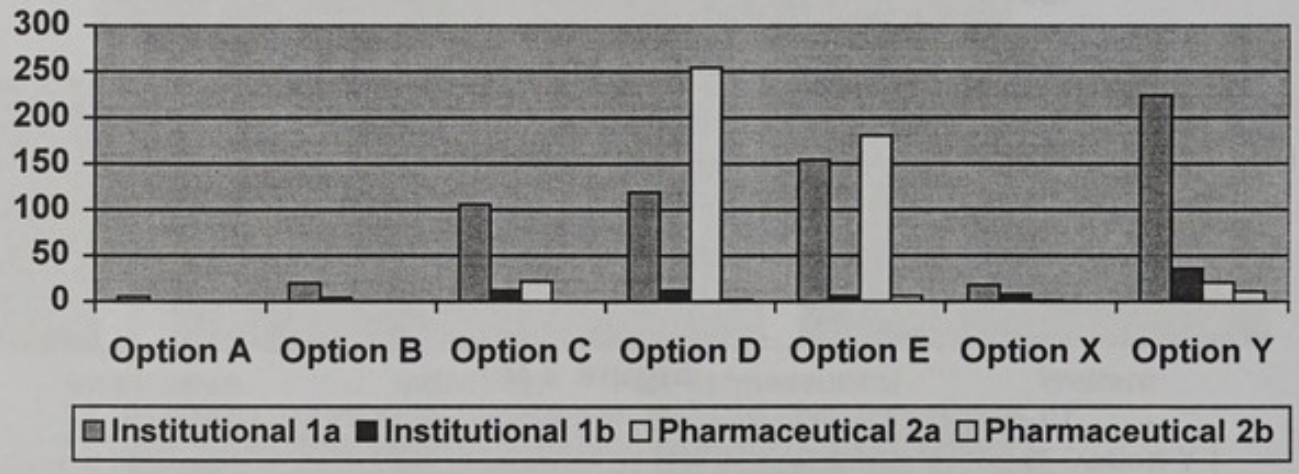

KEY TO FIGURE DIAGRAMS

Figure 1 (a)

Total responses on openness consultation paper

1. Institutional (Research/University/Government) responses.
2. Individual responses.
3. Pharmaceutical/CRO responses.
4. Animal Welfare Groups.

Figure 1 (b)

Total responses under each option on openness consultation paper

Figure 1 (c)

Total responses in Figure 1 (a) split under options chosen between

1 Institutional (Research/University/Government) responses.
2 Individual responses.
3 Pharmaceutical/CRO responses.
4 Animal Welfare Groups.

Figure 1 (d)

Total responses under each option in figure 1 (b) split as follows

1 Institutional (Research/University/Government) responses.
2 Individual responses.
3 Pharmaceutical/CRO responses.
4 Animal Welfare Groups.

Figure 1 (e)

Total responses in Figure 1 (a) split under options in different bar-chart to figure 1 (c) chosen between

1 Institutional (Research/University/Government) responses.
2 Individual responses
2 Pharmaceutical/CRO responses.
3 Animal Welfare Groups.

Figure 2 (a)

Total responses from Institutions & Pharmaceutical/CROs only split as follows.

1a Institutional (Research/University/Government) individual employee responses.
1b Institutional (Research/University/Government) on behalf of Dean, Certificate Holder/Manager responses.
2a Pharmaceutical/CROs individual employee responses.
2b Pharmaceutical/CROs on behalf of Dean, Certificate Holder/ Manager responses.

Figure 2 (b)

Total individual responses under each option.

Figure 2 (c)

Total animal welfare groups responses under each option.

Figure 2 (d)

Total Institutions & Pharmaceutical/CROs responses under each option.

Figure 2 (e)

Total responses from Institutions & Pharmaceutical/CROs only split between each option as follows.

1a Institutional (Research/University/Government) individual employee responses.
1b Institutional (Research/University/Government) on behalf of Dean, Certificate Holder/Manager responses.
2a Pharmaceutical/CROs individual employee responses.
2b Pharmaceutical/CROs on behalf of Dean, Certificate Holder/ Manager responses.

EXPLANATION OF OPTIONS

Option A Full information is made available about all matters.

Option B Full information is made available about all matters with the exception of information revealing identity & addresses of individuals.

Option C Full information is made available about all matters with the exception of information revealing identity & addresses of individuals or potentially patentable material before it is made public through the patent process or information about investigations into non compliance before completion thereof.

