

Terrestrial Animal Health Standards Commission Report

USA Comments

March 2009

General Comment: Please note that throughout this document, the use of the “~~strikethrough~~” is intended to indicate deleted wording; the use of the “double underline” is meant to indicate the addition of new text.

USE OF ANIMALS IN RESEARCH, TESTING OR TEACHING

Preamble

The purpose of this Chapter is to provide standards for OIE Members to follow when formulating regulatory requirements for the use of live animals in research, testing or teaching¹. It is the responsibility of all scientists using animals to ensure that they give due regard to these standards in designing and implementing their research protocols.

The OIE recognises the vital role played by the use of live animals in research. The OIE Guiding Principles state that such use makes a major contribution to the wellbeing of people and animals and emphasise the importance of the Three Rs of Russell and Burch (1959). Most scientists and members of the public agree that the use of animals in science should cause as little pain and/or distress to animals as possible, and those animals should only be used when necessary. The OIE also recognises the need for humane treatment of sentient animals and that good quality science depends upon good animal welfare. In keeping with the overall approach to animal welfare, as detailed in the Guiding Principles, the OIE emphasises the importance of standards based on outcomes for the animal; this does not preclude the use of some design standards.

- **Rationale:** There have been instances where confusion regarding the interpretation of a performance standard has led to a lack of compliance. Therefore, the needs of animals may best be met if some component of engineering standards is used in addition to performance standards. Where possible, engineering standards should be established using performance data.

A system of animal research 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 these standards 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 central role of veterinarians in animal-based research. Given their unique training and skills, they are an essential member 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 in science leads to high quality scientific outcomes and optimum welfare for the animals used.

¹ Wherever the term “research” is used, it means “research, testing or teaching”.

Article 7.X.X.

Definitions

Animal Care and Use Committee (ACUC)

means a committee responsible for overseeing the care and use of animals within an institution, including ethical considerations. It is also sometimes called Animal Care Committee, Animal Ethics Committee, Ethical Review Committee or Institutional Animal Care and Use Committee.

Project Proposal

or protocol, means a written description of a study or experiment, programme of work, or other activities that includes the goals, characterises the use of the animals, and includes ethical considerations. The purpose of the *Project Proposal* is to enable [an](#) assessment ~~of the quality and integrity~~ of the study, work or activity.

- **Rationale:** Suggested typographical correction, to remove the duplicate comma after “study or experiment”. Additionally, it is recommended the phrase “quality and integrity” be deleted, as this could be open to various interpretations and may lead to inconsistent application of this definition.

Operant (Instrumental) conditioning

means the association that an animal makes between a particular response (such as pressing a bar) and a particular ~~reinforcement~~ [consequence](#) (for example, a food reward). 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).

- **Rationale:** In conditioning, animals associate responses with reinforcement or punishment. Therefore we recommend the use of “consequence” as more inclusive text.

Biological safety or biosafety

means the application of knowledge, techniques and equipment to prevent personal, laboratory and environmental exposure to potentially infectious agents or biohazards.

Biological containment or biocontainment

means the system and procedures designed to prevent the accidental release of biological material. The objective of biocontainment is to confine biohazards and to reduce the potential exposure of the laboratory worker, animals ~~or~~ [used in](#) other studies, persons outside of the laboratory, and the environment to potentially infectious agents.

- **Rationale:** Editorial suggestion for clarification.

Bioexclusion

means the prevention of the unintentional transfer of pathogenic organisms and subsequent infection of animals by human, vermin or other means.

Humane endpoint

means the point at which an experimental animal's pain and/or distress is avoided, terminated, minimized or reduced, by taking actions such as giving treatment to relieve pain and/or distress, terminating a painful procedure, ~~or~~ humanely killing the animal, or otherwise removing the animal from the study to reduce or eliminate pain and/or distress.

