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Annex 36

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**REPORT OF THE FOURTH MEETING OF THE OIE AD HOC GROUP
ON LABORATORY ANIMAL WELFARE
Paris, 14-16 December 2010**

The OIE *ad hoc* Group on Laboratory Animal Welfare (the *ad hoc* Group) met at the OIE Headquarters on 14-16 December 2010. Dr D. Bayvel chaired the meeting.

The members of the *ad hoc* Group and other participants at the meeting are listed at Appendix I. The adopted Agenda is provided as Appendix II and a Glossary in Appendix III.

Meeting with Dr Bernard Vallat, Director General

Dr Vallat participated in the *ad hoc* Group meeting on Wednesday 15 December 2010.

Dr Vallat thanked the members of the *ad hoc* Group and emphasised the importance of their work, which will help to safeguard the future of scientific research and teaching on medical and veterinary science and related issues. Animal welfare standards are of critical importance to help to guarantee the continued use of animals in research and teaching and thereby to help assure human health and animal health and welfare globally. Dr Vallat congratulated the Group on the adoption of Chapter 7.8. in 2010 and noted that the relatively small number of comments received from Members subsequent to the 78th General Session reflects a general level of satisfaction with the text. However, there is more work to be done – particularly in raising OIE Delegates' awareness of this important issue and in encouraging them to liaise with competent authorities where the Veterinary Services are not responsible for the legislation covering the use of animals in research and teaching.

At Dr Bayvel's request, Dr Bayne summarised the work done by the *ad hoc* Group on the need for specialised training of veterinarians in laboratory animal medicine. Dr Bayvel also referred to the other two strategic priority areas i.e. air transport, and a strategy to reduce the use of animals in regulatory testing.

Dr Vallat agreed that it would be valuable to develop specific guidance for the use of institutes and airlines facing the sensitive topic of air transport of animals for use in scientific research and confirmed his support for continued work by the *ad hoc* Group on the topics identified..

Dr Vallat supported in principle the development of a model veterinary certificate to address the specific health and welfare issues associated with the international transport of laboratory animals and noted the request to invite Dr William White to the next meeting of the *ad hoc* Group to assist with this work.

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Regarding veterinary training, Dr MacArthur Clark suggested that the OIE consider closer collaboration with organisations such as the International Association of Colleges of Laboratory Animal Medicine (IACLAM) and the Institute for Laboratory Animal Research (ILAR), for example, to ensure the harmonization of post graduate education for veterinarians working with animals for research and education. It was agreed that the World Veterinary Year is a good window to promote the key role of veterinarians in respect of laboratory animal health and welfare; and the importance of standards for scientific institutes using animals and of professional training for veterinarians. Dr Vallat encouraged the *ad hoc* Group to liaise with the *ad hoc* Group on Veterinary Education, particularly as some countries have already banned the use of animals for teaching purposes at veterinary schools.

On the subject of animal use in regulatory testing, Dr Vallat agreed with the *ad hoc* Group that the OIE could encourage the use of alternatives to animals in regulatory testing, including through promoting the 3 Rs. Dr Vallat mentioned the OIE's close working relationship with VICH and the US Food and Drug Administration, and encouraged the Group to continue its liaison with VICH. Dr Vallat also expressed support for future liaison between the OIE and the ISO, noting that a formal agreement between the two organisations is under development.

Finally, Dr Bayvel thanked Dr Vallat for his ongoing support for the work of the *ad hoc* Group and added that some countries would be contacted by the *ad hoc* Group for comments on Chapter 7.8 as they have already expressed an interest to do so.

1. Feedback from the Chair on the Report of the Third Meeting of the OIE *ad hoc* Group on Laboratory Animal Welfare

Dr Bayvel reviewed the report of the Third Meeting of the OIE *ad hoc* Group on Laboratory Animal Welfare and noted that Chapter 7.8 was adopted at the 78th General Session in May 2010. He also mentioned that he was awarded with a Meritorious Service Award, which he accepted on behalf of both the *ad hoc* Group and OIE Animal Welfare Working Group Members.

Dr Bayvel reiterated the need to raise awareness on the importance of using animals in research and education. He noted that in some OIE Member countries the Veterinary Services are not the competent authority for laboratory animal welfare. He also mentioned that OIE Delegates and the animal welfare focal points are key elements to establishing a network to inform stakeholders about OIE animal welfare standards.

2. Feedback from the Chair on the Report of the Ninth Meeting of the Animal Welfare Working Group

The *ad hoc* Group acknowledged the report of the ninth Animal Welfare Working Group (AWWG) meeting. Dr Bayvel indicated that Air Transport was identified as the main priority topic to be addressed by the *ad hoc* Group. He updated the group regarding the existing *ad hoc* Groups on Production Systems and confirmed that it is proposed that the chapter on Broiler Chicken Production Systems be adopted at the next General Session. Dr Kahn mentioned the difficulties faced in developing standards that can be accepted by all 177 OIE Members, given the variations that exist between developing countries, where standards may be minimal, and the high standards of other countries, for example in the European Union. Dr Bayvel referred to a document written by Dr Fraser entitled "Guidance from the Animal Welfare Working Group to *ad hoc* Groups on the development of animal welfare standards" (Appendix IV).

Continuing with the AWWG report, Dr Bayvel noted that a joint meeting with the Animal Welfare Collaborating Centres (CCs) was held, and listed the attendees at that meeting. He also mentioned that this experience would be repeated, if possible, at the next AWWG meeting to be held at OIE Headquarters in June 2011, or by means of a teleconference. Dr Bayvel also described the system of rotation for AWWG observers. It was confirmed that IFAP has ceased to operate.

Dr Bayvel mentioned the Third OIE Global Conference on Animal Welfare to be held in January 2013 in Asia. Dr Kahn confirmed the location and commented that the existence of a Regional Strategy on Animal Welfare (RAWS) and countries keen to host this event helped the OIE to decide to hold the conference in the Asia, Far East and Oceania (AFEO) Region.

Dr Bayvel confirmed that the Australian Government has kindly agreed to continue funding the secretariat of the AFEO RAWS for a 2-year period and that the first meeting of the RAWS Coordination Group is expected to take place in March/April 2011.

Dr Kahn added that this strategy can serve as a model for other OIE regions and stressed the importance of funding support. She also commented about developing a RAWS for Europe, and the need to address the different standards that currently exist in western and eastern European countries. The ad hoc Group noted the focal point training to be held in Ukraine in March 2011, as an opportunity to analyse the feasibility of developing a RAWS in Europe and the potential commitment of the countries to this approach.

Dr Kahn then commented on the animal welfare focal point seminar held in Ethiopia in November 2010. It is not clear that Africa is ready to develop a RAWS; it may be worth considering the development of a strategy at a sub-regional level, for example in the South African Development Community, with support from the relevant Regional Economic Community. Dr Varas said that during the OIE animal welfare focal point seminar in Lebanon in November 2010, it was agreed to prepare a document for the implementation of a RAWS in the Middle East Region to be submitted to the OIE Members at the 79th General Session. She also mentioned that RAWS development in the Americas is ongoing and that a Coordination Group has been created.

3. Review of Code Commission and Member's comments on Chapter 7.8: Use of Animals in Research and Education

The *ad hoc* Group discussed and responded to comments provided by 3 Members, including the European Union, Chinese Taipei and the Republic of Korea and modified the text that had been reviewed by the Code Commission at its September 2010 meeting.

The Group also noted that the AWWG had made no specific comments and had generally supported the text.

The Group discussed the deletion of the wording “*Euthanasia*” from Chapter 7.8. and its inclusion in the Code Glossary. Dr Kahn clarified definitions are normally included in the Glossary if they are used in more than one Code chapter. The definition used in the Glossary was taken from the definition in Chapter 7.7 ‘Stray Dog Population Control’, i.e. *Euthanasia*: means the act of inducing *death* in a humane manner. An extract from the report of the Terrestrial Code Commission is presented in [Appendix V](#).

Chapter 7.8, including proposed text changes by the *ad hoc* Group, is at [Appendix VI](#).

4. Development of draft strategic direction for consideration by the Terrestrial Animal Health Standards Commission

The *ad hoc* Group confirmed that the three priority areas for future OIE work remained as follows:

- **Veterinary training**

Concerning Veterinary Training in Laboratory Animal Medicine, Dr Kahn mentioned the First OIE Global Conference on Veterinary Legislation held on 2-9 December 2010 in Djerba. One of the key points addressed during the conference related to Veterinary Education. Dr Kahn indicated that the recommendations focused on how to improve the competencies of veterinarians in delivering the OIE mandate and on the need for global harmonisation and evaluation of the veterinary curriculum.

