

# Investigation into the Home Office's regulation of animal experimentation

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## 1st Report

Session 2006- 07

Presented to Parliament pursuant to  
Section 10(4) of the  
Parliamentary Commissioner Act  
1967

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## Foreword

This report of an investigation into a complaint against the Home Office was concluded on 23 December 2005.

Comments on the report, together with extracts from it, have appeared on animal rights organisations' websites and in their newsletters. This has led to requests for copies of the report and stimulated enquiries to my office about the investigation.

Because of the level of interest shown, I have decided to lay the report before Parliament under section 10(4) of the Parliamentary Commissioner Act 1967.

I hope that by putting the report in its entirety into the public domain, many of the queries and concerns expressed to my office by Members of Parliament and members of the public will be answered.

Ann Abraham  
Parliamentary Ombudsman  
December 2006

## Matters investigated

1. Mrs G complained that the Home Office had failed properly to regulate research undertaken by company A (the company), under the Animal (Scientific Procedures) Act 1986 (the 1986 Act). Specifically Mrs G contended that the Home Office incorrectly assessed the severity limits of procedures when granting licences to the company under the 1986 Act. Furthermore, she complained that the issue of drug toxicity did not appear to have been taken into account when determining the severity of procedures that were to be carried out under the licences that were granted. Mrs G also alleged that the Home Office exhibited bias and maladministration in their consideration and approval of the company's licence applications. In addition, she contended that the Home Office's oversight of the company's compliance with the conditions of its licences was inadequate. Finally, Mrs G complained that a government minister gave a misleading answer to Parliament in connection with this issue. I have set out what I consider to be the essential background to the complaint in Annex A to this report.

2. Acting with the authorisation of the Parliamentary Ombudsman under the provisions of the Parliamentary Commissioner Act 1967, this constitutes my report of the investigation. The investigation was carried out after the Ombudsman had obtained comments from the Permanent Secretary of the Home Office following the referral of Mrs G's complaint by the Member. I have not included in this report every detail investigated by the Ombudsman's staff, but I am satisfied that no matter of significance has been overlooked.

## The Ombudsman's jurisdiction

3. The Ombudsman is not empowered to consider the content or interpretation of legislation; those are matters for Parliament and the courts respectively. It is also not for the Ombudsman to determine the Home Office's policy, although she can consider whether they have correctly implemented their own policies and internal procedures.

4. The Ombudsman can only comment on the actions of those bodies within her jurisdiction. As neither the company nor the Animal Procedures Committee are within the Ombudsman's jurisdiction, it follows that she cannot comment on the actions of those bodies.

5. When considering complaints concerning decisions that are reliant on professional judgments, the Ombudsman would not normally seek to substitute her judgment for that of the relevant experts. Mrs G will appreciate that there are many such decisions within this case, and this confines our legitimate interest to the overall process governing this area.

6. Finally, it is not within the Ombudsman's jurisdiction to investigate the answers that a government minister has given in Parliament. What she could look at, however, is whether the Home Office provided the minister with inaccurate information. Before she would do so, the Ombudsman would wish to see some evidence that the alleged maladministration on the part of the Home Office lead to an injustice for which there was a worthwhile remedy.

## The Ombudsman's investigation

7. I turn now to those aspects of Mrs G's complaint that we have been able to look into and the outcome of our consideration of each of those. We have, of course, carefully considered the substantial amount of supporting documentation that Mrs G and 'Uncaged Campaigns' have provided, including the detailed response that Uncaged Campaigns submitted in response to the draft decision, together with the responses to our enquiries given by the Permanent Secretary and his staff at the Home Office.

### **Incorrect assessment of severity**

8. Mrs G and Uncaged Campaigns contended that the Home Office assessed procedures as moderate when they were clearly within the substantial category. She said that, as a result of that, substantial suffering was allowed to occur without breaching the conditions of the company's licences. Furthermore, Mrs G argued that, if a substantial severity assessment had been made, the licence applications would have been put before the Animal Procedures Committee (an independent body to whom the Secretary of State may refer for advice). An incorrect assessment of severity would also have distorted the cost-benefit assessment. A moderate severity limit would be considered a lower cost than a substantial severity limit.