- **Rationale:** It is possible to set experimental endpoints that would result in no pain or distress to the animal (e.g., imaging showing metastasis before the tumours become too large), and these should also be considered. It is also possible to remove an animal from a study without having to kill it. For example, in experiments in which negative conditioning would continue, removal of the animal from the experiment is a valid option.

Genetically altered animal (GA animal)

means an animal that has had a random or targeted change in its nuclear or mitochondrial DNA achieved through a deliberate human technological intervention.

Harm-benefit analysis

~~means the process of weighing the likely adverse effects (harms) on the animals against the benefits likely to accrue as a result of the proposed project. The analysis should require more than just establishing that the benefit is likely to exceed the harms. The benefits should be maximised and the harms, in terms of animal use and suffering, should be minimised.~~

- **Rationale:** While it is noted that the concept of this definition is encompassed within the context of this document in various places, the term itself is not used anywhere else in this document. We recommend that the term be removed from the “Definitions” section to avoid any potential confusion. If the definition is retained and used in the document, we recommended that the second sentence be deleted as proposed: ~~“The analysis should require more than just establishing that the benefit is likely to exceed the harm”~~. This sentence could be open to various interpretations and thus lead to inconsistent application of this definition.

The Three Rs

means the internationally accepted philosophy of Russell and Burch (1959) for the use of animals in research. The Three Rs comprise:

- **replacement** which refers to methods ~~which~~ that do not require the use of animals to achieve the scientific aims;
- **Rationale:** Editorial suggestion for clarification.
- **reduction** which refers to methods that enable researchers to obtain comparable levels of information from fewer animals or to obtain more information from the same number of animals;
- **refinement** which refers to methods that prevent, alleviate or minimise known and potential pain, distress, discomfort or lasting harm and/or enhance animal welfare for the animals used; or which replace ~~higher animals~~ animals of high neurophysiological sensitivity with those animals of a significantly lower neurophysiological sensitivity which have less capacity to experience pain, distress, discomfort or lasting harm.
- **Rationale:** “Higher animals” is a term without scientific value. We recommend the additional text for clarification of the intent for the reader.

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 ~~aberrant~~ maladaptive behaviours, as well as provide cognitive stimulation.

- **Rationale:** The first change is suggested because animals living in confined groups may be or become incompatible and begin engaging in injurious “species-typical” aggression. This is not a desirable outcome. The second change is suggested because the term “aberrant behaviours” has no clearly defined meaning. “Maladaptive behaviours” is a term that is used in scientific literature.

Article 7.X.X.

Scope

These standards apply to animals as defined in the *Terrestrial Code* (excluding bees) bred, supplied and/or used in research, testing or teaching. Animals to be 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.

Article 7.X.X.

The Oversight Framework

The role of *Competent Authorities* is to implement a system (governmental or other) for verification of compliance by institutions. This usually involves a system of approval (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.

- **Rationale:** Editorial suggestion for clarification.

The framework for compliance should comprise three key elements:

1. Project Proposal review,
2. Facility Inspections; and
3. Animal Care and Use Programme (ACUP) Review.

Different systems of oversight may involve animal welfare officers, regional/local committees, or national bodies. One common system is for each institution using live animals for research to have an Animal Care and Use Committee (ACUC) that is responsible, at the institutional level, for ensuring compliance with applicable requirements regarding the use of live animals. ~~as well as cells, tissues and organs derived from live animals.~~

- **Rationale:** We recommend deleting the phrase at the end of the last sentence to clarify it is not intended that the ACUC have oversight responsibility for the use of cells, tissues and organs obtained from euthanized animals, but rather, for the use of the live animals only.

It is important that an ACUC should report to a senior individual within the institution to ensure the committee has an appropriate level of authority, resources and support; this senior individual must be able to ensure noncompliant items identified by the ACUC are corrected. An ACUC should undertake periodic review of its own policies, procedures and performance.