Dr Kahn added that the *ad hoc* Group on Veterinary Education was also holding its second meeting this week and it was agreed that the two *ad hoc* Groups should liaise on issues relating to veterinary education. She also mentioned the Second World Conference on Veterinary Education, to be held on 13-14 May 2011 in Lyon, where the work of the *ad hoc* Group on Veterinary Education would be presented, before being submitted to for consideration of OIE Members at the 79th General Session.

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Dr Bayne reported on actions taken subsequent to the development of the original Issues and Options paper regarding a potential role for the OIE in addressing international variability in training for veterinarians specializing in laboratory animal medicine. She noted that 2010 had offered a unique opportunity to meet with colleagues from around the world at three key meetings that were serendipitously scheduled in 2010, specifically:

- The June 2010 meeting of the Federation of Laboratory Animal Science Associations in Helsinki, Finland;
- The September 2010 meeting of the Association for Laboratory Animal Science in Atlanta, Georgia, United States; and
- The November 2010 meeting of the Asian Federation of Laboratory Animal Science Associations in Taipei, Taiwan.

Dr Bayne confirmed that a total of 106 individuals representing 27 countries participated in the three meetings, and that there was a strong consensus among the meeting participants that harmonizing the skill level and training of laboratory animal veterinarians, at the global level, was both timely and important. She explained that several themes emerged from the three focus group discussions. After discussion of the *ad hoc* Group, a document listing and identifying key factors for Training Veterinarians in Laboratory Animal Medicine was drafted (Appendix VII).

Dr Bayne stated that one specific recommendation that came out of the focus groups was that a repository of resources in a variety of languages should be developed and possibly placed on the OIE server.

Dr Bayne then led the group through the summary notes from the focus groups, elaborating on the context of the remarks with assistance from other *ad hoc* Group Members who attended one or more of the meetings, i.e. Drs. Demers, Kurosawa, and Souilem. She referred to the various supporting meeting documents related to veterinary training and qualifications in laboratory animal medicine and noted that these would serve as a good resource for this subject, but that other related information should also be forwarded by the *ad hoc* Group members. This review prompted additional constructive input into framing a planned article for the Journal of the Institute for Laboratory Animal Research (ILAR) and the proposed development of an OIE standard. An outline for the article was discussed and writing assignments were agreed (Appendix VIII). A timeline for the draft article and for proposed submission to the ILAR Journal was established, with the World Veterinary Association Congress, October 2011, as the target publication date. This congress marks the culmination of World Veterinary Year 2011.

Dr Bayne reminded members that input from the International Association of Colleges of Laboratory Animal Medicine (IACLAM) and the American Association of Veterinary Medical Colleges (AAVMC) would be sought in the review of the article for the ILAR Journal. The paper would provide a summary of the input from the three international focus groups and would recommend the development of international standards for training and qualification of veterinarians in laboratory animal medicine. She also mentioned that IACLAM partners in this activity would bring the expertise of the laboratory animal veterinary community. Publication of an article in the ILAR Journal provides the opportunity for disseminating the information obtained from the focus groups and provides a platform on which to build the recommendation for the development of international standards by the OIE. The AAVMC's interests lie in veterinary training and curricula.

Dr Bayvel noted that the OIE's strategic initiative on veterinary education initiated at the October 2009 global conference, fits well with this proposed new work in standards development and is highly relevant to the content of the Second World Conference on Veterinary Education.

There was consensus among the *ad hoc* Group members that an exchange of views with the *ad hoc* Group on Veterinary Education would be mutually beneficial given the synergies of the two Groups' mandates.

The *ad hoc* Group acknowledged Dr Bayne's considerable commitment and hard work and thanked her for attending these three meetings and for the feedback. It was agreed that Dr Bayne would finalise the Issues and Options Paper on this subject to reflect the outcome of the discussion.

- **Air transport**

Dr Bayvel briefly summarised the documents provided for the meeting on this topic, including the OIE/International Air Transport Association (IATA) Discussion Paper available on the OIE website at http://www.oie.int/eng/bien_etre/ENG_IATA%20paper_2009.pdf and Dr Varas' report on the IATA meeting held in Kuala Lumpur in October 2010. The OIE/IATA discussion paper which explains that, due to the decisions of many commercial airlines to cease carrying animals (especially dogs, cats and non-human primates), that are intended for use in scientific studies, it is increasingly difficult for institutes in developed countries to obtain these animals, which are needed for studies in some important areas of medical and veterinary research. In addition, there is a risk that the transport of laboratory animals may increasingly be undertaken by airlines that are less aware of OIE standards and IATA Regulations.

Dr Varas noted that few of the cargo airlines that attended the recent meeting in Kuala Lumpur were still transporting laboratory animals, and that these are basically limited to carrying rats and mice. This is based on commercial decisions of airlines, taking into account public opinion and the influence of lobby groups opposed to the use of animals. Dr Demers proposed that the *ad hoc* Group develop guiding principles on air transport of animals used in research for inclusion in Chapter 7.8. Dr Kahn reminded the Group that the OIE has a formal agreement with IATA and that the text of Chapter 7.4. 'Air Transport' is modified as required to reflect updates to the IATA Live Animals Regulations (www.iata.org).

It was agreed that the Group would develop a new Article 7.8.10 on Transport between Institutions (Appendix VIII), to be proposed to the Code Commission at its meeting in September 2011.

Dr Varas and Dr Kahn recommended that the Group also consider the Code recommendations on veterinary certification for international transport of animals, as the current Chapter 5.10. probably does not address the specific needs of animals used in research. The development of new text on air transport of animals should be undertaken in coordination with the IATA. It was proposed that the OIE invite Dr William White, currently serving as an expert advisor to IATA, to attend a meeting with the *ad hoc* Group, with the objective of providing input to the draft Code text and drafting a model Health Certificate that would specifically address the needs of international transportation of animals used in research and education, and to consider what other measures could be taken to support companies that are prepared to transport research animals and are looking for guidance on appropriate health and welfare standards.

- **Regulatory Testing and the adoption of alternatives to animal use: Liaison with VICH/ICH**

Dr Kahn mentioned that the OIE is working in collaboration with the US Food and Drug Administration (FDA), and that this could provide an opportunity for the development of recommendations on alternatives to reduce the use of animals in regulatory testing. She added that the International Federation for Animal Health (IFAH) and the FDA, at the Conference on Veterinary Legislation in Djerba urged the OIE to encourage and support the acceptance by developing countries of regulatory approvals provided by appropriate authorities (such as the European Medicines Agency (EMA) and FDA) as a means to improve efficiency in the appropriate approval of new drugs. This approach could also help to reduce the use of animals in regulatory testing.

As recorded in the report of the second meeting of the *ad hoc* Group, the organisation known as VICH (International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products), formed under the auspices of the OIE, is an important international organisation. The *ad hoc* group intends to further develop its relationship with VICH, particularly in relation to the strategy for reducing the use of animals in regulatory testing and their replacement, where possible, with scientifically validated non-animal tests.

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Following discussion about the strategic approach involving VICH/ICH, it was agreed that this project should initially focus on the adoption of alternatives for those regulatory tests within the remit of VICH. This would include some relatively severe tests, for example, testing batches of veterinary vaccines and other biological products.

The Group discussed the fact that far more animals are used in the regulatory testing of human drugs. The International Conference on Harmonisation (ICH) covers safety testing of products intended for human use. While the Group considered that it was too ambitious to develop a work programme with ICH at this time, this should be addressed in future. It was agreed that the two Europe-based Group members (Dr Joubert and Dr MacArthur Clark) would initially lead efforts to strengthen coordination with VICH and to develop a strategic approach, in liaison with Dr Varas at OIE Headquarters. It was also agreed that Dr Bayvel would finalise the revised position paper on this subject to reflect the outcomes of this meeting.

5. Other Business

- **Feedback from the Second Global Conference of OIE Reference Laboratories and Collaborating Centres**

It was indicated that all the presentations and recommendations of that conference are available online on the OIE website. Dr Bayvel mentioned that there are 35 OIE Collaborating Centres, and listed the three dealing with Animal Welfare (Italy, New Zealand-Australia, and Chile-Uruguay). Dr Bayvel commented on the applications from Mexico and Sweden and their status. He also commented on a potential new application from Edinburgh and Bristol, in the United Kingdom.

