

APHIS Animal Care Stakeholder Update on Revised Policies

March 7, 2006

As part of its mission, the Animal Care (AC) program of the Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) is charged with providing leadership in determining standards of humane care and treatment of animals. As a result, AC must identify and address any emerging issues where guidance and clarity on humane care regulations may be needed. AC recently revised several of its policies on licensing and registration of certain facilities and on the roles of members serving on Institutional Animal Care and Use Committees.

Policy #10 Revision

In February 2005, the American Anti-Vivisection Society (AAVS) petitioned AC to examine its regulatory authorities under the Animal Welfare Act (AWA) in regard to pet cloning companies, as well as facilities that conduct genetic engineering of animals. While the role of AC is not to determine whether animals should be used in research, AC does have the authority to set and enforce standards for the humane treatment and care of those animals. We have responded to AAVS' petition and would like to outline the role AC will play in the regulation of genetically engineered and cloned animals.

AC has determined that a facility conducting genetic engineering that results in a live (whole) animal species covered by the AWA should be regulated as a research facility under the AWA. As such, these researchers are expected to be registered with USDA, meet AWA requirements, and have Institutional Animal Care and Use Committees to oversee and approve their protocols. Furthermore, the welfare of genetically engineered animals is protected by the AWA when the animals are used in other regulated activities (i.e., dealing or exhibition).

AC has also determined that the act of cloning an animal does not alone determine if a facility must be licensed or registered with USDA. A facility producing cloned animals is considered to be breeding animals, and if they are being utilized for an AWA-regulated purpose (such as selling to pet stores or for exhibition), the facility must be licensed. AC will review other activities conducted by cloning companies on a case-by-case basis to determine whether a facility is conducting an activity regulated by the AWA that requires licensure or registration.

Finally, Policy #10 has been updated to differentiate between certain activities of licensed exhibitors. Licensed exhibitors that collect information on their animals in order to improve breeding, management, or care of the animals may be exempt from registration requirements if they meet certain criteria outlined in the policy. However, if a licensed exhibitor is conducting biomedical research (using animals as models for human applications), conducting invasive or painful/distressful procedures for nonhusbandry purposes, or if the research involves domestic dogs and cats, then the licensee must also be registered as a research facility with USDA.

Policy #15 Revision

All research facilities regulated by the AWA are expected to have Institutional Animal Care and Use Committees (IACUCs) to oversee and approve their protocols to ensure that adequate consideration of alternatives has been made for any potential painful and/or distressful results; that the activities do not unnecessarily duplicate previous experiments; that the animals' living conditions will contribute to their health and comfort; and that animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure. Members of the IACUC include an IACUC chairperson, an attending veterinarian, and a nonaffiliated member.

AC has revised Policy #15 to provide clarification on the qualifications required of members of the IACUC. The research facility is responsible for ensuring that IACUC members are qualified to assess the research facility's animal program, facilities, and procedures. This responsibility includes the provision of training and instruction to ensure that IACUC members have an understanding in areas such as the AWA, protocol review, and facility inspections.

To learn more about these policies and the activities that AC regulates, please visit our Web site at <http://www.aphis.usda.gov/ac> . To add or remove a name from this update, please send an email to: ac.stakeholder.update@aphis.usda.gov. Suggestions for future updates are encouraged and can be sent to the same address.

Sincerely,

A handwritten signature in black ink that reads "Chester H. Gipson". The signature is written in a cursive style with a horizontal line through the middle of the letters.

Chester Gipson, DVM
Deputy Administrator