

The **A S C**

Animals in Science Committee

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**Response to the Review of the Assessment of Cumulative
Severity and Lifetime Experience in Non-human Primates
Used in Neuroscience – the Pickard Report**

ASC response to Pickard report on Cumulative Severity

1. The Animals in Science Committee (ASC) received and discussed the Pickard Report on Cumulative Severity at the request of the Minister, Lord Taylor (then Home Office Minister for the regulation of animals in science). The Report, which was received by the ASC in the autumn of 2013, was undertaken by a working group established for the purpose by the ASC's predecessor the Animal Procedures Committee, which commenced its work in March 2011. The Report was welcomed by the ASC as an important milestone and a stimulating contribution to debates on the assessment of cumulative severity and lifetime experience in non-human primates (NHPs) used in neuroscience research. In discussion, a number of comments were made in which ASC members sought to highlight the distinctive contributions of the Report and identify and prioritise those elements of particular value in further research and future debate.
2. The ASC particularly welcomed the following aspects and contributions of the Report:
 - 2.1 The ASC recognised the Report had been enabled by initiating the development of dialogue, trust and cooperation between researchers, funders and others engaged with the use of NHPs in research. The Committee welcomed the commencement of these processes, and agreed animal welfare, scientific rigour and public engagement would be best served by those concerned with developing the welfare of NHPs working in a spirit of openness and trust, with the emphasis on mutual education and development through listening and constructive exchange of information, in accordance with the 2014 Concordat on Openness on Animal Research.
 - 2.2 The ASC acknowledged the contribution the Report had made in taking an initial step towards a framework for identifying, monitoring and collating information from which to build an evidence base for evaluating the cumulative severity and lifetime experience of non-human primates used in neuroscience research. The ASC appreciated the Report had demonstrated the value of sharing of experiences, observations and viewpoints across those involved in the assessment of cumulative severity in NHPs used in neuroscience research.

- 2.3 The recommendations of the Report identified a wide range of opportunities for further research, and touched upon some of the funding issues and interactions between research communities and roles which might best realise these. The ASC appreciated the scope and broad range of these recommendations (such as the use of CCTV, and other means of obtaining novel data to assess the quality of life of NHPs used in research).
3. The ASC noted the Report's value in opening up a number of different lines of scientific enquiry relevant to assess the lifetime experience of non-human primates and the cumulative severity of the procedures in which they are used. In discussion, the Committee sought to clarify and evaluate the next steps for enabling the relevant communities to build on this research.
- 3.1 The ASC recognised there were practical difficulties in recruiting researchers and other relevant individuals for this study, but felt that interpretation of some of the responses to the survey could be complicated by the risk of selection bias resulting from a self-identifying sample. Acknowledging the practical questions, the ASC noted it would be desirable for future work to be based on larger and more meaningful datasets derived from systematic sampling.
- 3.2 The ASC remarked that the Report was, as its authors indicate, to a large extent based on qualitative data, which were used to inform the production and presentation of summary statistics describing the respondents' perceptions of the animals' welfare. The Committee felt both the quantitative and qualitative data in the Report had value, but both could be supplemented by adding to the range, depth and objectivity of the data collected. The ability to draw inferences about an animal's welfare over time would be strengthened by more, quantitative data on a wider range of parameters. The ability to assess whether animals are suffering distress as a consequence of participating in neuroscience research was felt to require more detailed, longitudinal studies, and novel experimental approaches. The ability to understand the processes that support best outcomes (e.g. animal care staff's existing understandings of welfare indicators) could be strengthened by a more open-ended survey design, which did not simply offer a binary choice between "impact" and "no impact" for welfare impacts and so could capture the relative prevalence and intensity of various impacts as perceived by respondents.
- 3.3 In particular, the ASC noted that the Report leaned heavily on physical sources and indicators of stress (e.g. body weight) and thought it would be valuable to accumulate more data on emotional and psychological indicators of distress as a critical component of the assessment of animal welfare. The ASC strongly supports the report's recommendations that further collaborations with non-human primate behavioural scientists are

required. This work has the potential both to develop more accurate indicators of animal's affective states and to embed greater understandings of primate behaviour in the relevant research communities. Such work could also be instrumental in developing refinements to reduce the suffering, and improve the welfare, of primates used in research.