- **Rationale:** A major concern facing an oversight body is the need for resources from the institution. The first suggested change in the text makes clear this need. The second change points out that there must be one person at the research facility who can legally commit on behalf of the facility that the compliance requirements are being met. This type of reporting mechanism then precludes the misunderstanding that the ACUC is an “enforcement agent”.

In providing this oversight, the following expertise should be included, as a minimum:

- one scientist with experience in animal research, whose role is to ensure that protocols are designed and implemented in accordance with sound science;
- 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 the animals.
- a representative of the community (general public) not affiliated in any way with the facility other than as a member of the ACUC. This increases public confidence in the oversight process.
- **Rationale:** The inclusion of a nonaffiliated member on the ACUC not only increases public confidence in the oversight process, but it also ensures that the values of the community are brought to bear on ACUC decisions. While the roles of the scientist and the veterinarian focus on the specifics of protocol design and best practices for enhanced animal welfare, the community representative is an essential team member who bears witness to the manner in which animals are being used.

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 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 a student representative.

Care should be taken to ensure no one particular department is overly represented on the ACUC.

- **Rationale:** A balance of viewpoints within the ACUC creates an atmosphere more conducive to the thorough deliberative process necessary in this area.

1. Project Proposal Review

Project Proposals should be reviewed and approved prior to commencement of the research and when any significant changes occur during the research project, and should include a description of the following elements:

- **Rationale:** Research objectives and procedures within a project may change over time, as new data is gathered and analyzed. Any changes affecting the welfare of animals should be reviewed and approved by the oversight body prior to commencement.
 - a) the scientific aims;
 - b) the experimental design, including statistics where appropriate. If a statistical analysis is not appropriate, other justification for the proposed number of animals should be provided;

- **Rationale:** This justification for the number of animals to be used may be captured within the element considering the “application of the three R’s” stated below, however, it should be clearly delineated in the experimental design. Statistical analysis is an important component of experimental design in many, but not all, studies it can help determine how many animals are required to produce statistically significant scientific data. However, this is not useful in the design of pilot studies or research with descriptive endpoints such as anatomical experiments. Furthermore, in some cases a government agency may require that a specific number of animals be used in testing to meet regulatory requirements.
 - c) the experimental procedures;
 - d) methods of handling and restraint and consideration of alternatives such as animal training and operant conditioning;
 - e) the application of the Three R’s; including an assurance that non-animal methods were considered as an alternative approach to achieving the scientific goals of the project, and a written narrative description of the methods and sources used to determine that alternatives were not available.
- **Rationale:** Detailed examples of reduction are recommended under b), and examples of refinement are provided under d), f), g) and h). The suggested changes here provide for an equal emphasis on replacement, as well as guidance on the process of addressing the application of the Three R’s.
 - f) the methods to avoid or minimise pain, discomfort, distress or lasting impairment of physical or physiologic function, including the use of anaesthesia and/or analgesia;
- **Rationale:** Editorial suggestion for correction, to remove the duplicate comma after “physiologic function”.
 - g) application of humane endpoints and the final disposition of animals, including methods of euthanasia and carcass disposal;
- **Rationale:** To ensure biosafety and biocontainment, it is appropriate to include a specific direction that project proposals should include attention to methods of carcass disposal.
 - h) consideration of the husbandry and care of the species proposed to be used, including environmental enrichment and any special housing requirements;
 - i) consideration of the relevance of the experiment to human or ~~anima~~ animal health or the advancement of biologic knowledge;
- **Rationale:** Editorial suggestion to correct the spelling of “animal”.
 - j) an assessment for any occupational health and safety risks; and
 - k) resources/infrastructure necessary to support the proposed work (e.g. facilities, equipment, qualified staff).

The provision of a non-technical (lay) summary may enhance understanding of the 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. There should be a written assurance from the scientist that the proposal does not unnecessarily duplicate previous experiments.

- **Rationale:** This may be captured within the element considering the “application of the three R’s”, but if so, should be more clearly delineated to ensure this form of reduction is addressed.

