

# **Categorising the severity of scientific procedures on animals**

Summary and reports from three  
round-table discussions

*Edited by*

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The Boyd Group and the RSPCA

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# CATEGORISING THE SEVERITY OF SCIENTIFIC PROCEDURES ON ANIMALS

Summary and reports from three round-table discussions on the  
use of severity limits and bands in the UK

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## **ACKNOWLEDGEMENTS**

The discussions reported here involved Named Veterinary Surgeons and Named Animal Care and Welfare Officers, representatives of animal welfare and animal protection groups, and project licence holders and personal licensees. The Named Persons and licence holders came from a range of different kinds of establishment designated under the UK Animals (Scientific Procedures) Act 1986, with experience of a variety of laboratory animal species, scientific procedures and fields of research and testing. The animal welfare and protection group representatives were from FRAME, RSPCA, and SSPCA (who are also participants in the Boyd Group), and BUAV, Dr Hadwen Trust, NAVS, and Uncaged Campaigns.

The NVS/NACWO discussion was chaired by Professor David Morton; the animal welfare and protection group representatives' discussion was chaired by Professor Kenneth Boyd; and the licence holders' discussion was chaired by Dr Bryan Howard.

Venues and refreshments for the meetings were kindly provided by the Wellcome Trust (NVS/NACWOs meeting), RSPCA (animal welfare/protection) and the Medical Research Council (licence holders).

Reports from the individual discussions have each been approved by the relevant participants as an accurate record.

### **About The Boyd Group**

The Boyd Group is a forum for open exchange of views on issues of concern related to the use of animals in science. Participants in the Group span a range of expertise and perspective. They include veterinarians; scientists using animals (from industry and academia); members of animal welfare organisations; anti-vivisectionists; members of government and charitable bodies that fund or are directly engaged in research; philosophers and others. The Group's objectives are:

- (i) to promote dialogue between these diverse people and organisations;
- (ii) to clarify key issues of concern identified by participants, and to reveal the basis of the different opinions and beliefs; and
- (iii) where possible, to identify points of consensus and make practical recommendations.

### **About the RSPCA**

The RSPCA as a matter of policy is opposed to all experiments or procedures that cause pain, suffering or distress to animals. However, as in other areas of its work, the Society adopts a constructive, practical approach to the laboratory animals issue, and supports initiatives that lead to greater application of the 3Rs of reduction, refinement and replacement of animal experiments. The Society's Research Animals Department has a long-standing interest in questions surrounding severity assessment and categorisation, and this study forms part of the Department's on-going work in this area.

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## **1. BACKGROUND**

Methods for categorising animal suffering have long been the subject of discussion and debate. The issue has recently become a concern within Europe in relation to the current revision of Directive 86/609, and particularly in the UK in light of:

- the discussion and recommendations of an Animal Procedures Committee (APC) sub-group report on cost-benefit assessment in the use of animals in research (APC, 2003);
- Home Office responses to criticisms raised in recent anti-vivisection and animal welfare group reports on primate research and xenotransplantation (Home Office, 2002 and 2003a); and
- current APC discussions on retrospective reporting of animal suffering, as part of a review of the presentation of statistical data on animal experiments, and also in response to a specific request from the Home Office minister in relation to recommendations in a House of Lords' Select Committee report (House of Lords, 2002).

In the UK, severity classification involves the use of (i) severity bands, which are applied to each scientific project involving animals, and (ii) severity limits, which are applied to each of the individual protocols within a project. The system is described in the Box overleaf.

The work described in this report was initiated following discussions within the Boyd Group of the severity questions raised by a BUAV video of primate research. These discussions were informed by the previous and on-going work of the RSPCA's Research Animals Department, which has a long-standing interest in questions surrounding severity assessment, and has helped to inform discussions within the APC on these issues. It was concluded that there was a need to obtain more information on how the current severity categorisation system is interpreted and used in practice, and by whom, and to compare this practice with wider expectations of the system. From this, it was agreed that the Boyd Group, working together with the RSPCA, would organise a series of 'focus-group' style discussions, to consider the appropriateness and usefulness of the present system of severity categorisation under the Animals (Scientific Procedures) Act 1986 (A(SP)A), and to collate suggestions for improvement.

Three focus group discussions took place, involving:

- Named Veterinary Surgeons and Named Animal Care and Welfare Officers;
- representatives of animal welfare and anti-vivisection organisations; and
- project and personal licence holders under A(SP)A.

A detailed report from each of these three discussions, each agreed by all participants as an accurate record, is appended. The key points arising from all three discussions are brought together in the following synopsis.

## **The current system for classifying severity in the UK**

*Adapted from the Animal Procedures Committee review of cost-benefit assessment, 2003*

The system of classification of animal procedures into different levels of severity is not written into the text of the Animals (Scientific Procedures) Act 1986 (A(SP)A). Rather, it is explained in the *Guidance Notes* on how the Act is implemented (Home Office 2000, pp. 32-33). This *Guidance* requires that assessments of likely costs to animals are classified into different levels of severity: **mild, moderate, substantial or unclassified**. There are two distinct applications of this classification, to:

each **project**, which is assigned an overall *severity band*; and  
every **protocol**\* within the project, which is given a *severity limit*.

**The severity limit of each protocol** (e.g. oral gavage; induction of Parkinsonism) reflects the maximum level of suffering that an individual animal *may* suffer as a result of the protocol, i.e. it reflects the *upper limit* of suffering for any animal undergoing that procedure. Examples provided by the Home Office to illustrate how the severity limits are categorised include:

- *Mild* – for protocols that, at worst, give rise to slight or transitory minor adverse effects, e.g. small infrequent blood samples, minor surgical procedures under anaesthesia such as small superficial tissue biopsies;
- *Moderate* – e.g. toxicity tests that do not involve lethal end-points, many surgical procedures, provided that suffering is controlled and minimised by effective analgesia and post-operative care;
- *Substantial* – for protocols that result in a major departure from the animal's usual state of health and well-being, where one or more animals will be so affected – e.g. major surgery, some disease states where welfare is seriously compromised, acute toxicity tests and some efficacy tests of anti-microbials and vaccines that may involve significant morbidity or even death as an end-point;
- *Unclassified* – for protocols performed entirely under general anaesthesia, from which the animal does not recover consciousness.

**The overall severity band for the project as a whole** is intended to reflect the degree of suffering likely to be experienced by the *average* animal used in the project (Home Office, 1998), and again is categorised as mild, moderate, substantial or unclassified. The *Guidance* on the Act (Home Office, 2000) notes that the severity band reflects the number of animals used in each protocol and the actual suffering likely to be caused as result, taking into account the proportion of animals expected to reach the severity limit of the protocol, the duration of exposure to that severity limit, the nature and intensity of the adverse effects and the actions taken to relieve any suffering. On this basis, a project containing ten mild protocols, each involving 10000 animals, and one substantial protocol involving fifty animals, could well be classified as mild.

**An additional restriction on severity** arises from the requirements of Section 10(2A) of A(SP)A, in that "the Secretary of State will not licence any procedure likely to cause severe pain or distress that cannot be alleviated" (Home Office, 2000).

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\* A protocol is defined as a procedure or series of procedures carried out on an individual animal or group of animals for a single specific purpose within the context of a project.

*As the following summary makes clear, there was a remarkable convergence of opinion on the key issues and possible ways forward, both within and between the three, potentially divergent, focus groups. The individual reports from each of the three discussions (in Appendices 1 to 3) should be consulted in order to appreciate the reasoning behind the general conclusions set out below, as well as the broader context and nuances of the arguments.*

## **2. THE NEED FOR A SEVERITY CATEGORISATION SYSTEM**

All three focus groups observed that recognising, monitoring and assessing the severity of adverse effects caused to laboratory animals is vital. This is always the case, regardless of whether or not those adverse effects are then *categorised* in order to assign severity limits and bands, as is current practice under A(SP)A (see Box opposite). The narrative descriptions of severity in the 19b sections of project licences are essential tools in managing animal suffering and considering the ethical weighing of harms and benefits. Both the NVSs and licensees said that they find these descriptions more useful than the one-word severity 'labels' when communicating about animal suffering and considering harm-benefit assessment.

The general consensus of all three groups was that *categorisation of severity by means of severity limits applied to protocols* can bring additional benefits in practice, because:

- the *process* of assigning severity categories, supported by discussions with Named Persons and the local ethical review process (ERP) more generally, can assist licensees' thinking about levels of animal suffering and can encourage refinement of procedures;
- the *categories themselves* can
  - help to define clear upper limits on animal suffering, and therefore can assist in implementing humane end-points; and
  - identify techniques, procedures and protocols that cause the most animal suffering, as priorities for application of the Three Rs (including highlighting licence applications for additional review by the APC).

