

DISCUSSION PAPER: ISSUES AND OPTIONS REGARDING A FUTURE INTERNATIONAL ROLE FOR THE OIE IN LABORATORY ANIMAL WELFARE

Purpose

The purpose of this discussion paper is to assist the OIE in defining, and scoping, the unique international role it can play, in the future, in connection with laboratory animal welfare.

It is envisaged that the strategy underlying the OIE's involvement in laboratory animal welfare will include close liaison with the already established specialist international organisations. In this regard, a parallel already exists in relation to the working relationships between the OIE and IATA and AATA.

The unique benefit of OIE involvement would be the scientific and policy credibility provided by an internationally recognised inter-governmental body dedicated to animal health and welfare issues and representing 172 member countries.

OIE Update

The original version of this discussion paper was discussed at the fourth meeting of the OIE Permanent Working Group on Animal Welfare held in Teramo, Italy, in September, 2005.

It was agreed, at this meeting, to enter into dialogue with appropriate stakeholders to discuss what unique international role could be played by the OIE and what support there would be for the OIE assuming such a role.

It was initially proposed to hold such dialogue, in late 2005, but this did not prove possible. Arrangements were, however, made with the International Council of Laboratory Animal Science (ICLAS) to hold a half day OIE/ICLAS meeting in association with the 2006 meetings of the American Association of Laboratory Animal Science (AALAS) and ICLAS, in October 2006, in Salt Lake City. During 2006, a formal offer of support was also made to the OIE by the nascent International Association of Colleges of Laboratory Animal Medicine (IACLAM) by its inaugural President Dr Judy MacArthur Clark. IACLAM was subsequently invited to participate in the OIE/ ICLAS Meeting.

All participants at the Salt Lake City confirmed strong support for the OIE assuming an international laboratory animal welfare role.

Valuable additional discussions, with key international organisations involved in laboratory animal welfare, were also held in Lake Como in June 2007 and key matters arising from these discussions are included. These deliberations also provided important suggestions regarding ad hoc Group membership. A formal OIE/ ICLAS MoU was agreed at the May 2007 OIE General Session and it is anticipated that this will be formally signed in May 2008.

This version of the original paper has been prepared for discussion at the September 2007 meeting of the OIE Permanent Animal Welfare Working Group. The final agreed version of the paper will be considered at the December 2007 meeting of the Laboratory Animal ad hoc Group.

Introduction

The use of animals in research, testing and teaching was discussed at the February, 2004 OIE Global Conference on Animal Welfare as a possible future element of the OIE's strategic initiative on animal welfare. This led to an offer of international stakeholder support from a consortium co-ordinated by Dr Marilyn Brown and an invitation to speak at both the AALAS annual conference and the ICLAS International Committee meeting in October 2004. Laboratory Animal Welfare, was one of four priority strategic items identified at the December, 2004 meeting of the Permanent Animal Welfare Working Group. At that time, the Director-General emphasized the importance of the OIE's international network of reference laboratories and diagnostic centres and the role that laboratory animals play both in these centres and in the regulatory testing of veterinary medicinal and biological products conducted by OIE member countries.

Support for OIE involvement in laboratory animal welfare was received at the May, 2005 OIE General Session and a written offer of support was subsequently received from the CVO of Finland. The opportunity was also taken to briefly discuss potential OIE involvement in this area, with staff from the Teramo OIE Collaborating Centre for Animal Welfare at meetings in London and Paris in March and May 2005 respectively.

Relevant review papers by Drs Clement Gauthier and Vera Baumanns were published in the August 2005, OIE Scientific and Technical Review Series issue "Animal Welfare: Global Issues Trends and Challenges". A number of key current international issues and trends were also addressed in the concluding paper of this publication. At the 2006 meeting of the OIE International Committee, delegates were updated on progress to date with this new area of strategic involvement.

This discussion paper is designed to provide some selected background information, identify some key issues and potential roles and make some recommendations for initial OIE involvement in this specialised and often controversial area of animal use.

Background

The use of animals for scientific purposes is the subject of an extensive international literature, with a number of well-established international organisations playing key roles in promoting humane science and good laboratory animal practice, in encouraging ethical debate, in countering the misinformation promulgated by "antivivisection" groups and in fostering the ethical principles of the Three Rs of Russell and Burch.

Key organisations include:

- International Council for Laboratory Animal Science (ICLAS)
- American Association for Laboratory Animal Science (AALAS)
- Institute for Laboratory Animal Research (ILAR)
- Canadian Council for Animal Care (CCAC)
- Universities Federation for Animal Welfare (UFAW)
- Australian and New Zealand Council for the Care of Animals in Research and Teaching (ANZCCART)
- American College of Laboratory Animal Medicine (ACLAM)
- Japanese College of Laboratory Animal Medicine (JCLAM)

- European College of Laboratory Animal Medicine (ECLAM)
- Korean College of Laboratory Animal Medicine (KCLAM)
- International Association of Colleges of Laboratory Animal Medicine (IACLAM)
- European Centre for the Validation of Alternative Methods (ECVAM)
- US Interagency Coordinating Committee for the Validation of Alternative Methods (ICCVAM)
- Fund for the Replacement of Animals in Medical Experimentation (FRAME)
- Interniche
- Council of Europe ETS 123 Review
- European Food Safety Authority (EFSA) Working Group on Experimental Animal Welfare
- American Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC International)
- Various Governmental Three Rs Organisations
- The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH)
- The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)
- International Organisation for Standardization (ISO)
- Federación de Sociedades Sudamericanas de la Ciencia de Animales de Laboratorio (FESSACAL)
- The Organisation for Economic Co-operation and Development (OECD)
- Japanese Center for the Validation of Alternative Methods (JacVAM)
- Federation of European Laboratory Animal Science Associations (FELASA)
- Asian Federation of Laboratory Animal Science Associations (AFLAS)
- Mexican Association for Laboratory Animal Science (AMCAL)

The Three Rs of Russell and Burch have provided an important ethical underpinning for the use of animals in science and groups are established in Baltimore, Davis, Utrecht, Palmerston North and London to specifically promote the Three Rs and encourage relevant research.