9. In response the Home Office have explained that all of the company's licence applications were carefully and properly assessed, and that not all of the applications were granted licences. Advice was sought, where appropriate, from the Animal Procedures Committee, the

Department of Health, the United Kingdom Xenotransplantation Interim Regulatory Authority and an independent external assessor. Different elements of the company's research were assigned different severity limits, and some procedures were assigned a substantial severity limit. For those procedures assigned a moderate severity limit, the Home Office have acknowledged that the animals occasionally experienced suffering at the 'upper limit considered proper in that category'. However, the Home Office do not accept that any procedures were wrongly classified.

10. The Ombudsman's staff note that the Home Office acknowledged, in its written response to the Home Affairs Select Committee letter of 30 June 2003, that the documents provided by Uncaged Campaigns in support of this complaint do indicate that suffering occurred that was 'inconsistent with a moderate severity limit'; however, they argue that it is necessary to put those documents into context by examining the full records. The document extracts do not take account of the clinical treatment that was administered to relieve the suffering, or the fact that some of the conditions observed were as the result of treatment (e.g. sedatives), rather than an indication of untreated suffering.

11. In view of the concerns put forward by Uncaged Campaigns in respect of documents they had provided, which showed specific examples of animals being found dead or in extreme suffering, the Ombudsman's staff asked the Home Office to address those instances where animals were found dead and explain how they did not breach the moderate severity limit that was assigned to the procedures.

12. In response, the Home Office have addressed each of the specific instances referred to. They have explained that some deaths were

to be expected during the early post-operative period, but that the animals did not suffer to an extent that would exceed the moderate severity limit. The Home Office said that in other cases, animals died as a result of factors that could not have been foreseen at the cost-benefit assessment and severity limit consideration stage. However, the Home Office remained convinced that, although some animals did experience suffering at the higher end of the moderate severity limit, that limit was not breached.

13. In considering the explanations given by the Home Office, the Ombudsman's staff have noted that death, in itself, does not appear to constitute a breach of the moderate severity limit within 'The Guidance on the Operation of the Animals (Scientific Procedures) Act 1986'. This view is supported by the 'Report of the cost-benefit working group of the Animal Procedures Committee', which considered 'The weight assigned to "death of an animal" in itself (i.e. in absence of suffering)'. Within that heading they weighed various arguments put forward on whether a humane death (that is one without suffering) should be included in the cost-benefit assessment. A number of indirect 'harms' were put forward, which could be caused by the death of an animal, and that might be considered within the cost-benefit assessment. Uncaged Campaigns also contributed to this debate. The report observed, however, that 'whilst these potential harms are important and should be considered within the cost-benefit assessment, they are not relevant to the question of whether death in itself is a harm'.

14. Whilst there would appear to be an element of subjectivity involved in the assessment of severity, decisions about what severity limit to apply to the various procedures, and whether various observed symptoms were

indications of severe suffering, were matters for the Animals (Scientific Procedures) Inspectorate's (the Inspectorate) professional judgment and expertise. I do not see any basis upon which this Office could seek to question their assessment of the position (paragraph 5). In the light of that, and the fact that death, in itself, does not constitute a breach of the moderate severity limit, I remain of the view that we have not seen evidence of administrative fault by the Home Office in their handling of this matter, and I do not therefore see that there is anything further that the Ombudsman's continued intervention could achieve here.

### **The issue of drug toxicity**

15. Mrs G contended that the issue of drug toxicity should have been taken into account in determining the severity limit for the company's licence applications. I presume that she reached the view that it was not properly considered, because it was not mentioned as an expected problem in copies of the licence applications that were provided by Uncaged Campaigns.

16. The Home Office have however since confirmed that, although drug toxicity was not highlighted as a problem in the company's licence applications, the Inspectorate did identify it as a significant issue during their assessment of the applications. The Inspectorate discussed drug toxicity with the company and it was taken into consideration in the cost-benefit assessment, in the assessment of severity and in the endpoints that were to be applied. The Ombudsman's staff understand from the Home Office that they have sought to explain to Uncaged Campaigns on a number of occasions that the documents in their possession do not provide a complete picture and that reliable conclusions cannot be drawn from them about the assessment and monitoring of the company's research. I would

have to say that this might well explain why Uncaged Campaigns believe that drug toxicity was not taken into account appropriately, when it appears from the evidence that we have seen that it was in fact seen by the Inspectorate as an important issue in relation to the licence applications in question.