Views were more mixed on the value of severity categorisation in assisting harm-benefit assessment, as part of an ethical judgement on whether or not work should be licensed. There was, however, firm agreement from all participants that *severity bands of projects* are of very limited value in this regard (as well as for public information purposes – see section 5, page 7). This is because it is very difficult to give a single, realistic narrative assessment of the overall severity of a project that involves a variety of protocols of different severities, let alone to label this overall assessment with a single word from a choice of only four. Moreover, a label which refers to the experience of the 'average' animal (as Home Office

guidance suggests the severity band should do) is both misleading and ethically dubious, because each animal should 'count as one'.

Aside from these practical uses of severity assessment as a tool in project management and in the licensing process, there was also discussion of the use of severity categorisation for *public information purposes*. The key points that emerged are summarised in section 5 below.

### **3. DIFFICULTIES IN USING THE CURRENT SEVERITY SYSTEM**

There were some differences of opinion in the Named Persons and licensees' groups on the value of severity categorisation *per se*. However, the general conclusion from all three groups was that a severity categorisation system can bring sufficient practical benefits in relation to the *management of animal suffering* to warrant retaining it, but that the current system could be improved.

It was agreed that in general the system is difficult to apply and, more widely, to understand in practice because there is insufficient guidance on its use. Current guidance (Home Office, 2000 pp. 32-33):

- provides only very brief and vague definitions of the severity categories;
- includes very few examples, most of which refer to procedures (e.g. 'blood samples', 'skin irritation tests') rather than their outcomes in terms of the adverse effects on the animals; and
- does not provide any illustrative case studies.

Moreover, it is particularly difficult to assign severity categories when adverse effects are uncertain or unpredictable, such as in the production of genetically modified animals or in toxicity testing.

It was observed that the above factors can lead to inconsistencies in application of the categories, for example between different kinds of protocol and between different Home Office inspectors.

It was further agreed that there are also difficulties with the categories themselves. In all three groups:

- the overall consensus was that 'moderate' is too comfortable a term for many of the adverse effects it encompasses. Participants in the NVS/NACWO and animal protection focus group also felt that use of the term 'moderate' is often at odds with everyday understanding of the word; and the latter group felt that this can downplay the suffering involved;

- it was also observed that the moderate category tends to become the 'default' and as a result encompasses a very wide range of different protocols with a wide range of severities to match;
- it was emphasised that the categories should encompass *all* potential adverse effects – psychological as well as physical. Licensees also specifically argued that the current severity labels are too pain-related and do not adequately reflect other kinds of adverse effect, such as stress, anxiety, and other more specific effects, such as nausea.

The animal protection group also discussed difficulties with the *unclassified* category and the definition of 'severe' (as opposed to 'substantial') suffering, concluding that:

- the use of an 'unclassified' category shows that the whole lifetime experience of an animal is not taken into account in assessing severity; and
- the line between 'substantial' and 'severe' suffering is very fuzzy, and this poses problems for proper implementation of the law because 'substantial' suffering is permitted under A(SP)A (provided it can be 'justified' in terms of anticipated benefits), whereas 'severe' suffering is absolutely prohibited.

It is clear that there are differing perceptions of what 'mild', 'moderate', 'substantial' and 'severe' animal suffering comprises. For example, most animal protection group participants would regard as 'moderate' many of the procedures currently classified as 'mild', and would therefore start the classification at 'moderate' not 'mild'. By the same token, they would include at least one more category at the top end, to describe the most extreme effects, which are currently classified as 'substantial' (without, however, accepting that it should be permissible to cause such suffering).

## **4. SUGGESTED PRACTICAL SOLUTIONS TO THESE PROBLEMS**

### **4.1 General approach to the assessment of severity**

With regard to severity assessment generally, it was agreed by all participants that this should:

- focus on the individual animal (not the 'average', as in severity bands for example);
- be assessed from the animal's point of view as far as possible\*; and

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\* Two different, but not incompatible, views were also expressed in the focus groups in relation to this point. The licensees' group added that it is important to avoid unjustifiable anthropomorphism or weighting in favour of species with which humans are most familiar. The animal protection group argued that assessment should start from "the commonsense perspective which asks, 'What would a human experience in such circumstances?', taking into account relevant differences in biology and behaviour between humans and the species in question".

- adopt a 'holistic' approach, in which there is an attempt to consider all factors that can potentially influence well-being, including:
  - psychological/emotional effects (e.g. anxiety, fear, boredom) as well as physical effects, and their *duration*; and
  - wider factors, such as transport and husbandry, as well as the procedures themselves. Note that this last point was qualified by licensees, who said that they specifically include such wider factors in categorising severity *only* when the factors differ from the norm – e.g. when gregarious animals are singly housed. They argued that the more routine aspects of husbandry and care are the concern of the ERP and not part of the severity assessment within project licences.

The animal protection group emphasised that such a severity assessment should include anticipated as well as unanticipated (out of the ordinary) effects. Most participants in this group also argued that the effects on stock animals used to breed animals for use in experiments should specifically be taken into account as part of the assessment of severity.

#### **4.2 Better guidance to assist in severity assessment and categorisation**

It was agreed by all groups that there is an urgent need for better guidance on assessing animal suffering in general – and, in particular, on how to assign severity categories. This guidance, it was suggested, should:

- cover all animals protected under A(SP)A – i.e. all classes of vertebrates (not just mammals) and protected invertebrate species (at present, only *Octopus vulgaris*), as well as their protected developmental stages;
- encompass a wide range of different kinds of adverse effects (including their duration), protocols and techniques;
- as far as possible be based on empirical evidence (though it is acknowledged that there is a need for more research in this area);
- include detailed worked examples to illustrate the application of severity categories in practice, particularly at their boundaries.

#### **4.3 Improvements to the severity categorisation system**

With regard to the 'meaningfulness' of the severity classification itself, it was agreed that:

- word labels for different severity levels are better than numbers in focusing minds;
- there is a need for modification and/or addition of labels, in order to make the classification either:
  - not so 'pain-centric' (licensees' group)
  - or 'value-laden' (NVS/NACWOs' group); and/or
  - to reflect more accurately the subjective feelings of the animals involved (animal protection group); and, similarly, in relation to the 'moderate'

category, to accord with everyday understanding of the term (NVS/NACWO and licensees' groups);

- further to the last point above, it was agreed that consideration should be given to sub-dividing the moderate category, which, it was argued, is too broad. The consensus in the NVS/NACWO and animal protection groups was that the 'moderate' category should be sub-divided, but opinion was divided in the licensees' group, with some participants arguing that increasing the number of severity categories would make the system too complicated;
- the licensees' group suggested that, particularly in relation to use for public information purposes, the application of severity categories should reflect more closely the *probability* that the adverse effects will occur in practice (see 5.2.3 below);
- the NVS/NACWO group thought that consideration should be given to possible needs for new severity categories for behavioural protocols and for breeding transgenic animals; to expanding the 'mild' category to include more surgical procedures when these are followed by effective use of analgesia; and to widening the 'substantial' category to cover more 'distress'.

## **5. PUBLIC INFORMATION ABOUT SEVERITY**

As noted above, severity categories are also used to provide public information about animal suffering under A(SP)A.

### **5.1 Data on severity bands of project licences**

At present, the sole information about severity provided in the public domain are data on numbers of project licences in each overall severity band (see Home Office 2003b page 83 for the most recent data). All three groups firmly agreed that these data are not useful or appropriate for purposes of public information, because they:

- are average, prospective assessments that do not reflect the actual harms to the individual animals involved (all focus groups);
- downplay animal suffering (animal protection group);
- do not indicate how the animals were used, nor why (all groups).

### **5.2 Better means of providing statistical data on severity**

#### **5.2.1 Retrospective reporting of actual severity experienced**

All three groups agreed that *retrospective reporting of the severity of adverse effects actually experienced by the animals* would provide the most pertinent statistical information about severity. However, in both the NVS/NACWO and licensees' groups, opinion was divided on whether the benefits of providing this information would justify the effort required to record it. For example, licensees whose projects involve using large numbers of

animals, and/or whose animal facilities hold large numbers of animals, were concerned that collecting these data would be overly burdensome. In the NVS/NACWO group there was concern that animal care staff need to preserve as much time as possible to check and tend to the animals in their care, rather than fill in forms for statistical purposes.

#### 5.2.2 Data on animals used by protocol severity limit

All three groups agreed that reporting *number of animals used by protocol severity limit* would be an improvement on the present system – but this would still be prospective and would represent the 'worst-case' scenario.

#### 5.2.3 Data on animals used by a second protocol severity label, reflecting 'most likely' severity

In this context, some, but not all, participants in the licensees' group thought that a second severity label could usefully be added to each protocol. This could reflect the 'usual' or 'most likely' severity that animals involved in that protocol will experience and/or the proportion of animals likely to approach the upper severity limit, and could be used for public information purposes. However, in certain wide-ranging projects this estimate might require re-evaluation according to the purpose for which the protocol is being used.