Option D Full information is made available about all matters with the exception of information revealing identity & addresses of individuals or potentially patentable material before it is made public through the patent process and any other strategic research and development information of commercial value to competitors or compliance, monitoring and enforcement.

Option E Full information is made available except in relation to matters which have been the subject of a requirement from affected persons for confidentiality.

COMMENTARIES ON SELECTED RESPONSES ON THE VARIOUS OPTIONS

1 Summary Of The Responses From Individual Members Of The Public

1.1 Some noteworthy points from respondents:-

- Too much repetition on "experiments"
- Inspectorate failing to inspect
- 21 Inspectors for 2,000,000 procedures is inadequate: the public need to be able to assist them
- The true reason for the desire for secrecy is that the unacceptable is occurring
- Public money ultimately pays for much work on animals: the public has a right to know what its money is financing
- The Research Defence Society actively encourages people to abuse confidentiality
- Secrecy always leads to abuse of public trust
- The long standing activities at Huntingdon Life Sciences are just one example of bad practice
- False information is supplied about animal suffering
- Irresponsible lawbreakers already have access to as much information as they need: it is the responsible law abiders alone who are kept in ignorance. The latter could make a valuable contribution to the three Rs.
- The wide scientific community could make a more effective contribution both to human well-being and the three Rs if it had information at an earlier stage
- Blind alley results should be published but are not
- The public, not commercial interest should determine what results are published
- The scientific community is mistaken in thinking that "It knows best"
- People working around procedures become used to the suffering of animals and fail to refrain from causing it or to protest about it.

2 Summary Of The Responses From Animal Welfare Organisations

2.1 Almost all of the respondents argued for either option A or option B, with only 2 or 3 exceptions. B was the most popular of the options on the grounds of maximising openness without endangering the personal security of researchers. However, a range of points were put forward which went beyond those outlined in each of the options.

2.2 There was unanimous and strong support for wider openness. The current system is regarded almost universally with suspicion and is seen by all as too restrictive for the purposes of proper, democratic debate. The operation of Section 24 caused particular concern. It is seen as contradictory to the principle

of freedom of information and as leading effectively to self-regulation in this field. In other words, the fact that those individuals and institutions directly involved in animal experiments control what information can be released has helped to undermine the confidence of animal protection groups in the operation of the Act. It was noted that the Home Secretary cannot even give important details to Parliament without permission. This has lead to strong doubts that effective democratic debate on key aspects of how the Act works in practice is possible. Sections 5(4) and 5(5) were mentioned several times in that regard.

2.3 The persistent exposures of malpractice in the industry were also cited constantly as evidence that access to wider information is necessary. Such investigations are seen as the only available source of information that isn't controlled by the animal research community and therefore highly valued by animal protection groups. It is also seen as clear evidence that the Act is not working in practice and that researchers arguing for restricted information 'have something to hide'. Whether or not malpractice is widespread, the current level of secrecy clearly contributes to the widespread impression that the system is ineffective.

Main points

2.4 There were a large number of general points about animal experimentation, to which most of the respondents were opposed in principle. This summary though looks only at those specifically referring to freedom of information.

2.5 With regard to licences the point was made that access to information should be allowed before decisions were made. The options presented by the sub-committee were useful for prompting debate but seen as too narrow by many respondents. Openness was seen as something that should be applied to all aspects and all levels of animal experimentation. For example, as well as access to licence information and applications:

- Access to Inspectorate databases on policy, precedent etc
- Openness with regard to meetings between the Home Office and other institutions/ bodies, including animal welfare groups (what was discussed, aims of meeting etc).
- Access to information from those directly responsible for animal use (e.g. DTI, DETR, HSE, MCA, VMD) and those that fund the research (e.g. MAFF, MRC, BBRC etc)
- Access to information from local ethical committees

2.6 Access to information was also seen as important for researchers and institutions themselves. This could for example lead to a reduction in repetition of experiments as researchers gain access to wider details of research in their field.

2.7 A number of responses advocated scrapping Section 24 of the Act and replacing it with a presumption of openness unless there were genuine grounds for concern about personal safety. The potential of abuse of this Section was noted with reference to the RDS's recent advice to members to mark all correspondence with the Home Office as confidential. It was pointed out though that the Home Office could take action even without abolishing Section 24 simply by restricting the basis on which it was prepared to take evidence. For example, licence

application forms could be amended in order to ensure that all non-personal information was only accepted on the basis that it was non-confidential.