Dr Varas mentioned that the OIE will launch its new portal in early 2011, and that, during the joint meeting between the CCs and the AWWG meeting in June 2010, it was proposed to facilitate communication between CCs through this new portal, making their annual reports available online.

Dr Bayvel referred to the concept of twinning, supported by the World Fund, and mentioned the ongoing twinning interest between Malaysia, India and Bangladesh with the NZ-AUS CC.

Dr Kurosawa mentioned that CCs should be encouraged to work with animals for research and education. Dr Bayvel added that in the case of the NZ-AUS CC it is planned to do so, with expertise existing at both Massey and the University of Queensland.

The *ad hoc* Group noted that the Second Global Conference of OIE Reference Laboratories and Collaborating Centres will be held in 2014.

- **Directive 2010/63/EU on the protection of animals used for scientific purposes**

Dr MacArthur Clark noted that the new Directive had been approved by all parties and entered into force on 10 November 2010. This means that all Member States must have implemented it into their domestic legislation by 10 November 2012, with a view to applying the new legislation from 1 January 2013. Key aims were to harmonise rules across Member States, to raise standards of animal welfare, and to promote alternatives (the 3Rs). It was generally agreed that all policy objectives had been achieved although the application in each Member State would not be identical.

Examples of harmonization included that each Member State would have a system of project authorization, as well as an inspectorate to monitor compliance. Each establishment would be required to specify a number of responsible individuals including a designated veterinarian. There was some disappointment that the veterinarian was not an obligatory member of the Animal Welfare Body, but it was felt that most would nevertheless strongly influence the activities of that Body in each establishment. All procedures would be classified according to predicted severity, and reporting would include a retrospective review of actual severity.

Dr Joubert agreed with this summary and mentioned that a number of Member States were struggling with how best to implement project authorization. Dr Bayne mentioned that a number of Member States had expressed an interest in the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) system of accreditation as a possible means of delivering inspection.

- **Eighth World Congress on Alternatives and Animal Use in the Life Sciences (WC8)**

Dr Demers confirmed that Canada will be hosting the Eighth World Congress on Alternatives and Animal Use in the Life Sciences in Montreal in August 2011 (www.wc8.ccac.ca). He mentioned he would be chairing a session on ethical review.

Dr Kurosawa proposed a satellite prior meeting of the *ad hoc* Group but it was decided that this would not be feasible. It was agreed to liaise with the 2013 conference organisers, with a view to OIE involvement in the conference programme.

- **Australian College of Veterinary Scientists**

Dr Bayvel and Dr MacArthur Clark had been invited to examine the first Fellowship candidates for the Australian College of Veterinary Scientists Animal Welfare Chapter. They had prepared two written papers (three hours each) and then attended "Science Week" for the day of practical and oral exams on the Gold Coast in Queensland. The Fellowship standard had been set at that for Diplomas of other Colleges such as the Royal College in the UK. Two candidates had presented and both had passed. This now means that Australia and New Zealand has Fellowship level graduates in this subject able to conduct future exams in this topic.

- **International Conference on Veterinary and Animal Ethics**

Dr MacArthur Clark has been invited to participate in the first international conference on Veterinary and Animal Ethics due to be held in London in September (12th to 14th) 2011. A detailed programme should be available shortly on the website (www.icvae.co.uk).

- **International Organization for Standardization (ISO)**

Dr Kurosawa advised that, in contrast to ICH and VICH, which mainly discuss medicinal drugs, the ISO focuses on medical devices. The ISO is discussing the International Standard (IS) for testing medical devices under the ISO Technical Committee (TC) 194: Biocompatibility testing of medical devices. ISO has decided to set an IS for therapeutic use of live human cells and is going to extend its work to embryonic stem (ES) cells and Induced Pluripotent Stem (IPS) cells through TC150, which is responsible for the horizontal standard for medical devices. TC194 references the OIE regarding the safety of animal products utilized for medical devices in relation specifically to Transmissible spongiform encephalopathy (TSE) agents. TC194 created a subcommittee to address this issue and made ISO 22442 to clarify the safety of animal products for medical devices in terms of prions. The geographical location of source animal safety relied on the OIE BSE risk status of the cattle population of a country, zone or compartment. Any further discussion of the therapeutic use of cells using bovine and calf serum for cell cultures should be made in terms of BSE risk. ISO TC194 (Biological Evaluation of Medical Devices) has a working group (WG3) in which animal welfare requirements are discussed. ISO standard 10993, part two, refers to the 3Rs.

The *ad hoc* Group decided that the OIE should collaborate with the ISO on the issue of regulatory testing and the adoption of alternatives to animal use.

- **Brazil Conference : Feedback from Dr Rivera**

Dr Rivera provided feedback from the First International Trans Disciplinary Congress on Fauna Protection held recently in Brazil. The recommendations from this successful Congress will be discussed separately with Dr Vallat, with a view to future OIE involvement, including subsequent conferences involving the Brazilian veterinary and legal professions.

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- **American Veterinary Medical Association (AMVA) update**

Dr Bayne briefed the group on the status of the American College of Animal Welfare (ACAW), a proposed board certification specialty group under the auspices of the American Veterinary Medical Association (AMVA). ACAW filed its petition for recognition last winter and has undergone a one year comment period. Those comments were addressed by the ACAW Organizing Committee, and the information has been forwarded to the AVMA's American Board of Veterinary Specialties—the body within the AVMA that reviews board specialty applications. The ACAW application packet will be reviewed in February 2011, and it is hoped that approval of Provisional Status of the College will be granted at the April 2011 meeting of the AVMA Executive Board. Of further note, the AVMA recently modified the oath taken by every graduating veterinary student to include reference to animal welfare.

- **Institute for Laboratory Animal Research (ILAR) update**

Both Dr Bayne and Dr MacArthur Clark are members of ILAR Council. Dr MacArthur Clark reported on the development of the International Primate Plan (IPP) for which ILAR was currently seeking financial support. The EU Commission had provided funding through the EUPRIM-Net II programme which would cover the costs of European participation as well as hosting a workshop in Europe. It was hoped that similar funding would come forward from South East Asia (probably China) and the remainder of the funding be derived from NIH in the USA as well as from the pharmaceutical industry. It was hoped to commence the development of the IPP during 2011 with a consensus report produced by a committee with international membership in 2013. It was agreed that the IPP was an important international initiative and the Group should monitor its development.

Dr Bayne updated the group on the status of the 8th edition of the Guide for the Care and Use of Laboratory Animals (National Research Council). The revised version is in press at the National Academies and has been published in December 2010. In its review of the pre-publication version, AAALAC International's Council on Accreditation identified 121 items for attention. AAALAC intends to publish several new documents (Position Statements and Frequently Asked Questions) to clarify its position on the new Guide. Standards included were largely based upon performance (as opposed to engineering standards) and this approach had been welcomed by the community at large.

- **Council For International Organizations of Medical Sciences (CIOMS) Guiding Principles**

Dr Demers reported on recent activities in relation to the ICLAS revision of the 1985 CIOMS Guiding Principles for Biomedical Research Involving Animals.

Following the Fourth ICLAS meeting on Harmonization held in Indianapolis, USA, in November 2008, the revision process has continued through the production and dissemination of documents via email including the production of a Chart comparing documents (Statements, Guidance, and Principles regarding the humane care and use of animals in research produced by other international and national organisations). Then, several drafts of revised principles were produced.

These drafts were discussed during several Scientific meetings held in 2009-2010 in Thailand (TALAS), USA (PRIM&R), Finland (FELASA), Poland (PAS), Taiwan (AFLAS), India (LASA) ...etc.

The Fifth ICLAS Meeting on Harmonization of Guidelines held in Helsinki, Finland (FELASA) on June 14, 2010, was used to refine the last draft version of the CIOMS Guiding Principles. The final draft document was completed on November 24th, 2010.

The next few months (until May 2011) will be used for a large consultation with the national and international organisations, scientific societies and interested parties (NIH). The Issues to consider are:

- Do the revised Guidelines provide a foundation for the future?
- Review of the content – what's missing?
- Are they achievable and culturally sensitive for developing countries?
- Do they facilitate science while enhancing animal welfare?

The ICLAS *ad hoc* group, which includes Dr Bayne, will be meeting in 2011 to complete the work.

The publication of the final document is expected for 2011-2012.