#### 5.2.4 Need to link statistical data with better explanation of the severity classification system

All groups again emphasised the importance of providing sufficient *explanation* of the classification system to ensure that the data provided are meaningful. Note, for example, that the animal protection group agreed that the *process* of describing and evaluating severity is the vital step, and that the word 'labels' that are eventually assigned are not all that important, *provided that* there is sufficient narrative, case material (and preferably full transparency – see below) to show what the labels mean in practice.

### **5.3 Use of narrative descriptions to provide information about severity**

#### 5.3.1 Project licence summaries

All three groups suggested that narrative summaries of scientific projects involving animals could be used to provide more pertinent and valuable information on severity for public information purposes. These could include the nature, degree and duration of adverse effects likely to be (or actually) experienced by the animals, together with estimates of (or actual) numbers so affected. Moreover, these effects would then be linked with the reasons for the studies concerned, and some description of the procedures involved.

#### 5.3.2 Full transparency

Beyond this, the animal protection group favoured full transparency, in which whole project licences are made available (with due regard to anonymity, security and commercial and academic confidentiality) in order to show everyone concerned how the Act actually works in practice.

## **6. FEEDBACK ON HOW THE SYSTEM IS WORKING IN PRACTICE**

The animal protection and licensees groups both suggested and agreed that there would be merit in a properly conducted research study to compare predicted versus actual adverse effects and their severity, in order to inform future decisions and descriptions of severity categories for a range of different types of protocols. The results could be fed back to licensees and used to improve assessment and monitoring, and to target refinements in future.

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## **APPENDIX 1:**

**Report of a round-table discussion  
involving NVSs and NACWOs,  
on the use of severity limits and bands under A(SP)A**



## **1. INTRODUCTION**

Following discussions at the Boyd Group meeting on 16 June, this meeting was organised in order to learn the views of Named Veterinary Surgeons (NVSs) and Named Animal Care and Welfare Officers (NACWOs) on the appropriateness and usefulness of severity limits and bands in practice, and to hear their suggestions for improvements.

The meeting involved six NACWOs and seven NVSs. Both groups included representatives from the pharmaceutical industry, CROs and academia, who were involved in the care of a wide range of species, which included large animals and 'exotics'. Some of the particular questions addressed in discussion are listed in the Box below, and the main points emerging from the meeting, including suggestions for ways forward are summarised in the following report.

### **Some questions addressed in the NVS and NACWOs' discussions:**

- a) In practice, how do you assess and measure the full impact of a project on animals? How do you deal with the broad range of adverse effects, including psychological aspects such as boredom and fear as well as pain and distress?
- b) In practice, how do you categorise these effects in order to assign limits and bands?
- c) How do you use the severity limits and bands in the project licences you work with?
- d) What effects do you think the limits and bands (and how these are arrived at) have on personal licensees and project licence holders?
- e) How appropriate and useful do you think the severity classification system under ASPA is in relation to each of the three functions listed below:
  - for assessing levels of suffering and encouraging refinement
  - as a project management tool
  - to help in carrying out the cost/benefit assessment?
- f) Could there be a better system, or systems, better able to fulfil the three functions above? If so, what would this entail?
- g) How appropriate and useful do you think the publication of data on severity bands of projects is as a public information tool? Have you suggestions for providing more meaningful information about animal suffering in the Home Office Statistics?

## 2. USE OF THE CURRENT SEVERITY CLASSIFICATION SYSTEM

### 2.1 Assessing and measuring the full impact of a project on animals

NACWOs and NVSs help potential project licence holders to identify the particular clinical signs likely to result from each protocol in their licence applications, to describe the steps that will be taken to avoid or mitigate these adverse effects, and to set humane end-points. Sometimes templates of common signs are used as aides-memoir to start this process. Many establishments have internal web-sites which include guidance on assessing severity, good practice in frequently used procedures (e.g. maximum injection volumes), and humane end-points. It was noted that it is important that the 19b(vi) sections of project licences list *all* the potential adverse effects of the protocols, not just the unexpected effects, as is sometimes the case.

Physical signs and effects (e.g. weight loss, staring coat) are most commonly considered in these assessments. Both NACWOs and NVSs acknowledge that there is a need for greater understanding of the likely psychological effects of procedures on animals – especially because attention to these effects, including the interplay between the psychological and physical, can be an important step in refining the use of animals. For example, a NACWO described how a protocol had been reduced from 'upper moderate' to 'lower moderate' severity by using rats rather than gerbils, because gerbils were believed to suffer more psychological stress than rats involved in the procedure concerned.

In practice, assessment of severity of projects and protocols is usually restricted to the sum of the adverse effects of the regulated procedures, rather than the full range of effects from birth to death of the animals involved. This is because wider impacts, such as source, transport and husbandry of animals, and their life-spans, are not usually considered within project licences (except where they are non-standard), and the Home Office assessment of severity generally starts only from the moment the animals enter a protocol. Nevertheless, some NACWOs and NVSs reported that their assessments begin when an animal enters the establishment, and that the source of animals should always be a component of the severity assessment. It was noted that some establishments, for example, audit their suppliers for quality and welfare issues, including transport procedures.

There was some debate about whether and how such wider impacts should be covered in project licences. It was agreed that explicit consideration of aspects of routine husbandry, source and transport of animals, either in section 18b of a licence application, and/or in a summary of the application prepared for the ERP, could encourage potential licence holders to consider possible refinements to these aspects. Using the ERP summary could be a valuable option, since ERPs review applications with respect to local standards of animal care and husbandry, and include input from animal care staff.

It was firmly agreed that, in relation to these wider aspects of severity, there is an urgent need for review and updating of the Home Office Codes of Practice for the housing and

care of animals used in scientific procedures (1989), and in designated breeding and supplying establishments (1995), which are still in first edition. Moreover, that in future these publications should be regularly reviewed (perhaps every five years) and updates issued as appropriate.

It was noted that the NACWO and NVS voices are very important in the ERP, particularly in relation to severity and refinement issues – yet sometimes experienced animal care staff are not included, or are under-represented, in ERP committees and/or are not encouraged to speak up in discussions. It is vital that the views and input of animal care staff are *actively* sought.

## 2.2 Assigning severity limits and bands in protocols and project licences

This can be difficult. The Home Office Guidance defines the labels 'mild', 'moderate', and 'substantial' mainly by reference to examples of *procedures*, rather than the adverse effects which result from the procedures (Home Office, 2000, page 32) – yet there are myriad different procedures, whose effects can vary widely according to the particular circumstances involved.

More information is needed on the application of the limits and bands in practice. Some participants (mainly NACWOs) felt that such guidance would be useful in their work, others that it would be valuable for public information purposes only. The information could include:

- (i) descriptions of the types of adverse effect that would fall into each severity category;
- (ii) worked examples to illustrate how severity limits for protocols are decided; and
- (iii) guidance on how to weigh up the effects of all the protocols in a project licence, in order to arrive at an overall severity band for that project (if the severity band is retained).

The 'moderate' category of severity is perceived as too wide. In practice there is a tendency to use phrases such as 'lower', 'middle' and 'upper' moderate severity, in order to be more discriminating. This suggests that there is a need to sub-divide this category.

NVSs also asked whether there could be cases for:

- a) expanding the 'mild' category to include many surgical procedures when these are followed by effective use of analgesia; and
- b) widening the 'substantial' category to cover more 'distress'?

## 2.3 Use/value of the severity limits and bands in practice

Everyone agreed that the narrative 19b(vi) sections of project licences are of crucial importance in assessing and managing severity, encouraging refinement, and weighing costs and benefits.

NVSs suggested that licensees, the ERP, Home Office and Named Persons can all fulfil their roles without need for the severity limit 'labels' to be applied to the 19b narratives. However, although the limits are not seen as a vital tool, they have some value in helping licensees' thinking about severity and in highlighting substantial protocols for special consideration.

NACWOs use the labels as a way into discussions with licensees about the adverse effects of projects. The words mild, moderate and substantial provide 'hooks to hang thoughts on', helping to provide clear concepts of the degrees of harm caused to the animals. They are a good trigger for encouraging refinement ("See if you can find ways to make this protocol mild rather than moderate"), and for negotiation with licensees ("Six blood samples in 24 hours would be more than mild, so let's try to restrict it to three"). The *process* of deciding on severity limits, moreover, helps in defining humane end-points, and the limits themselves are rules-of-thumb that can guide implementation of these end-points.

The severity limits, NACWOs in particular agreed, are useful tools, but more such tools are needed. More categories would be helpful in promoting implementation refinements and end-points, and better definitions and examples of the different categories would help to improve the audit trail.

Overall severity bands of projects are of no use to NVSs or NACWOs in practice.

