

Reports and Comments

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The ethics of research involving animals

On 25 May 2005 the Nuffield Council on Bioethics launched its new publication, *The Ethics of Research Involving Animals*. Compiled by the Council's Working Party after a two-year review process, which included discussions with scientists, philosophers, members of animal protection groups and members of the public, as well as a number of visits to research establishments, the Report discusses areas of research in which animals are used and makes practical recommendations for future practice and policy. The main aim was to clarify the complex ethical issues raised by research involving animals, and to advocate dialogue and debate by encouraging the thorough and careful consideration of these issues by lay and non-lay people alike.

While it was not possible for stakeholders to agree on all issues, a significant agreement was reached on a number of topics including the benefits of specific cases of research involving animals, the ethical importance of the Three Rs (replacement, reduction and refinement), regulation, and the avoidance of duplication of experiments. The culmination of this agreement is presented in a 2-page consensus statement located in the summary at the beginning of the report and in the discussion in Chapter 15. The statement includes the assertion that in any activity involving animals it is important to consider "the impact on the lives and welfare of animals that different uses have, the broader consequences if there were a ban on using animals in specific circumstances, a comparison of the benefits arising from the different uses of animals, and the numbers of animals involved" and that "the validity, usefulness and relevance of specific types of animal research, for example in relation to the use of animals for the study of human diseases, needs to be ascertained".

The body of the report contains 15 chapters, within 4 sections. The first of these sections outlines the structure of the report, discussing the background and controversy to the debate (Chapter 1) including details of the numbers of animals involved and the different types of research that are carried out, together with the associated issues raised by each. Chapter 2 presents the context of animal research, both past and present. Topics include early forms of animal research, scientific developments and public opinion in the 18th and 19th centuries, and developments in policy and public opinion. Chapter 3 gives a brief outline of the ethical issues raised by animal research, a topic revisited in detail on several occasions later in the report. The difficult subject of the capacity of animals to experience pain, distress and suffering is the topic of Chapter 4, which includes a discussion of the

philosophical problems associated with, and the subjective and objective elements of, assessing welfare.

Section 2 discusses the areas of research in which animals are used, beginning with a general discussion on basic biological research (Chapter 5), including studies of animal development, genetics, behaviour and physiology, and the research tools and techniques used. Chapter 6 is concerned with the use of animals in the study of human diseases, including the pathogenesis of disease, new therapeutic strategies for rheumatoid arthritis, transmissible spongiform encephalopathies, and diseases for which treatments and cures have been difficult to develop. Case studies are presented including the use of chimpanzees in the discovery of the hepatitis C virus, and the development of the polio vaccine. The use of genetically modified animals in the study of human disease is discussed separately in Chapter 7, with specific reference to the use of mice, rats and zebrafish as disease models. Chapter 8 discusses pharmaceutical research, namely the processes involved in research and development: (i) the selection of compounds that may make effective medicines, (ii) the classification of potential candidate medicines, (iii) medicine selection and tests of safety, (iv) clinical trials on humans, and (v) support for the marketed medicine. A discussion of the validity of animal models used in such research is also presented. Toxicity studies are the subject of Chapter 9, including the main types of animal based toxicity tests (acute toxicity, repeated-dose toxicity studies, carcinogenicity, genotoxicity, effects on reproduction and development, safety pharmacology, ecotoxicity), together with the associated welfare issues.

The principles of humane experimental technique (Three Rs) is the topic of Section 3 (Chapters 11 and 12), including their potential in different areas of research and possible barriers to their development and how these could be overcome. The importance of the Three Rs concept is stressed throughout the Report and in the consensus statement which asserts that "...practical advances in scientific methods can reduce areas of conflict" and that "...for this reason, the importance of the Three Rs, and especially of the need to find Replacements, cannot be overstated". In particular, the need to develop rigorous and validated alternative methods for areas where none currently exists and to devise mechanisms that assist in the practical implementation of available validated methods is also discussed.

After the preceding discussion on the science of research using animals, Section 4 discusses the legal, ethical and policy issues involved. Chapter 13 is concerned with the historical background to the Animals (Scientific Procedures) Act 1986 (A[SP]A) as well as its more general aspects. Recent debated issues and international regulations are also discussed. The ethical issues raised by animal research are revisited in Chapter 14 where the four stances on animal research are looked at in detail: the 'anything goes' view, the 'on balance justification' view, the 'moral dilemma' view, and the 'abolitionist' view. Public policy in

relation to these varying and divergent moral views is also discussed. This section concludes with a discussion and number of recommendations (Chapter 15), in which the consensus statement found in the summary is reiterated.