2.8 Most respondents recognised the concern about personal safety of researchers as legitimate. Several though felt it was exaggerated and a number expressed doubt about whether this was the real reason for much of the current secrecy. For example much of the information that might help extremists determined to harass or harm researchers was easily available from published research papers, while information that might contribute to legitimate debate remains restricted. Generally, though this was recognised as a serious problem and few organisations made any serious attempt to argue that the identity or addresses of individuals should be made available. It was regularly noted however, that this should not prevent release of licences and applications (and indeed other documents), as they could easily be edited to remove such information. One suggestion was that licence applications should come in two sections; a confidential section with the applicant's name and details and an open section with details of the research planned.

2.9 Other arguments for restricting openness were less well received by the animal protection community. For example, while some felt that commercial confidentiality might be a reason for restricting information, others were more sceptical. Indeed, some pointed out that restricting information that could prevent other companies or individuals from repeating these experiments or refining their own research in the light of lessons learned by others seems actually to contravene Sections 5(4) and 5(5) of the Act. It was also pointed out that, while the lessons of failed research could often be valuable to other researchers in the field, such research was rarely published. Freedom of information was felt to be important in bringing such information out.

2.10 Finally, several groups made points, not just about the type of information available but its format and layout. The annual statistics published by the Home Office for example were acknowledged by some to be detailed and fairly comprehensive. However, the current format might give a lot of detail of how many animals were used in a particular category of research (e.g. number of dogs used in applied toxicity studies concerning the respiratory/cardiovascular system) but give no indication of what was actually done to the dogs or why they were carried out. This makes assessment of the costs and benefits almost impossible without wider access to information.

Conclusion

2.11 Broadly speaking, the animal protection community would like to see all information published excepting only personal information that could endanger individual security. They argue for this to apply to all areas, not just information on licensing and view this as essential for effective debate. There would be little or no confidence in any changes that left broad 'loopholes' for commercial/ economic reasons, especially if decisions on what counted as commercially sensitive were left in the hands of the animal research community.

3 Summary Of The Responses From Commercial Institutions

3.1 Although the Institutions supported the principle of further openness about animal procedures, there was serious concern over personal security/safety, commercially sensitive information, information supplied in confidence, impact on the UK science base and the administrative burden on ABCU. There were also some positive suggestions as to how some information could be provided without compromising security and confidentiality.

3.2 Personal security/safety

3.2.1 The activities of the extreme animal rights groups pose a real risk to scientists, their families and their property. Many scientists have suffered verbal and physical abuse and there is no sign of this activity decreasing in the future.

3.2.2 The Institutions were adamantly opposed to the release of any information in personal or other licences that could identify individuals or their place of work.

3.3 Commercially sensitive information

3.3.1 A project license often includes new ideas, detailed plans for future work and hypotheses to be tested, as well as proprietary information. The release of such sensitive information could imperil commercial competitiveness, compromise intellectual and commercial property rights and may jeopardise the award of a patent.

3.3.2 The Institutions were opposed to the release of such information without the specific permission of the project licence holder on the grounds that it could be impossible or difficult for the ABCU staff to identify such information unaided. One Institution commented that Article 13 of the Council of Europe Directive 86/609[on animal experimentation] stated: *"Member States shall take all necessary steps to ensure that the confidentiality of commercially sensitive information communicated pursuant to this Directive is protected"*

3.4 Information supplied in confidence

3.4.1 The 1986 A [SP] Act was seen to work well because the Institutions have felt confident in providing highly detailed complex scientific information for confidential consideration by experts. Public disclosure of this information could lead to it being quoted out of context by animal rights groups intent on discrediting scientific work.

3.4.2 The Institutions believe that it would be unreasonable for the Government to insist on the same level of detail, but to refuse to hold it in confidence. They are insistent in wanting information provided in confidence to continue to be treated as confidential.

3.5 Impact on UK science base

3.5.1 The Institutions believe that if disclosure impacts on commercial confidentiality, or intellectual property rights, or if information is used to harass individuals and institutions, innovative research in the medical and biosciences will be transferred overseas, undermining the quality of the research base of the UK.

3.6 Administrative burden on the ABCU

3.6.1 The Institutions are concerned that the present licensing procedures are slow and consequently damaging to biomedical research. Any additional burden imposed by the F of I Act would impinge on the current workload of the Inspectors to approve licences, inspect premises etc and result in even more delays. The statutory 20 days in the F of I Act is assumed to take priority over the ABCU commitment [which is not legally binding] to deal with certain aspects of the licensing process within 25 days.

