THE GOVERNMENT REPLY TO THE REPORT OF THE HOUSE OF LORDS SELECT COMMITTEE ON ANIMALS IN SCIENTIFIC PROCEDURES SESSION 2001-2002 HL 150-I

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Introduction

The Government welcomes the Select Committee's report, which deals with important and sensitive issues concerning the use of animals in scientific procedures. The Committee's final report is comprehensive, makes an important contribution to the ongoing debate, and provides a credible basis for all concerned to consider where we should be going from here.

2. The Government notes in particular, and endorses, the Select Committee's finding that animal experiments are currently necessary to develop human and veterinary medicines and to protect humans, and the environment. We also welcome the Select Committee's recognition of the progress that has been made since 1987 in reducing the number of animals used in scientific procedures and in establishing a culture of care in establishments designated under the Animals (Scientific Procedures) Act 1986, which is widely regarded as the most rigorous piece of legislation of its type in the world. The Government also accepts that more needs to be done and we reconfirm our commitment to the fullest possible application of the 3Rs[1] and report below, in response to the Select Committee's specific recommendations, some of the current work in hand to achieve this. We also agree that the case put forward by the Select Committee for a United Kingdom centre for the 3Rs focused largely, but not exclusively, on toxicity testing, as a complement to other initiatives in this area, is worth exploring further. At the same time, we remain firmly of the view that the development of the 3Rs must continue to be an integral part of mainstream research programmes and toxicity work, and should not be seen as a separate activity.

3. The Government also notes the Select Committee's view that the United Kingdom should aim to have the best regulation of animal procedures, properly enforced, rather than the tightest regulation. The Government already strives for the most efficient and effective regulation. However, we believe that it is right that the 1986 Act imposes stringent criteria to be satisfied before licence authorities are granted. We further believe that this approach is essential to generate and maintain public confidence in the regulatory system. At the same time, we accept that the administrative burden must be kept to a minimum without compromising the welfare of the animals used.

4. The Government also shares the Select Committee's view that there is a need for more open and better informed debate about the use of animals in scientific procedures. Government departments, industry, the scientific community and funders of such research all have an important role to play in explaining their legitimate use. We also believe that more good quality information should be made available to the public explaining the scientific work that is done using animals and the reasons for it. Subject to safeguards for personal and confidential information, we are, therefore, proposing to publish summaries of project licences as part of the Home Office publication scheme. However, we are conscious that there remains a significant level of concern in the scientific community about the implications of repealing s.24 of the 1986 Act, as the Select Committee recommends. We, therefore, propose to consult further with the scientific community before reaching final decisions on its future.

[1]The 3Rs are Refinement of scientific procedures; Reduction in numbers of animals used; and their Replacement wherever possible.

Select Committee Conclusions

Select Committee Conclusion 1: The view of the Select Committee is that it is morally acceptable for human beings to use other animals, but that it is morally wrong to cause them unnecessary or avoidable suffering. (paragraph 2.5)

5. The Government shares the Select Committee's view and believes it to be the view held by the great majority of people in the United Kingdom. These principles underpin the Animals (Scientific Procedures) Act 1986, which provides for the protection of animals used for experimental or other scientific purposes and is widely regarded as the most rigorous piece of legislation of its type in the world. Parliament has built in considerable safeguards to allow experimentation in limited circumstances and to ensure both proper regulation and monitoring. The Government will continue to ensure that it is implemented rigorously.

Select Committee Conclusion 2: There is at present a continued need for animal experiments both in applied research and in research aimed purely at extending knowledge. (paragraph 4.14)

6. This is also the Government's view. Fundamental and applied scientific research is essential for progress and, in the field of healthcare, research using animals has contributed to almost every medical advance in the last century. Although the situation may change in the future, the development of all new drugs, and a number of medical and veterinary technologies which help to reduce suffering and prevent large-scale infections among humans and animals continues to depend on this carefully regulated and responsible use of animals for research, drug development and testing.

Select Committee Conclusion 3: Toxicological testing in animals is at present essential for medical practice and the protection of consumers and the environment, as it often provides information that is not currently available from any other source. (paragraph 4.25)

7. The Government notes and welcomes the Committee's endorsement of the current system of safety regulation. There is still, nevertheless, a need to ensure that such testing has a sound scientific basis, and that every effort is made to minimise both the amount of animal testing that is undertaken and the suffering that is caused. The Government actively supports initiatives to develop, validate and make effective use of advanced methods that replace animal tests, reduce the numbers of animals used, and refine the protocols applied. We also actively encourage and facilitate data sharing and seek to harmonise international test requirements.