Following approval of a project proposal, consideration should be given to implementing an oversight method to ensure that animal activities conform to those described in the approved project proposal.

2. Facility inspection

There should be regular inspections of the facilities. These inspections should include the following elements:

- a) the animals and their records, including cage labels and other methods of animal identification;
- **Rationale:** A variety of methods (e.g., tattoos, microchips), in addition to cage labels, are appropriately used to identify animals. What method is most appropriate will depend on animal type and housing design, and the need for (and appropriateness of) identifying individual animals as compared with groups of animals.
- b) husbandry practices;
 - c) maintenance and cleanliness and security of the facility;
 - d) type and condition of caging and other equipment;
 - e) environmental conditions;
 - f) occupational health and safety concerns.

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

3. Animal Care and Use Programme (ACUP) Review

Critical elements of the Animal Care and Use Programme (ACUP) should be included in relevant regulations to empower the government authority to take appropriate action to ensure compliance. The ACUP should be reviewed regularly to include the following:

- a) training and competency of all staff;
 - b) the programme of veterinary care;
 - c) husbandry and operational conditions (including contingency plans);
- **Rationale:** Research facilities should be prepared to care for their animals during a natural disaster or other emergency, to ensure continued humane treatment, under what may be less than optimal conditions.

- d) sourcing and final disposition of animals; and
- e) occupational health and safety programme.

A requirement for keeping records on animal use, as appropriate to the institution, project proposal and species, should be included. It may be appropriate to maintain such records on a regional or national basis and to provide some degree of public access without compromising personnel or animal safety, or releasing proprietary information.

Article 7.X.X.

Assurance of Training and Competency

An essential component of the ACUP is the assurance that the personnel working with the animals are appropriately trained and qualified to work with the species used and the procedures to be performed. A system (institutional, regional or national) to assure competency should be in place. Continuing professional and paraprofessional educational opportunities should be made available to relevant staff.

- **Rationale:** Editorial suggestion to change “education” to “educational” for clarification.
- a) ~~Scientists~~ Scientific Staff. 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, institutional policies and ethical considerations. The laboratory animal veterinarian is often a resource for this and other training. ~~Competency in performance of procedures related to the scientist’s research (e.g., surgery, anaesthesia, sampling and administration, etc.) should be verified.~~ Scientific staff should have demonstrated competency in procedures related to their research (e.g., surgery, anaesthesia, sampling and administration, etc.).
 - **Rationale:** The first change is suggested in order to be more inclusive of the research personnel who may be working with the animals. The second change is suggested to create consistency with the language used under d) for “Students”, below, in that demonstrated competency should be the requirement for assessing training.
- b) Veterinarians. It is important that veterinarians working in an animal research environment have veterinary medical knowledge, ethological knowledge and experience in the species used and they should understand research methodology. Relevant approvals issued by the *Veterinary statutory body* and appropriate national schemes (where these exist) should be adopted as the reference for veterinary training.
 - **Rationale:** It is important for veterinarians to not only have medical knowledge, but to also have ethological knowledge such that they are familiar with the typical behaviour and behavioural needs of the species used, in order to adequately assess the “behavioural status of an animal”, included under Provision of Veterinary Care. The change from “methodology” (meaning the study of methods) to the word “methods” is an editorial suggestion for clarification.
- c) Animal Care Staff. Animal care staff should receive training that is consistent with the scope of their work responsibilities ~~and their competency in the performance of these tasks should be verified~~ and have demonstrated competency in the performance of these tasks.
 - **Rationale:** The suggested wording change is consistent with the language used under d) for “Students”, below.