3.6.2 The Institutions were anxious that the ABCU would not be able to function effectively under the F of I Act without substantial further resources.

3.7 Suggestions for increased openness

3.7.1 The Home Office should invest in education and building public confidence in the work of the Inspectors and the legislative controls on animal experimentation.

3.7.2 Industry should take pro-active steps towards increasing public understanding of just why animal use is essential for research, the potential benefits, and why present alternatives are not yet sufficient.

3.7.3 Establishments should be encouraged to open their animal facilities to the responsible public.

3.7.4 Project licence application forms should be modified so that there is a separate, commercially sensitive section, kept confidential, and a lay summary for public disclosure

3.7.5 Project licence holders should be asked if they would be prepared to answer follow-up questions via their Home Office Inspector.

3.7.6 There should be a standing forum of representatives of the responsible public, scientists, animal protectionists, ethicists and Government administrators to discuss issues of animal welfare.

4 Summary Of The Responses From Individuals In Institutions

4.1 This document briefly summarises the text and views provided by eight selected individuals from pharmaceutical commercial institutions ranging from :

- drug companies (3)
- contract research establishments (3)
- animal suppliers (1)
- private medical consultants (1)

(However, it should be noted that the two responses from the drug companies contained identical text).

4.2 Where a preferred option was indicated (6 out of 8 responses) the preference was equally balanced between options D and E. Several responses commended the principle of FofI as a laudable objective.

4.2 The common major concerns expressed by all respondents were:

- the issues of personal security
- the safety of individuals conducting research in their institutions and the matter of protection of intellectual property
- the further administrative burden and 'timeline pressures' likely to be placed on institutions to deal with any additional work that might ensue from FofI legislation, with respect to the proposed statutory requirement to respond to requests for disclosure within 20 working days.

4.4 A number of respondents emphasised their current 'heightened' awareness of the enhanced level of terrorism by animal rights groups recently against targeted institutions such as Huntingdon Life Sciences and Hillgrove Farms.

4.5 Another concern was the consequence of enhanced FofI for animal experimentation on the potential erosion of the quality and financial security of the UK research 'base'. Legislation for increased openness could lead to export of R&D work or research personnel abroad.

4.6 Several responses considered the consultation paper and its options to be inappropriate for such a complex and emotive issue and considered that the exercise may result in an unrepresentative result when the total responses are collated.

4.7 Suggestions to pragmatically reduce the administrative burden on institutions and relieve some of the fears and commercial and personal safety, were either

- to modify the project licence application format to include a new and separate section containing all 'sensitive and confidential information' which would not be released, or
- to provide limited information for public access in the spirit of FofI which would not endanger commercial or individual safety.

4.8 One final comment indicated that perhaps the APC itself should have more freely available access to all information pertaining to project licence applications, processes, compliance reports and infringement investigations etc, and in the true spirit of FofI, visit more commercial institutions.

5 Summary Of The Responses From Academics And Academic Institutions

5.1 Although the responses from these groups were mainly spread over all categories, they raised a surprisingly consistent series of views.

5.2 Many stressed that the whole reason for academic research as one of openness via refereed publications. The role of Universities was similarly embedded in knowledge, openness and transparency. Three major reasons for restricting openness in the context of animal experimentation were raised.

5.2.1 The first, an overwhelming concern stated by almost all respondents was fear from personal institutional attacks by animal terrorists. In several cases examples

were given from personal harassment (phone calls etc), to damage of property, attacks on individuals (including with bombs) and death threats. Generally the fear of the academic community was widespread, deeply felt and palpable. Similarly, threats to establishments ranging from intimidation outside premises, threats to shareholders and suppliers, and arson attacks were reported. Almost all respondents did not wish names, addresses and institutions to be released and information that could directly lead to this such as license application, HO Inspector's files, ERP minutes etc.

5.2.2 The second concern of this group, was confidentiality of research. It was pointed out that submissions for licences contained information on research ideas yet to be carried out and these need to be kept confidential from research competitors especially overseas. Eventually research is published in refereed journals so from academic scientists was in the public domain. further points were made:

- research grants are refereed preventing repetitive and low quality research
- similarly with research publications
- the Government's RAE (Research Assessment Exercise) for Universities implies confidentiality or research cannot be published and credited
- if the academic environment became hostile and unworkable, scientists would move abroad

5.2.3 The third concern was about intellectual property (IP). It is estimated that 1:20,000 drug indications and 1:100 drugs entering clinical trials reach the market place at an average cost of $600M each (except for orphan drugs). This immense investment requires protection especially as most pharmaceutical companies are multinational and can move their research easily abroad. this is also an issue for academic establishments who wish to protect the market IP. Remember this is all for the benefit of humans or animals.