8. With regard to the New EU Chemicals Strategy, the Government believes that vertebrate animal testing should be kept to the absolute minimum necessary to ensure that sufficient information is available for decision-making on health and environmental protection.

Select Committee Conclusion 4: The UK should strive not for the tightest regulation, but for the best regulation, properly enforced. (paragraph 5.33)

9. The Government already strives for the most efficient and effective regulation. The responsibilities placed upon the Secretary of State by the 1986 Act impose stringent criteria that must be satisfied before licence authorities are granted. We believe that this is as it should be and necessary in order to generate and maintain public confidence in the regulatory system. The discussions through the Prime Minister's Pharmaceutical Industry Competitiveness Task Force in 2001 identified a number of practical measures which the Government and the scientific community can, and do, already use to minimise the administrative burden without compromising the welfare of the animals used.

Select Committee Conclusion 5: The availability to the public of regularly updated, good quality information on what animal experiments are done and why, is vital to create an atmosphere in which the issue of animal experimentation can be discussed productively. (paragraph 9.1)

10. We agree. For some time now, Ministers have taken the position that greater openness and transparency regarding the regulation and use of animals in scientific procedures is desirable, providing it does not jeopardise the safety of individual scientists and their establishments, or their legitimate commercial and intellectual interests. There is a widespread lack of awareness of the regulatory system and the purposes for which animals are used, which has allowed many misconceptions about such use to go unchallenged. There is a need for more open and better informed debate about the use of animals in scientific procedures. Government departments, industry, the scientific community and funders of such research all have an important role to play in explaining their legitimate and responsible use.

Select Committee Conclusion 6: There is scope for the scientific community to give a greater priority to the development of non-animal methods, and more consideration could be given to the pursuit of the Three Rs - reduction, refinement and replacement. (paragraph 4.15)

11. The Government welcomes the Select Committee's recognition of the progress that has been made since 1987, both with regard to the number of animals used - which has fallen significantly - and in particular in establishing a culture of care in designated establishments. During this period great progress has been made in the introduction of non-animal methods and the refinement of procedures that still require the use of animals. However, the Government is not complacent and remains committed to the fullest possible application of the 3Rs. We see progress with the 3Rs to be the responsibility of the entire biomedical research community, and believe that the development of 3Rs strategies should be embedded in mainstream biomedical research rather than separated from it.

12. The Government also notes that the Select Committee is disappointed with the profile of alternatives research and those who do it. This appears, in part, to arise from a belief that alternatives are developed by those working at the margins of, or outside, the core biomedical research community, rather by those working within the community. In fact, the bulk of work on the 3Rs is done by mainstream scientists trying to overcome the technical limitations of existing systems and methodologies. As such, alternative methods are in reality, and best referred to as, advanced methods. It is also important to remember that all sectors have a role to play. The user community is at the forefront of developing potential new 3Rs testing strategies. The Government acknowledges that there is a real need for the improved identification and dissemination of research that progresses the 3Rs, which is conducted within mainstream research programmes. However, the Government recognises that in order for alternative methods to receive regulatory acceptance they require validation and that acceptance needs to be at an international level. To this end, the ICH[2] has made some commendable progress in standardisation of regulatory testing strategies for pharmaceuticals and by doing so has assisted in the reduction element of the 3Rs. In addition, ECVAM[3] and ICCVAM[4] have also made progress in the validation of alternative methods.

[2]International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

[3]European Centre for the Validation of Alternative Methods

[4]Interagency Co-ordinating Committee for the Validation of Alternative Methods

Select Committee Conclusion 7: The development of scientifically valid non-animal systems of research and testing is important, not just to improve animal welfare, but to provide substantial benefits for human health. (paragraph 4.33)

13. This is true and reinforces the point that "alternative methods" are often, in reality, "advanced methods" broadening the scope and overcoming some of the limitations of existing animal models. The Government also places importance on the development of more advanced systems of research and testing which avoid and refine the use of animals. However, as was explained in evidence to the Committee, the straightforward, single interaction/single mechanism animal tests have now largely been replaced with non-animal tests. Developing replacement tests for the more complex, multiple interaction/multiple mechanism animal models is much more difficult and breakthroughs are likely to be hard to achieve in the short term. For that reason, the Government believes that in the immediate future the main gains will be achieved in the areas of reduction and refinement and that a broad approach focusing on these, as well as replacement, is required. Any advances have to receive international acceptance, both from fellow scientists and regulators. This can take up to ten years for some of the more technical and advanced methods. The Government, therefore, recognises that progress in the 3Rs, and with replacement in particular, is a long-term commitment with no quick fixes.