A total of 26 recommendations are made, directed at government, researchers and funding bodies. These include the recommendation that retrospective information about the level of suffering involved during procedures should be made publicly available and that case studies describing procedures classified as 'mild', 'moderate', 'substantial' and 'unclassified' should be included in the annual statistics. A review of the current system of severity banding for project licenses is also recommended, particularly the use of the 'moderate' category. The Council stresses that "all approaches [both anti and pro the use of animals in research] based on violence and intimidation are morally wrong", but that those involved in research need to be more proactive in explaining and describing their research.

A number of appendices are included, including two which present statistics on the numbers of animals used for different purposes in the UK, such as education (zoos, hunting/shooting etc), sport (horse and greyhound racing), pest control, working animals (police and guide dogs) and clothing (wool), as well as the numbers of different species used in different types of research in the UK, EU, USA and Japan. For those requiring more information on this topic a useful list of reports by other organisations is provided. Information relating to the compilation of this report, such as details of the stakeholder meetings, visits to research establishments and public consultation, is also presented.

This publication represents an important body of work and will be of use to anyone with an interest in the topic of research using animals, not just those working or campaigning in this area. The balance of views put forward and the sympathetic nature of the discussion make this an objective and valuable publication, qualities necessary in order to take the debate further and for progress to be made.

The Ethics of Research Involving Animals (2005). Produced and published by the Nuffield Council on Bioethics, 28 Bedford Square, London WC1B 3JS. 335 pp A4 paperback (ISBN 1 904384 10 2). Printed copies available from this address or the website <http://www.nuffieldbioethics.org>. An electronic version of the report is available to download from the Council's website.

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Report on the welfare of farmed animals at gatherings and the welfare implications of farm assurance schemes

The UK's Farm Animal Welfare Council (FAWC), the independent advisory body to the UK government on matters pertaining to farm animal welfare, has recently published two new reviews, one concerned with the welfare of farmed animals at gatherings, and the other with the welfare implications of farm assurance schemes.

The Report on the Welfare of Farmed Animals at Gatherings includes cattle, sheep, pigs, horses and ponies, although its

principles and recommendations are applicable to other species, such as deer, rabbits and poultry, for which such gatherings are much less common. The Council's previous review on the welfare of livestock at markets was published in 1986, and much has changed within the industry in the ensuing 19 years, including the introduction of new EU legislation on transport and new UK animal welfare legislation (eg *The Welfare of Animals at Markets Order 1990*, *The Welfare of Horses at Markets [and Other Places of Sale] Order 1990*, and *The Animal Gatherings [England] Order 2004*). Changes have also occurred in animal handling systems and market design, and in the aftermath of the Foot and Mouth Disease outbreak of 2001. The review, which is based on a series of extensive consultations within the industry and scientific evidence, details the welfare challenges at different types of gatherings, including markets and sales, agricultural shows and exhibitions, and horse and pony sales and fairs. The review serves to highlight the disparities in legislation and protection afforded to animals at different types of gatherings, and calls for a single coherent piece of legislation covering all such gatherings.

The review begins by discussing the welfare principles common to all types of gathering and existing legislation, many of which, such as *The Animals Gatherings (England) Order 2004* and the (Wales) *Order 2004*, do not contain any requirements relating to welfare. Currently, different types of gathering differ in terms of whether specific welfare controls exist, who is responsible for the welfare of animals on-site, whether the establishment is licensed or approved, and who is responsible for enforcement. The position adopted by FAWC in the Report is that it is the conditions and level of care given to the animals that is important, not the function of the event or establishment, and thus "consolidating the requirements for animal welfare under one piece of legislation which embraces all animal gatherings would help to harmonise controls and regulate sites and occasions when any farm animals or horses are brought together".

The main body of the Report looks at the welfare of animals at specific types of gathering: (i) livestock markets (including the topics of people, animal handling, minimum levels of care, facilities, and enforcement and supervision), (ii) other gatherings, (iii) shows and exhibitions (including people, animal handling and care), and (iv) the welfare of horses and ponies at markets and other gatherings (including people, handling of horses, care of horses, facilities, and enforcement and supervision).

The Report includes a total of 108 recommendations, many of which are common to all types of gathering although some are more type specific. In general terms, FAWC recommends that:

- "It should be a legal requirement that whilst an animal is at a gathering, the welfare of that animal becomes the explicit responsibility of those operating the gathering, irrespective of the animal's ownership.
- It should be a legal requirement that gatherings have a person formally designated with responsibility for animal welfare, such as an Animal Welfare Officer (AWO), whose