5.3 Several additional comments were made:

- Britain has the highest animal welfare standards and tightest animal welfare regulations in the world.
- lay summaries of research could be produced, or specific exemplar case-histories used provided establishments and individuals could not be identified
- the Government has the power to outlaw particular procedures already
- the Inspectorate is the best mechanism for enforcement
- communication with the public needs to be improved
- none of the issues can be dealt with by openness alone
- pragmatic solutions to specific problems are needed
- the animal terrorists will not be placated by openness only
- all scientific experiments need to be repeated; repetition by other laboratories

is a key attribute of good, sound science

- basic, curiosity driven science leads to knowledge not uses
- uses cannot be always predicted at the time of the initial experiment
- the scientist cannot demonstrate personal risk unless s/he has already been attacked
- the onus should be on others to demonstrate why there should be disclosure
- issues of infringement etc should be kept confidential whilst investigations take place
- who will pay the costs?
- greater involvement of lay people in ERP
- HO inspection files should not be available
- husbandry guidelines could be established and published
- in case of GMOs (ACRE) openness was abused
- none would take a job as named vet if name were disclosed
- more attention should be given to policy and practice
- the APC (or another organisation as in Australia) should inform the debate
- Ombudsman for animals

ANNEX C

HOME OFFICE

Constitutional & Community Policy Directorate
Animals, Byelaws & Coroners Unit
Room 980, 50 Queen Anne's Gate, London, SW1H 9AT
Tel: 0171 273 3777 Fax: 0171 273 2029

Reference: 3-4.98

1 April 1998

To: All PCD Holders
Members of the Animal Procedures Committee
Other Consultees

ANIMALS (SCIENTIFIC PROCEDURES) ACT 1986: ETHICAL REVIEW PROCESS

1. Introduction

1.1 I wrote to you on 23 February 1998, explaining that it would be a Government requirement that all establishments designated under the 1986 Act should have an *ethical review process* satisfactorily installed by 1 April 1999. This requirement was announced by Lord Williams, Parliamentary Under Secretary of State at the Home Office, on 6 November 1997. My letter set out the background to the requirement and the proposed purposes and characteristics of a suitable *ethical review process*.

2. Consultation

2.1 The period set for consultation was very short because we wished to maximise the time available to establishments to explore, set up or expand suitable procedures. Although several respondents asked for an extension to the consultation exercise, I prefer to stick to a full 12 months' preparatory period to April 1999.

2.2 In taking this view, I stress the relative flexibility of the requirement, as set out here. We retain as central the notion that *ethical review processes* must be appropriate and proportional to the size, complexity and functions of the establishment. This puts an emphasis on evolving suitable procedures in practice rather than consulting further about the principles.

2.3 Over 50 responses were received, only one arguing against establishment of local ethical review processes. Comments were received from a range of organisations and individuals, including professional and scientific associations, medical and veterinary research centres, universities and colleges, commercial establishments, breeders, interest groups and animal protection societies, and an accredited trainer. Some were very detailed, suggesting changes in the particulars of the requirement; others raised more general concerns. These points are addressed below and in the Annex to this letter.

2.4 Material in the Annex which has been inserted since my letter of 23 February has been added *in italics* for the sake of clarity.

2.5 I am extremely grateful for the comments, produced under pressure of time. I do not intend to reply to individual letters, in the main, but take this opportunity to acknowledge the scope and value of the material received.

2.6 Particularly as some letters began to explore the draft requirements in terms of the individual establishment, material is being copied on to the relevant Inspector. This will further the dialogue between establishments and, in the first instance, the Home Office Inspectorate which will support implementation of this policy.

3. Varying circumstances

3.1 Scope for considering the implications for using protected animals and making improvements to the standards of animal care and accommodation exists in all designated establishments. The requirement for an *ethical review process* extends to designated supplying and breeding establishments as well as user establishments. We look to the Certificate holder and other senior managers to demonstrate commitment and support for the local *ethical review process* since it is designed to be a means of helping ensure responsibilities under the 1986 Act are discharged properly.