Select Committee Recommendations

Chapter 3: The purpose and nature of animal experiments

Select Committee recommendation 8: The Animal Procedures Committee should invite submissions from the Royal College of Veterinary Surgeons, the Farm Animal Welfare Council and others to establish the appropriate application of the 1986 Act or the modification of its regulations for experimental farm animals. (paragraph 3.17)

14. In this context, it should be noted that the Animals (Scientific Procedures) Act 1986 regulates on the basis of why a procedure is to be carried out, rather than what is to be done or by whom - for example, whether the person is a veterinary surgeon or not. It regulates only the use of animals for "experimental and other scientific purposes". Separate provision in law is made for the protection of animals subjected to recognised veterinary, agricultural or animal husbandry practices. The Home Office has regular dialogue with the Royal College of Veterinary Surgeons about the boundary between the 1986 Act and the Veterinary Surgeons Act 1966, and the Royal College has published guidance for veterinary surgeons on the issue. The Government does not believe that the scope of the 1986 Act should be modified with regard to the regulation of these activities.

15. As regards the housing and care of farm animals in projects licensed under the 1986 Act, where the intention is to investigate what might happen in a farm setting, the use of facilities providing good, contemporary agricultural standards is acceptable. Otherwise, when Home Office codes of practice set out minimum provisions higher than those encountered in good agricultural practice, the intention is both to make proper provision for the welfare of the animals and to safeguard the scientific validity of the studies by avoiding unnecessary experimental variables.

16. On the issue of the re-use of animals, s.14 of the 1986 Act overrides what would otherwise be an absolute prohibition on re-use. Section 14 was originally introduced with higher species and large animals in mind. The Government acknowledges that its current provisions are imperfect and will look to the pending revision of European Directive 86/609/EEC both to make better provision for responsible re-use without compromising animal welfare and to ensure that there is a level European playing field.

Select Committee recommendation 9: Government funded research or training using animals abroad should be consistent with the requirements of the 1986 Act. (paragraph 3.26)

17. The Government notes the Committee's commendation of the proactive approach taken by the Ministry of Defence in applying the 3Rs in the animal research it undertakes. We also note its concerns about the training of military surgeons in Denmark and can reassure the Committee that the training is subject to Danish law[5] on the use of live animals in experiments and for educational and training purposes.

18. The training exercise was developed by the Danish Military Medical Services as part of the trauma training for their surgical teams. The United Kingdom and other NATO and Partnership for Peace nations are invited to participate. The exercise is controlled by a civilian veterinary surgeon from the Ministry of Justice, with a veterinary or anaesthetic nurse accompanying each animal throughout the exercise. The animals are anaesthetised throughout and, at the end, are put down humanely without regaining consciousness. The Ministry of Defence believes that the protocols and management of the surgical training exercises would be consistent with the requirements of the 1986 Act.

19. The Ministry of Defence has no current plans to seek authorities to conduct such training in the United Kingdom. Participation in the Danish exercises provides UK military medical teams with sufficient opportunity to undertake training of this nature. At present no equally effective alternative form of training exists to prepare military surgical teams for the treatment of trauma under battlefield conditions. Some UK military surgeons undertake hospital training in countries where gunshot cases occur more frequently than in the UK. However, the nature of wounds encountered, the equipment used and staffing levels are not representative of battlefield conditions. Computer generated training tools are not sufficiently technologically advanced to provide adequate realism for the foreseeable future and other simulations available are similarly unrealistic.

20. As regards the wider point of principle, the Government accepts that Government funded research, or training, abroad using animals should be consistent with the principles of the 1986 Act.

Chapter 4: The efficacy of animal experiments

Select Committee recommendation 10: The Government should take greater steps to promote the adoption of replacements and the incorporation of refinements into animal test guidelines issued by the International Conference on Harmonisation and the Organisation for Economic Co-operation and Development. (paragraph 4.40)

21. The United Kingdom already has a good record in this area and is pro-active in a variety of international forums. For example, we played a leading part in the deletion of OECD Guideline 401 (the 'LD50 Test'), in the development and acceptance by the OECD of the "fixed dose procedure" (a replacement for the LD50 Test) and in the promotion of the murine local lymph node assay. The Home Office is represented at the UK OECD toxicology shadow Group. It is also amongst UK nominated experts involved in International Standards Organisation committees concerned with the biocompatibility of materials used in medical devices and advises other Government Departments on the relevant issues. Through these activities, the Home Office will seek to ensure that appropriate provision is made for the accommodation and care of animals, as well as for the most refined protocols.