6. Emerging/Strategic Issues

- The following topics were identified as priorities in relation to welfare of animals used in research and education:
- Biotechnology research
- Globalization of research
- Veterinary legislation
- The OIE Global Fund
- The OIE PVS Tool

7. Review and finalise report of meeting

The *ad hoc* Group agreed on the work needed to complete the draft text for Article 7.8.10 and the discussion papers on veterinary training and animal use in regulatory testing.

8. Programme for further work after this meeting

The *ad hoc* Group developed a proposed future work programme

9. Next Meeting

Proposal: 5-7 July 2011 with second option: 19 to 21 July 2011.

.../Appendices

4th MEETING OF THE OIE AD HOC GROUP ON LABORATORY ANIMALS WELFARE**Paris, 14-16 December 2010****List of Participants****MEMBERS OF THE AD HOC GROUP****Dr David Bayvel (Chair)**

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4th MEETING OF THE OIE *AD HOC* GROUP ON LABORATORY ANIMALS WELFARE

Paris, 14-16 December 2010

Adopted Agenda

Welcome and introduction – Dr Sarah Kahn

1. Comments from Chair of AHG on the Report of the Third Meeting of the OIE *ad hoc* Group on Laboratory Animal Welfare
2. Feedback from Chair of AHG on the report of the Ninth meeting of the OIE Animal Welfare Working Group
3. Review of Code Commission and Member's comments on the Chapter 7.8: Use of Animals in Research and Education
4. Development of draft text strategic direction for consideration by the Terrestrial Animal Health Standards Commission
 - a) Veterinary Training in Laboratory Animal Medicine
 - b) Air transport of laboratory animals: IATA, Discussion paper and update
 - c) Regulatory Testing and the adoption of alternatives to animal use: Liaison with VICH/ICH
5. Other Business
 - Feedback from the Second Global Conference of OIE Reference Laboratories and Collaborating Centres
 - EC Directive Update
 - Liaison with VICH/ICH
 - Eighth World Congress on Alternatives and Animal Use in the Life Sciences
 - ECLAM-European Association of Veterinarians in Education, Research and Industry Draft Document
6. Emerging/Strategic Issues
7. Review and finalise report of meeting
8. Programme for further work after this meeting

UNOFFICIAL REPORT

GLOSSARY

3Rs	Replacement, Reduction, and Refinement
AAALAC	Association for Assessment and Accreditation of Laboratory Animal Care International
AAVMC	American Association of Veterinary Medical Colleges
ACAW	American College of Animal Welfare
AFEO	Asia, Far East and Oceania
AVMA	American Veterinary Medical Association
AWWG	Animal Welfare Working Group
BSE	Bovine spongiform encephalopathy
CCs	OIE Collaborating Centres
CIOMS	Council For International Organizations Of Medical Sciences
EC	European Commission
ECLAM	European College of Laboratory Animal Medicine
EMA	European Medicines Agency
FDA	Food and Drug Administration
IACLAM	International Association of Colleges of Laboratory Animal Medicine
IATA	International Air Transport Association
ICH	International Conference on Harmonisation of Technical Requirement for Registration of Pharmaceuticals for Human Use
ICLAM	International Committee for Insurance Medicine
ICLAS	International Council for Laboratory Animal Science
IFAH	International Federation for Animal Health
ILAR	Institute for Laboratory Animal Research
INRA	Institut Nationale de la Recherche Agronomique
IPP	International Primate Plan
ISO	International Organization for Standardization
PETA	People for the Ethical Treatment of Animals
RAWS	Regional Animal Welfare Strategy
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products

UNOFFICIAL REPORT

GUIDANCE FROM THE ANIMAL WELFARE WORKING GROUP TO AD HOC GROUPS ON THE DEVELOPMENT OF ANIMAL WELFARE STANDARDS

When 'welfare codes' were first developed in the 1970s and 1980s, they tended to contain truisms such as 'Animals should have adequate space' and 'Noise levels should not be excessive'. Although such statements can be useful to identify important variables in the course of providing more specific advice, they do not provide any implementable information or any means of determining whether a given practice or facility is in compliance. In contrast, an OIE animal welfare standard should contain recommendations that can be implemented, and criteria that can be used to tell whether a given practice or facility is in compliance with the standard.

Outcome-based or animal-based criteria should be used where possible because they are generally related most directly to animal welfare, and because they can be applied to a wide range of production systems. Such criteria can be qualitative (all animals should be able to lie down at the same time without lying on top of each other) or quantitative (no more than 1% of animals should be dead on arrival).

In some cases, input-based or resource-based criteria may be possible, for example if welfare is likely to be reduced by a certain factor in a wide range of systems. Again these can be qualitative (no animal should be hoisted while conscious) or quantitative (ammonia level in the air should not exceed 25 ppm).

In other cases, 'conditional' criteria can be used. These generally specify what actions should be taken under certain conditions. These can include both qualitative and quantitative elements, as in: (1) If more than 2% of birds arrive at the slaughter plant with broken wings, catching crews should be re-trained to catch birds in ways that are less likely to cause injuries. (2) In months where hot weather is expected, stocking density should be reduced so that birds have enough space to perform wing-stretching unimpeded.

For certain variables, it is possible to identify 'critical levels' beyond which welfare is expected to be affected. Such levels are normally determined by scientific research. For example, welfare in many species is noticeably affected if ammonia levels in the air exceed 25 ppm.

For other variables (percent lame, percent dead during transport) there are no critical levels but it may be possible to set or recommend 'performance targets'. In the case of performance targets, an *ad hoc* committee may be able to agree that a certain level of performance should be achieved broadly, for example, that no more than 1% of animals should fall while being moved in a slaughter facility. In other cases, there may be so much variation between breeds or locations that a standard merely identifies variables that should be used to assess performance, and calls for national or breed-specific targets to be set. In such cases it is helpful to provide examples of performance targets from other standards that are broadly applicable under different conditions.

June 25, 2010

Dr David Fraser

UNOFFICIAL REPORT

**EXTRACT FROM THE REPORT OF THE TERRESTRIAL ANIMAL HEALTH CODE
COMMISSION**

The Code Commission received comments from Chinese Taipei and the EU.

The Code Commission noted Members' comments calling for modification of terms such as 'committee', 'local committee' and 'ethics committee' in Chapter 7.8. The Commission noted that the goal of this chapter is to identify an overall framework for correct use of animals, and not to specify the detailed structure to be used. For this reason, the chapter provides for flexibility in selecting elements within the framework. The Commission did not see value in trying to achieve more specificity by qualifying 'committee' or other terms used in this chapter.

The Code Commission proposed to delete the definition of 'euthanasia' from Article 7.8.1. and include it in the Glossary.

The Code Commission modified the text of point 5 Article 7.8.7 to clarify the distinction between genetically altered and cloned animals.

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CHAPTER 7.8.

USE OF ANIMALS IN RESEARCH AND EDUCATION

Preamble: The purpose of this chapter is to provide advice and assistance for OIE Members to follow when formulating regulatory requirements, or other form of oversight, for the use of live animals in research and education¹. A system of animal use oversight should be implemented in each country. The system will, in practice, vary from country to country and according to cultural, economic, religious and social factors. However, the OIE recommends that Members address all the essential elements identified in this chapter in formulating a regulatory framework that is appropriate to their local conditions. This framework may be delivered through a combination of national, regional and institutional jurisdictions and both public sector and private sector responsibilities should be clearly defined.

The OIE recognises the vital role played by the use of live animals in research and education. The OIE Guiding Principles for Animal Welfare state that such use makes a major contribution to the wellbeing of people and animals and emphasise the importance of the Three Rs (see Article 7.8.3.). Most scientists and members of the public agree that the animals should only be used when necessary; ethically justified (thereby avoiding unnecessary duplication of animal-based research); and when no other alternative methods, not using live animals, are available; that the minimum number of animals should be used to achieve the scientific or educational goals; and that such use of animals should cause as little pain and/or distress as possible. In addition, animal suffering is often recognised separately from pain and distress and should be considered alongside any lasting harm which is expected to be caused to animals.

The OIE emphasises the need for humane treatment of animals and that good quality science depends upon good animal welfare. It is the responsibility of all involved in the use of animals to ensure that they give due regard to these recommendations. In keeping with the overall approach to animal welfare detailed in the Guiding Principles, the OIE stresses the importance of standards based on outcomes for the animal.

The OIE recognises the significant role of veterinarians in animal-based research. Given their unique training and skills, they are essential members of a team including scientists and animal care technicians. This team approach is based on the concept that everyone involved in the use of animals has an ethical responsibility for the animals' welfare. The approach also ensures that animal use leads to high quality scientific and educational outcomes and optimum welfare for the animals used.

