

Terrestrial Animal Health Standards Commission

September 2012 Report

USA Comments - recommended changes shown in blue font

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 education. Wherever the term “research” is used, it includes basic and applied research, testing and the production of biological materials; “education” includes teaching and training. 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 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 recognises that the use of live *animals* in research and education is a legitimate activity and, as a consequence, domestic and international transport of *animals* is essential to maintaining progress in advancing human and animal health. Such transport should be conducted in a legal manner, ensuring the safety of the *animal* and applying humane principles.

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.

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.

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 or distress is avoided, terminated, minimised or reduced, by taking actions such as giving treatment to relieve pain or distress, terminating a painful procedure, removing the *animal* from the study, or humanely killing the *animal*.

Laboratory animal: means an *animal* that is intended for use in research. In most cases, such *animals* are purpose-bred to have a defined physiological, metabolic, genetic or pathogen free status.

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 that is the outcome of the impact on an *animal* of a variety of noxious stimuli 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 or used in research (including testing) and higher education. *Animals* to be used for production of biologicals 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 utilising 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 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, or projects) and compliance which may be assessed at the institutional, regional 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 reports 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.

Ethical review of animal use may be undertaken by regional, national or local ethical review bodies or committees. Consideration should be given to ensuring the impartiality and independence of those serving on the committees.

Annex XVII (contd)

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.

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 primary 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;
- 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 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;

Annex XVII (contd)

- 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 minimised;
- 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.

- l) the duration of approval of a project should normally be defined and progress achieved should be reviewed in considering renewal of a project approval.

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.

Annex XVII (contd)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 or local regulatory framework and institutional policies. The laboratory *animal/veterinarian* 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. Furthermore, they should be educated and experienced in the normal behaviour, behavioural needs, stress responses and adaptability of the species, as well as research methodologies. 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. In exceptional circumstances, where species unfamiliar to the veterinarian are involved, a suitably qualified non-veterinary expert may provide advice.

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.

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.

Annex XVII (contd)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 minimise 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 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*. The use of wild caught nonhuman primates is strongly-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.

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.

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

A genetically altered *animals* is one 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 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.

Annex XVII (contd)8. Transport, importation and exportation

Animals should be transported under conditions that are appropriate to their physiological and behavioural needs and pathogen free 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.

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

See Article 7.8.10.

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*.

Annex XVII (contd)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.

Article 7.8.10.

Transportation

Transportation is a typically stressful experience for *animals*. Therefore, every precaution should be taken to avoid unnecessary stress caused by inadequate ventilation, exposure to extreme temperatures, lack of feed and water, long delays, etc. General recommendations are made in Chapters 7.3. and 7.4. "There may be a justifiable reason to transport animals whose welfare is compromised as a consequence of scientific procedures which the animals are under going or for which they are intended. "In such cases", every precaution should be taken to avoid further stress. In addition, *animals* should be transported under conditions and in *containers* that are appropriate to their physiological and behavioural needs and pathogen free status, with care to ensure appropriate physical containment and safety of the *animals*. ~~In the event of a delay,~~ A contingency plan which addresses any possible delays should be in place, and the name of an emergency contact person should be prominently displayed on the *container*.

Rationale: The United States does not believe that the three newly proposed sentences add anything new to the chapter. The first sentence which begins with «General recommendations» is already known. The second sentence beginning with “There may be a justifiable reason” is duplicative of the second and fifth paragraphs of the preamble. The third sentence beginning with “In such cases”, is just repeating the second sentence of this same Article 7.8.10., Transportation, that reads “Therefore, every precaution should be taken to avoid unnecessary stress caused by ... etc.” Therefore, we recommend their deletion.

- 1) The source of *animals* and therefore the mode and conditions of *transport* should be considered in the project proposal review described in point 1 c) of Article 7.8.4.
 - a) The consigner and consignee should coordinate the means, route and duration of *transport* with emphasis on the potential impact on the health and *welfare* of the *animal(s)*.
 - b) The potential for delays in transportation should be anticipated and avoided.
- 2) The documentation required for international *transport* should be based on the OIE Model Veterinary Certificate for International Trade in Laboratory Animals (Chapter 5.13.):
 - 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) Electronic certificates should be implemented, wherever possible.
- 3) There should be a well defined *journey* plan, commencing from the point when *animals* are placed in their *containers* until they are removed from the *containers* at their final destination:
 - a) The *journey* plan should be designed so that the time in transit is the shortest possible and most comfortable for the *animal*. Where *journeys* of some distance are involved, this is often best achieved through air transport, preferably by direct routes.
 - b) Key staff should be identified who have responsibility for the *animals* and have the authority for making decisions in unforeseen circumstances. Such staff should be contactable at all times.
 - c) The *journey* plan should be under the general oversight of a *veterinarian* or other competent person, knowledgeable and experienced in the biology and needs of the particular species. The following should specifically be addressed:
 - i) Some *animals*, such as genetically altered *animals* may have special requirements.
 - ii) Issues of biosecurity and bioexclusion, e.g. through *container* design and handling.

- 4) In accordance with Chapters 7.3. and 7.4. and IATA regulations, an appropriate environment, such as *container* design and construction, temperature, food, and water should be provided to the *animal* throughout the planned *journey*. Adequate supplies of food, water and bedding should be provided to accommodate a delay of at least 24 hours.

Annex XVII (contd)

- 5) Personnel handling *animals* throughout the planned *journey* should be trained in the basic needs of *animals* and in good handling practices for the species to facilitate the *loading* and *unloading* of *animals*.
- 6) Delivery
 - a) Consignments of *animals* should be accepted into the facility without avoidable delay and, after inspection, should be removed from their *containers* under conditions compatible with their pathogen free status.
 - b) They should then be transferred to clean cages or pens and be supplied with feed and water as appropriate.
 - c) Social *animals* transported in established pairs or groups should be maintained in these on arrival.

— Text deleted.