[5]Ministry of Justice Law No 726 of 9 September 1993

22. There are, however, three main obstacles to the quicker adoption and incorporation of refinements. In order for an alternative method to be adopted by the OECD and published as an OECD test guideline there is a need for all member countries to agree that the method has been adequately validated and that it represents a practical approach to investigating the effect in question. The OECD works by consensus and one member country can prevent a new method being adopted. In practice, validation data are needed involving studies in a number of countries to provide adequate information to enable regulators in all member countries to have sufficient confidence in the new approach to allow its acceptance as a new OECD guideline. Furthermore, in some cases, different methods for similar end-points have been developed in different countries and there is a tendency for countries to favour the progression of their own method. These difficulties all take time to overcome. However, the strength of the system is that once all member countries are signed up and the method adopted as an OECD guideline, member countries are obliged to accept data generated on chemicals by the method for regulatory purposes, providing also that the OECD principles of Good Laboratory Practice were observed.

Select Committee recommendation 11: The Government and the scientific community should engage in a systematic and visible search for methods involving the Three Rs in toxicology. The Government should nominate one department to take the lead on this. (paragraph 4.44)

23. We agree that a systematic and visible effort is required. As a first step, the Home Office is currently leading a review of the scope to improve the application of the 3Rs and to promote research into alternatives through the Inter-Departmental Data Sharing Group[6]. The work of the group includes a review of the implementation of the Inter-Departmental Data-Sharing Concordat announced in August 2000, the Guidelines on Regulatory Toxicology and Safety Evaluation Studies published in February 2001, and the statement of principles concerning animal welfare endorsed by the Home Office and other regulatory authorities in 1999[7]. It is hoped to complete the work in the next few months. We will consider what further steps are required when it has been completed and in the light of our further consideration of the proposed new centre discussed below at recommendation 24.

Select Committee recommendation 12: The UK Government should use their influence to urge the EU to make the development and validation of replacements for animal experiments a priority, particularly in toxicology. (paragraph 4.45)

24. While replacement should, of course, be the ultimate goal, the Government does not believe that it should be made a priority at the expense of reduction or refinement, as these are where progress can be made more quickly. The Government will continue to support the work of ECVAM and warmly welcomes the liaison between ECVAM and ICCVAM as a means of achieving greater progress, more quickly and ensuring commitment from more than one economic region.

25. In addition, the Government, through its agencies, contributes to the ICH process. As a result of this process, a number of guidelines and 'points to consider' documents have been provided to standardise regulatory toxicological test strategies at an international level. These documents have contributed to a reduction in duplication of test strategies in order to meet previously different national test

[6]Membership of the Group is drawn from the Home Office, the Department of Health, the Department for the Environment, Food and Rural Affairs, the Department of Trade and Industry, the Office of Science and Technology, the Health and Safety Executive and other agencies.
[7]Annex 1 to the Regulatory Toxicology Guidelines

protocols. These guidelines have also ensured that the data provided to support Marketing Authorisations of pharmaceuticals is more readily extrapolated to the human situation and therefore of greater predictive value for human adverse events.

Select Committee recommendation 13: The promotion of the commercial advantages of the Three Rs needs a clear lead from a nominated department within Government. (paragraph 4.49)

26. The Committee is right that the 3Rs have commercial as well as animal welfare advantages. Replacement methods, such as in vitro screening and computer modelling, can be more reliable, quicker, more efficient and cost effective than animal models. They may also lead to patentable technologies. Reduction is self-evidently more cost-effective. Refinement reduces the stress on animals and improves the reliability of results. These advantages are already promoted by Government Departments. However, it must be primarily for industry to be alert to commercial advantage, but we will reconsider the need for a greater role as part of our consideration of the proposed centre for alternatives discussed below in the context of recommendation 24.

Chapter 5: Regulation and the Animals (Scientific Procedures) Act 1986

The Animals (Scientific Procedures) Inspectorate

Select Committee recommendation 14: The Home Office Inspectorate should be subject to periodic review, by a body other than the Inspectorate itself. (paragraph 5.13)

27. The Government welcomes the Committee's endorsement of the Inspectorate's important contribution to the creation of a culture of care in designated establishments and its recognition of the value of the synergy between the Inspectorate's advisory and monitoring roles. We also recognise the importance of maintaining public confidence in the independence of the Inspectorate and the impartiality of the regulatory system and will consider whether some form of periodic review might contribute to this. As currently constituted, we do not believe that the Animal Procedures Committee would be the appropriate body to undertake such a task. We understand that this view is shared by the Animal Procedures Committee.