The OIE recommends that records on animal use should be maintained at an institutional level, as appropriate to the institution and project proposals and species used. Key events and interventions should be recorded to aid decision making and promote good science and welfare. A summary of these records may be gathered on a national basis and be published to provide a degree of public transparency, without compromising personnel or animal safety, or releasing proprietary information.

Article 7.8.1.

Definitions

Biocontainment: means the system and procedures designed to prevent the accidental release of biological material including allergens.

Bioexclusion: means the prevention of the unintentional transfer of adventitious organisms with subsequent infection of animals, resulting in adverse effects on their health or suitability for research.

Annex 36 (contd)Appendix VI (contd)

Biosecurity: means a continuous process of risk assessment and risk management designed to minimise or eliminate microbiological infection with adventitious organisms that can cause clinical disease in the infected *animals* or humans, or make *animals* unsuitable for biomedical research.

Cloned animal: means a genetic copy of another living or dead *animal* produced by somatic cell nuclear transfer or other reproductive technology.

Distress: means the state of an *animal*, that has been unable to adapt to stressors, and that manifests as abnormal physiological or behavioural responses. It can be acute or chronic and may result in pathological conditions.

Endangered species: means a population of organisms which is at risk of becoming extinct because it is either few in numbers, or threatened by changing environmental or predation parameters.

Environmental enrichment: means increasing the complexity (e.g. with toys, cage furniture, foraging opportunities, social housing, etc.) in a captive *animal's* environment to foster the expression of non-injurious species-typical behaviours and reduce the expression of maladaptive behaviours, as well as provide cognitive stimulation.

Ethical review: means consideration of the validity and justification for using *animals* including: an assessment and weighing of the potential harms for *animals* and likely benefits of the use and how these balance (see harm-benefit analysis below); and consideration of experimental design; implementation of the Three Rs; animal husbandry and care and other related issues such as personnel training. Ethical judgements are influenced by prevailing societal attitudes.

~~**Euthanasia:** means the act of inducing *death* using a method that causes a rapid and irreversible loss of consciousness with minimum pain and distress to the *animal*.~~

Harm-benefit analysis: means the process of weighing the likely adverse effects (harms) to the *animals* against the benefits likely to accrue as a result of the proposed project.

Humane endpoint: means the point in time at which an experimental *animal's* pain and/or distress is avoided, terminated, minimised or reduced, by taking actions such as giving treatment to relieve pain and/or distress, terminating a painful procedure, removing the *animal* from the study, or humanely killing the *animal*.

Operant conditioning: means the association that an *animal* makes between a particular response (such as pressing a bar) and a particular reinforcement that may be positive (for example, a food reward) or negative (e.g. a mild electric shock). As a result of this association, the occurrence of a specific behaviour of the *animal* can be modified (e.g. increased or decreased in frequency or intensity).

Pain: means an unpleasant sensory and emotional experience associated with actual or potential tissue damage. It may elicit protective actions, result in learned avoidance and distress and may modify species-specific traits of behaviour, including social behaviour.

Project proposal (sometimes called protocol): means a written description of a study or experiment, programme of work, or other activities that includes the goals of the work; characterises the use of the *animals*; and includes ethical considerations.

Suffering: means an unpleasant, undesired state of being, which is the outcome of the impact on an *animal* of a variety of noxious stimuli and/or the absence of important positive stimuli. It is the opposite of good *welfare*.

Proposed text by the ad hoc Group

Suffering: means an unpleasant, undesired state of being ~~which~~ that is the outcome of the impact on an *animal* of a variety of noxious stimuli and/or the absence of important positive stimuli. It is the opposite of good *welfare*

Article 7.8.2.

Scope

This chapter applies to *animals* as defined in the *Terrestrial Code* (excluding bees) bred, supplied and/or used in research (including testing) and higher education. *Animals* to be used for production of biologicals and/or humanely killed for harvesting their cells, tissues and organs for scientific purposes are also covered. Members should consider both the species and the developmental stage of the *animal* in implementing these standards.

Article 7.8.3.

The Three Rs

The internationally accepted tenet, the 'Three Rs', comprises the following alternatives:

1. replacement refers to the use of methods utilizing cells, tissues or organs of animals (relative replacement), as well as those that do not require the use of animals to achieve the scientific aims (absolute replacement);
2. reduction refers to the use of methods that enable researchers to obtain comparable levels of information from fewer animals or to obtain more information from the same number of animals;
3. refinement refers to the use of methods that prevent, alleviate or minimise pain, suffering, distress or lasting harm and/or enhance welfare for the animals used. Refinement includes the appropriate selection of relevant species with a lesser degree of structural and functional complexity in their nervous systems and a lesser apparent capacity for experiences that derive from this complexity. Opportunities for refinement should be considered and implemented throughout the lifetime of the *animal* and include, for example, housing and transportation as well as procedures and euthanasia.

Article 7.8.4.

The oversight framework

The role of a *Competent Authority* is to implement a system (governmental or other) for verification of compliance by institutions. This usually involves a system of authorisation (such as licensing or registering of institutions, scientists, and/or projects) and compliance, which may be assessed at the institutional, regional and/or national level.

The oversight framework encompasses both ethical review of animal use and considerations related to animal care and *welfare*. This may be accomplished by a single body or distributed across different groups. Different systems of oversight may involve *animal welfare* officers, regional, national or local committees or bodies. An institution may utilise a local committee (often referred to as Animal Care and Use Committee, Animal Ethics Committee, Animal Welfare Body or Animal Care Committee) to deliver some, or all, of this oversight framework. It is important that the local committee report to senior management within the institution, to ensure it has appropriate authority, resources and support. Such a committee should undertake periodic review of its own policies, procedures and performance.

Annex 36 (contd)Appendix VI (contd)

Ethical review of animal use may be undertaken by regional, national or local ethical review bodies or committees. Consideration should be given on how to ensure impartiality and independence from all those serving on the committees. In providing this oversight and ensuring the implementation of the Three Rs, the following expertise should be included as a minimum:

- a) one scientist with experience in *animal* research, whose role is to ensure that protocols are designed and implemented in accordance with sound science;
- b) one *veterinarian*, with the necessary expertise to work with research *animals*, whose specific role is to provide advice on the care, use and *welfare* of such *animals*;
- c) one public member to represent general community interests who is independent of the science and care of the *animals* and is not involved in the use of *animals* in research, where appropriate.

Proposed text by the *ad hoc* Group

Ethical review of animal use may be undertaken by regional, national or local ethical review bodies or committees. ~~Consideration should be given on how to ensure impartiality and independence from all those serving on the committees.~~ Consideration should be given as to how impartiality and independence from those with vested interests in the work is to be achieved

In providing this oversight and ensuring the implementation of the Three Rs, the following expertise should be included as a minimum:

- a) one scientist with experience in *animal* research, whose role is to ensure that protocols are designed and implemented in accordance with sound science;
- b) one *veterinarian*, with the necessary expertise to work with research *animals*, whose specific role is to provide advice on the care, use and *welfare* of such *animals*;
- c) one public member, where appropriate, to represent general community interests who is independent of the science and care of the *animals* and is not involved in the use of *animals* in research ~~where appropriate~~.

Additional expertise may be sought from the animal care staff, as these professional and technical staff are centrally involved in ensuring the *welfare* of *animals* used. Other participants, especially in relation to ethical review, may include statisticians, information scientists and ethicists and biosafety specialists, as appropriate to the studies conducted. It may be appropriate, in teaching institutions, to involve student representation.

Oversight responsibilities include three key elements:

1. Project proposal review

The purpose of the project proposal is to enable assessment of the quality of, and justification for, the study, work or activity.

