



The American Physiological Society

9650 Rockville Pike • Bethesda, Maryland 20814-3991 USA • TEL: 301.634.7164 • FAX: 301.634.7241

www.the-aps.org • webmaster@the-aps.org • [facebook.com/AmericanPhysiologicalSociety](https://www.facebook.com/AmericanPhysiologicalSociety) • twitter.com/APSPHysiology

The American Physiological Society (APS) is pleased to provide comments on APHIS Docket 2014–0098 concerning a petition to develop specific ethologically appropriate standards for nonhuman primates in research.

The APS is a professional society of more than 11,000 physiologists who are greatly invested in animal research. The humane use of animals in research is critical to helping us understand basic biological systems and processes, which is essential both to our efforts to diagnose and cure disease as well as to answer important questions about how organisms adapt to their environments. The APS strongly supports efforts to ensure that federally-funded researchers can pursue important lines of research involving animals in an optimal regulatory environment.

Our responses to the questions in the RFI are provided below.

1. Should APHIS amend § 3.81 of the AWA 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?

The petitioners claim that APHIS should develop minimum regulatory standards for an ethologically appropriate environment for nonhuman primates (NHP) in research because “ambiguities” in the current regulations give research facilities “broad discretion regarding the actual environment provided to nonhuman primates” such that they “can meet the requirements in §3.81 without actually meeting their intent.” Petitioners therefore assert that minimum regulatory standards are needed to correct this situation. They go on to assert that NIH’s recommendations to provide an ethologically appropriate environment for chimpanzees should be adapted for all nonhuman primate (NHP) species in research settings.

The American Physiological Society disagrees with the petitioners’ claim. That is, we believe that current regulations are adequate and disagree that an ethologically appropriate environment as defined by the petitioners will improve the welfare of NHPs in research.

The legislative authority for §3.81 of the Animal Welfare Act (AWA) regulations comes from §2143 of the AWA. This section of the law instructs USDA to “promulgate standards to govern the humane handling, care, treatment, and transportation of animals by dealers, research facilities, and exhibitors,” including “a physical environment adequate to promote the psychological well-being of primates.” §3.81 of the AWA regulations says that dealers, exhibitors, and research facilities are required to “develop, document, and follow an appropriate plan for environment enhancement adequate to promote the psychological well-being of nonhuman primates,” and that this 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.”

The petitioners' purported evidence that regulations specifying minimum standards consists of a biased review of dated reports and surveys. From this, they conclude that research facilities consistently fail to promote the psychological well-being of NHPs and/or USDA inspectors are unable to determine whether they are successfully doing so. However, as noted in comments provided by the National Association for Biomedical Research (NABR), the evidence to support the petitioners claims "heavily relies on outdated, inaccurate and incomplete data to reach its conclusion that the current regulations require changes." [NABR, p. 2]

To illustrate this point, NABR investigates the petitioners' assertion that "social housing is *not* consistently the default standard" for NHPs in research. NABR points out that in contrast to the data cited by the petitioners, a 2013 survey by the Association of Primate Veterinarians (APV) contradicts this claim. The APV obtained information about the social housing status of 89,362 animals, accounting for almost 90% of NHPs reported to USDA by research facilities in 2013. Of these animals, about 84% were housed either socially or in pairs, thus showing that social housing is, in fact, the norm. Of the remaining animals, about 4% were housed singly with regularly scheduled tactile contact with other NHPs; another 12% were singly housed with only irregular contact with other NHPs; and only .03% were singly housed and had no contact with other animals. [NABR, p. 2-4] Moreover, OLAW FAQ F.15 states that "nonhuman primates should be socially housed" and goes on to say that exemptions "must be based on strong scientific justification approved by the IACUC or for a specific veterinary or behavioral reason." In addition, AAALAC, International considers social housing of nonhuman primates to be the norm unless there is a compelling reason not to do so.

NABR has documented other misrepresentations. For example, contrary to the petitioners' assertion that without the minimum regulatory standards petitioners are proposing, the psychological well-being of NHPs cannot be assured, NABR notes that these concerns were raised when the §3.81 regulations were relatively new. NABR also suggests that inspectors' inability to assess compliance may have been an indication of a need for additional training. [NABR, p. 5]

The National Primate Research Centers (NPRC) further point out in their comments that the petition "oversimplifies the etiology of abnormal behavior," noting that it is "inappropriately simplistic to assert that all expression of abnormal behavior is solely due to environmental conditions present in the laboratory." [NPRC, p. 5]

Given that the petitioners failed to demonstrate that adherence to the current regulations does not meet the intent of the AWA, there is no need for APHIS to issue further regulations.

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 noted in the response to question 1, the petitioners failed to demonstrate a need for additional regulations. However, even if they had succeeded, applying the NIH's recommendations concerning ethologically appropriate environments for chimpanzees to other NHP species would be inappropriate. Research facilities have already demonstrated many valid approaches to

promoting the psychological well-being of NHPs. These include social housing; environmental enrichment (e.g., foraging opportunities, manipulanda, and sensory and cognitive stimulation); positive reinforcement training; and behavioral management programs.