17. Uncaged Campaigns have made the point that the final project licences formed the legal basis on which the work would be carried out, thus they were required to contain all the relevant information about the procedures that they related to. They have argued that the Home Office's assertions on the issue of drug toxicity and this Office's treatment of them are 'wholly inadequate'. I am afraid that I cannot accept that assertion. The Home Office have confirmed that the potential drug toxicity was managed within the terms and conditions of the licence authorities (both project and personal licences) assigned to each procedure and the conditions of issue, particularly condition six of the project licence. The Ombudsman's staff have seen the final project licences that were granted to the company and we are satisfied that the potential adverse effects of the immunosuppressants were taken into account. In the light of the explanations given, and the evidence seen by the Ombudsman's staff, I cannot see that there are any grounds for pursuing this issue further.

### **Bias and maladministration in the consideration of licence applications**

18. Uncaged Campaigns suggested that a number of the documents that they had provided indicated a collusive relationship between the Home Office and the company. Mrs G also alleged that the Home Office failed adequately to scrutinise the company's licence applications and were maladministrative in their assessment of the likely benefits of the research

when conducting the cost-benefit assessment. Specifically, she contended that the Home Office approved the company's licence applications on the basis of unrealistic claims made about the success of earlier research and the prospect of further benefits. In particular, Mrs G believed that the Home Office were swayed by the company's claims about the imminence of clinical trials.

19. The Home Office's position is that the clinical trials were only ever considered to be the eventual long-term goal of the company's research. Any single project licence could only cover a small fraction of the work required in the overall project. Therefore, each component part of the research had to be, and was, judged on its own merits, and not on the eventual goal. The project licences covered a five-year plan of work. Although the licences contained some flexibility, the company were required to show that progress was being made before they were allowed to proceed to the next stage.

20. The Home Office maintain that the company in fact achieved most of their objectives. This included demonstrating that:

*'the relevant genetic alterations to the donor animals did not themselves impose any welfare costs once breeding lines were established; how to produce high-health-status donor animals without otherwise seriously compromising their welfare; and that transplantation of the genetically altered organs was not routinely associated with hyperacute rejection. They also partially characterised some of the performance characteristics of the transplanted organs; developed an understanding of other forms of delayed xenograft rejection and gained insights into the likely risk of disease transfer between species. All of these were verified as the programme evolved.'*

However, problems then arose in the next stage of the research, which was a pre-requisite if long-term studies were to be allowed. It was the Inspectorate's concerns about the limited prospects of success with the company's preferred strategy that led to the company discontinuing their work in the United Kingdom.

21. Uncaged Campaigns have questioned both the Home Office's claim that the company achieved most of its objectives and their account of why the company's research in the United Kingdom ceased. In respect of the first point, Uncaged Campaigns argued that the objectives that were required to be met before clinical trials could be allowed were set out in a project licence from 1994 and that these objectives correspond to the objectives listed by the Chief Inspector of the Inspectorate in his review of the company's compliance. Those objectives were:

- i. Prevent hyperacute rejection and elucidate subsequent rejection mechanisms*
- ii. Achieve long-term xenograft survival through an effective immunosuppressive protocol*
- iii. Assess the ability of the organ to function sufficiently to maintain life of recipient'*

Uncaged Campaigns assert that the Home Office have 'stretched out licence objective one to encompass five out of the six different objectives on their own list (paragraph 20), while the second and third licence objectives are not even listed'. They state that the evidence provided to the Ombudsman's staff by the Home Office is 'grossly misleading'.

22. The objectives to which Uncaged Campaigns refer represent just one part of the work covered by that project licence. Each of the three project licences granted to the company covered a number of different aspects of their

planned research, each of which had their own objectives. It seems to me somewhat spurious to suggest that the Home Office's evidence is 'grossly misleading' because the achievements that they have highlighted do not correspond with the objectives from one part of a single project licence. In addition, the objectives contained within the Chief Inspector's report are presented in general terms and do not claim to represent the specific objectives of one single project licence. I am also satisfied that they do not correspond exactly to the objectives in the 1994 project licence, as alleged by Uncaged Campaigns.