Project proposals, or significant amendments to these, should be reviewed and approved prior to commencement of the work. The proposal should identify the person with primarily responsibility for the project and should include a description of the following elements, where relevant:

- a) the scientific or educational aims, including consideration of the relevance of the experiment to human or animal health or welfare, the environment, or the advancement of biological knowledge;

Annex 36 (contd)Appendix VI (contd)

- b) an informative, non-technical (lay) summary may enhance understanding of the project and facilitate the ethical review of the proposal by allowing full and equitable participation of members of the oversight body or committees who may be dealing with matters outside their specific field. Subject to safeguarding confidential information, such summaries may be made publicly available;
- c) the experimental design, including justification for choice of species, source and number of *animals*, including any proposed reuse;
- d) the experimental procedures;
- e) methods of handling and restraint and consideration of refinements such as animal training and operant conditioning;
- f) the methods to avoid or minimise pain, discomfort, distress, suffering or lasting impairment of physical or physiological function, including the use of anaesthesia and/or analgesia and other means to limit discomfort such as warmth, soft bedding and assisted feeding;
- g) application of humane endpoints and the final disposition of *animals*, including methods of euthanasia;
- h) consideration of the general health, husbandry and care of the species proposed to be used, including environmental enrichment and any special housing requirements;
- i) ethical considerations such as the application of the Three Rs and a harm/benefit analysis; the benefits should be maximised and the harms, in terms of pain and distress, should be minimized;
- j) an indication of any special health and safety risks; and
- k) resources/infrastructure necessary to support the proposed work (e.g. facilities, equipment, staff trained and found competent to perform the procedures described in the proposed project).

The oversight body has a critical responsibility in determining the acceptability of project proposals, taking account of the animal welfare implications, the advancement of knowledge and scientific merit, as well as the societal benefits, in a risk-based assessment of each project using live animals.

Following approval of a project proposal, consideration should be given to implementing an independent (of those managing the projects) oversight method to ensure that animal activities conform with those described in the approved project proposal. This process is often referred to as post approval monitoring. Such monitoring may be achieved through animal observations made during the conduct of routine husbandry and experimental procedures; observations made by the veterinary staff during their rounds; or by inspections by the oversight body, which may be the local committee, animal welfare officer, compliance/quality assurance officer or government inspector.

Annex 36 (contd)Appendix VI (contd)2. Facility inspection

There should be regular inspections of the facilities, at least annually. These inspections should include the following elements:

- a) the *animals* and their records, including cage labels and other methods of animal identification;
- b) husbandry practices;
- c) maintenance, cleanliness and security of the facility;
- d) type and condition of caging and other equipment;
- e) environmental conditions of the *animals* at the cage and room level;
- f) procedure areas such as surgery; necropsy and animal research laboratories;
- g) support areas such as washing equipment; animal feed, bedding and drug storage locations;
- h) occupational health and safety concerns.

Principles of *risk management* should be followed when determining the frequency and nature of inspections.

3. Ethical evaluation

The ethical evaluation reflects the policies and practices of the institution in complying with regulations and relevant guidance. It should include consideration of the functioning of the local committee; training and competency of staff; veterinary care; husbandry and operational conditions, including emergency plans; sourcing and final disposition of *animals*; and occupational health and safety. The programme should be reviewed regularly. A requirement for the components of such a programme should be included in relevant regulations to empower the *Competent Authority* to take appropriate action to ensure compliance.

Article 7.8.5.

Assurance of training and competency

An essential component of the animal care and use programme is the assurance that the personnel working with the *animals* are appropriately trained and competent to work with the species used and the procedures to be performed, including ethical considerations. A system (institutional, regional or national) to assure competency should be in place, which includes supervision during the training period until competence has been demonstrated. Continuing professional and paraprofessional educational opportunities should be made available to relevant staff. Senior management, given their overarching responsibility for the animal care and use programme, should be knowledgeable about issues related to the competence of staff.

1. Scientific staff

Researchers using *animals* have a direct ethical and legal responsibility for all matters relating to the *welfare* of the *animals* in their care. Due to the specialised nature of animal research, focused training should be undertaken to supplement educational and experiential backgrounds of scientists (including visiting scientists) before initiating a study. Focused training may include such topics as the national and/or local regulatory framework and institutional policies. The laboratory *animalveterinarian* is often a resource for this and other training. Scientific staff should have demonstrated competency in procedures related to their research (e.g. surgery, anaesthesia, sampling and administration, etc.).

2. Veterinarians

It is important that *veterinarians* working in an animal research environment have veterinary medical knowledge and experience in the species used, including the normal behaviour of the species, and they should understand research methodology. Relevant approvals issued by the *veterinary statutory body* and appropriate national or regional schemes (where these exist) should be adopted as the reference for veterinary training.

3. Animal care staff

Animal care staff should receive training that is consistent with the scope of their work responsibilities and have demonstrated competency in the performance of these tasks.

4. Students

Students should learn scientific and ethical principles using non-animal methods (videos, computer models, etc.) when such methods can effectively reduce or replace the use of live *animals* and still meet learning objectives. Wherever it is necessary for students to participate in classroom or research activities involving live *animals*, they should receive appropriate supervision in the use of *animals* until such time that they have demonstrated competency in the related procedure(s).

5. Members of the local oversight committee or others involved with oversight

Continuing education about the use of *animals* in research and education, including associated ethics, regulatory requirements and their institutional responsibility, should be provided.

Occupational health and safety training for research animal related risks should be provided as part of the assurance of training and competency for personnel. This might include consideration of human infectious *diseases* which may infect research *animals* and thus compromise research results, as well as possible *zoonoses*. Personnel should understand that there are two categories of hazards, those that are intrinsic to working in an animal facility and those associated with the research. Specific training may be required for particular species, for specific procedures, and for the use of appropriate protective measures for personnel who may be exposed to animal allergens. Research materials, such as chemicals of unknown toxicity, biological agents and radiation sources, may present special hazards.

Article 7.8.6.

Provision of veterinary care

Adequate veterinary care includes responsibility for promoting an *animal's* health and *welfare* before, during and after research procedures and providing advice and guidance based on best practice. Veterinary care includes attention to the physical and behavioural status of the *animal*. The *veterinarian* should have authority and responsibility for making judgements concerning *animal welfare*. Veterinary advice and care should be available at all times.

1. Clinical responsibilities

Preventive medicine programmes that include vaccinations, ectoparasite and endoparasite treatments and other disease control measures should be initiated according to currently acceptable veterinary medical practices appropriate to the particular animal species and source. Disease surveillance is a major responsibility of the *veterinarian* and should include routine monitoring of colony *animals* for the presence of parasitic, bacterial and viral agents that may cause overt or sub clinical *diseases*. The *veterinarian* should have the authority to use appropriate treatment or control measures, including euthanasia if indicated, and access to appropriate resources, following diagnosis of an animal *disease* or injury. Where possible, the *veterinarian* should discuss the situation with the scientist to determine a course of action consistent with experimental goals. Controlled drugs prescribed by the veterinary staff should be managed in accordance with applicable regulations.

Annex 36 (contd)Appendix VI (contd)2. Post-mortem examinations

In the case of unexpected *diseases* or *deaths*, the *veterinarian* should provide advice based on post-mortem examination results. As part of health monitoring, a planned programme of post-mortem examinations may be considered.

3. Veterinary medical records

Veterinary medical records, including post-mortem records, are considered to be a key element of a programme of adequate veterinary care for *animals* used in research and education. Application of performance standards within the veterinary medical record programme allows the *veterinarian* to effectively employ professional judgment, ensuring that the *animal* receives the highest level of care available.

4. Advice on zoonotic risks and notifiable diseases

The use of some species of *animals* poses a significant risk of the transmission of zoonotic *disease* (e.g. some nonhuman primates). The *veterinarian* should be consulted to identify sources of *animals* that minimise these risks and to advice on measures that may be taken in the animal facility to minimize the risk of transmission (e.g. personal protective equipment, appropriate *désinfection* procedures, air pressure differentials in animal holding rooms, etc.). *Animals* brought into the institution may carry *diseases* that require notification to government officials. It is important that the *veterinarian* be aware of, and comply with, these requirements.

5. Advice on surgery and postoperative care

A programme of adequate veterinary care includes input into the review and approval process of preoperative, surgical and postoperative procedures by an appropriately qualified *veterinarian*. A *veterinarian's* inherent responsibility includes providing advice concerning preoperative procedures, aseptic surgical techniques, the competence of staff to perform surgery and the provision of postoperative care. Veterinary oversight should include the detection and resolution of emerging patterns of surgical and post procedural complications.

6. Advice on analgesia, anaesthesia and euthanasia

Adequate veterinary care includes providing advice on the proper use of anaesthetics, analgesics, and methods of euthanasia.

7. Advice on humane endpoints

Humane endpoints should be established prior to commencement of a study in consultation with the *veterinarian* who also plays an important role in ensuring that approved humane endpoints are followed during the course of the study. It is essential that the *veterinarian* has the authority to ensure euthanasia or other measures are carried out as required to relieve pain and distress unless the project proposal approval specifically does not permit such intervention on the basis of the scientific purpose and the ethical evaluation.