The current AWA regulations rely upon performance-based standards that permit research facilities to try a variety of strategies to accomplish the goal of promoting the psychological well-being of NHPs. The advantage of this approach is that the veterinary staff can create customized enrichment plans that address the needs of specific animals engaged in particular research studies based upon their knowledge of the behavior of that species, rather than a generic approach. The emphasis is on providing experiences comparable to those in the wild, rather than replicating them. This is both more feasible and more appropriate for a research setting. In addition, not all aspects of the natural environment foster the well-being of animals, e.g., disease and parasite loads, inconsistent availability of food and water, injury, etc.

Petitioners assert that the NIH's recommendations for ethologically appropriate environments for chimpanzees offer "a reference point for the development of such generally applicable minimum standards and as evidence of their feasibility," but the utility of this approach has not yet been validated, and thus it is inappropriate to apply it broadly to other species.

The term "ethologically appropriate environment" was introduced in the Institute of Medicine's 2011 report *The Use of Chimpanzees in Biomedical and Behavioral Research: Assessing the Necessity*. However, the IOM did not define the term. Therefore, one of the tasks of the working group convened by NIH to implement the IOM's recommendations was to develop a definition. They defined it as an environment "that not only *allow[s]*, but importantly, *promote[s]* the full range of natural chimpanzee behaviors." [Report of the Council of Councils Working Group on the Use of Chimpanzees in NIH-Supported Research 22 January 2013, pp. 2-3.] This definition is closely related to the language of AWA §2143, which calls for a "physical environment adequate to promote the psychological well-being of primates." However, developing specific criteria for such an environment based upon how the species lives in the wild is a new approach.

How the NIH Working Group moved from a definition of what an ethologically appropriate environment for captive chimpanzees should *do* to specific recommendations for what such an environment should *contain* provides a telling example of how difficult this is to do. NIH's Working Group developed 10 recommendations, and while NIH ultimately adopted 9 of the 10, it did so with reservations. For example, NIH agreed that the minimum social group be 7 animals, but it also stipulated that "compelling factors" might prevent social housing of some animals. While concurring that "housing chimpanzees in larger groups has the potential to offer greater social complexity and more environmental stimuli than housing them in smaller groups," NIH nevertheless said facilities would need to "evaluate individual chimpanzees to determine their suitability for successful integration into larger social groups," taking into account the individuals' needs, the facility's own capabilities, and any ongoing research involving those animals. [NIH [Announcement of Agency Decision](#) June 25, 2013, p. 6]

It is also worth noting that the NIH Working Group's final recommendations failed to achieve consensus approval from the experts on this topic.

Another consideration is how useful such recommendations are in practice. With respect to the NIH example, at this point, we do not know how many of the ~1,000 NIH-supported chimpanzees will require exceptions to one or more of the Working Group's criteria. It may turn out that exceptions are needed for a significant portion of that population. Without knowing how well NIH's recommendations work in practice, it is premature to use this approach as the basis to develop comparable recommendations for other NHP species. Moreover, doing so would require extensive information-gathering to determine the precise requirements for each species (as well as the age and sex of the animal), which may vary among dispersed populations that have adapted to conditions in various regions.

Given the effort needed to develop a prescriptive approach and the limitations in trying to use one, it does not make sense to try to transpose NIH's criteria to other NHPs.

Performance-based standards utilize assessments of animal behavior and welfare to determine success or failure. Prescriptive criteria would be more difficult to apply in certain situations, which would then require extensive paperwork to justify exceptions.

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?

This question is virtually impossible to answer because of differences between species and within those species. Moreover, an animal's requirements may change because of its own health status or the specific needs of the research protocol. Naturalistic environments introduce variability that is problematic when research is intended to obtain information about integrative functions under specific conditions. Generalized standards may produce an environment that is inappropriate for some animals. Introducing such standards would create a situation where trying to meet the needs of a particular animal must be treated as an exception. Therefore, the APS believes that prescriptive standards actually pose an obstacle to providing the highest level of welfare for each animal.

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 noted, the American Physiological Society believes it is inappropriate to recommend the use ethologically appropriate environments based upon how species live in the wild as a standard to promote the psychological well-being of all NHPs used in research.

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?

As previously noted, the American Physiological Society does not believe that the concept of ethologically appropriate environments based upon how species live in the wild should be applied to all NHPs in research. In any case, investigators should work with the attending veterinarian who is in the best position to assess the welfare of the animals in the facility as currently required under §3.81 of the AWA regulations.

Unannounced APHIS inspections already enable the agency to determine whether facilities are meeting regulatory requirements to provide an environment that promotes the psychological well-being of NHPs. Inspectors can observe first-hand the condition of NHPs and confer with veterinary staff regarding the specific requirements of the each research protocol.