3.2 It is, however, critically important to devise and adopt a system appropriate to the individual establishment. The outcome of the *ethical review process* is more important than how it is done. We do not prescribe the precise form of the *ethical review process* for a particular establishment or types of establishment but invite Certificate holders to submit details of the system for their particular situation, taking into account the size, type and facilities of their establishments and the procedures and functions being carried out. The consultation process had led to the removal of some presumption about typical structures. Thus, paragraphs 4, 5 and 6 in particular have been varied in the Annex.

3.3 Our aim is not to increase bureaucracy but to promote the ethical consideration of animal use and to exploit potential for refining procedures, reducing numbers of animals, and replacing them wherever possible (the 3Rs) and for ensuring high standards of care and welfare.

3.4 Thus, where helpful structures already exist, where project refinement processes are in place, where there are suitable fora, or where responsibility and advisory systems are already working, these need not be duplicated but should drawn creatively into the wider process. Consideration of what already works well in existing systems and of the kinds of problems encountered is to be encouraged. By the same token, there is no requirement to collapse all existing systems into one set of structures.

3.5 A small number of consultees commented on what they saw as the circularity of Named Persons offering advice about the 3Rs and about standards of care and accommodation as part of their role under the 1986 Act; and then being offered advice, in turn, from the *ethical review process* (paragraph 3.2 of draft Annex). While one might conceive that Named Persons themselves cannot be omniscient in their advice, our intention was not to undermine the importance of their roles and input. Paragraph 3.2 has therefore been recast.

3.6 The suggestion that the *ethical review process* may be promotional or educational in

nature (paragraph 8 of Annex) received comment in the consultation. It is clear that reference to managerial structures, staff training and competence, communications and a promotional role stretch the concept of "ethical review" beyond some people's understanding of the concept. We take the view that ethical consideration should infuse and reinforce managerial processes which are needed to deliver responsibilities under the 1986 Act. We would therefore like a broader, educational role to be examined as part of establishments' consideration of the new requirement. It must, however, like all other features, be appropriate to the individual establishment and thought through for the particular situation.

3.7 In summary, variations on the theme set out in the Annex are welcomed as long as they deliver the desired outcomes. Application will lead to variation in practice. Evolving ideas should be discussed in the first place with your Inspector during 1998/99. The *ethical review process* should "add value" to the consideration of animal use and the standards applied in the establishment. This is as much an issue of cultural as structural change.

3.8 Such variation was borne out in the findings of a workshop convened by Maggy Jennings, Graham Moore and Bryan Howard in October 1997. The report of the workshop is enclosed. It contains valuable information about the nature and effectiveness of different forms of *ethical review process* as applied in a variety of establishments. The report was mentioned in my letter of 23 February and I am indebted to the authors and their organisations for permission to distribute copies.

3.9 I am also pleased to say that a UFAW and FRAME booklet on replacement methods will be distributed with a future PCD holders' letter.

4. Those to be involved

4.1 Not surprisingly, paragraph 5 of the draft Annex provoked a great deal of comment.

4.2 First, it is our intention that an Inspector be allowed occasionally to join meetings and to see the records associated with the *ethical review process*. It is to be hoped that the Inspector will not limit openness of discussion, nor be regarded as a formal member of any committee. His or her involvement should not be used to bypass the need for local *ethical review*. We intend that the Inspector will need to assess occasionally how effectively the process is operating. This puts the new requirement on the same basis as other aspects of the establishment's operation under the 1986 Act - open to inspection and advice.

4.3 Secondly, we believe that the *ethical review process* will benefit from the input of non-users and those who do not hold responsibilities under the Act. Depending on the nature of the establishment and the procedures carried out, it would be useful to consult non-scientific staff and possibly people outside the establishment to provide a wider perspective. This bears on the question of establishment culture and the recognition that lay people also have a legitimate voice in considering the use of animals in scientific procedures. Thus, reference to those "not involved in animal work" was an ambiguous phrase (paragraph 5) and was careful in not stipulating how an establishment might achieve this input from those not holding responsibilities under the Act: and whether it was appropriate to recruit people independent of the establishment in every case.

4.4 In the consultation, various helpful examples of current practice were provided: colleagues from the accounting and personnel departments are involved in the *ethical*

review process; non-using scientists and colleagues from different disciplines are enrolled; suitable contacts from outside the establishment are usefully brought in. We took the view that involvement of the Named Vet was not, in itself, sufficient - unless there were reasons why wider involvement can not be possible.

