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Michael David, MS, VMD, MPH
 USDA-APHIS-VS
 Sanitary International Standards Team
 Riverdale, MD

Dear Dr. David:

The AVMA appreciates the opportunity to provide comments on the following report extracted from the March 2009 meeting of the Terrestrial Animal Health Standards Commission: a proposed Chapter in the Terrestrial Animal Health Code (TAHC), currently under development as **CHAPTER 7.X—USE OF ANIMALS IN RESEARCH, TESTING, OR TEACHING**. As requested, our responses are formulated for each section of the proposed Chapter as suggested revised language and comments followed by our rationale for the change. When language revision is suggested, recommended deletions are ~~struck through~~, recommended additions are underlined.

Definitions

Biological containment or biocontainment, sentence two—“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.

The three Rs, replacement—“replacement which refers to methods ~~which that~~ do not require the use of animals to achieve the scientific aims;” Rationale—Editorial suggestion.

The Oversight Framework

1. Project Proposal Review; f)—“the methods to avoid or minimise pain, discomfort, distress or lasting impairment of physical or psychologic function,⁵ including the use of anaesthesia and/or analgesia;” Rationale—Editorial suggestion to delete extraneous comma.

1. Project Proposal Review; g)—“application of humane endpoints and the final disposition of animals, including methods of euthanasia and body disposal;” Rationale—To ensure biosafety and biocontainment, we believe it appropriate to include a specific direction that project proposals should include attention to methods of body disposal.

1. Project Proposal Review; i)—“consideration of the relevance of the experiment to human or animal health or the advancement of biologic knowledge;” Rationale—Typographical error, missing ‘l’ in ‘animal.’

2. Facility Inspection; 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.

Assurance of Training and Competency

Paragraph 1, sentence 3—“Continuing professional and paraprofessional educational opportunities should be made available to relevant staff.” Rationale—Editorial suggestion.

b) Veterinarians, sentence one—“It is important that veterinarians working in an animal research environment have veterinary medical knowledge and experience in the species used and they should understand research methodology.” Rationale—Editorial suggestion. ‘Methodology’ means ‘the study of methods’; therefore, ‘methods’ is a more appropriate word choice.

Provision of Veterinary Care

a) Clinical Responsibilities, sentence 2—“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.” Rationale—Editorial revision to remove space between ‘sub’ and ‘clinical.’

c) Advice on zoonotic risks and notifiable diseases, sentence 4—“It is important that the veterinarian be aware of, and complies with, these requirements.” Rationale—Editorial revision to add missing comma.

e) “Advice on handling and restraint, analgesia and anaesthesia.” 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 not equivalent.

Concluding paragraph, sentence 2—“It is essential that the veterinarian have the responsibility and authority to ensure appropriate treatments, including but not limited to euthanasia, are carried out as required to relieve pain and distress unless the *Project Proposal* approved 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.

Source of animals

a) Animal procurement, sentence 1—“Animals ~~should~~must be acquired legally.” Rationale—We believe the legal acquisition of animals is a ‘must,’ rather than a ‘should.’

f) Animals captured in the wild, sentence 2—“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.

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.

Occupational Health and Safety

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 really 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?

Paragraph one, sentence 2—“National or state legislation should requires employers to provide a safe working environment for staff.” 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.

a) Infectious diseases; ii) Zoonoses, sentence 1—“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.” 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.

c) Physical injuries, sentence 2—“These injuries can be minimized by 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.” Rationale—Editorial suggestion to preserve parallel sentence structure.

d) Chemical injuries, paragraph 2, sentence 1—“Material Safety Data Sheets should be made available to personnel who are likely to come into contact with hazardous materials.” Question—Should ‘material safety data sheet’ be defined? It is not clear to us that the meaning of this phrase will be universally understood by all member countries, particularly if there is no requirement to create such information under that country’s laws.

e) Radiation, sentences 1 and 2—“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 license and should impose restrictions on the use of radioisotopes.” Rationale—Nuclear safety may be regulated at various (and multiple) levels of government in member countries; therefore, we believe use of the general term ‘governmental’ is more appropriate.

Section title (~~Post-Approval~~Postapproval Monitoring) and sentence 3—“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.” Rationale—Editorial suggestion; ‘post’ is a prefix.

Postapproval Monitoring, sentence 2—“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, governmental agency, etc.) Rationale—Editorial suggestion; should be singular.

As always, we appreciate the opportunity to provide input. Should you have questions or require additional information about our comments, please do not hesitate to contact Dr. Gail Golab, Director of our Animal Welfare Division. She may be reached at the phone number provided in the letterhead (ext. 6618), on her direct line at 847-285-6618 or via e-mail at ggolab@avma.org.

Sincerely,

A handwritten signature in black ink that reads "W. Ron DeHaven". The signature is written in a cursive style with a large, stylized initial "W".

W. Ron DeHaven, DVM, MBA
Executive Vice President and Chief Executive Officer