



FASEB

Federation of American Societies
for Experimental Biology

Representing Over 125,000 Researchers

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Carol Clarke, DVM, DAACLAM
Research Program Manager
United States Department of Agriculture
APHIS, Animal Care
4700 River Road, Unit 84
Riverdale, Maryland 20737-1234

Re: Petition to Develop Specific Ethologically Appropriate Standards for Nonhuman Primates in Research

Dear Dr. Clarke:

On behalf of the Federation of American Societies for Experimental Biology (FASEB), we offer comments in response to the Notice of Petition: Petition to Develop Specific Ethologically Appropriate Standards for Nonhuman Primates in Research [Docket No. APHIS-2014-0098]. FASEB is composed of 27 scientific societies collectively representing over 125,000 scientists and engineers, many of whom use animals in biomedical and biological research. The role of animals remains critical to the understanding of fundamental processes of life and in developing treatments for injury and disease. Any changes to laws, regulations, and/or policies affecting animal research should benefit research animals and promote science. The petition for rulemaking submitted by the New England Anti-Vivisection Society, the North American Primate Sanctuary Alliance, the Laboratory Primate Advocacy Group, and the Animal Legal Defense Fund (petitioners) to develop ethologically appropriate standards for all nonhuman (NHP) primate species does not meet those principles. We strongly urge the Animal and Plant Health Inspection Service (APHIS) to reject the petition for the following reasons:

- Proposed changes would not benefit the animals;
- Information contained within the petition, and which form the basis of the proposed changes, is outdated and inaccurate;
- The current regulations are achieving the goal of providing for the psychological well-being of NHPs; and
- APHIS inspectors are already in a position to recognize when plans to ensure the psychological well-being of NHPs are not being followed.

Our comments below elaborate on these points and address the questions posed by APHIS in the Federal Register notice.

1. Should APHIS amend Section 3.81 of the Animal Welfare regulations to require research facilities to construct and maintain an ethologically appropriate environment for nonhuman primates, and specify the minimum standards that must be met for an environment to be considered ethologically appropriate?

Section 3.81 of the Animal Welfare Regulations (AWRs) states that, “Dealers, exhibitors, and research facilities must develop, document, and follow an appropriate plan for environment enhancement adequate to promote the psychological well-being of nonhuman primates. The plan must be in accordance with the currently accepted professional standards as cited in appropriate professional journals or reference guides, and as directed by the attending veterinarian.” In addition, the plan must include “specific provisions to address the social needs of nonhuman primates of species known to exist in social groups in nature.”

As indicated in the Federal Register notice, the petitioners are requesting that APHIS amend Section 3.81 of the AWRs to require research facilities to construct and maintain ethologically appropriate environments for NHPs by specifying minimum standards that must be met. When describing the reasons why they believe such standards must be developed, the petitioners state that the requirement for an environmental enhancement plan is so “vague that it lacks any enforceable definition to evaluate if such a plan is actually effectively designed or implemented (p. 3)” and that there is a “preponderance of the single-housing of primates (p. 16).” FASEB disagrees with these claims for the following reasons:

APHIS VMOs are able to recognize whether environmental enhancement plans provide for the psychological well-being of NHPs

The aforementioned petitioners’ assertion is without merit. APHIS Veterinary Medical Officers (VMOs) are able to identify instances where environmental enhancement plans are not followed. In a letter submitted in response to this request for information, the National Association for Biomedical Research cites 12 instances of non-compliance with the requirement to provide for the psychological well-being of NHPs for fiscal years 2012 through 2014. While we do not condone non-compliance, these data show that environment enhancement plans are enforceable and VMOs are able to evaluate if plans are or are not being followed.

The majority of NHPs are socially housed

The petitioners’ claim that “social housing is *not* consistently the default standard (p. 15, petitioners’ emphasis)” is inaccurate. A 2014 study conducted by the Association of Primate

Veterinarians surveyed US research facilities that housed NHPs during fiscal year 2013¹. With responses from facilities that housed approximately 90 percent of all NHPs, the survey indicated that over 84 percent of NHPs housed in research facilities were either group- or pair-housed. A mere 0.03 percent of NHPs were housed singly with no other NHP contact. These data emphasize that: 1) the vast majority of NHPs are socially housed and 2) the AWRs are fulfilling their intended goal of providing for an animal's psychological well-being through social housing.