The six World Congresses on Alternatives and Animal Use in the Life Sciences, held from 1993 to 2007, have made a major contribution to international dialogue on this subject. These congresses are excellent examples of a forum where a range of view-points can be heard, within a framework of problem solving and trust. Regular updates are provided at these conferences on the reduction, refinement and replacement of animal use in regulatory testing of veterinary biological products, in particular.

The issue of international harmonisation of the use of animals in regulatory testing is being addressed by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicine Products (VICH) programme. The VICH is an international forum to provide guidance on technical requirements for the registration of new veterinary medicinal products in order to protect public health and animal health and welfare, as well as the environment. VICH is a programme of collaboration primarily between the regulatory authorities and the animal health industry of the EU, Japan and the USA. Australia, New Zealand and Canada participate as active observer members, while the OIE participates as an associate member in supporting and disseminating outcomes worldwide.

VICH was officially launched in 1996, under the auspices of the OIE, and the factors which influenced its establishment specifically included:

- The drive to reduce the number of animals used in regulatory testing by eliminating the need for duplication of tests in each VICH region
- The international drive to harmonize regulatory standards and minimize their impact on trade

The objectives of VICH also specifically refer to establishing and monitoring harmonized regulatory requirements for veterinary medicinal products in the VICH regions, which meet high quality safety and efficacy standards and minimize the use of test animals and costs of product development.

Replacement of animal use in veterinary undergraduate teaching is another area where major advances have been made in recent years. Considerable expertise has been developed in, for example, the veterinary schools in Norway and New Zealand and there would be scope for the OIE to facilitate uptake and adoption of such teaching techniques.

ICLAS/OIE Salt Lake City Meeting, October 2006

This well-attended and successful, by invitation only, meeting had the objectives detailed in Appendix 1. Appendices 2 and 3 provide agenda and participant details.

Key issues identified in the formal presentations, and arising from subsequent discussion, included the following:

- The important role being played by the ICLAS Working Group on the Harmonisation of Guidelines and the commitment to an international harmonisation, rather than a standard setting approach.
- ICLAS resourcing issues and the need to consider a new international location for the secretariat, after 10 years of being hosted by the CCAC in Canada.
- An indication that the European Commission might consider a case for financial support for a possible EU member country location.
- The OIE's commitment to ensuring that animal welfare standards and guidelines have broad applicability internationally.
- The potential for the OIE to raise awareness internationally at both a government and stakeholder level.

- The strategic significance of the establishment of IACLAM and its particular interest in laboratory animal transport (including primates) and *in-vitro* and *in-silico* testing methods for both animal and human pharmaceuticals.
- The important international role played by AAALAC International, with its commitment to performance standards and practical harmonisation.
- The important international role played by ILAR including the ILAR Journal, ILAR Care and Use Guidelines and other international reference documents.
- The role of the OECD model in facilitating the international regulatory acceptance of non-animal tests.
- The value of the ISO model in facilitating the international regulatory acceptance of human medical devices.
- The “European Partnership on Alternative Approaches to Animal Testing” (EPAA) as an example of an action programme including the EC and all stakeholders (Refer Appendix 4).
- The need for greater research support (Refer Framework 7 programme in Europe and research coordination).

Strong support was given to the OIE’s proposed involvement in the international laboratory animal welfare area. In addition to the areas originally identified in 2005, the following were suggested as particular priorities:

- Revision, promulgation and, if necessary, updating of 1985 Committee of International Organisations of Medical Science (CIOMS) “International Guiding Principles for Biomedical Research involving Animals”.
- Provision of expert international advice in relation to transport of laboratory animals, including primates, to ensure that the role played by such animal use in animal disease diagnosis and animal disease research is fully recognised and that the assessment of zoonoses transmission is both science- and risk-based
- Ongoing provision of secretariat support for ICLAS, as the established international platform for the harmonisation of laboratory animal welfare standards
- Value of OIE participation in the 2007 meeting of the ICLAS Working Group on Harmonisation

To complement the proposal that the OIE formalises and strengthens its ties with ICLAS, it was suggested that a similar strong relationship be developed with IACLAM. Appendices 5 and 6 outline the established international role of ICLAS and the expertise underpinning the priorities of IACLAM.

Recommendations

In recognition of the complexity and specialised nature of this topic, it is recommended that the OIE adopt a very focused strategy and establish an ad hoc Group of experts to make recommendations regarding:

- 1) The need to establish Guiding Principles for Laboratory Welfare and the relevance of the 1985 CIOMS Principles.

- 2) The development of a strategy which would prioritise and address the following areas of potential involvement
- The availability of guidelines for the use of animals in regulatory testing of veterinary medicinal, biological and chemical products.
 - Liaison with VICH and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), to facilitate the regulatory acceptance and adoption of internationally validated non-animal test methods.
 - Potential OIE role in provision of expert international advice on the transport of laboratory animals, including primates
 - Issues relating to the use of animals in research and diagnostic testing.
 - Options for OIE involvement in the use of animals in research and diagnostic testing.
 - The availability of guidelines for the use of animals in education and teaching.
 - Identification of key international stakeholders and availability of relevant resource material.

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