Ideal humane endpoints are those that can be used to end a study before the onset of pain and/or distress, without jeopardising the study's objectives. In consultation with the *veterinarian*, humane endpoints should be described in the project proposal and, thus, established prior to commencement of the study. They should form part of the ethical review. Endpoint criteria should be easy to assess over the course of the study. Except in rare cases, death (other than euthanasia) as a planned endpoint is considered ethically unacceptable.

Article 7.8.7.

Source of animals

Animals to be used for research should be of high quality to ensure the validity of the data.

1. Animal procurement

Animals should be acquired legally. It is preferable that *animals* are purchased from recognised sources producing or securing high quality *animals*. Purpose bred *animals* should be used whenever these are available and *animals* that are not bred for the intended use should be avoided unless there is compelling scientific justification or are the only available and suitable source. In the case of farm *animals*, non traditional breeds and species, and *animals* captured in the wild, non purpose bred *animals* are often used to achieve specific study goals. The use of wild caught nonhuman primates is generally discouraged.

Proposed text by the *ad hoc* Group

Animals should be acquired legally. It is preferable that *animals* are purchased from recognised sources producing or securing high quality *animals*. The use of wild caught nonhuman primates is generally discouraged.

Purpose bred *animals* should be used whenever these are available and *animals* that are not bred for the intended use should be avoided unless there is compelling scientific justification or are the only available and suitable source. In the case of farm *animals*, non traditional breeds and species, and *animals* captured in the wild, non purpose bred *animals* are often used to achieve specific study goals. ~~The use of wild caught nonhuman primates is generally discouraged.~~

2. Documentation

Relevant documentation related to the source of the *animals*, such as health and other veterinary certification, breeding records, genetic status and animal identification, should accompany the *animals*.

3. Animal health status

The health status of *animals* can have a significant impact on scientific outcomes. There also may be occupational health and safety concerns related to animal health status. *Animals* should have appropriate health profiles for their intended use. The health status of *animals* should be known before initiating research.

4. Genetically defined animals

A known genetic profile of the *animals* used in a study can reduce variability in the experimental data resulting from genetic drift and increase the reproducibility of the results. Genetically defined *animals* are used to answer specific research questions and are the product of sophisticated and controlled breeding schemes which should be validated by periodic genetic monitoring. Detailed and accurate documentation of the colony breeding records should be maintained.

Annex 36 (contd)Appendix VI (contd)

5. Genetically altered (also genetically modified or genetically engineered) or cloned animals (~~also genetically modified animal and genetically engineered animal~~).

A genetically altered ~~or cloned~~ *animals* is one an animal that has had undergone genetic modification of its nuclear or mitochondrial genomes through a deliberate human intervention, or the progeny of such an *animal(s)*, where they have inherited the modification. If genetically altered or cloned *animals* are used, such use should be conducted in accordance with relevant regulatory guidance. With such *animals*, as well as harmful mutant lines arising from spontaneous mutations and induced mutagenesis, consideration should be given to addressing and monitoring special husbandry and *welfare* needs associated with abnormal phenotypes. Records should be kept of biocontainment requirements, genetic and phenotypic information, and individual identification, and be communicated by the animal provider to the recipient. Archiving and sharing of genetically altered lines is recommended to facilitate the sourcing of these customised *animals*.

6. Animals captured in the wild

If wild *animals* are to be used, the capture technique should be humane and should give due regard to human and animal health, *welfare* and safety. Field studies have the potential to cause disturbance to the habitat thus adversely affecting both target and non-target species. The potential for such disturbance should be assessed and minimised. The effects of a series of stressors, such as trapping, handling, transportation, sedation, anaesthesia, marking and sampling, can be cumulative, and may produce severe, possibly fatal, consequences. An assessment of the potential sources of stress and management plans to eliminate or minimise distress should form part of the project proposal.

7. Endangered species

Endangered species should only be used in exceptional circumstances where there is strong scientific justification that the desired outcomes cannot be achieved using any other species.

8. Transport, importation and exportation

Animals should be transported under conditions that are appropriate to their physiological and behavioural needs and pathogen status, with care to ensure appropriate physical containment of the *animals* as well as exclusion of contaminants. The amount of time *animals* spend on a journey should be kept to a minimum. It is important to ensure that there is a well constructed journey plan, with key staff identified who have responsibility for the *animals* and that relevant documentation accompanies *animals* during transport to avoid unnecessary delays during the journey from the sender to the receiving institution.

9. Risks to biosecurity

In order to minimise the risk of contamination of *animals* with unwanted infectious microorganisms or parasites that may compromise the health of *animals* or make them unsuitable for use in research, the microbiological status of the *animals* should be determined and regularly assessed. Appropriate biocontainment and bioexclusion measures should be practised to maintain their health status and, if appropriate, measures taken to prevent their exposure to certain human or environmental commensals.

Article 7.8.8.

Physical facility and environmental conditions

A well-planned, well-designed, well-constructed, and properly maintained facility should include animal holding rooms as well as areas for support services such as for procedures, surgery and necropsy, cage washing and appropriate storage. An animal facility should be designed and constructed in accordance with all applicable building standards. The design and size of an animal facility depend on the scope of institutional research activities, the *animals* to be housed, the physical relationship to the rest of the institution, and the geographic location. For indoor housing, non-porous, non-toxic and durable materials should be used which can be easily cleaned and sanitised. *Animals* should normally be housed in facilities designed for that purpose. Security measures (e.g. locks, fences, cameras, etc.) should be in place to protect the *animals* and prevent their escape. For many species (e.g. rodents), environmental conditions should be controllable to minimise physiological changes which may be potentially confounding scientific variables and of *welfare* concern.

Important environmental parameters to consider include ventilation, temperature and humidity, lighting and noise:

1. Ventilation

The volume and physical characteristics of the air supplied to a room and its diffusion pattern influence the ventilation of an *animals* primary enclosure and are thus important determinants of its microenvironment. Factors to consider when determining the air exchange rate include range of possible heat loads; the species, size, and number of *animals* involved; the type of bedding or frequency of cage changing; the room dimensions; and the efficiency of air distribution from the secondary to the primary enclosure. Control of air pressure differentials is an important tool for biocontainment and bioexclusion.

2. Temperature and humidity

Environmental temperature is a physical factor which has a profound effect on the *welfare* of *animals*. Typically, animal room temperature should be monitored and controlled. The range of daily fluctuations should be appropriately limited to avoid repeated demands on the *animals*' metabolic and behavioural processes to compensate for large changes in the thermal environment as well as to promote reproducible and valid scientific data. Relative humidity may also be controlled where appropriate for the species.

3. Lighting

Light can affect the physiology, morphology and behaviour of various *animals*. In general, lighting should be diffused throughout an animal holding area and provide appropriate illumination for the *welfare* of the *animals* while facilitating good husbandry practices, adequate inspection of *animals* and safe working conditions for personnel. It may also be necessary to control the light/dark cycle.

4. Noise

Separation of human and animal areas minimises disturbance to animal occupants of the facility. Noisy *animals*, such as dogs, pigs, goats and nonhuman primates, should be housed in a manner which ensures they do not adversely affect the *welfare* of quieter *animals*, such as rodents, rabbits and cats. Consideration should be given to insulating holding rooms and procedure rooms to mitigate the effects of noise sources. Many species are sensitive to high frequency sounds and thus the location of potential sources of ultrasound should be considered.

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Article 7.8.9.

Husbandry

Good husbandry practices enhance the health and *welfare* of the *animals* used and contributes to the scientific validity of animal research. Animal care and accommodation should, as a minimum, demonstrably conform to relevant published animal care, accommodation and husbandry guidelines and regulations.

The housing environment and husbandry practices should take into consideration the normal behaviour of the species, including their social behaviour and age of the *animal*, and should minimise stress to the *animal*. During the conduct of husbandry procedures, personnel should be keenly aware of their potential impact on the *animals' welfare*.

1. Transportation

Transportation is a typically stressful experience. Therefore, every precaution should be taken to avoid unnecessary stress through inadequate ventilation, exposure to extreme temperatures, lack of feed and water, long delays, etc. Consignments of *animals* should be accepted into the facility without avoidable delay and, after inspection, should be transferred to clean cages or pens and be supplied with feed and water as appropriate. Social *animals* should be transported in established pairs or groups and maintained in these on arrival.

2. Acclimatisation

Newly received *animals* should be given a period for physiological and behavioural stabilisation before their use. The length of time for stabilisation will depend on the type and duration of transportation, the age and species involved, place of origin, and the intended use of the *animals*. Facilities should be available to isolate *animals* showing signs of ill health.