- d) ~~Students. Wherever possible, students should learn scientific and ethical principles using non-animal methods (videos, computer models, etc).~~ Students should learn scientific and ethical principles using nonanimal methods (videos, computer models, etc) when such methods can effectively replace the use of animals and still meet learning or instruction objectives. Wherever it is necessary for students to participate in classroom or research activities involving animals, they should receive appropriate supervision in the use of animals until such time that they have demonstrated competency in the related procedure(s).
- **Rationale:** The suggested change emphasizes the need to ensure the learning or instructive objectives are met. For example, veterinary technician students must handle live animals to gain competency in proper handling and restraint techniques, which will prevent unnecessary pain or distress to animals later in their career.

Article 7.X.X.

Provision of Veterinary Care

Adequate veterinary care includes responsibility for promoting and monitoring an animal's welfare before, during and after research. Veterinary care includes attention to the physical and behavioural status of the animal. The veterinarian must have ~~the~~ authority and responsibility for making judgements concerning animal welfare.

- **Rationale:** Removing the word "the" from the sentence allows for the ACUC or other oversight body to share both authority and responsibility for animal welfare with the veterinarian.
- a) 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 subclinical diseases. The veterinarian must 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. ~~The veterinarian has the responsibility to ensure that~~ Controlled drugs prescribed by the veterinary staff must be managed in accordance with applicable national, regional and local regulations.
- **Rationale:** Editorial correction to remove the space between “sub” and “clinical”. In addition, there is concern the original language gives the veterinarian more responsibility than allowed by law in some locales, where regulations mandate that scientists maintain primary responsibility for drugs used on their animals.
- b) Veterinary Medical Records. Medical records are considered to be a key element of a programme of adequate veterinary care for animals used in research, teaching, and testing. Application of performance standards within the medical record program allows the veterinarian to effectively employ professional judgment, ensuring that the animal receives the highest level of care available.
- c) 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 minimize these risks and to advise on measures that may be taken in the animal facility to minimize the risk of transmission

(e.g., personal protective equipment, 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 complies, with these requirements.

- **Rationale:** Added a comma for editorial clarity after “and complies”.
- d) 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 monitoring, and providing recommendations concerning, preoperative procedures, aseptic surgical techniques, the qualifications of institutional staff to perform surgery and the provision of postoperative care.
- e) Advice on [handling and restraint](#), analgesia and anaesthesia. Adequate veterinary care includes providing guidance to animal users and monitoring animal use to ensure that appropriate methods of handling and restraint are being used as well as the proper use of anaesthetics, analgesics, tranquilizers, and methods of euthanasia for all species.
 - **Rationale:** The explanatory paragraph following the heading specifically addresses handling and restraint, in addition to analgesia and anesthesia. These are understood to be related, but are not equivalent.
- f) Advice on humane endpoints and euthanasia. Endpoints are established for both experimental and humane reasons. An experimental endpoint is chosen to mark the planned end of an experimental manipulation and associated data gathering. In experiments with unrelieved or unanticipated pain/or distress, humane endpoints are criteria that indicate or predict pain, distress, or death and are used as signals to end a study early to avoid or terminate pain and/or distress. Ideal endpoints are those that can be used to end a study before the onset of pain and/or distress without jeopardizing the study’s objectives. However, in most cases, humane endpoints are developed and used to reduce the severity and duration of pain and/or distress. [Humane endpoints should be established prior to commencement of a study concomitant with development of the experimental design. Pilot studies may be helpful in guiding the development of humane endpoints when a completely novel protocol is proposed.](#)
 - **Rationale:** Recommended this additional language for clarification purposes, to emphasize establishing humane endpoints in the planning stage of a protocol, and to provide an example of one method by which an endpoint may be determined.

The veterinarian and the ACUC where applicable, have a key role in ensuring that approved humane endpoints are followed during the course of the study. It is essential that the veterinarian have the responsibility and authority to ensure [appropriate treatments, including but not limited to](#), euthanasia ~~is~~ 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.

- **Rationale:** Treatments to ensure a humane endpoint are not limited to euthanasia, but may include cessation of an experiment or activity or provision of appropriate medication or analgesia.

Article 7.X.X.

