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# Federation of American Societies for Experimental Biology

April 14, 2011

Patricia Brown, VMD, MS, DACLAM  
Office of Laboratory Animal Welfare  
Office of Extramural Research  
National Institutes of Health, RKL1, Suite 360  
6705 Rockledge Drive  
Bethesda, MD 20892-7982

RE: Proposed Adoption and Implementation of the Eighth Edition of the *Guide for the Care and Use of Laboratory Animals* [FR Doc. 2011-4172]

VIA EMAIL TO: [olaw@mail.nih.gov](mailto:olaw@mail.nih.gov)

Dear Dr. Brown,

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to comment on the National Institutes of Health's (NIH's) acceptance of the eighth edition of the *Guide for the Care and Use of Laboratory Animals (Guide)*, as solicited by the announcement that appeared in the *Federal Register* on February 24, 2011. FASEB is a coalition of 23 life science societies representing more than 100,000 biomedical researchers, many of whom are involved in the humane use of animal models in research and education.

FASEB strongly supports deferring to the professional judgment of animal care staff in developing performance based standards that provide the best welfare for laboratory animals. Performance based standards are guiding principles that, while describing a desired outcome, provide flexibility in achieving that outcome by granting discretion to those responsible for managing the animal care and use program. Flexibility is important for providing optimal care to laboratory animals and ensuring the integrity of scientific research as it allows researchers, veterinarians, and animal care staff to take into consideration information on the species, individual animal, and research goals that may impact animal care and use. FASEB encourages NIH to follow the suggestions in the *Guide* and promote performance based standards and professional judgment.

Our specific comments concern two points: 1) Should NIH adopt the *Guide* as a basis for evaluation of institutional programs receiving or proposing to receive Public Health Service (PHS) support for activities involving animals? and 2) If NIH decides to adopt the eighth edition of the *Guide*, should NIH use it as the basis for evaluation by March 31, 2012? Below we have commented on each of these points.

**1. FASEB recommends that NIH adopt the eighth edition of the *Guide* as a basis for evaluation of institutional programs receiving or proposing to receive PHS support for activities involving animals with the following caveats:**

- a. FASEB appreciates the importance of housing animals in cages appropriate for their physical, physiologic, and behavioral needs. In evaluating social housing needs for laboratory animals, we, again, strongly encourage NIH to place greater emphasis on performance based standards rather than engineering standards. Engineering standards are prescriptive and provide limited flexibility for implementation. For example, logistical barriers sometimes prevent social housing of animals. Odd numbers of animals needed for a particular experiment would leave one animal not pair-housed. In order to ensure all animals are socially housed, more animals than necessary would be utilized, which is inconsistent with the goal of reducing the number of animals used for research.
- b. FASEB is particularly concerned about the new cage size requirements for rabbits and rodents. For example, FASEB finds that the change to a two-inch higher cage size for rabbits is especially troublesome. We suggest that the current rabbit cage sizes of 14 inches in height as defined in the 1996 *Guide* be maintained as opposed to the 16-inch standard in the 2011 *Guide* unless animals cannot make postural adjustments in the cages. In those cases, performance standards dictate that larger caging should be used. The rationale for increasing the height two inches is unclear, and it is uncertain whether this change would improve the quality of care for laboratory rabbits. Moreover, the current Animal Welfare Act standard is 14 inches in height. In the absence of a clear rationale, congruency between NIH and the United States Department of Agriculture should be maintained. This is consistent with President Obama's Executive Order 13563 and would reduce confusion and maintain efficient work-flow among researchers and institutions. In addition, imposing the new 16-inch standard will render current rabbit caging systems obsolete and necessitate a significant expenditure of funds by research facilities to replace this caging. The resulting expense in both equipment and administrative costs is not balanced by improvements in animal welfare.

In a change to rat caging standards, the 2011 *Guide* now requires that when the weight of paired rats increases to a point that they no longer meet the engineering standards of the *Guide*, they must be separated or moved to a larger cage. Individually housing these animals would conflict with the guidelines on social housing, yet meeting the new engineering standards set forth in the *Guide* would require a larger cage size, which is potentially problematic in terms of additional cost. Again, the fiscal constraints that institutions are under due to reduced federal and state support may make it difficult for institutions to implement the changes. It is important for NIH to provide clear guidance about what should be done in these cases.

In addition, the 2011 *Guide* spells out specific cage size requirements for female rodents plus their litters, as well as other breeding configurations. Implementing these changes would add huge costs and reduce breeding capacity for many institutions. Again, performance standards should be paramount when evaluating cage spacing requirements.

**2. FASEB recommends that: 1) NIH delay the implementation of the *Guide*, and 2) NIH allow institutions time to develop a comprehensive plan that outlines implementation of new *Guide* regulations over a predefined period of time, if needed.**

In order for institutions to implement the changes outlined in the new *Guide*, a concrete plan must be devised, which may include consultation with experts, hiring new staff, training existing staff, developing new standard operating procedures, and ordering and purchasing caging to meet new social housing and caging requirements. It will take a substantial amount of time to devise this plan, have it approved by the Institutional Animal Care and Use Committee (IACUC), and complete at least one semiannual program and facility evaluation. This process alone could take well over a year. Additionally, the budgetary constraints faced by research institutions and NIH may make it difficult for some institutions to implement the changes recommended in the new *Guide* by March 31, 2012. Therefore, FASEB recommends that the implementation date be March 31, 2013.

For institutions unable to implement all the changes at once in order to be in compliance with the new *Guide*, FASEB recommends they be allowed to develop and submit a plan to implement the necessary changes over a predefined period of time. This plan, for example, could state that an institution would replace all non-compliant cages over the period of four years (25% per year). As long as the institution meets the milestones outlined in the implementation plan, they would be considered in compliance with IACUC and the Office of Laboratory Animal Welfare. This strategy would allow institutions to prepare better for the financial challenges and infrastructural changes that would need to take place in order to be in compliance with the new *Guide*. This plan would need to be in place by March 31, 2013.

FASEB recognizes that humane animal care and high-quality science go hand-in-hand, and the biomedical researchers represented by FASEB take humane care very seriously. FASEB also appreciates NIH's commitment to providing guidelines that ensure the optimal care and welfare for research animals, and we thank you for this opportunity to provide comments. If you have questions or need additional information, please do not hesitate to contact us.

Sincerely,



William T. Talman, MD  
FASEB President