3. Cages and pens

Cages and pens should be made out of material that can be readily cleaned and decontaminated. Their design should be such that the *animals* are unlikely to injure themselves. Space allocations should be reviewed and modified as necessary to address individual housing situations and animal needs (for example, for prenatal and postnatal care, obese *animals*, and group or individual housing). Both the quantity and quality of space provided is important. Whenever it is appropriate, social *animals* should be housed in pairs or groups, rather than individually, provided that such housing is not contraindicated by the protocol in question and does not pose an undue risk to the *animals*.

4. Enrichment

Animals should be housed with a goal of maximising species appropriate behaviours and avoiding or minimising stress induced behaviours. One way to achieve this is to enrich the structural and social environment of the *animals* and to provide opportunities for physical and cognitive activity. Such provision should not compromise the health and safety of the *animals* or people, nor interfere with the scientific goals.

5. Feeding

Provision should be made for each *animal* to have access to feed to satisfy its physiological needs. Precautions should be taken in packing, transporting, storing and preparing feed to avoid chemical, physical and microbiological contamination, deterioration or destruction. Utensils used for feeding should be regularly cleaned and, if necessary, sterilised.

6. Water

Uncontaminated potable drinking water should normally be available at all times. Watering devices, such as drinking tubes and automatic watering systems, should be checked daily to ensure their proper maintenance, cleanliness, and operation.

7. Bedding

Animals should have appropriate bedding provided, with additional nesting material if appropriate to the species. Animal bedding is a controllable environmental factor that can influence experimental data and animal welfare. Bedding should be dry, absorbent, non-dusty, non-toxic and free from infectious agents, vermin or chemical contamination. Soiled bedding should be removed and replaced with fresh material as often as is necessary to keep the animals clean and dry.

8. Hygiene

The successful operation of a facility depends very much on good hygiene. Special care should be taken to avoid spreading infection between animals through fomites, including through personnel traffic between animal rooms. Adequate routines and facilities for the cleaning, washing, decontamination and, when necessary, sterilisation of cages, cage accessories and other equipment should be established. A very high standard of cleanliness and organisation should also be maintained throughout the facility.

9. Identification

Animal identification is an important component of record keeping. Animals may be identified individually or by group. Where it is desirable to individually identify animals, this should be done by a reliable and the least painful method.

10. Handling

Staff dealing with *animals* should have a caring and respectful attitude towards the *animals* and be competent in handling and restraint. Familiarising *animals* to handling during routine husbandry and procedures reduces stress both to *animals* and personnel. For some species, for example dogs and non-human primates, a training programme to encourage cooperation during procedures can be beneficial to the *animals*, the animal care staff and the scientific programme. For certain species, social contact with humans should be a priority. However, in some cases handling should be avoided. This may be particularly the case with wild *animals*. Consideration should be given to setting up habituation and training programmes suitable for the *animals*, the procedures and length of projects.

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BASICS FOR TRAINING LABORATORY ANIMAL VETERINARIANS

1. Characterizing (defining) the Laboratory Animal Veterinarian (LAV)
2. This should be post-graduate training (i.e., to occur after completion of general veterinary training)
3. Distance learning, mentor programs will likely play a key role to reach the diversity of target countries
4. Ladder approach to the skills and knowledge *
5. Assessing competency
6. Resource issues (people, funding, and educational materials)
7. Translation strategy and accessibility of information
8. Ensuring veterinary training and skills matches researchers' needs so that veterinary participation is considered as a 'value added' by the scientist
9. Continuing professional development (CPD)
10. Regulatory authority appreciation of the need for specialised training for laboratory animal veterinarians
11. Partnership approach, between veterinarian and technician
12. Role within a team

*

The veterinarian should be skilled in diagnostics. Optimally, take the ACLAM Role Delineation Document (RDD) as a model for describing the necessary skills (for non-country-specific topics). (Dr W. White)

Knowledge of the moral and ethical use of laboratory animals (e.g., the 3Rs); knowledge of the regulations; basic surgical skills; research methodology; recognize clinical signs.

Training in protocol review, literature searches to assist the investigator in identifying the appropriate model, endpoints

Important for LAV to be familiar with the regulations in his/her own country and/or territory.

Impact of facility environmental factors on health and welfare of animals, to include biosecurity; effects of non-experimental variables.

Preventive medicine

Role of veterinarian in research team: brings to the team knowledge of and experience in working with: the regulatory framework of the country, as well as pharmacology, basic sciences and basic pathology.

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ILAR JOURNAL ARTICLE ASSIGNMENT

- 1) Introduction: Dr Bayne and Dr MacArthur Clark
 - a. Zurlo article
 - b. Convening of focus groups
- 2) Core knowledge and practical skills: Dr Demers, Dr Ouajdi, Dr Bayne, Dr Kurosawa
- 3) Delivery of Training: Dr Demers, Dr Bayne and Dr Pat Turner (regional conferences, mentors, distance learning)
- 4) Ladder approach: Dr Bayne, Dr Demers, Dr Rivera
- 5) Assessing competency: Dr Demers and Pat Turner
- 6) Accessibility and translation: Dr Rivera, Dr Kurosawa and Dr Demers
- 7) Recommendations
 - a. Team approach: J Dr Mac Arthur Clark and Dr Joubert
 - b. Conflict of interest: Dr Bayne and Dr Mac Arthur Clark
 - c. Standards development: Dr Bayvel
 - d. CPD: Dr Bayvel
- 8) Conclusions
 - a. WVY: Dr Bayvel
 - b. OIE: Dr Bayvel

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Article 7.8.10 (Under Development)

Transportation

Transportation is a typically stressful experience for *animals*. Therefore, every precaution should be taken to avoid unnecessary stress through inadequate ventilation, exposure to extreme temperatures, lack of feed and water, long delays, etc. In addition, *animals* should be transported under conditions that are appropriate to their physiological and behavioural needs and pathogen status, with care to ensure appropriate physical containment of the *animals* as well as exclusion of contaminants. The amount of time *animals* spend on a journey should be kept to a minimum. Consignments of *animals* should be accepted into the facility without avoidable delay and, after inspection, should be transferred to clean cages or pens and be supplied with feed and water as appropriate. Social *animals* should be transported in established pairs or groups and maintained in these on arrival.

1. An ethical review of the planned transport should occur during the broader review of the proposed use of the animals. (cross-ref to 7.8)
 - a) The source and transport of *animals* should be justified based on a scientific rationale or to obtain an animal of defined genetic or health status (e.g., a specialized colony located at a different institution, animals from a commercial breeder), with alternative sources considered.
 - b) The method, and route and duration of transport should be addressed with reference to the impact on the health and welfare of the animal.
 - c) The potential for delays in transportation should be anticipated and avoided through the development of a complete and well constructed journey plan.
2. The documentation required to accomplish the transport should be based on the OIE Model Veterinary Certificate for Movement of Live Animals (chapter 5.10) to facilitate the safe and efficient movement of the animals.
 - a) There should be assurance that complete, relevant and legible documentation accompanies *animals* during transport to avoid unnecessary delays during the journey from the sender to the receiving institution.
 - b) Newer technologies, such as electronic certificates that minimize errors in paperwork, and the potential consequent impediments to transport, should be implemented.
3. The journey plan and the monitoring of the transport, should always be under the general oversight of a veterinarian knowledgeable and experienced in the biology and needs of the particular species to ensure animal welfare is preserved throughout the journey.
 - a) The transportation of research animals should be managed so that the journey time is the shortest possible and most comfortable for the animal to minimize stress to the animal. Where journeys of some distance are involved, this is generally best achieved through air transport, preferably by direct routes where possible.
 - b) Some animals (e.g., genetically altered animals) may have special requirements that should be addressed by the veterinarian in the journey plan.
 - c) Issues of biosecurity and biosafety should always be addressed in the journey plan. (*Get input from Bill white*)

Annex 36 (contd)Appendix VIII

4. In accordance with the relevant OIE standards and regulations (e.g., IATA), an appropriate environment (e.g., container design and construction, temperature, food, and water) must be provided to the animal at the point of departure, throughout transport, and at the point of arrival.
 5. Personnel handling *animals* at the point of departure, throughout transport, and at the point of arrival, should be trained in the species-specific requirements of the animals, in good handling practices to facilitate the loading and unloading of *animals*, and in the husbandry and environmental requirements of *animals* being transported.
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