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 dedicated to, or assigned for, that purpose. Security measures (e.g., locks, fences, cameras, etc.) should be in place to protect ~~the animals from removal, prevent contact with feral animals, protect animals from predators~~ 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.

- **Rationale:** A more complete explanation of the types of security measures is needed to help emphasize their importance and the intent of the guideline.

Article 7.X.X.

Source of animals

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

- a) Animal procurement. Animals ~~should~~ must be acquired legally. It is preferable that animals are purchased from recognised sources producing or securing high quality animals.
- **Rationale:** It would be an enormous breach of public trust not to mandate that animals used in research be legally obtained.

~~Purpose bred animals should be used whenever these are available and animals that are not bred for the intended use should be avoided unless scientifically justified or the only available source.~~
The use of non purpose bred animals, including farm animals, non-traditional breeds and species, and animals captured in the wild, is sometimes necessary to achieve study goals.
Purpose bred animals should be used when they are available and animals that are not purpose bred for the intended use should only be used when scientifically justified or when other sources are unavailable.

- **Rationale:** This change in wording is recommended to emphasize the importance of scientific necessity in selecting the appropriate animal model.
- b) Documentation. Relevant documentation related to the source of the animals, including health and other certification, breeding records, genetic status and animal identification, should accompany the animals.
 - c) 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.

- d) 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 must be validated by periodic genetic monitoring, typically using biochemical or immunological markers. Detailed and accurate documentation of the colony breeding records must be maintained
- e) Genetically altered animals. If genetically altered animals are used, such use should be conducted in accordance with relevant regulatory guidance. Consideration should be given to monitoring and addressing special husbandry and welfare needs associated with abnormal phenotypes. Records should be kept of biocontainment requirements, genetic information, and individual identification, and be communicated by the animal provider to the recipient.
- **Rationale:** The creation of novel genetic alterations in animals may result in unanticipated harms, thus the need to monitor for unexpected results as well as addressing them if they should occur is indicated to ensure the humane treatment of the animals.
- f) 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 and safety. Endangered species should only be used in exceptional circumstances where there is strong scientific justification that desired outcomes which cannot be achieved with using any other species.
- **Rationale:** Editorial suggestions for clarification.
- g) 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 relevant documentation accompanies animals during transport to avoid unnecessary delays during the *journey* from the sender to the receiving institution.
- h) Biosecurity risks. To reduce biosecurity risks related to animals, the pathogen status of animals should be confirmed and appropriate biocontainment and bioexclusion measures should be practised. Biosecurity risks to animals arising from exposure to humans should also be addressed.

Article 7.X.X.

Husbandry

General comment—As in previous drafts, there appears to be an overemphasis on behavior in this section with insufficient attention paid to equally critical issues such as health, disease, and injury.

High standards of care and accommodation 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 national or international animal care, accommodation and husbandry guidelines.

- a) 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 animal transportation, the species involved, place of origin, and the intended use of the animals.

- b) Normal Behaviour Species-specific needs. The housing environment and husbandry practices should provide adequate food and water and take into consideration the normal behaviour of the species and age and species-specific needs of the animal to minimise stress to the animal.
- **Rationale:** The term “normal behaviour” may be misunderstood in the context of captive animal welfare. Recommend substituting the term “species-specific needs”, which can also address the requirements for food and water. Behavioural needs are addressed under the “enrichment” section that follows.
- c) Enrichment. Animals should be housed with a goal of maximising species-specific behaviours and minimising or avoiding stress-induced behaviours. One way to achieve this is to enrich the structural and social environment of the research 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 significantly interfere with the scientific goals.
- **Rationale:** The first change is suggested because avoiding stress-induced behaviours is a worthy goal that then eliminates the need to treat or minimise any resulting maladaptive behaviours. The second change is recommended to clarify that providing enrichment should not be an obstacle in achieving the scientific goals of the experiment.

Article 7.X.X.

