



National Association for  
Biomedical Research

**Sent via Electronic and U.S. Mail**

Carol Clarke, DVM, DACLAM  
Docket No. APHIS-2014-0050  
Regulatory Analysis and Development  
PPD, APHIS, Station 3A-03.8  
4700 River Road Unit 118,  
Riverdale, MD 20737-1238

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

Dear Dr. Clarke:

This letter is in response to the United States Department of Agriculture's request for comments that appeared in the Federal Register on May 1, 2015, concerning a "Petition To Develop Specific Ethologically Appropriate Standards for Nonhuman Primates in Research" (Petition) (80 Federal Register 24840-41). The National Association for Biomedical Research (NABR) represents more than 360 public and private universities, medical and veterinary schools, teaching hospitals, voluntary health organizations, professional societies, pharmaceutical and biotechnology companies advocating sound public policy for the humane use of laboratory animals in biomedical research.

On behalf of our institutional membership, NABR appreciates the opportunity to provide comments and additional information to assist APHIS in its consideration of the Petition. As explained in more detail below, the research community has made, and continues to make, the physical and psychological well-being of nonhuman primates a high priority. Since implementation of §3.81, research facilities have undertaken significant efforts to meet the complex needs of these animals. Today, the majority of nonhuman primates housed at research facilities are in social groups and have access to an environment that enhances their psychological well-being.

The Petition misrepresents reality by painting a picture that alleges research facilities are bad actors and nonhuman primates at research facilities are routinely and callously neglected. NABR cannot overstate how strongly it opposes this false mischaracterization. Research facilities, researchers, attending veterinarians, professional support and animal care staff are committed to and strongly emphasize providing nonhuman primates with an environment that meets their complex needs.

Moreover, the Petition heavily relies on outdated, inaccurate and incomplete data to reach its conclusion that the current regulations require changes. USDA's own data demonstrate that the current regulations are enforceable and in the unusual circumstances when research facilities have not been in compliance, those facilities have been cited. Moreover, the requested changes would make the use of nonhuman primates in research prohibitively expensive and would make environmentally induced, non-experimental variability difficult, if not impossible, to control. Therefore, NABR strongly recommends that the USDA **not** initiate the rulemaking requested by the Petition.

NABR's comments address the alleged basis for the proposed regulatory changes contained in the Petition and the inaccuracies and selective misrepresentation that the Petitioners rely on to reach the false conclusion that changes are needed. NABR's comments also address the request for information contained in Docket No. APHIS 2014-0098, and the five questions separately posed by the Agency.

**I. The Petition Misrepresents the Reality of Non-Human Primate Housing in Research Facilities and Relies on Outdated, Inaccurate and Incomplete Data to Reach Its Conclusion that Regulatory Changes are Needed**

As an initial matter, NABR notes that the Petition is 59 single-spaced pages and contains inaccuracies, hyperbole and isolated examples that misrepresent the current state of nonhuman primate housing environments throughout its entirety. While NABR could address each error or misrepresentation, it believes its comments on the Petition will be more useful to the agency by instead providing reliable evidence about the current state of housing in research facilities. However, NABR does feel compelled to correct a few egregious errors and misrepresentations in the Petition.

**A. Since Enactment of §3.81, the Percentage of Socially Grouped Nonhuman Primates Has Significantly Increased and Today Virtually No Nonhuman Primates are Housed Singly Without "Contact" with Other Animals of the Same Species**

In 2000-2001, USDA conducted a survey of research facilities to obtain information about the housing options and animal groupings used in registered research facilities.<sup>1</sup> Whether intentionally or not, the Petition fails to reference this survey which found that 72% of the nonhuman primates were housed in either pairs or groups and less than 5% were singly housed. For research facilities, the numbers at the time of the survey were 65% and 13% respectively.

Recognizing that this information had become dated in the nearly 15 years since its collection, the Board of Directors of the Association of Primate Veterinarians (APV) supported a follow-up survey that was conducted in 2014.<sup>2</sup> The purpose of the survey was to gather data about how nonhuman primates were currently being housed in registered research facilities.

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<sup>1</sup> USDA's 2000-2001 Nonhuman Primate Housing Survey.

<sup>2</sup> See

<http://www.primatetvets.org/Content/files/Public/education/APV%202014%20NHP%20Housing%20Survey.pdf>, see

The USDA's Animal Care Information System (ACIS) database was used to identify the 184 research facilities housing nonhuman primates in FY 2013. Contacts were identified at 160 of those facilities and each contact was provided a survey to complete. The survey instrument used was based upon the same housing options and animal groupings used in the USDA Animal Care 2000-2001 Nonhuman Primate Survey, with the exception of the original Option 1 = paired or group housing, which was split into Option 1 = group housing and Option 2 = paired housing.