23. In respect of the Home Office's account of why the company's research in the United Kingdom ceased, Uncaged Campaigns have claimed that this has changed over time. Initially, in the Chief Inspector's report of 2001, the Home Office said that 'this moratorium was voluntarily proposed and implemented by [the company's] management'. Uncaged Campaigns alleged that this statement was deliberately intended to give the impression that the company were sensitive to their regulatory and animal welfare responsibilities. They argued that this line was put forward by the Home Office to benefit the company who were engaged in legal proceedings with Uncaged Campaigns. They have compared this statement with the explanation given by the Home Office, in its response to the Home Affairs Select Committee in 2003, which was that 'the Home Office implemented a moratorium on [the company's] main programme of work'. Uncaged Campaigns said that in a letter from the Home Office, of 26 October 2004 (not seen by the Ombudsman's staff) the position had become that 'the moratorium on [the company's] operative surgery was agreed between [the company] and the Home Office'. Uncaged Campaigns have argued that the Home Office's changing accounts of why the company's work

ceased show that their explanations cannot be accepted at face value.

24. The Ombudsman's staff sought the Home Office's comments on the arguments put forward by Uncaged Campaigns. In response, the Home Office stated that they did not accept that their statements regarding the moratorium had been contradictory. They said that they had raised with the company the prospect of the licences being suspended if the company sought to proceed in spite of concerns expressed by the Home Office and the company's then parent company. The Home Office have said that, in the light of this, the company proposed a voluntary moratorium, which was enforced by the Home Office's determination to revoke the licences if the company did not adhere to the moratorium. The Home Office have argued that the statements that they made have all been correct and that the moratorium was voluntarily implemented, but under pressure from them. I do not consider that the Home Office's statements were contradictory and the Ombudsman's staff have seen no evidence of bias by the Home Office in connection with their statements.

25. Furthermore, it seems to me that the allegations of bias appear, in part, to be based on notes of meetings at which Home Office staff were not present, and communications to which the Home Office did not appear to have been privy. The company's internal communications do seem to have been rather informal in their language and tone, and their comments would appear to reflect more on the company's attitude toward the Home Office, rather than any bias on the part of the Home Office's staff. The 1986 Act effectively legislates for the 'negotiation' of licences. Whilst this may give the appearance of an overly close relationship between the Inspectorate's staff and applicants, I do not see it as evidence of bias.

26. Whatever claims the company might have been making internally, the Home Office are adamant that they did not take into account the long-term goal of clinical trials, when carrying out the cost-benefit assessment. The Inspectorate monitored the company's progress and the success of their strategies through the inspection programme and the reports submitted by the company, as required by their licences. Ultimately it was the Inspectorate's concerns that led to the company moving its research out of the United Kingdom. This Office is clearly not in a position to verify the scientific benefits that the Home Office maintain flowed from the earlier stages of the company's research; however, I have not seen any evidence that would lead me to disbelieve the Home Office's version of events. I have also seen no evidence whatsoever to support the allegation of bias on the part of the Home Office's staff. It follows that I do not therefore uphold this aspect of the complaint.

### **Inadequate oversight of compliance**

27. A recurrent theme in this complaint is that the Home Office failed to act to enforce the conditions of the licences that had been granted to the company, and failed to take account of the results of the research that was being carried out by the company. In effect, that the Inspectorate's oversight of the company's compliance with the licence conditions was inadequate.

28. As part of our enquiries we have, therefore, looked very carefully at the Inspectorate's monitoring regime. We have found that the Inspectorate's visiting programme takes account of the size of an establishment, the nature of the work being carried out, the number and species of the animals being used, and the local management culture. The

Inspectorate's current target is for half of the visits made to each establishment to be unannounced. The Home Office have explained, and I have no reason to doubt, that the company was given a high priority within the visiting programme and their research received some of the most intense monitoring and inspection of any research carried out under the 1986 Act since it was implemented. During the six years that the company carried out the research in question they received 123 inspection visits. This figure is fifty percent higher than it would have been, had the visiting programme been based solely on the size of the establishment. More than half of the visits were unannounced. In the main the visits were carried out by one of two inspectors who were familiar with the establishment and the work and who had a special interest 'in the care and use of non-human primates'. A number of joint visits were also undertaken. These involved inspectors from other regions and inspectors, including the Chief Inspector, who had some specialist knowledge of the research being undertaken. During the inspections instances of non-compliance were identified on occasion. The report which followed set out how the non-compliance had come to light, and what action the Home Office had taken. I note that the Home Office have said that they knew of, or had dealt with, all of the non-compliances raised by Uncaged Campaigns.