### **3. CHANGES TO THE SEVERITY CLASSIFICATION SYSTEM**

#### **3.1 Severity limits: managing severity and refining protocols**

In light of the above discussions, it was agreed that:

- (i) it would be helpful to draw up agreed templates of clinical signs that can guide NACWOs, licensees and others in assessing the severity of protocols and assigning limits – these should include indicators of psychological distress wherever possible. Existing schemes such as those of Baumans *et al.* (1994 – the report of a FELASA working group) and Morton and Hau (2002) would be valuable in designing these templates;
- (ii) similarly, guidance on the wider factors (beyond the procedures themselves) that contribute to severity would be useful – to enable a broad 'risk assessment' to be carried out, including all the potential impacts on the animals, from birth to death;
- (iii) such risk assessments could help to promote refinement of the wider factors that can cause adverse effects to animals. Description of the steps taken in response to the assessments could be included as part of section 18b of project licence application forms, or in project licence summaries for the ERP;

- (iv) the Home Office should provide more narrative description and examples to demonstrate the types of adverse effects that could fall within each of the categories of severity – this should involve input from licensees and Named Persons;
- (v) consideration should be given to sub-dividing the moderate severity category. Overall, there should be an even number of categories, to reduce the likelihood that, where there is doubt, the reaction will be to 'go for the middle category';
- (vi) words are better than numbers as labels for the categories – they focus minds better. However, there is a need for a new language for the labels, since the current words are too value-laden (but finding new terms will require imaginative thinking!). In particular, 'moderate' sounds too comfortable compared with substantial, and its use in practice is often at odds with everyday understanding of the term. There is particular need for a new category between moderate and substantial;
- (vii) consideration should be given to possible needs for new severity categories for behavioural protocols and for breeding transgenic animals. The 'mild' category should be expanded to include more surgical procedures when these are followed by effective use of analgesia, and the 'substantial' category widened to cover more 'distress';
- (viii) any changes to the severity classification system should be made in full consultation with all stakeholders.

### **3.2 Providing public information about severity**

#### **3.2.1 Overall severity bands: a public information tool?**

Overall severity bands of projects, as published in the annual Home Office Statistics are of no value in providing public information about animal suffering. They are average, prospective assessments that do not reflect the actual costs to the animals, nor do they indicate the numbers of animals or types of procedures involved.

#### **3.2.2 Retrospective reporting of actual suffering**

It was agreed that a system of retrospective reporting of the actual suffering experienced by animals is required for public information purposes, but that it is crucial that this is linked to the aims of the work in which the animals are used. This could be achieved via annual (or 5 yearly – to mark the termination of project licence) summaries, which include the numbers of animals used and descriptions of the effects of the studies on the animals.

Meaningful statistical data on animal suffering are harder to collect. Some felt that an immediate improvement would be to record the number of animals used by protocol severity limit. It was suggested that this information could be collected via existing systems with minimal extra effort, and could be made more useful if the existing severity categories were to be expanded – see 3.1(v) above. It was argued that these data, published alongside better descriptions of what the different labels mean in practice, would be more

pertinent than overall bands, relating to individual rather than 'average' animals. However, the information would still be prospective and would not necessarily reflect the *actual* suffering experienced – and other participants felt that these data would be as meaningless as severity bands, and, in fact, misleading, since they would report the 'worst case' severity.

Gathering retrospective data on the degree of suffering experienced would, some argued, be very onerous – particularly for animal staff, who need to preserve as much time as possible to check and tend to the animals in their care, rather than fill in forms for statistical purposes. On the other hand, it was suggested that since written records of clinical observations (e.g. score sheets) should in any case be kept when animal suffering is likely to approach the severity limits for protocols and in all the more substantial procedures, the extra effort involved in reporting which animals experience suffering *below* the particular limit label (i.e. mild within the moderate category; and mild or moderate within the substantial category) might not be that great. However, it was also pointed out that putting these records in a form that would be appropriate for annual reporting specific to severity would likely be very time-consuming.

It was generally accepted that a system of retrospective reporting of animal suffering would provide more accurate information on the actual harms to animals caused in scientific projects, and so would have value in wider public debate, helping to avoid both over- and under-estimation of animal suffering. However, it was also argued that for such a system of retrospective reporting to be widely accepted by the scientific community, there would also have to be more practical benefits to justify the time and efforts put into it. In light of this concern, it was suggested that retrospective reporting could be useful in highlighting areas of work that should be targeted for refinement.

#### 4. FURTHER WORK

It was agreed that consideration of the suggested changes to the severity categories, their descriptions, and the application of severity limits in practice should be the first priority. Once these aspects have been addressed, means of improving public information on laboratory animal suffering might become clearer. Some participants felt that there could be value in a study of public perceptions of severity, covering a range of contexts of animal use including farm and companion animals as well those used in laboratories.

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## **APPENDIX 2:**

**Report of a round-table discussion  
involving representatives of animal  
welfare and animal protection groups,  
on the use of severity limits and bands under A(SP)A**



## 1. INTRODUCTION

This focus group meeting was organised as part of a Boyd Group initiative to explore the views of a range of interested parties on the appropriateness and usefulness of severity limits and bands under ASPA, and to collate suggestions for improvements to the present system of classification. The meeting involved ten participants from a variety of welfare, anti-vivisection and animal protection organisations. Some of the questions addressed in discussion are listed in the Box below, and the main points that emerged, including suggestions for ways forward, are summarised in the following report.

***When reading this report it should be borne in mind that all of the organisations represented at the meeting are opposed to the use of animals in any scientific procedure likely to cause the animals pain, distress or other suffering. Discussion of how to assess and categorise the severity of this suffering was uncomfortable for people who believe it wrong to cause such harms to animals in the first place.***

### **Some questions addressed in the animal welfare and animal protection group representatives' discussions:**

- a) Is there a need to classify the severity of protocols and projects under ASPA? If so, what should such a classification aim to achieve?
- b) In your view, how does the present use of severity limits and bands (and how these are arrived at) affect the way that people working under the Act think about the impacts of their work on animals?
- c) What do you understand by the labels 'mild', 'moderate', 'substantial' and 'unclassified', as applied to protocols and projects under ASPA? What effects do you think the current uses of these labels have on your, and wider public, perceptions of the suffering caused to animals in scientific experiments?
- d) How appropriate and useful do you believe the present severity classification scheme to be, in relation to each of the following suggested functions:
  - for describing levels of animal suffering and encouraging refinement of protocols in project licence applications and on-going work
  - in managing and limiting animal suffering during studies
  - to help in carrying out the initial and on-going cost (to animals)/benefit assessment of projects required under ASPA?
- e) Can you think of a better system (or systems), better able to fulfil each of the three functions listed above? For example: What factors do you believe should be taken into account in assessing and describing the impact of scientific work on animals? How would you categorise the various levels of suffering? How do you think the resulting information and 'labels' should be used, and by whom?
- f) How useful and meaningful do you think the publication of data on severity bands of projects is as a public information tool? Have you suggestions for improving public information about the suffering experienced by animals used in scientific procedures – particularly in relation to the data published in the Home Office Statistics?

## 2. THE NEED FOR A SEVERITY CLASSIFICATION SYSTEM

Clearly, there is always a need to *assess* and *monitor* the suffering caused to animals in scientific studies, in order that all possible steps can be taken to relieve that suffering, implement humane end-points and refine procedures. Such assessments are essential in their own right, whether or not the adverse effects on the animals are then *classified* into categories of severity.

A recent Home Office report (relating to a BUAV investigation of primate neuroscience research at Cambridge University) suggests that, in practice, detailed narrative descriptions of animal suffering (such as those provided in the 19b(vi) sections of project licences) are used for the purposes of cost-benefit assessment and management of animal suffering under ASPA, and that severity 'labels' (i.e. limits and bands) play "limited roles" in assessment of project licence applications. The report questions the utility of severity classification, and asks whether the labels are in fact "required for the 1986 Act to be effectively implemented" (Home Office, 2002, page 5). This perspective contrasts with that expressed in earlier Home Office guidance on the operation of the Act (2000).

Participants in these discussions believe that some form of categorisation of the severity of the suffering likely to be experienced by the animals is vitally important, in addition to the narrative descriptions.

Classification and labelling of severity, it was argued, is required in order to:

- assist in the weighing of the likely costs to animals and potential benefits of proposed studies, as part of a judgement on whether the work should take place *at all*;
- highlight the techniques, procedures and protocols that cause most suffering to animals and work towards eliminating these (in the first instance);
- raise licensees' awareness of the severity of the effects of their work on animals and (since most will strive for the lowest possible severity classification) provide a 'lever' to encourage refinement;
- set upper limits to the degree of harm that can be caused to animals in particular protocols and projects;
- highlight projects and protocols for review by the APC;
- act as a source of public information (including via the Home Office Statistics), which can be used to raise wider awareness of the costs to animals of scientific work; and
- highlight trends in the severity of scientific procedures over time and monitor changes in the degree of suffering caused to animals.

However, participants also agreed that the current method of classifying severity under ASPA falls short of achieving these objectives, for a number of reasons. These are explored below, together with some recommendations for ways forward.