The questions asked are presented below:

2014 APV Primate Housing Survey						
Please answer all questions and <b>SAVE</b> before returning the survey						
1. Name:						
2. Institution:						
3. email address:						
4. Please indicate how many nonhuman primates of each type your facility has in each housing option.:						
			Housing Option			
		1	2	3	4	5
USDA	2					
Grouping	3					
	4					
	5					
	6					
Housing Options: Option 1 = group housing Option 2 = paired housing Option 3 = singly housed with <b>some contact</b> & scheduled tactile NHP interactions (such as through adjacent bar or wire mesh) Option 4 = singly housed with <b>some contact</b> & no scheduled/regular NHP tactile contact Option 5 = no other NHP contact <b>Some contact</b> = auditory, visual, and/or olfactory contact						
USDA Grouping:						
USDA Grouping 1 = marmosets, tamarins, and infants (less than 6 months of age) of various species						
USDA Grouping 2 = capuchins, squirrel monkeys and similar size species, and juveniles (6 months to 3 years of age) of various species						
USDA Grouping 3 = macaques and African species						
USDA Grouping 4 = male macaques and large African species						
USDA Grouping 5 = baboons and nonbrachiating species larger than 33.0 lbs. (15 kg.)						
USDA Grouping 6 = great apes over 55.0 lbs. (25 kg.)						

Responses were received from 94% of the institutions contacted. In total, information about the housing options of 89,362 animals was obtained. A search of the ACIS database for FY 2014 found that research facilities reported a total of 99,099 animals in Columns B and F of the Annual Report, so the 2014 survey included information on approximately 90% of the NHPs housed in research facilities during the time of the survey.<sup>3</sup>

A comparison of the results of the survey shows the following:

	Option 1	Option 3	Option 4	Option 5
<b>2000-2001 USDA Survey</b>	65.20%	15.60%	5.90%	13.20%

also, B. Taylor Bennett, *Association of Primate Veterinarians (APV) 2014 Nonhuman Primate (NHP) Housing Survey*, Journal of the American Association for Laboratory Animal Science, submitted for publication.

<sup>3</sup> In comparison, the data presented from the 2014 APV Survey includes information from 25 more facilities than the 2000-2001 USDA Survey and data on 43,763 more animals than reported in the USDA survey.

<b>2014APV Survey<sup>4</sup></b>	84.35%	3.79%	11.83%	0.03%
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Today, 88.14% of nonhuman primates at research facilities are group housed, pair housed, or have scheduled tactile contact with other nonhuman primates. More than 84% of the nonhuman primates housed in research facilities are maintained in either social groups or are paired housed, compared to 65% of the animals included in the previous USDA survey. In fact, the 2014 APV survey found that almost 62% of the animals are housed in social groups. On the opposite end of the housing spectrum, less than 0.03% of the nonhuman primates are housed singly without contact with other animals, compared to just over 13% in the USDA survey.

Since the USDA conducted its original survey, the percentage of socially housed NHPs has increased by approximately 20 percentage points, or almost 1/3 more animals, while the percentage of animals housed singly without visual, auditory and olfactory contact has dropped from just over 13% to 0.03%, which represents a reduction from 6,555 animals to 25. This clearly indicates that the number of animals being singly housed has significantly improved since the enactment of the current standards contained in §3.81,<sup>5</sup> in stark contrast to the claims found in the Petition.

The Petition systematically misrepresents the current housing of nonhuman primates in research facilities. Among other misrepresentations, the Petitioners cite two surveys conducted in 1994 and 2003 and claim these surveys demonstrate that only 1/3 of the animals lived with one or more companions while 2/3 lived alone. The fact is the 2003 survey (Journal of Primatology) indicates that overall 73% of the animals were socially housed.

The 2014 APV survey data clearly demonstrates that additional regulation is unnecessary because research facilities are proactively and effectively complying with both the letter and the spirit of §3.81. Research facilities and their staff are committed to providing the proper level of care, and the current regulations and standards provide a workable and efficient framework for meeting the complex psychological housing needs of nonhuman primates.