- 3.4 The Report's authors considered whether animals' (evident) willingness to undertake procedures should be taken as evidence that the experience was a positive one for them, or whether it should be ascribed to the phenomenon of learned helplessness (LH). LH is sometimes considered to be a model of clinical depression and is most often evoked experimentally by repeatedly exposing rodents to an inescapable aversive stimulus such as electric shock. After multiple inescapable shocks animals cease their attempts to escape the aversive stimulus, even when the possibility of escape becomes available. In the case of NHPs performing behavioural tasks there is no evidence that the animals would have withdrawn performance if they were in a state of LH. In fact, as they perform tasks for so long (years in many cases) they could be performing habitually, in other words, in a more automatic (less cognitively demanding) manner. Task-induced negative affective states may well be demonstrated in more complex responses than simple refusal to engage with the task. The willingness of NHPs to perform behavioural tasks neither proves nor disproves the presence of negative affective states in these animals and the Committee was concerned that the absence of overt LH in its simplest form, manifested as a refusal to engage with behavioural tasks should not be interpreted as confirmation that the animals were in a positive state without further evidence to confirm or refute this. The ASC strongly endorsed the view that further species-specific investigations of the motivation of animals undergoing procedures would be required before firm inferences could be drawn.
- 3.5 The authors' recommendations specifically address the definition of severity limits in the context of cumulative severity. Severity limits have recently been subject to review by a European Commission Expert Working Group¹. Here, the ASC felt there was a potential divergence between the proposal in the Report for a new category of 'multiple moderate without significant impact on welfare' and the agreed severity classifications set out in European Union Directive 2010/63/EU. Whilst welcoming the aspiration to provide a time dimension to the evaluation of severity limits, and to differentiating those procedures where impacts cumulate over time from those which do not, given that procedures without significant welfare impact

¹ http://ec.europa.eu/environment/chemicals/lab_animals/pdf/Endorsed_Severity_Assessment.pdf

do not require licensing, the Committee felt this proposed category had the potential to cause some confusion.

- 3.6 The ASC noted the authors' preference for the term 'cumulative experience' rather than 'cumulative severity'. This was discussed at length. It was agreed the move to acknowledge the lifetime experience of NHPs, and explore the ways in which this could be improved, was important progress. The Committee welcomed the introduction of this new concept, but concluded that both cumulative severity and lifetime experience should be assessed and reviewed separately, to reflect their different uses in (i) reporting actual severity as required by the Directive and (ii) identifying areas where refinement is needed, respectively. The ASC felt the resolution of data and understandings of processes influencing affective states were not yet sufficient to suggest that negative welfare impacts could easily be offset by equal and opposite positive experiences. Overall, the Committee strongly welcomed the development of interest in this area and the potential for more research on these two distinct phenomena in the future.
4. The Pickard Report identified a range of administrative and governance related recommendations for furthering the welfare of non-human primates used in neuroscience research. In discussion, the ASC made the following observations, concerned to identify responsibilities and clarify the contexts in which these recommendations might be implemented.
 - 4.1 The ASC believed more consideration was needed as to where the presumption should lie in cases where direct evidence as to the harms imposed by a given procedure or regime was lacking. In particular, consideration was needed as to whether a 'precautionary' approach should be taken in the absence of direct evidence, or whether it was wrong to assume the existence of harms where there was no concrete evidence for this. In addition, whilst sharing commitments to developing this evidence, the ASC noted some of the implications of these for animals (e.g. the use of anaesthetics for MRI scans) could cause suffering and so would need a careful harm/benefit evaluation.
 - 4.2 The ASC noted the value that the authors of the Report attached to the promotion of a 'no blame' culture in the reporting of welfare concerns that had arisen, such as poor recovery from surgery or significant behavioural problems. The ASC recognised the importance of researchers being able to report difficulties that they might have encountered in this respect, and also the importance of personnel such as animal technologists and other researchers being able to report difficulties that have arisen without feeling as though they were being disloyal to colleagues. They shared the authors' view that this was to be welcomed, but also noted there may be occasions in which individuals might be guilty of culpable acts of omission or

commission and felt it was important that in such instances the possibility of sanctions on the individuals concerned should remain.

- 4.3 Finally, the Report identified many issues that should be the focus of future collaboration to develop, embed and advance best practice. The ASC agreed with the wide range of the recommendations regarding securing funding, staff training, management structures, continuous professional development and monitoring. In addition, the ASC noted many of these tasks were already the remit of the range of Named Persons and project and personal licence holders, and, if shortcomings in these areas had been identified in the process of compiling the Report, that there was scope to refine the target of these recommendations to make them measurable and immediate improvements. The ASC would strongly support the refinement of these recommendations to ensure that best practice was in routine operation.
- 4.4 With respect to this, the ASC believes that it is essential to revisit the recommendations and ensure that each one is clearly aimed at defined persons, bodies or roles, such as the Named Veterinary Surgeon, the Named Person Responsible for Compliance, Home Office Animals in Science Regulation Unit (ASRU), project licence holders, specific funding bodies, the Animal Welfare and Ethical Review Body (AWERB) or other relevant local committee. Every recommendation should also have specific actions, outcomes, measures of success and follow-up programmes in place. This would demonstrate that the fundamental and legitimate concerns about this use of primates are being taken seriously, and that there is a genuine will to move forward.

**Dr John Landers,
Chair, Animals in Science Committee
15 July 2014**