28. The Government also notes the Committee's comments regarding the review of the Ethical Review Process (ERP). However, it cannot agree with the Committee's conclusions. We believe that the Inspectorate was uniquely qualified to conduct the review because of its role in advising certificate holders on their proposals to set up their local ethical review processes, their subsequent involvement with their operation and the impact ERPs have on their work both on site and in assessing project licence applications. As to future reviews of the implementation of policy, and of regulatory issues related to the 1986 Act, the Government will continue to decide, on a case by case basis, how they might best be carried out.

Select Committee recommendation 15: Designated establishments should be inspected at least once a year by an Inspector from another area. (paragraph 5.17)

29. The Government believes that there are clear benefits in the current arrangements under which each designated establishment has a dedicated inspector responsible for the provision of advice and for monitoring. Detailed local knowledge of the establishments and their personnel play an important part in the assessment and inspection systems, and an identified point of contact makes communication easier. This arrangement does not preclude visits by other inspectors. Indeed, joint visits of inspection, involving more than one inspector, are already part

of the normal inspection programme. In the first half of 2002 just over a third of designated establishments were visited by more than one inspector. However, since half of the establishments designated under the 1986 Act have five, or fewer, project licences, it would not be the best use of Inspectorate resources to have a mandatory programme of dual visiting, even once a year. We believe that the value in a second inspector's view is generally best directed at the larger establishments.

30. With regard to the Committee's proposal that consideration should be given to "lay visitors" accompanying inspectors on their visits, the Government is not convinced that such arrangements would have an impact on the consistency of inspection, or public acceptance of the regulatory system. However, visits to other facilities by Named Animal Care and Welfare Officers and Named Veterinary Surgeons may help to spread best practice. Such arrangements would raise issues of general security and biosecurity, which would be for establishments to consider and resolve. Subject to that, the Government will bring this recommendation to the attention of certificate of designation holders.

Weighing of harms and benefits

Select Committee recommendation 16: The substantive details of anonymised project licences, which describe the expected benefits of the research and harms to the animals involved, should be made public after they have been approved and funded. (paragraph 5.24)

31. The Government agrees that there are strong arguments for publishing more information about projects licensed under the 1986 Act. At the moment, other than comprehensive, but mainly descriptive, statistics of animal use, we publish virtually none. In addition, where research results are published in scientific journals this can often be delayed many years and they are likely to be seen only by other scientists. All of this contributes to a widespread lack of awareness of the regulatory system and the purposes for which animals are used and hinders informed debate on the use of animals in scientific research. The Government believes that there is a need for more open and better-informed debate about the use of animals in scientific procedures.

32. The publication by the Home Office of summaries of project licences setting out the salient features of the programmes of work which have been approved, would allow significantly more information to be placed in the public domain. It would also go some way towards addressing the current gap in public awareness and help to stimulate informed debate on the issues. The Government believes that there is evidence that the scientific community will accept a requirement for the publication of licence summaries, subject to safeguards for personal and commercial confidentiality. We, therefore, intend to consult the scientific community and animal welfare groups on the issue before finalising proposals regarding their format and content. We have in mind that they should be modelled on the so-called "lay summaries" already provided for the non-scientific members of some local ethical review committees. This should ensure that the requirement does not add significantly to the regulatory burden on applicants for project licences. A formal Regulatory Impact Assessment will be prepared when consultations have been completed and the details of the requirement have been fully worked out. Summarised information about licensed projects could be published without the need to amend s.24 of the 1986 Act.

Select Committee recommendation 17: The current restrictions on the use of terminally anaesthetised animals for training surgeons should be relaxed. (paragraph 5.27)

33. The 1986 Act does not prohibit the authorisation of projects for training in surgery. However, at present the only such licences issued relate to training clinicians in microvascular techniques.[8] Should an application be made for other categories of training in manual skills, this could be considered.

Licence applications and bureaucracy

Select Committee recommendation 18: Urgent consideration should be given by the Home Office to the simplification of project licences, with the aim of reducing the length of a typical licence to 10 pages. (paragraph 5.40)

34. We accept that the project licence application form, which becomes the main part of the licence, when granted, should be as short and simple as possible, consistent with providing the minimum information required for the Inspectorate to conduct the necessary assessments under the 1986 Act. That is clearly in the interests of regulated and regulator alike. However, the production of a much shorter application form and licence that will still meet existing regulatory needs poses a severe challenge, as previous efforts to that end by Government and representatives of the research community have shown. The legislation is rightly demanding, and the data to be captured at the licence application stage inevitably reflects that. It is in our view of little value to make comparisons with the licences of other countries, where the regulatory regimes are different. Nor is it particularly helpful to specify a maximum number of pages as a target for reducing licences. Licences must be as long as they need to be for essential regulatory purposes, but not a page longer than that. We will revisit this matter with the research community, with a view to the production of a revised application form/licence that all concerned accept is as simple and short as it can possibly be to meet statutory requirements.