### 3. LANGUAGE OF CURRENT SEVERITY CATEGORY LABELS

If the labels are to fulfil the various functions listed above, they should describe the suffering likely to be, or actually, experienced by the animals as appropriately and meaningfully as possible. On this point, it was firmly agreed that there is a gap between the 'rhetoric' of the labels mild, moderate and substantial, and the 'reality' of the actual adverse effects caused to animals. The 'moderate' category, it was argued, is especially misleading.

Most participants in this discussion only very rarely have access to project licences or to animals undergoing procedures. However, whenever such information has become available, they have been astonished at the severity of animal suffering counted as 'moderate'. Recent examples brought to public attention include protocols involving heterotopic transplantation of pigs' kidneys into macaque monkeys, with removal of the monkeys' own kidneys; and surgery to make lesions in the brains of common marmosets in order to mimic the effects of human conditions such as stroke and Parkinson's disease – both of which protocols the Home Office asserts were correctly classified as 'moderate' and not 'substantial' (Home Office 2003 and 2002). Indeed, in the latter case the Home Office position is that no animal was at risk of suffering substantially.

It was felt that use of the term 'moderate' for such work downplays the suffering actually involved and is at odds with everyday understanding of the word (see also Boyd Group, 2003). For example, it was asked how restraint of a monkey in a primate chair (including head restraint) for 5-6 hours a day could be classified as 'moderate'.

Some participants believe that the law is not being applied properly by the Home Office Inspectorate in such cases, and are urging the Home Affairs Committee to initiate a full independent inquiry into licensing decisions, particularly in respect of the xenotransplantation work mentioned above (<http://www.xenodiaries.org/collapsed.pdf>)\*. However, it was also suggested that because there is little published guidance on how the severity labels are defined in practice (see 5 below), and because *judgements* are involved, the Home Office could in most circumstances argue that the labels had been correctly applied.

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\* Regarding the legal situation, it was also observed that breaches of the severity limit are not considered a potential criminal offence at present. At least two participants believed that they should be, and that the qualification of 'unexpected' or 'extraneous' reasons for such breaches should not apply.

Whatever their view on the legality of the situation, all participants agreed that the term 'moderate' is inappropriate to describe much of the animal suffering it presently encompasses and is too broad a category. Many of the effects currently described as 'moderate' would be more appropriately labelled as 'substantial'. The term 'moderate' is 'too comfortable' to fulfil the role of raising animal users' awareness and acting as a lever to encourage refinement. It was suggested that 'significant' might be a better word. 'Moderate' appears to distort the cost-benefit assessment by down-playing animal suffering, and does not enable accurate portrayal of animal suffering for purposes of public information. Furthermore, the current substantial category encompasses only the most extreme adverse effects and so fails to highlight many protocols that cause very significant suffering.

Taking into account all the different impacts on laboratory animals' well-being (from birth to death – see 6 below), most participants' starting points in the classification would be 'moderate' not 'mild', and would include at least one more category at the top end, to describe the most extreme effects, which are currently classified as 'substantial' (without, however, accepting that it should be permissible to cause such suffering).

Further ideas on re-shaping the classification system in order better to fulfil the roles set out in the list on page 24 are explored in points 6-8 below.

## **4 OTHER LABELS: 'SEVERE' AND 'UNCLASSIFIED'**

### **4.1 Severe suffering**

To be 'substantial', it seems, a protocol must carry a risk that "some animals might die before appropriate clinical investigation and management or euthanasia [can] be applied" (Home Office, 2003) – or result in "a major departure from the animal's usual state of health or well-being" (Home Office, 2000). However, what comprises a 'major' departure is not defined. Further commentary suggests that the category includes "suffering of a nature, intensity or duration not normally encountered or tolerated in clinical practice and/or when effective treatment is withheld" (Home Office, 2003).

According to European law (Article 8 of Directive 86/609), animals must not be "subject to severe pain, distress or suffering" for scientific purposes. This provision is enacted in Britain via Section 10(2A) of A(SP)A, in that "the Secretary of State will not license any procedure likely to cause severe pain or distress that cannot be alleviated" (Home Office 2000).

'Severe', however, is not defined in the Act or in guidance on its operation (Home Office 2000). Nor, moreover, is 'substantial' defined in such a way as to distinguish it clearly from 'severe'. In particular, there is no indication of the time-frame within which suffering must be alleviated in order for it to count as 'substantial' and not 'severe'.

The line between 'substantial' and 'severe' suffering is very fuzzy, and this, it was argued, poses problems for proper implementation of the law, because 'substantial' suffering is permitted under A(SP)A (provided it can be 'justified' in terms of anticipated benefits), whereas 'severe' suffering is absolutely prohibited.

#### 4.2 Unclassified severity

Protocols "performed entirely under general anaesthesia, from which the animal does not recover consciousness" are of 'unclassified' severity. This includes the preparation and use of decerebrated animals (Home Office, 2000). The use of an unclassified category for animals who suffer distress from confinement in unnatural conditions, it was argued, shows that the whole lifetime experience of an animal is not taken into account in assessing severity (see 6 below for further discussion).

### 5. TRANSPARENCY IN SEVERITY CLASSIFICATION

Participants agreed that the current definitions of severity are very vague and subjective. The categories need clarification and illustration, particularly with respect to the particular adverse effects that the different labels encompass and their duration. Everyone involved (not just those opposed to the use of animals) is hampered by the very limited range of cases available to illuminate judgements about the severity of effects on animals, and this allows too much leeway in cost-benefit assessment under ASPA.

It was agreed that the guidance offered by the Home Office (2000, page 32) should be expanded to include a more comprehensive description of the range of adverse effects covered in each severity category, together with case studies and other examples to illustrate how the categories are applied in practice.

It was further suggested that it is difficult to have confidence in the Act without better understanding of what actually happens to the animals in practice. Whole project licences need to be made available (with due regard to anonymity, security and commercial and academic confidentiality) in order to show everyone concerned how the Act actually works in real situations.

It was observed that it is perhaps not surprising that there is some reluctance to open the detailed application of the Act to wider scrutiny. This is because human *judgement* is involved in assessing severity and in weighing costs and benefits, and the people making such judgements are aware that their conclusions are *contestable* and can be questioned. On the other hand, it was argued that the inherently vague and subjective nature of the assessment of degree of 'cost' to animals is the very reason why transparency is so important.

Following from this discussion, it was agreed that a retrospective review/audit should be carried out to compare prospective assessments of severity with what the animals actually experience in practice. This could be an 'academic' study, funded independently of the Home Office or others involved in the administration of the Act, and should involve objective, disinterested observers, drawn from a variety of perspectives and disciplines. It might begin with a pilot study of selected protocols and species. Such a review would both build up knowledge to assist in future assessments and encourage consideration of new ways of approaching the judgements.

## 6. FACTORS TO TAKE INTO ACCOUNT WHEN ASSESSING SEVERITY

In considering how severity assessment should be approached in practice, in order better to fulfil the functions listed on page 24, it was agreed that there is a need for everyone involved to be alert to, and consider, *all* the harms that an animal might experience over his/her whole life-time – from birth to death. This is vital in ensuring that all possible sources of suffering are recognised and alleviated wherever possible.

It was further agreed that there is currently insufficient concern about *psychological/emotional* suffering and the guidance should make clear that adverse effects such as anxiety, fear and boredom should always be taken into account, and efforts made to alleviate them. It was observed that laboratory animal science plays a very important role in assisting recognition, evaluation and alleviation of such effects, but that difficulty in providing empirical *proof* that animals experience such suffering should not prevent such effects being taken into account. The onus of proof should rest with those who assert that there is no suffering. Assessments of costs to animals should start from the commonsense perspective which asks, "What would a human experience in such circumstances?", taking into account relevant differences in biology and behaviour between humans and the species in question.

It was agreed that the project licence application form should be re-designed to encourage licensees to consider and account for all the different sources of suffering involved in their work. This might involve including the following sub-headings, for example:

**Suffering associated with**     .... *source and transport of animals*  
    .... *housing and care of animals*  
    .... *the techniques performed on the animals (e.g. gavage)*  
    .... *the effects of the procedures on the animals (e.g. the effects of the substance gavaged)*  
    .... *the fate of the animal at the end of the protocol*

Such a scheme would be particularly valuable in encouraging people to think about anticipated as well as unanticipated effects on the animals.

Most people felt that the adverse effects caused to the stock animals used to breed animals for use in experiments should be taken into account as part of the assessment of severity. Breeding systems vary between establishments and can impose different costs to animals. It is therefore important that this aspect of severity is specifically included – so that the effects can be recognised and alleviated. For example, marmosets can suckle only two babies, yet, in captivity, often give birth to triplets. Establishments differ in how they deal with this difficulty, and in some, but not all places, the third baby is killed. It was further argued that, even where standards are high, animals may well suffer as a result of the conditions in which they are kept.