29. The company's licences required them to submit regular progress reports to the Inspectorate. The Home Office have informed the Ombudsman's staff that the Inspectorate chased up and obtained any overdue reports. These reports were used to assist the Inspectorate in assessing the progress that the company were making. The reports were also considered by the primates sub-committee of the Animal Procedures Committee. A number of factual errors were identified and on occasion

the reports were not as clear or as informative as they could have been. Most of these errors only occurred once. The Inspectorate had also required one six-month overview report to be rewritten, because in their opinion it did not contain sufficient information for a proper assessment of the work to be made.

30. Uncaged Campaigns have asserted that, given the Inspectorate's role in negotiating licence applications (paragraph 25), it is not possible for their visiting programme to be impartial. It seems to me that the dissatisfaction expressed by Uncaged Campaigns here relates more to the legislative framework, rather than to any evidence of maladministration on the part of the Home Office. As I explained in paragraph 3, the legislative framework is not a matter for the Ombudsman.

31. But in any event, it would appear from the evidence that we have seen that, far from failing to maintain adequate oversight of the company's compliance with their licence conditions, the Home Office in fact devoted significantly greater resources to monitoring the company's research than would normally have been the case. Further, as soon as the Inspectorate suspected that the company were unlikely to achieve the anticipated benefits with their preferred strategy, the Inspectorate raised their concerns with the company. I am satisfied that, as a direct result, the company ceased their research in the United Kingdom. I therefore do not uphold this part of the complaint.

### **Ministerial statements to Parliament**

32. This aspect of the complaint refers to a written answer given to Parliament by a then Home Office Minister on 28 June 2000, in response to a question from another Member. Uncaged Campaigns alleged that the Minister

misled Parliament about the deaths of three primates in transit from the Philippines. They argued that if the Home Office had provided the Minister with inaccurate information, then that would be evidence of maladministration.

33. The Minister said that the deaths in question had probably been caused by a combination of factors, which included:

- *‘the animals were larger than normal;*
- *although International Air Transport Association minimum dimensions were not breached, the containers were not large enough to allow these particular animals to stand up and turn around freely; and*
- *all the dead animals had been in central compartments, which were less well ventilated.’*

34. Uncaged Campaigns asserted that, contrary to the Minister’s written answer, the International Air Transport Association regulations were breached. They stated that those regulations required that the containers should have been ventilated on at least three sides. In respect of dimensions, the regulations say that the container must ‘in general allow the animal to stand, turn and lie down in a natural manner’.

35. The Minister’s response acknowledged that the containers were not large enough and that a lack of ventilation contributed to the deaths of the animals. I do not see that this was misleading. The only matter of contention seems, therefore, to me to be whether the dimensions of the containers breached the relevant regulations. That is not something that the Ombudsman can determine. Certainly we have seen no evidence to suggest that the Home Office believed that they did breach them, or that they provided the Minister with inaccurate information. I do not therefore see what is to be

gained by the Ombudsman’s further intervention in the matter. Accordingly, I propose to let matters rest there.

## Conclusion

36. I do appreciate that both Mrs G and Uncaged Campaigns feel very strongly about the issues involved, but it seems to me that their dissatisfaction stems more from the regulatory system itself and the definitions applied, than from any failing in the Home Office’s monitoring of compliance in this particular instance. In the light of the evidence that we have seen, I am afraid that I really do not see that there are any grounds for the Ombudsman’s further intervention in these matters. I hope, however, that they have at least found the above explanations helpful in understanding why that is.

[Signed]  
Director of Investigations  
duly authorised under section 3(2) of the  
Parliamentary Commissioner Act 1967

December 2005

## Annex A

1. The responsibilities of those with roles under the 1986 Act, together with how the 1986 Act is administered and enforced is set out in the Guidance on the Operation of the Animals (Scientific Procedures) Act 1986 (the Guidance). Relevant extracts from the Guidance are set out below.