Plans for environmental enhancement must be in accordance with professional standards and guides. The *Guide for the Care and Use of Laboratory Animals*² states that, "Social animals should be housed in stable pairs or groups of compatible individuals," and the Association for Assessment and Accreditation of Laboratory Animal Care International cites social housing as the "default method of housing"³. Additionally, the Association of Primate Veterinarians⁴, the American Society of Primatology, and the National Primate Research Centers all advocate for social housing. These guidance documents and standards are used by research facilities when devising their environmental enhancement plans. Since all of these guidance documents and position statements already call for animals to be housed in compatible pairs or groupings, additional requirements to ensure social housing of NHPs are not necessary.

For these reasons, we urge APHIS not to amend Section 3.81 of the AWRs. Regulations currently in place provide for the social housing needs and psychological well-being of NHPs in research facilities and are enforceable by APHIS VMOs.

2. What constitutes an ethologically appropriate environment for a nonhuman primate? Does this differ among species of nonhuman primates? If so, how does it differ?

As the National Primate Research Center Directors state in their response to the petition (p. 6), "an appropriate environment is one that promotes species-typical behavior." They also assert that there is no single "ethologically appropriate" environment for a NHP species given that, in nature, there are great differences in habitats, social structure, geography, demography, and seasonal changes within and among NHP species (p. 4). Codifying prescriptive standards for NHPs would be nearly impossible and not result in enhanced animal welfare.

FASEB concurs with our colleagues and strongly supports deferring to the professional judgment of animal care staff in developing performance based standards that provide the best welfare for

¹ www.primatetvets.org/Content/files/Public/education/APV%202014%20NHP%20Housing%20Survey.pdf

² grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf

³ aaalac.org/accreditation/positionstatements.cfm#social

⁴ www.primatetvets.org/Content/files/Public/education/APV%20Social%20Housing%20Guidelines%20final.pdf

NHPs. Performance-based standards provide flexibility in achieving well-being 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 believes that existing regulations provide necessary flexibility to laboratory animal veterinarians, Institutional Animal Care and Use Committees (IACUCs), and primate behaviorists to ensure the psychological well-being of NHPs. Therefore, the development of additional, prescriptive regulations is not necessary.

3. Are there any environmental conditions that make an environment ethologically inappropriate for a nonhuman primate? If so, what are they? Do they differ among species of nonhuman primates?

Environments that do not allow for species-typical behavior could be considered inappropriate. Current regulations provide research facilities, laboratory animal veterinarians, IACUCs, and primate behaviorists with the flexibility to satisfy the needs of NHPs on the species and individual level and should not be changed.

4. Does an ethologically appropriate environment for nonhuman primates used in research differ from an ethologically appropriate environment for nonhuman primates that are sold or exhibited? If so, in what ways does it differ?

As previously stated, FASEB does not believe that the development of additional standards for ethologically-based environments is necessary. An appropriate environment for NHPs is one that promotes species-typical behavior; therefore, it should not matter whether an NHP is housed for use in research, sold, or exhibited. The same standards should apply to all.

5. Who should make the determination regarding the ethological appropriateness of the environment for nonhuman primates at a particular research facility: The attending veterinarian for the facility, APHIS, or both parties? If both parties should jointly make such a determination, which responsibilities should fall to the attending veterinarian and which to APHIS?

FASEB contends that local entities, such as laboratory animal veterinarians, IACUCs, and primate behaviorists are in the best position to ensure the psychological well-being of NHPs in research facilities. The Secretary of Agriculture, when drafting the AWRs, also understood this to be the intent of Congress since Section 3.81 states that the plan for environment enhancement to promote the psychological well-being of NHPs “must be in accordance with the currently accepted professional standards as cited in appropriate professional journals or reference guides, and *as directed by the attending veterinarian* (emphasis added).” As stated previously, APHIS, through regular unannounced inspections, has the ability to assess whether institutions are providing for the psychological well-being of NHPs and are able to do so effectively.

In conclusion, we strongly urge that the petition be rejected based upon the factors outlined in this letter. Thank you for the opportunity to provide input on the Notice of Petition.

Sincerely,

A handwritten signature in black ink, appearing to read "Parker B. Antin". The signature is written in a cursive style with a large initial "P".

Parker B. Antin, PhD
FASEB President