## 7. HOW SEVERITY SHOULD BE CATEGORISED

In considering what alternative classification would more accurately reflect the suffering experienced by the animals, it was strongly argued that such a scheme should continue to label the categories with *words* rather than numbers (although numbers might be useful in sub-dividing some categories). As already noted, if the classification scheme is to fulfil the important roles listed in 2 above, which include enhancing awareness of animal suffering and promoting refinement, it is vital that the severity labels reflect the suffering likely to be, or actually, experienced by the animals as appropriately and meaningfully as possible.

As noted, participants felt that the moderate category is both too comfortable and too wide, and that term does not accurately reflect the degree of suffering encompassed within it. It was agreed that, as a first step, there is a need to sub-divide the moderate category, and that this sub-division might involve the use of numbers.

Participants suggested that taking into account all the different adverse effects on the animals (as in 6 above) would mean that most protocols and projects would start at a 'moderate' level of suffering, and that this would push most of the work currently classified as moderate into the substantial category. Therefore, at least one new category above 'substantial' would be required.

In this light, it was suggested that new words might also be needed, in order to reflect more accurately the subjective feelings of the animals. It was also suggested that the categories might be applied on several different scales according to the nature of the adverse effects involved\*.

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\* In this context, it was later observed that a paper published by ANZCCART (Mellor and Reid, 1994), classifies severity on a five-point severity scale in each of "five domains of potential welfare compromise". These domains are: 1. thirst/hunger/malnutrition; 2. environmental challenge; 3. disease/injury/functional impairment; 4. behavioural/interactive restriction; and 5. anxiety/fear/pain/distress. These proposals might be an interesting starting point in developing meaningful severity classification, but this would need careful thought and considerable modification.

It was further suggested that the process of describing and evaluating severity is the vital step – the word 'labels' that are eventually assigned are not all that important, *provided that* there is sufficient narrative, case material, and full transparency, to show what the labels mean in practice.

Finally, it was firmly agreed that in such assessments the focus should be on what happens to individual animals (see also 8 below). However, it was noted that some project licences are very complicated and it can sometimes be difficult to follow exactly what could happen to an individual animal in a given protocol. It is vital that each protocol is described in such a way that it is possible to get a clear sense of the effects, including cumulative or sequential effects (and not just clinical signs), that each individual animal is likely to *experience*.

## 8. USE OF SEVERITY CLASSIFICATION FOR COST-BENEFIT ASSESSMENT

It was agreed that severity bands as currently deployed are of limited value in cost-benefit assessment and for public information.

Whilst it was agreed that is important to have a global judgement of predicted severity to weigh against likely benefit in a project licence application, it was firmly agreed that using an 'average' severity (as Home Office guidance says the severity band estimates) downplays the suffering of individual animals and is misleading. As noted above, each animal should 'count as one' in severity evaluations. Furthermore, the breadth of some projects makes assessment of their 'overall' severity very difficult or impossible – therefore meaningful cost-benefit assessment (as required under A(SP)A) is impossible in such cases.

It was suggested that the narrative descriptions and severity limits are more appropriate than severity bands for cost-benefit assessment purposes, since they can highlight where the maximum costs lie – and so trigger further review and efforts to avoid or reduce those costs. The aim should always be to move thinking on, in order to avoid or reduce animal suffering, and never to rest with the *status quo*.

## 9. USE OF SEVERITY CLASSIFICATION FOR PUBLIC INFORMATION

With regard to public information, the preference is for full openness and transparency and public accountability. This should include information about what is (or was) done to the animals, why it is done, and how much suffering is caused – particularly in order to enable retrospective assessment of whether the suffering was 'worth it'. To assist in this, the Home Office Statistics should retrospectively report the number of animals experiencing

each particular severity by protocol, and these data should be linked to the purpose of the work. It was agreed that the ERP could collect these data and that there would be value in them, particularly in highlighting where efforts to develop refinement or replacement methods should be directed in the first instance. This would make the effort required to collect the information worthwhile.

The general view was that there would be merit in a properly conducted research study to compare actual cf. predicted severity, in order to inform future decisions and descriptions of severity categories for a range of different types of protocols.

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## **APPENDIX 3:**

**Report of a round-table discussion  
involving project licence holders  
and personal licensees,  
on the use of severity limits and bands under A(SP)A**



## 1. INTRODUCTION

This meeting was the third in a series of 'focus group' discussions organised by the Boyd Group, aiming to explore a range of perspectives on the appropriateness and usefulness of severity limits and bands in practice, and to hear suggestions for improvements. Some of the particular questions addressed in discussion are listed in the Box below. The main points that emerged, including suggestions for ways forward, are summarised in the following report.

Eleven project licence holders and personal licensees from a variety of different backgrounds took part in the discussions. They included representatives from industry and academia, involved in a wide range of different kinds of study – including psychopharmacology, neuroscience, immunology, basic and applied physiology (in small and large animals), genetic modification of animals, regulatory toxicology and pharmaceutical development. A Home Office Inspector was in attendance and the meeting was chaired by the President of LASA.

### Some questions addressed in the project and personal licensees' discussions:

- a) In practice, what strategies do you use to assess the severity of the adverse effects of scientific studies on the animals involved, and what factors do you take into account?
- b) How do you set about categorising these adverse effects in order to decide whether the severity of the effects can be described as mild, moderate, or substantial – in order to:
  - assign severity limits to protocols, prospectively?
  - ensure that severity limits are adhered to in practice?
  - decide on the overall severity band of a project?
- c) Do you use any particular published guidance, or consult any other people to help you in these assessments and categorisation? If so, how helpful are these sources? Is there need for further guidance in this area? If so, what would be useful to you?
- d) In your view, how appropriate and useful is the current severity scheme in relation to each of the following three functions:
  - for describing levels of animal suffering and encouraging refinement of protocols in project licence applications and on-going work
  - in managing and limiting animal suffering during studies
  - to help in carrying out the initial and on-going cost (to animals)/benefit assessment of projects required under ASPA?
- e) What other benefits, if any, do you think the use of severity limits and bands (and how these are arrived at) brings in practice?
- f) Can you think of a better way (or ways) of fulfilling each of the three functions listed in (d) above? Do we need a severity classification system at all?
- g) How useful and meaningful do you think the publication of data on severity bands of projects is as a public information tool? Have you suggestions for improving public information about the suffering experienced by animals used in scientific procedures – particularly in relation to the data published in the Home Office Statistics?

## 2. USE OF THE CURRENT SEVERITY CLASSIFICATION SYSTEM

### 2.1 Strategies for assessing adverse effects on animals

It was observed that recognition and assessment of the adverse effects caused to animals in scientific studies is vital, whether or not the severity of these adverse effects is then categorised according to the current scheme under A(SP)A. Apart from welfare concerns, there can be strong scientific motivation to identify and better understand adverse effects on animals, e.g. as part of the development of animal models for human disease, or in characterising the effects of exposure to pharmaceuticals and other chemical substances.

Such assessment is, and should be, a continuous process – involving:

- (i) *prediction* of likely adverse effects when licence applications are submitted (in order, for example, to assist in defining humane end-points and weighing likely harms and benefits);
- (ii) on-going *monitoring*, to identify and attempt to ameliorate actual effects when studies are in progress, as well as to weigh actual harms and benefits; and
- (iii) *review* and *retrospective evaluation* of actual adverse effects and control measures when the study is completed, in order to inform similar assessments in future work.

It was noted that, at all stages, judgements are involved; judgements which, by their nature, are often difficult.

In practice, licensees base their assessments on a combination of:

- personal and/or research team and/or industry experience of carrying out particular protocols and types of study (sometimes over many years);
- discussions with other colleagues involved in similar work both within and outside their own establishments;
- consultation with the local NVS and NACWO(s);
- published literature (e.g. other scientific studies, and guidelines from relevant expert bodies such as LASA, UKCCCR, IASP and others);
- where relevant, comparison with human experience of the condition or disease under consideration;
- discussion with the Home Office Inspector.

It was agreed that severity assessment should focus on the individual animal, and should aim to evaluate how far an experimental protocol (or project) impacts on the normal well-being of each animal involved. Adverse effects should be assessed from the animal's point of view, and (rather like 'quality of life' assessments in humans) should adopt a global/holistic approach, in which there is an attempt to consider all factors that can potentially influence well-being.

However, it was observed that, in practice, such assessments tend to focus on pain, which, compared with other adverse effects, is relatively easily recognised. It was suggested that this is a serious problem, since other potential adverse effects may be equally, or even more, aversive than pain, but are often more difficult to detect (in this context, the example of nausea in rodents was discussed at some length).

Some participants found it surprising that simple measurements of food and water intake and body weight are not used more frequently for early detection that 'something is wrong' with an animal. It was agreed that such assessments can be useful, but that the relationship between decreases in these measures and animal suffering is not necessarily simple; moreover, that the assessments themselves can cause stress to the animals.