General comment—Although obviously an important consideration in the performance of duties associated with conducting research, testing and teaching, “occupational health and safety” is not actually an animal welfare concern (other than that caretaker health and well-being affects how caretakers are able to interact with their animal charges). For this reason, we wonder whether this discussion is appropriately included in guidelines that are developed to ensure animal welfare in OIE member countries?

Occupational Health and Safety

Institutional occupational health and safety programmes should be developed and implemented to protect personnel from workplace hazards. National or state legislation should requires employers to provide a safe working environment for staff. In addition to national or state legislative requirements, particular precautions need to be in place for those involved in the care and use of animals. These measures should extend to animal users, animal care staff, students, and others who may be exposed to animals or animal by products.

- **Rationale:** While desirable, it is not clear that all OIE member countries have laws in place that require employers to provide safe working environments for employees. This should therefore be stated as a recommendation, rather than a fact.

Occupational health and safety training for animal related risks should be provided as part of the assurance of training and competency for personnel. Specific training may be required for particular species, and for specific procedures/studies involving animals.

- a) Infectious diseases. To protect personnel, all infectious diseases or potentially infectious diseases within the institution, including zoonoses, should be identified.
- i) Biological Hazards

Hazards can arise from pathogens that are endemic to the particular animals as well as from pathogens (bacteria, viruses, parasites, fungi, prions) that have been brought into an institution for research purposes. National or state regulations or guidelines for working with biological hazards (biohazards) must be followed. These should include requirements for biocontainment, laboratory design, personal hygiene and safety. Any ~~biozardous~~ biohazardous materials should be labelled as such. Necropsy of animals with highly infectious agents should be carried out in certified biological safety cabinets or other containment environments dictated by the agent and the size of the animal. Animals, animal waste and carcasses should be disposed of appropriately, depending on the pathogenicity of the organisms to which they have been exposed. Material contaminated with highly infectious agents should be decontaminated before disposal.

- **Rationale:** The first change is an editorial correction of the spelling of “biohazardous”. The second change clarifies that not all animals will fit in a biological safety cabinet, and other containment devices may be appropriate depending on the size of the animal, agent under study, and other local considerations.

ii) Zoonoses

The institutional veterinarian(s) should be able to provide input to the occupational health and safety program concerning any zoonoses (infections that are ~~secondarily~~ transmitted from between animals ~~to~~ and humans) that might be contracted from or transmitted to the species used by the institution. He/she should also be able to provide advice on the measures needed to protect those involved with the animals. These may include personal protective equipment, vaccination, special restrictions for vulnerable employees (e.g., pregnant women). In general, the closer phylogenetically a species is to humans, the greater the likelihood of zoonoses.

- **Rationale:** Transmission of zoonoses is bidirectional, not unidirectional. Although the focus of this section is human health and safety, we do not believe the meaning of the term should be obscured, particularly when it is important that those involved in using animals for research, testing, and teaching understand that some animals can become ill (or at least infected) from exposure to their caretakers as well as the reverse. This seems particularly important if this section of the Chapter is to be made germane to animal welfare.

Particular precautions should be taken when working with non-human primates

b) Allergies

Individuals exposed to laboratory animals run a risk of developing allergies. Protective measures should be in place for personnel who may be exposed to animal allergens. These should include:

Environmental control and air handling systems to control air flow and contain allergens in the areas where the animals are housed and/or used;

Personal protective equipment such as masks, gloves and clothing dedicated to animal rooms;

Equipment such as filtered bedding disposal units and ~~ventilated hoods~~ biological safety cabinets or other containment devices for carrying out procedures;

- **Rationale:** Ventilated hoods are specifically designed for containment of hazardous materials; biological safety cabinets or other equivalent devices are more portable, less expensive, and equally adequate for the intended purpose of controlling exposure to animal allergens.

Use of filtered transfer cages when transporting animals through spaces where individuals are not required to wear protective gear and where dissemination of allergens could pose hazards to human health.