Training modules

Select Committee recommendation 19: Visiting scientists and students in higher education should be allowed to carry out work under the licences of an established licence-holder, who would take responsibility for their actions and for the maintenance of animal welfare. (paragraph 5.46)

35. The Government notes that this recommendation is based on the view that scientists and students wishing to come to the United Kingdom from abroad to engage in animal research are inordinately delayed by unnecessarily having to complete a Module 1[9] training course on the 1986 Act. However, the Government believes that it is essential that those working under the 1986 Act are familiar with its requirements and take personal responsibility for their actions. We do not think, therefore, that completion of Module 1 training is an unreasonable requirement. It need not cause significant delay, as the licence application can be processed before the person arrives in the UK and the licence granted as soon as the training certificate is received. Training assessments can be produced in half a day, and certificates very shortly thereafter. The current mandatory training requirements for visiting scientists from overseas already represent a significant exemption from those usually applying to personal licence applicants. The Government does not believe that further exemptions are justified or desirable. The Government will, however, encourage discussions between accredited training providers and the scientific community sponsoring overseas scientists about the development of a distance learning package for overseas applicants. We will also draw attention once again to the most efficient current methods of obtaining licences for overseas visitors.

[8]Present Government policy—based on commitments given during the passage of the 1986 Act—is that such applications are referred routinely to the Animal Procedures Committee for advice. We are, however, awaiting advice from the Animal Procedures Committee on the continuing need for this practice.

[9]Module 1 covers historical background, an introduction to the ethical aspects of the use of animals in scientific procedures, the key features of the Animals (Scientific Procedures) Act 1986, and other relevant legislation.

Select Committee recommendation 20: Scientists of whatever grade should have a personal responsibility for the welfare of animals in their care. (paragraph 5.47)

36. This is already a requirement and is enforced through personal licence conditions. Standard condition 12 states that "[t]he personal licensee is entrusted with primary responsibility for the welfare of the animals on which he or she has performed regulated procedures; the personal licensee must ensure that animals are properly monitored and cared for, and must take effective precautions, including the appropriate use of sedatives, tranquillisers, analgesics or anaesthetics, to prevent or reduce to the minimum level consistent with the aims of the procedure any pain, suffering, distress or discomfort caused to the animals used".

The Animal Procedures Committee

Select Committee recommendation 21: The Secretariat of the Animal Procedures Committee should be strengthened and more clearly separated from the Home Office regulators. (paragraph 5.52)

37. The Animal Procedures Committee (APC) is a non-departmental public body and as such is already independent of the Home Office. The functions of the Committee, as set out in section 20 of the 1986 Act, are essentially advisory and it has no executive function. Since 1997, the Government has encouraged the Animal Procedures Committee to take a more proactive role. It has increased and broadened the membership of the Committee and provided additional administrative resources. For convenience, its Secretariat has hitherto been recruited from Home Office staff, but recruitment from the wider civil service, or beyond, is possible. The Government will consider sympathetically any reasoned request from the Committee for further resources to assist in its work.

38. As to the issue of whether APC members should be paid, the Government is very grateful to members for the time and effort they devote to the work of the Committee. However, the 1986 Act makes no provision for the payment of members of the APC (other than the Chairman) and we have no plans to amend it in this regard. Section 19(8) does, however, provide for payments to members for expenses incurred in the performance of their duties and they have been reminded of that arrangement.

Chapter 6: The Ethical Review Process

Select Committee recommendation 22: The Home Office should delegate interim authority to the local Ethical Review Process to approve routine or minor amendments. (paragraph 6.11)

39. We recognise the concern underlying this recommendation, and accept in principle the idea of minor variations to research protocols being approved more speedily at local level, although the variations to be handled in that way would need to be very precisely defined. However, we do not share the Select Committee's view that this can be achieved without primary legislation. We are advised that the 1986 Act as it stands does not allow the Secretary of State to delegate his functions in that way to persons for whose actions he cannot be held directly accountable. Primary legislation solely for this purpose would not in our view be justified. We will, however, consider whether there might be more that local ERPs can do under the existing law - perhaps through the way project licences themselves are framed and interpreted - so as to reduce delays without compromising animal welfare.