It was also suggested that there is an element of species bias in the way that severity is currently assessed – particularly in favour of (certain) mammals at the expense of other, less familiar species\*. It was agreed that there is a need to avoid uncritical anthropomorphism or unjustifiable weighting of concern in favour of species with which humans are more familiar and/or may feel more natural empathy. By the same token, it was further agreed that in situations where there is uncertainty about what an animal might be experiencing, but (bearing in mind what is known about the animal's biology) it could reasonably be expected that the animal is experiencing adverse effects such as pain, distress or anxiety, the benefit of the doubt should lie with the animal, unless and until further evidence suggests otherwise.

Following from these observations, it was firmly agreed that there is a need for better empirical evidence and guidance to support severity assessments (see 3.1 and 4.2.5 below, for further discussion).

## 2.2 Strategies for assigning severity limits and bands

It was generally agreed that assigning severity 'labels' (mild, moderate, substantial) is difficult, and at times can feel rather arbitrary, particularly at the boundary of mild and moderate. Some, but not all, participants believe that the moderate category is too wide: a 'catch-all'.

Licensees observed that there are few useful published guidelines to help in assigning severity categories. The Home Office Guidance (2000) is used, but coverage of the issues is very brief and is not based on empirical evidence. It was agreed that gaps in the available guidance need to be filled, so as to provide more pertinent assistance in relation

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\* In relation to this general point, it was observed that this lack of/difficulty in understanding the feelings of other animals, particularly those that differ from the familiar mammalian (or human) organisation, make the edict to 'involve animals [vertebrates] of the lowest degree of neurophysiological sensitivity', under both EU Directive 86/609 and Section 5(5)(b) of the Animals (Scientific Procedures) Act 1986 difficult to apply in practice – even rather meaningless.

to the wide variety of research areas, protocols, species and adverse effects encountered in practice. As noted in 2.1 above, such guidance will also provide vital assistance in recognising and managing adverse effects on animals, whether or not these effects are then classified into severity categories.

As in recognising adverse effects *per se* (2.1 above), licensees' previous experience, advice from Named Persons, consultation with other colleagues and with the Home Office Inspectorate (HOI) can all assist in assigning appropriate severity labels to protocols and projects. Several participants observed, however, that HOI advice on appropriate severity categories varies between Inspectors, and it was further suggested that the pool of experience in the HOI is too narrow in relation to the variety of species, protocols and adverse effects encountered in practice. However, it was also observed that the focus of the HOI is (and should be) on the control and reduction of severity in practice rather than the particular labels used.

Local ethical review processes (ERPs), it was agreed, also play a valuable role. Project licence applicants submit severity estimates which are discussed and sometimes revised via the ERP, and this can be of help in thinking about, and managing, severity. Several participants said that they particularly value the input of lay participants in these discussions. The role of the HOI in relation to that of the ERP was also discussed. It was observed that the ERP sometimes places protocols in a higher severity category when compared with the HOI. Practice seems to vary in how the local HOI interacts with the ERP. Some participants said that they would value more such interaction (both participation and communication); others that their HOI already takes a strong interest in the ERP and that the two work well together. It was agreed that it is important to involve the HOI at an early stage in planning scientific work involving animals.

Protocols in which adverse effects are uncertain clearly pose particular difficulties for prospective severity classification and cost-benefit assessment more generally. For example, where protocols to produce genetically modified animals are concerned, it is often difficult to predict the phenotypic consequences of the genetic alteration (and, depending on the method involved, sometimes difficult to control the genetic change itself). One licensee reported that in their experience of such cases, severity is estimated in advance and a severity limit set in consultation with colleagues, the Named Persons, and ERP. Once the genetic modification is made, the welfare consequences are evaluated (using clinical score sheets) and the original severity estimate is refined and, where necessary, procedures for alleviating the particular adverse effects are added.

Licensees report that they take husbandry and care of the animals into account in assessing and categorising severity when this differs from the norm (e.g. when gregarious animals are singly housed or when environmental enrichment is withheld as part of a protocol). However, it was felt that the more routine aspects of husbandry and care are the concern of the ERP and are not part of severity assessment within project licences.

It was agreed that estimating the number of animals likely to experience the various adverse effects is an important part of the process of assigning severity categories, but that it is difficult to know how to integrate these assessments in order to arrive at a single severity limit for a protocol, and even more difficult to arrive at an overall severity band for a project, which might involve numerous different protocols.

It was further agreed that it is important that severity categories also reflect the duration of the adverse effects on the animals.

### **2.3 Use of severity limits and bands in practice: benefits and difficulties**

It was agreed that overall severity bands for projects are of little or no use in practice. It is very difficult to give a single, realistic narrative assessment of the overall severity of a project that involves a variety of protocols of different severities, let alone to label this overall assessment with a single word from a choice of only four (including 'unclassified'). Such a one-word, global assessment, it was agreed, is too crude a measure for purposes either of cost-benefit assessment or public information.

Similarly, licensees find the narrative descriptions contained in the 19b sections of project licences more useful than the one-word severity limit 'labels' when communicating about animal suffering and considering cost-benefit assessment. The HOI also focuses on these narrative descriptions in licensing decisions.

Despite these observations, most, but not all, participants agreed that the process of assigning severity limits focuses minds and can provide a stimulus to refine protocols – particularly when severity approaches the 'substantial' category. Moreover, these participants feel that the labels have value in clearly defining humane end-points, and therefore are of help in implementing them.

It was suggested that the words 'mild', 'moderate' and 'substantial' act as a trigger to make people think, but that they may not be the most appropriate terms. In particular, it was argued that the labels are too 'pain' related and that there is a need for different, or further, terms to encompass other kinds of adverse effects as well. Some participants also thought that 'moderate' is too comfortable a term for many of the procedures it currently covers. It was observed that, with only three categories, there is a tendency to place most uses of animals in the middle, moderate category – but opinions differed on the desirability of increasing the number of categories (see 3.2 below).

Sometimes, it was observed, there appear to be inconsistencies in the application of severity limits, which become apparent when project licence holders apply for secondary availability at other establishments and their licences are reviewed by different ERPs and HOIs.

It was also noted that there can be discrepancies when labels given to different kinds of protocol are compared. For example, the Fixed Dose Procedure (a way of assessing acute toxicity that should avoid death of the animals involved, but which may require animals to be humanely killed owing to the severity of toxic signs or inadvertently cause death) is routinely classified as 'substantial'; whereas a protocol involving dose ranging for a genetic toxicity study (in which the aim is to find the highest non-lethal dose) is usually classified as 'moderate'.

Finally, it was suggested that severity limits are sometimes over-estimated in order to avoid inadvertent technical breaches of licences.

### 3. SUGGESTED CHANGES TO THE SEVERITY CLASSIFICATION

Licensees generally felt that the application of severity categories to protocols brings sufficient benefit to warrant retaining the system, but that there are several ways in which the current system might be improved.

#### 3.1 Need for better guidance

There is an urgent need for better guidance on the assessment and categorisation of adverse effects.

- This should take the form of nationally accepted, 'official' guidelines covering a wide range of protocols and techniques in the different classes of vertebrates (not just mammals), as well as *Octopus vulgaris* and any other invertebrate that might be included under the Act in future. These should include a wide range of adverse effects, psychological as well as physical, and not simply pain-oriented.
- Furthermore, there should be more 'worked examples' to illustrate the application of the severity classification in practice, particularly around the boundaries of the classification categories.
- As far as possible, all such guidance should be based on empirical evidence, but it is recognised that evidence is likely to be lacking in some areas. There is a need for more research on recognising and assessing laboratory animal suffering and efforts to set this in context with respect to other human uses of animals, such as in agriculture.

#### 3.2 Changes to severity categories

It was generally agreed that the current three severity categories (four including unclassified) seem to work and are understood. As noted above, some participants suggested that the moderate category is too wide and might benefit from sub-division (this would also help to avoid a tendency 'to go for the middle'); others, however, thought that increasing the number of severity categories would make the classification too complicated. There was also some discussion about the word 'labels' themselves. It was generally

agreed that words are better than numbers, but that the terms might need modification, so as better to encompass adverse effects other than pain, e.g. stress, anxiety, or nausea.

### 3.3 Feedback on the effectiveness of the system in practice

Feedback on how well the system is operating in practice would be useful and could help to improve assessment and categorisation in future. Two possibilities were suggested:

- Writing up of (anonymous) cases where severity limits are unexpectedly approached or even exceeded ('near-misses'). This would identify areas of difficulty, educate others who might be carrying out similar procedures, and work towards improving detection and alleviation of adverse effects and refinement of techniques in such cases.
- A wider study to compare predicted versus actual adverse effects and their severity. The results could be fed back to licensees and used to improve assessment and monitoring, and to target refinements in future.