4.5 We agreed with suggestions that colleagues or outsiders with particular skills or perspectives should be involved in the *ethical review process*. For example, an expert in experimental design and statistical analysis could usefully be involved at all stages of projects to maximise opportunities for refining programmes and reducing the number of animals required.

5. Role of Inspectors

5.1 The implication was drawn by several consultees that the Inspectorate may withdraw from close involvement with project refinement, from initial conception through planning, execution and evaluation. This was not intended and paragraph 10 of the Annex has therefore been extended.

5.2 Inspectors will be pleased to discuss initial ideas and, as at present, be available to advise on the continuing refinement of project plans. But, when the plan is getting to a stage when application to the Home Office is likely, or even before this, it will need to be considered within the local *ethical review process*.

5.3 There can not be generalised, hard-and-fast rules about handling plans, because establishments differ and projects also differ. A judgement will be needed about when to take a particular project application through the process, so balancing the Inspectorial and local inputs and avoiding wrong footing either of them. This will need to be considered by each establishment, with the advice of the Inspector. The value of discussion with the Inspector needs to be emphasised but the establishment itself must decide what types of work it will sanction and can justify.

5.4 The *ethical review process* could make material differences to the establishment's present handling of ideas and plans. After all, the aim is that procedures be evolved locally which ensure ethical considerations be built in - it is hoped without undue bureaucracy or delay. But this is not to outlaw the advice and counsel of Inspectors at each stage of project planning and review. The process is intended to complement, rather than duplicate or replace, the work of the Home Office Animals (Scientific Procedures) Inspectorate and funding bodies.

5.5 Equally, it is not possible to set out generalised rules about the handling of amendments or secondary availabilities. These must be evolved locally, again because establishments differ and projects certainly differ. Every application should, at some stage, be reviewed in the process but not every amendment need be. Each establishment will need to set a threshold for scale and type of amendment which makes sense in that setting and to the project in hand. It would be ideal if the spirit of *ethical review* were applied, not a minimal requirement of the Home Office.

In this, and all other features of the *ethical review process*, it will be the responsibility of the Certificate holder to present to the Inspectorate, in the first instance, a description of an *ethical review process* suitable for the establishment. The Inspector will give a view on whether the features of the system appear to meet the requirements set out in the Annex and are as extensive as the situation allows. A sustained dialogue may be required in some cases to ensure the process has evolved locally as far as possible during the year.

The Inspectorate will be setting up procedures to ensure internal consistency. We have not determined yet whether further guidance or seminars will be needed before April 1999.

5.7 Evidence of practical outcomes will accrete (some will be available for some features already) and will in turn suggest refinements to the *ethical review process*. In my earlier letter, these were envisaged as evidence of promotional efforts, increased awareness and raised standards of facilities, working practices, project applications and scientific procedures. Clearly, outcomes in all of these areas may not be capable of demonstration before April 1999 (even in establishments already operating many of the features of an *ethical review process*) but a case can be made for acceptance of a scheme and evidence added as the process is put into operation.

6. Timetable

6.1 Establishments now have a year in which to devise or revise local processes and to demonstrate to the Home Office how they will be effective. The aim is for establishments to have met the requirements, as set out in the Annex, by April 1999. A condition should then be added to the Certificate of Designation.

6.2 This condition will require that an appropriate form of *ethical review process* is in place which demonstrably meets the needs of the establishment and the aims of the policy. The ultimate sanction for not complying with this condition will be revocation of the certificate, subject to the right to make representations. As I explained before, if an *ethical review process* is agreed to be suitable before April there is no reason why the Certificate should not be amended beforehand.

6.3 We will institute a formal review of the *ethical review process* policy at some point after April 2000 when the procedures have been fully operating for at least a year.

Yours sincerely

RICK EVANS (Head of Unit)

THE ETHICAL REVIEW PROCESS

The Policy

1. The Secretary of State requires that an ethical review process be established and maintained in each establishment designated under section 6 or 7 of the Animals (Scientific Procedures) Act 1986. Every establishment should explain to and test with the Animals (Scientific Procedures) Inspectorate a viable process, appropriate to that establishment, before 1 April 1999. From that date, the requirement for a local ethical review process will be a standard condition for every designated user and breeding/supplying establishment.

Ethical review process

2. The Certificate holder should ensure as wide an involvement of establishment staff as possible in a local framework acting to ensure that all use of animals in the establishment, as regulated by the Animals (Scientific Procedures) Act 1986, is carefully considered and justified; that proper account is taken of all possibilities for reduction, refinement and replacement (the 3Rs); and that high standards of accommodation and care are achieved.

