

The response reproduced below was submitted to the consultation held by the Nuffield Council on Bioethics on the ethics of research involving animals during October-December 2003. The views expressed are solely those of the respondent(s) and not those of the Council.

Covance Laboratories and the British Toxicology Society, UK

Question 1

The primary point is that the use of animals in research, either fundamental or applied, provides extremely valuable information that cannot be obtained by any other means.

As is well known all use of animals is closely regulated by UK Government law and all work must be justified to obtain a Project Licence. This justification is accepted by the vast majority of the scientific community. It is possible to find the scientific equivalent of the "Flat Earth Society" who will refute this view but they are an extremely small minority.

In addition to the recognition of the need for the use of animals by the scientific community there are some areas where the use of animals is mandated by government authorities. The prime example of this is regulatory toxicology where a series of studies, appropriate to the drug type, are absolutely required before the new medicine can be registered for use.

There a great number of examples where the use of animals has been instrumental in understanding human biology and disease with resultant development of therapies. This subject is very well dealt with in a document written by the Biosciences Federation which I know has been included as an appendix to the response provided by this body

It is important to recognise the work of the Home Office in regulating research involving the use of animals. There is no doubt that the environment in which we work in this country is one of the most enlightened in the world. There are no restrictions to work provided there is justification and demonstrable benefit. In addition to strictly applying the law the Home Office work with laboratories to ensure that the highest standards of welfare are maintained -- this is not entirely altruistic as the healthier and more unstressed an animal is, the better model it becomes.

The use of animals for the betterment of society is an accepted fact by the great majority and it matters not whether it is to provide food or to develop safe medicines.

Question 2

There has been a marked increase in the use of genetically modified animals, principally mice, in research.

There are two main areas where their use has been beneficial. Firstly, as disease models to better understand disease process and assess efficacy. Secondly, as test systems to better assess some aspects of the safety of medicines.

One of the uninformed criticisms of the use of animals is that they differ from humans. Although the genetic similarities between humans and animals are much greater than commonly appreciated development of models which even more closely resemble humans can only be a good thing.

Development of these modified mouse models has also allowed reduction in use of other species such as primates.

Genetically modified mice are also used in the assessment of carcinogenic potential of new medicines. While not appropriate in all circumstances the use of these mice can reduce the number of animals used and the duration of study.

Question 3

The use of alternatives is actively pursued both by academic and applied research.

The lack of success in developing alternatives, be it isolated cell cultures or computer models, emphasises the need to use animals as a complete organism.

At the current stage of development alternatives are very unlikely to significantly contribute to replacing animals in research. Extensive use of modelling structure: activity relationships and using physico-chemical properties may well improve decision making in deciding which of a number of candidate new medicines to develop but will not significantly aid proving safety.

Question 4

This can be either be a very simple or very complex question. If humans are prepared to use animals for food then, in my view, there is no difference if animals are used to improve the lot of humans through better understanding of disease and developing more effective and safer medicines.

The broader question of using animals for any purpose for the benefit of humans is the fundamental one to answer and actually goes beyond the scope of this reply.

Question 5

The regulation of animal use in research in this country is strict but very well informed.

The operation of the Animals (Scientific Procedures) Act generally runs very smoothly and the application of cost/benefit analysis to proposed licences has shown the process to be robust.

The increased application of internal ethical review has been a major step forward since 1999.

In my own field of toxicology it is inconceivable that regulatory bodies will remove the requirement for the use of animals to establish the safety of medicines for the foreseeable future. It is my view that the environment provided by UK regulation ensures the best possible conditions for animals undergoing studies to establish safety. We should be extremely proud of the way we regulate this work, both enforced by the Home Office and self imposed standards which frequently exceed even the levels required by law.

Question 6

There is a great deal of information available but it is often difficult to find -- it is assumed that this question is largely aimed at non-scientists.

In view of the often violent activities of animal rights activists it is unsurprising that many scientists are reluctant to be open about their work.

The introduction of medical ethics to the national curriculum has given the opportunity for schools to include debate on the use of animals in research in their activities. My own laboratory has long offered a resource to local schools to provide information on the use of animals, but it is sad to say that there has not been a significant increase in demand since ethic was introduced as a subject.

I am uncertain of the mechanism by which people have become more informed but it seems that there has been a definite change in the last 3 years. I am the company spokesperson if we are approached by media and there is no doubt that the understanding of people to whom I speak has substantially increased.