Select Committee recommendation 23: Each Ethical Review Process should be required to have an external, lay member, whose term of office should be time-limited. (paragraph 6.21)

40. The Government shares the Committee's belief that the involvement of lay members in local ethical review processes is beneficial and will continue to encourage it. However, we understand that some establishments, particularly the smaller ones, have found it difficult to identify and recruit lay members. Concerns also exist about issues of confidentiality and security. In the circumstances, we do not consider that it is practical, or reasonable, at the present time, to make such involvement mandatory.

Chapter 7: The three Rs: alternatives to animal experiments

Select Committee recommendation 24: A Centre for the Three Rs should be set up, consisting of a small, administrative hub which co-ordinates research units embedded in existing centres of scientific excellence. (paragraph 7.18)

41. The Government broadly accepts the Committee's recommendation. However, we remain firmly of the view that the development of the 3Rs should continue to be part and parcel of mainstream research programmes and toxicity work, and should not be seen as a separate activity. Most research that leads to alternatives arises from research that has been done primarily for some other purpose, answering a specific scientific question. This will continue to be the case.

42. Although deliberately of very different kinds, two "centres" already exist. The Medical Research Council's Centre for Best Practice for Animals in Research (CBPAR) is oriented towards developing, disseminating and implementing best practice in animal research and welfare in the academic research community for which the Medical Research Council is responsible. The Biotechnology and Biological Sciences Research Council (BBSRC) is also becoming increasingly involved in the Centre's activities. In collaboration with BBSRC and other parties, the CBPAR is likely to pursue several of the specific suggestions made by the Committee in its further work. These include developing "standard" key words that would make relevant literature easier to retrieve; discussing with research funders how grant applicants might be required to state explicitly whether their research might lead to the development of alternatives (and how they would publish it); discussing with journal editors whether there are problems with publishing such research and, if so, how these might be overcome; and contributing to the dissemination of information to research groups likely to benefit from using it, the translation of relevant findings into guidelines, and co-ordinating research efforts where the Councils continue to encourage research directly aimed at the 3Rs through special funding. A second centre of activity is provided by the Inter-Departmental Data Sharing Group, led by the Home Office. Its focus is on reducing the need for toxicity testing through better sharing of data, and encouraging the validation and acceptance of alternatives. These are largely matters of policy, but have a crucial role to play in the promotion of the 3Rs.

43. Direct funding of the 3Rs in relation to toxicity testing remains primarily for industry. However, the Government agrees that the case for a UK centre focused largely, but not exclusively, on toxicity testing, as a complement to the MRC's Centre and the Inter-Departmental Group, is nonetheless worth exploring further. The Government would not wish to be over-prescriptive about the nature, functions or location of such a centre. We intend to consult further with a view to inviting proposals from interested parties in due course, but envisage that the functions would be largely those of an administrative hub. Its remit might include consulting industry and developing R&D programmes through LINK[10] and other mechanisms; promotion to industry of the commercial advantages of the 3Rs; horizon-scanning publicly funded research for opportunities for industry to develop alternatives to toxicity testing; contributing to improved welfare of animals used in toxicity testing; working with the Animals (Scientific Procedures) Inspectorate, MRC Centre and with organisations

[10]The LINK scheme is the Government's principal mechanism for promoting partnership in pre-competitive research between industry and the research base.

in Europe and abroad[11]; working with the data-sharing group and industry to encourage data-sharing; maintaining up-to-date data on measures taken to promote the 3Rs, particularly by Government; responding to inquiries from the press and public on the use of animals in toxicity testing; and co-ordinating workshops, conferences and seminars to promote best practice.

44. The Government is also aware that an EU-wide industry initiative is under way to found a European centre for alternatives research. We believe that the final decision on a United Kingdom centre should take account of the outcome of this initiative.

Select Committee recommendation 25: The current Animal Procedures Committee research budget of £280,000 should be given to the Centre to disburse. The Centre should co-ordinate the Government spend on the Three Rs across all departments. A Centre would also require further funding from Government, industry, and animal welfare charities. (paragraph 7.23)

45. Our further exploration of the case for a UK centre for alternatives research will also consider funding issues. However, much of the budget allocated to the APC over the next few years is already committed to existing projects.

Funding bodies should encourage applicants who propose using animals to state what developments in the 3Rs each application incorporates (7.28)

Academic and professional journals should agree a standard set of keywords for articles relating to research on the 3Rs, so that relevant articles can more easily be found in databases (7.29)

Journals should encourage contributors to include information on how the 3Rs are developed or used in their research (7.30)

46. As indicated above, these are proposals that the MRC Centre is likely to pursue, in collaboration with other interested parties.