- **Rationale:** The addition of the underlined phrase provides criteria to determine when the use of filtered cages is necessary.

c) Physical injuries

Injuries that can be incurred as a result of handling animals include: bites, scratches, or being kicked, stepped on or crushed by larger species. These injuries can be minimized by training animals to cooperate during procedures and ensuring that all personnel are: competent to handle the animals; aware of the particular hazards associated with each species; familiar with the hazards of the experiment; ~~are~~ provided with a proper working area and protective clothing; and have access to and use the appropriate restraining equipment or drugs. A mechanism should be in place to deal with animal inflicted injury, including referral for further medical treatment. Cuts, bites, scratches or needle punctures acquired while working with non-human primates require particular attention and should be reported to the medical authority designated by the institution.

- **Rationale:** There is literature demonstrating that animals who voluntarily cooperate during procedures have no reason to show aggressive defence reactions that could possibly injure the handler; hence, physical injuries are minimized through the implementation of training protocols that encourage the research subject to cooperate rather than resist during handling. The second change (removing the word “are”) is an editorial suggestion to preserve parallel sentence structure.

Other physical injuries can occur as a result of working in a laboratory animal facility (e.g. burns, injuries from lifting animals or heavy equipment, repetitive strain injuries). These should be minimized through the implementation of an occupational health and safety programme, which examines the workplace hazards and ensures that adequate safeguards are in place for personnel.

d) Chemical injuries

There are potentially hazardous materials involved in most animal-based studies. These include drugs; cleaning agents and chemical compounds used for research studies. All hazardous substances must be labelled appropriately. The relevant national or state authority should provide licences to veterinarians or scientists requiring access to drugs for animal based studies. Licence holders are thereby responsible and liable for the use of substances purchased by them. Drugs must be handled, stored and used according to the requirements of national or state legislation.

Material Safety Data Sheets should be made available to personnel who are likely to come into contact with hazardous materials. Personnel should also be trained to use hazardous materials safely.

- **Recommendation for clarification:** It is not clear that the meaning of the phrase “material safety data sheet” will be universally understood by all member countries, particularly if there is no requirement to create such information under that country’s laws. Suggest that a definition be provided in this document.

e) Radiation

Where radioactive materials are to be used, the national governmental authority responsible for nuclear safety should be informed. National Governmental authorities should require personnel

to obtain a licence and should impose restrictions on the use of radioisotopes. A radiation safety officer should be designated within the institution to be responsible for radioactive material use and disposal. Strict measures should be in place to limit and contain radioactive contamination, including appropriate signage and limiting access to rooms containing radioactive material. Strict measures should also be in place to protect personnel working with radioactive animals, and staff in the vicinity, from exposure to the animals, animal wastes and carcasses.

- **Rationale:** Nuclear safety may be regulated at various (and multiple) levels of government in member countries; therefore, the general term ‘governmental’ is more appropriate.

Article 7.X.X.

Postapproval Monitoring

The institution should ensure that a culture of compliance exists within the animal care and use programme. Key to that compliance is assuring that studies are conducted in accordance with the written description in the project proposals that has been approved by the oversight body (animal care and use committee, government agency, etc.). The focus of postapproval monitoring is to determine what happens to the animals after approval of the work has been granted and the study is underway. Such monitoring may be achieved through animal observations made during the conduct of routine husbandry procedures; observations made by the veterinary medical staff during their rounds; or by inspections by an animal care and use committee, animal welfare officer, compliance/quality assurance officer or government inspector.

- **Rationale:** Editorial suggestions that “project proposal” should be singular, and to remove the space between “post” and “approval”.

General Comment: Strongly recommend that the list of references remain as a component of this document in its final form and that the references be organized by topic or application to assist utilization.

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European Commission guidelines for the accommodation and care of animals used for experimental and other scientific purposes,

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- **Rationale:** Ready access to reference materials of relevance will help promote the ‘assurance of training and competency’ of research personnel.