### Extracts:

2. A project licence specifies a programme of work. That is a combination of regulated procedures and endpoints designed to achieve the objectives specified in the licence (chapter 5.1).
3. A project licence issued under the 1986 Act defines the specific objectives of the research to be carried out; itemises the realistic likely benefits; outlines the plan of work; details the experimental or other scientific protocols to be followed; identifies the likely adverse effects, the means by which they will be avoided, recognised and alleviated; and sets the severity limit for individual protocols and the severity band of the project as a whole (chapter 5.4).
4. The Secretary of State is required to weigh the likely adverse effects on the animals used against the likely benefits to result from the programme of work when considering whether to grant a licence (cost-benefit assessment) (chapter 5.10).
5. The severity limit for a particular protocol is determined by the upper limit of the expected adverse effects on an animal, having taken account of the measures specified in the licence for avoiding and controlling adverse effects. It indicates the worst potential outcome for any animal used in the protocol, even if it may only be experienced by a small number of the animals used (chapter 5.40).
6. When assessing the severity limit of a protocol, account should be taken of all the procedures that are to be applied to each animal or group of animals; the nature and extent of the likely adverse effects; the action taken to mitigate those effects; and the humane endpoints to be applied (chapter 5.41).
7. There are four categories of severity limits: unclassified; mild; moderate; and substantial (chapter 5.42).
8. If it seems likely that the severity limit of a procedure has or may be exceeded, the licence holder must contact the Home Office. If the licence holder can show sufficient justification the Secretary of State may allow a temporary higher severity limit in order for the balance of the likely benefit and likely cost to be reviewed and for consideration of amendment to the licence (chapter 5.44).
9. The assessment of the severity band for a project as a whole reflects the number of animals used in each procedure and the

actual suffering likely to be experienced by each animal and not just the single worst possible case. It takes account of the number of animals expected to reach the severity limit of the protocol and the duration of that exposure, the nature and intensity of the adverse effects, and the actions to be taken to relieve suffering (chapter 5.48).

10. Inspectors at the Animals (Scientific Procedures) Inspectorate (the Inspectorate) are the primary assessors of licence applications submitted to the Secretary of State. Project licence applications are assessed in detail and challenged where necessary to determine whether the benefits likely to result from the project outweigh the cost in suffering to the animals used, and whether there is scope for replacement, reduction or refinement alternatives. To make these judgments, inspectors must take a view on the significance, scientific quality and validity of the proposed work, the appropriateness of the animal use and the measures to be taken to minimise suffering (appendix G paragraph 12).
11. It is generally necessary for inspectors to discuss the proposals in detail with applicants (appendix G paragraph 13).
12. The number and nature of visits of inspection to each establishment made by the Inspectorate will be determined by the size and nature of the establishment, the types of work carried out, and the proportion of Inspectorate resources devoted to the visiting programme. The majority of visits are made without notice (appendix G paragraph 17).
13. The cost-benefit assessment requires more than establishing that the likely benefit exceeds the likely cost. The benefits must be maximised and the cost, in terms of animal use and suffering, must be minimised (appendix I paragraph 1).
14. The likely benefit is primarily derived from the utility of the data or product to result from the programme of work, rather than the importance of the general area of study. Thus, although the long-term objective may be to find new medical treatments, the benefit for the purposes of the cost-benefit assessment relates to the progress likely to result directly from the programme outlined in the application (appendix I paragraph 6).
15. Although the 1986 Act only requires that the Secretary of State weighs the costs and benefits before granting project licences, the cost-benefit assessment is not a single event exercised only at the beginning of a programme of work. It is a continuous process throughout the life of the licence. Every effort must be made to maximise benefit and minimise severity when work is being planned and whilst work is in progress. The emerging and actual costs and benefits must be evaluated and reviewed, to ensure that the original assumptions and assessment remain sound (appendix I paragraph 13).

Millbank Tower  
Millbank  
London SW1P 4QP

Helpline: 0845 015 4033  
Fax: 020 7217 4000

Email: [phso.enquiries@ombudsman.org.uk](mailto:phso.enquiries@ombudsman.org.uk)  
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