Aims

3.1 To provide independent ethical advice to the Certificate holder, particularly with respect to project licence applications and standards of animal care and welfare.

3.2 To provide support to named people and advice to licensees regarding animal welfare and ethical issues arising from their work.

3.3 To promote the use of ethical analysis to increase awareness of animal welfare issues and develop initiatives leading to the widest possible application of the 3Rs.

Responsibility of the Certificate Holder

4. The Certificate holder will be responsible to the Home Office for the operation of the local ethical review process and for the appointment of people to implement its procedures.

Personnel

5. A named Veterinary Surgeon and representatives from among the Named Animal Care and Welfare Officers should be involved. In user establishments, project licensees and personal licensees should also be represented. As many people as possible should be involved in the ethical review process. Where possible, the views of those who do not have responsibilities under the Act should be taken into account. One or more lay persons, independent of the establishment, should also be considered. Home Office inspectors should have the right to attend any meetings and have access to the records of the ethical review process.

Operation

6. These people should deliberate regularly and keep records of discussions and advice. All licensees and Named Animal Care and Welfare Officers must be informed of the ethical review process and should be encouraged to bring matters to its attention. An operating description should allow for input by colleagues and other people from outside the establishment. It should be clear how submissions can be made. The people involved should be regarded as approachable, dealing in confidence with complaints and processing all suggestions for improvement.

7. Specifically, the process should allow (where appropriate) the following:-

7.1 promoting the development and uptake of reduction, replacement and refinement alternatives in animal use, where they exist, and ensuring the availability of relevant sources of information;

7.2 examining proposed applications for new project licences and amendments to existing licences, with reference to the likely costs to the animals, the expected benefits of the work and how these considerations balance;

7.3 providing a forum for discussion of issues relating to the use of animals and considering how staff can be kept up to date with relevant ethical advice, best practice, and relevant legislation;

7.4 undertaking retrospective project reviews and continuing to apply the 3Rs to all projects, throughout their duration;

7.5 considering the care and accommodation standards applied to all animals in the establishment, including breeding stock, and the humane killing of protected animals;

7.6 regularly reviewing the establishment's managerial systems, procedures and protocols where these bear on the proper use of animals;

7.7 advising on how all staff involved with the animals can be appropriately trained and how competence can be ensured.

8. Commonly, there should be a promotional role, seeking to educate users (in applying the 3Rs) and non-users (by explaining why and how animals are used), as appropriate. There should be some formal output from the ethical review process for staff and colleagues in the establishment, made as widely available as security and commercial/intellectual confidentiality allow.

9. Receipt of a project licence application signed by the Certificate holder will be taken by the Home Office to mean that the application has been through the ethical review process for that establishment.

10. Once the system is established, Inspectors will still be happy to discuss early ideas with prospective project licence holders and will be available for advice and clarification at any point. But an application will not be considered for formal authorisation by the Home Office until the prospective project has been considered appropriately within the ethical review process. The Inspector will not negotiate with any advisory group. Local

arrangements and the individual case will dictate whether amended applications must re-enter the ethical review process. It will be a matter of judgement in the particular case how best to balance the inputs of the ethical review process and the Inspectorate without duplicating effort or creating undue delay.

Home Office
1 April 1998

Written No 1
(1.11.00)

Mrs Eileen Gordon (Romford) : To ask the Secretary of State For the Home Department, if he will review the arrangements For requiring establishments designated under the Animals (Scientific Procedures) Act 1986 to have an ethical review process (136224)

MIKE O'BRIEN

I have asked the Home Office Animals (Scientific Procedures) Inspectorate to carry out a review of the operation of the ethical review process, to see what improvements can be made in the way in which local reviews are carried out to enhance animal welfare. The terms of reference of the review are as follows :

To review the efficiency and effectiveness of the operation of the Ethical Review Process, as set out in PCD Circular 3-4.98 issued on 1 April 1998, and in particular to consider :

(a) whether the aims of the process, as specified in paragraph 3 of the Annex to the Circular, have been achieved;

(b) what problems may have been encountered; and

(c) what the resource implications have been

and to recommend any changes in the arrangements and to identify best practice.

The review will take account of the views of all the stakeholders in the process, including certificate holders and licencees under the 1986 and animal welfare organisations. The Inspectorate have been asked to report by the middle of 2001.