### 3.4 Reflecting the probability that adverse effects will occur in practice

The severity classification should reflect more closely the *probability* that particular adverse effects will occur in practice. This is particularly important if prospective severity assessments are to be used for public information purposes (see 4 below). One possibility would be to have two severity labels for each protocol:

- the current severity limit, which reflects the 'worst case scenario' and sets an upper limit to the suffering that can be caused to any individual animal involved in that protocol;
- an estimate of the 'usual' or 'most likely' severity that animals involved in that protocol will experience and/or the proportion of animals likely to approach the upper severity limit, which could be used for public information purposes. Such labels could be regarded as similar to the current severity bands, but expressed at the protocol rather than the project level. (Note: in certain wide-ranging projects this estimate might require re-evaluation according to the purpose for which the protocol is being used – e.g. in project licences for the production of GM animals, depending on the nature and purpose of the genetic alteration; in project licences for toxicity testing, depending on the nature of the substance being tested).

However, it was noted that in 19b sections of project licences there is already a requirement to indicate the proportion of animals likely to experience any particular adverse effect. Whilst the possibility of having two severity labels for each protocol found favour with most participants, at least one was unhappy about adding more 'global' labels to these narrative descriptions.

### 3.5 Interaction with the Home Office Inspectorate

Several licensees said that they would value more interaction with the HOI to discuss severity issues at an early stage. Again, however, experiences seem to differ on this point,

with other licensees reporting that they have close working relationships with their HOIs, including regular discussion of questions and concerns to do with severity.

## 4. PUBLIC INFORMATION ABOUT SEVERITY

### 4.1 Who is the information for?

Before deciding what information about the effects of experiments on animals should be presented for public information it was agreed that it must first be decided what is meant by 'the public' in this context; what does this public (or these publics) want or need to know; and why? It was suggested that the Boyd Group should organise a fourth focus group to probe such questions. [*The findings from the most recent MORI study to examine public attitudes towards the use of animals in medical research, conducted on behalf of the Coalition for Medical Progress in 2002, might provide some useful background here. Key points relevant to the questions above are summarised in the Box opposite.*]

In discussion, it was observed that there are several different reasons for providing such public information, and that different approaches might be needed in each case:

- to meet the demands of anti-vivisection groups and individual activists, and the interests and information needs of animal welfare organisations\*;
- to reassure other members of the public that animals are used responsibly;
- to provide a measure of public accountability for the use of public money in funding research which involves the use of animals;
- in order to inform members of the public and enhance understanding of science.

Some participants felt that, whatever the motivation for describing severity, the information was likely to be misinterpreted.

Pending clear answers to the questions posed at the beginning of this section, sections 4.2 and 4.3 below set out points of agreement with respect to provision of public information about severity.

### 4.2 Statistical information about severity

#### 4.2.1 Severity bands of projects

Severity bands of projects (currently the only information about severity provided in the Home Office Statistics) are not appropriate for public information, because they:

- do not reflect the experience of individual animals in the various different protocols used in the project, referring instead to the experience of the 'average' animal over the whole project;

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\* These groups, it was agreed, are the main consumers of such information, not the more ordinary 'lay' members of the public. The latter group are unlikely actively to seek out information and vary considerably in their degree of interest in the topic – indeed, some would rather not know (MORI/Coalition for Medical Progress 2002 – see Box opposite).

## Some findings relevant to provision of public information about the severity of animal procedures, from a MORI research study conducted for the Coalition for Medical Progress in 2002

The study comprised two quantitative surveys, involving a combined representative sample of 1125 adults aged 15+ across Great Britain; and four focus groups. The full report can be downloaded from [www.mori.com](http://www.mori.com).

1. The use of animals in medical science has become less of an issue for the general public over the past few years. In a previous survey for the MRC carried out by MORI in 1999, 67% of respondents were interested. In 2002, three in five (59%) said they were interested; the remaining two in five showed little or no interest. This fall is statistically significant.
2. Two-thirds of the public report that they are concerned about the use of animals in medical research, but it should be remembered that there are almost always other, more personal, concerns which will be higher priority. In 2002, fewer than 1 in 10 (7%) said that they were both **very** interested and **very** concerned about the use of animals in medical science. (However, when extrapolated to the total population, this proportion would represent around 3.2 million adults).
3. The majority of participants in the focus groups felt that they were not very well informed about the use of animals in medical research. Information is largely gleaned from the media – mainly newspapers and television, but also magazines and radio. Animal activist groups also featured as a source of information. In the quantitative research, six in ten agreed that they would like to know more about animal experiments before forming any firm opinions. In the focus groups, many also said that they would like more information, but it is likely that few would be proactive in obtaining such material as few had actually done so already. It is highly probable that people's main source of information would continue to be the media. However, it was also felt that newspapers would be unlikely ever to present a balanced view.
4. There was also some discussion in the groups about whether people really wanted to know more. The general feeling was that not knowing means you don't have to worry about it.
5. Although the study revealed some apprehension that some or all experiments performed on animals are unnecessary, the overriding concern was that pain to the animals be minimised or eradicated and animal welfare regulations be strictly adhered to.
6. Compared with the 1999 survey, fewer people reported a lack of trust in the regulatory system (64% in 1999, down to 50% in 2002); and more people said that they trusted scientists not to cause unnecessary suffering to the animals being experimented on (29% in 1999; 39% in 2002).
7. Regarding sources of information, animal welfare groups and vets were the most trusted sources for honest and balanced information about animal experiments – each being mentioned by around half of all respondents. It is suggested that any communications campaign should therefore ideally incorporate these groups. One in three respondents (33%) said that they would trust information from the Medical Research Council; and one in four people felt that scientists (type unspecified) would provide honest and balanced information. Fewer than 1 in 10 (7%) would trust Government for such information and only 1 in 20 (5%) 'The Media'.

- are prospective assessments which may not represent the actual adverse effects on the animals;
- are not linked to the reasons why the project is performed, nor its likely or actual benefits.

#### 4.2.2 Number of animals by protocol severity limit

Reporting the numbers of animals used by protocol severity limit would be an improvement, and could be linked to the general purpose of the protocol. However, this would still represent a prospective measure of severity which is also likely to over-estimate the actual effects on the animals, because the limit represents the 'worst-case' scenario.

#### 4.2.3 Number of animals by a protocol label reflecting 'likely' severity

Reporting the numbers of animals used by a second descriptive severity label applied to protocols at the licensing stage (as described in 3.4 above) could provide more meaningful information about the likely effects on the animals, but would still be an estimate and might not be representative of the actual effects. This second label, as noted above, could refer to the 'usual' or 'most likely' severity that animals involved in that protocol will experience, and/or the proportion of animals likely to approach the upper severity limit.

In this context, it was observed that it is also possible to envisage further descriptive labels that capture not only what the animals are likely to experience, but also the efforts made to alleviate those adverse effects: e.g. 'probable but controlled'. However, it was also pointed out that such descriptions might not be easily understood, because of well known difficulties in public understanding of relative risk and probability.

#### 4.2.4 Retrospective reporting of actual severity

It was suggested that retrospective reporting of the severity of adverse effects actually experienced by the animals would provide the most pertinent statistical information about severity and could be linked with the general reasons for using the animals.

However, whilst some participants felt that the benefits of providing this information would make the effort required to record it worthwhile, others (whose projects involve use of large numbers of animals; and/or whose animal facilities hold large numbers of animals) were concerned that collecting these data would be overly burdensome.

In this context, it was further suggested that "all the public needs to know is that the use of animals complies with the authorities given in licences granted under ASPA" (which law reflects the will of society), and that publication of retrospective data on severity would not necessarily provide reassurance to the public.

#### 4.2.5 Need for explanation and interpretation of statistical data on severity

Finally, it was agreed that whatever statistical data on animal suffering are presented, it is vitally important that sufficient *explanation* is provided in order to make the information meaningful:

- A nationally agreed scheme for assessment and categorisation of adverse effects based on available empirical evidence, together with a range of illustrative worked examples (as outlined in 3.1 above) would (a) help to standardise and enhance the integrity of the data collected and (b) help people to interpret the data and better understand the degree of suffering actually experienced by the animals. For public information purposes it was also suggested that, as a comparison, examples of procedures and conditions of similar severity encountered in human clinical practice could also be given (though this would assume similar sentience in all species and neglect different perceptions between humans).
- Reports of severity data should also be linked to the *reasons* for using animals in the first place, so as to provide some indication of the potential benefits of the work and set the harms in context (see also comments on lay summaries below).

#### 4.3 **Narrative descriptions of severity**

It is very difficult to capture accurate and meaningful information about animal suffering in the kind of quantitative, short-hand, statistical terms described above. Freedom of Information legislation and, with it (most likely) a requirement for proactive publication of anonymous summaries of scientific projects involving animals, opens the possibility that such information could be provided via narrative descriptions. Well written summaries could:

- reflect the nature, degree and duration of adverse effects likely to be (or actually) experienced by the animals more clearly and accurately than statistical information;
- link this with proper explanation of the reasons for the study and the benefits sought (or actually accrued) – but, it was argued, without pressure that these should be clinical benefits, since a valid case can also be made for 'scientific knowledge' benefits; and
- include estimates of (or actual) numbers of animals experiencing the various effects described.

Participants in general felt that such 'lay summaries' would be a better means of providing information about severity than statistical data.