Chapter 8: Genetically Modified animals

Select Committee recommendation 26: A welfare assessment of all new strains of animals used in experiments (whether produced by new technologies or by more traditional methods) should be made as a matter of course. (paragraph 8.12)

47. The Government agrees and this is current policy. However, local practices vary and there is as yet no common assessment system. Discussions are, however, in hand with major funding bodies to develop a practical system that can be widely applied.

Select Committee recommendation 27: Animals from genetically modified strains which are bred but not otherwise used in regulated procedures should be excluded from the Home Office Statistics, provided that they have no characteristics with adverse welfare implications. (paragraph 8.16)

48. The Government agrees that the current practice of including all genetically modified animals that are bred, whether or not they suffer adverse welfare effects, in the headline figures in the Statistics of Scientific Procedures on Living Animals may give some readers a false impression of the nature and extent of the use of animals for experimental and other scientific purposes. However, it does not believe that such animals should be excluded entirely from the annual statistics. It will instead consider, as part of a wider review of the statistics, how best to modify the presentation of the annual statistics to eliminate any scope for misunderstanding.

[11]e.g. FRAME, ECVAM, Johns Hopkins CAAT

Chapter 9: Public information

Select Committee recommendation 28: Section 24 of the 1986 Act (the "confidentiality clause") should be repealed. Specific justification should then be made for each class of information that needs to be kept confidential, such as the identity of researchers and matters of commercial confidentiality and intellectual property. (paragraph 9.18)

49. For some time now the Government has taken the view that greater openness and transparency regarding the regulation and use of animals in scientific procedures is desirable, providing it does not jeopardise the safety of individual scientists and their establishments or their legitimate commercial and intellectual interests. At the same time, we have undertaken to review all statutory bars to the disclosure of information as part of our commitment to freedom of information.

50. As part of that review, we have been looking at s.24 of the Animals (Scientific Procedures) Act 1986, which makes the unauthorised disclosure of confidential information relating to the use of animals in scientific procedures by Home Office Ministers and officials, members of the Animal Procedures Committee and others appointed by the Secretary of State for specific purposes under the Act, a criminal offence. The Government recognises that there remains a significant level of concern in the scientific community about the implications of repealing s.24. We, therefore, propose to consult the scientific community further, through a joint working group, before reaching final decisions on the future of s.24.

Select Committee recommendation 29: The Inspectorate should convene a regular forum to discuss specific scientific and welfare issues related to the use of animals in experiments. (paragraph 9.22)

51. The Government recognises the value of constructive discussion on issues relating to the use of animals in scientific procedures. The Home Office hosted a forum in July 1999 attended by representatives from all sides of the debate. It agrees with the Committee that such discussions work best when they focus on specific issues rather than on a general agenda. It is intended that the recently expanded Inspectorate will have a significant outreach and education function that will help the Home Office to lead in a number of ventures intended to promote awareness of, and progress with the 3Rs. In addition, the Government is considering holding an event to discuss the revision of European Directive 86/609/EEC, when it gets under way. However, we do not see the Inspectorate as best placed to lead in convening forums of the sort envisaged by the Committee and will instead ask the Animal Procedures Committee to consider if it is a role it could undertake. The MRC Centre and proposed new centre would also have a role.

Select Committee recommendation 30: A formal consultation on the Statistics should be carried out with a view to making them easier to interpret. (paragraph 9.29)

52. The Statistics of Scientific Procedures using Living Animals provide a wealth of detailed information. However, the Government is conscious that they are not presented in a readily digestible form. We will review, in consultation with stakeholders, how they might be improved.

Select Committee recommendation 31: Serious efforts should be made to provide better statistics on animal suffering. The Home Office Inspectorate should develop or approve a "scoring system" for animal suffering which could be operated by Named Animal Care and Welfare Officers and Named Veterinary Surgeons, and used to provide data for the Statistics. (paragraph 9.38)

53. The Government agrees that the provision of further and better information on the life experience of each animal used in scientific procedures would be desirable and further believes that it could serve to reassure the general public in this regard. However, it also believes that the difficulty of devising a method of capturing this information should not be underestimated. It will, nevertheless, and as a first stage, seek views on the information that would be of use as part of the wider review of the statistics.

The Home Office and Inspectorate should involve responsible animal welfare groups in their work (9.5)

54. The Home Office and Inspectorate already have a productive relationship with responsible animal welfare organisations. Through its increasing outreach and educational functions, the Inspectorate will seek to involve all stakeholders to further the principles of humane animal research, and efficient and effective regulation.

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