**B. Much of the Outdated Information the Petition Relies on Was Collected Nearly 20 Years Ago, Is Misrepresented by the Petition, and Does Not Reflect the Current State of Nonhuman Primate Housing at Research Facilities**

Throughout the Petition, the Petitioners frequently refer to three publications to support the need for more prescriptive standards: The Final Report on Environment Enhancement to Promote The Psychological Well-Being of Non-Human Primates (USDA, APHIS, AC – July 15, 1999); USDA Perspective on Environmental Enrichment for Animals (ILAR, Vol. 46, No. 2, 2005, pg. 83-94); and Survey of Environmental Enhancement Programs for Laboratory Primates ( American Journal of Primatology 69:377-394 (2007)). In many instances the Petitioners selectively use “bits and pieces” from the original publication to support their position. A prime example of this appears on page 4 of the Petition where an apparent quote from the USDA document is included. All of the material in that quote does appear on page 11 of the document,

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<sup>4</sup> Housing options 1 and 2 were combined to provide complementary data between the two surveys for comparison purposes.

however when the selected “bits and pieces” are combined, it produces a statement that misrepresents the totality of the information in the article itself.

The ILAR article was prepared by USDA staff and relies heavily upon surveys of USDA inspectors (1993 & 1996) and interviews conducted in 1997. Of interest are the results of a 1993 internal survey that appears on page 11 of the Petition, indicating that AC staff were unable to distinguish compliance from a violation, that exemptions were being used more for convenience than scientific necessity, and that they were dissatisfied with how research facilities were implementing enrichment. Of note is the fact that this survey was conducted only two years after the implementation of the final rule; a rule which often required facilities to purchase and/or modify equipment, train staff and change husbandry practices. In fact, facilities were given until February 15, 1994 to meet the new space requirements (Fed Reg. – 1991 – 6471), so any evaluation of the impact of the new regulations before that date was meaningless. More importantly from an implementation perspective the responses call into question the training provided by the Agency on the implementation and enforcement of the new standards. In fact, three years later nearly half of the inspectors were still unclear about what facilities needed to do in order to comply.

The situation today is much different than it was more than 20 years ago. The agency has had significant experience evaluating environmental enrichment plans to determine if such plans are sufficient to meet the psychological needs of nonhuman primates. A search of the ACIS database revealed that for FY2012-2014 there were 12 citations for noncompliance with requirements to provide an environment which enhances the psychological well-being of nonhuman primates. This demonstrates that the inspectors are enforcing the regulations and that research facilities are ensuring compliance with the regulations.

The petition also includes misleading and inaccurate information about the Animal Welfare Act, the regulations and standards and a proposed policy. To support the claim that current standards are unenforceable, the Petitioners quote language in the background to the Draft Policy on Environment Enhancement suggesting that the regulations, “*were sowing confusion among the regulated public concerning on what basis they will be judged by inspectors as meeting or not meeting the requirements.*” What that section actually states is that the VMOs surveyed in 1996 did not believe facilities knew how to develop an enhancement plan and that the issue of what constitutes performance standards was not clearly understood. To address these concerns the Agency developed a draft policy that unfortunately did not accurately reflect the recommendations contained in The Final Report on Environment Enhancement to Promote The Psychological Well-Being of Non-Human Primates. Had it done so, some of the concerns expressed by the regulated community during the comment period may not have arisen.

Fortunately, in the nearly 20 years since the VMOs were surveyed, facilities have obtained significant expertise developing environmental enrichment plans and VMOs have gained experience reviewing such plans. In this time, the agency has worked with the research community to ensure environmental enrichment plans adequately meet the psychological needs of nonhuman primates and has cited facilities when such needs are not adequately being met.

C. The Current Regulations Adequately Ensure the Psychological Needs of Nonhuman Primates Are Addressed and the Concept Put Forth by the IOM Should Not Be Adopted

The Petition requests prescriptive new regulations for all nonhuman primates modeled on those accepted by the NIH's Council of Councils (CoC) for providing an "ethologically appropriate environment" for chimpanzees used in NIH supported research. Page 3 of the Petition asserts that, "The new NIH recommendations are based on scientific evidence and expertise from some of the world's leading experts on chimpanzee well-being." However, a review of the comments submitted from facilities that currently house chimpanzees called into question the scientific basis for some of the recommendations.

On page 19 of the Petition, in the section on the Institute of Medicine (IOM) Conclusions, the petitioners assert that the IOM "...introduced the concept of 'ethologically appropriate physical and social environments.'" The use of the term concept is important because "ethologically appropriate" is not a term that had been previously defined. Webster defines concept as "something conceived in the mind, such as a thought, notion or an abstract or generic idea generalized from particular instances." This definition is important because developing regulatory standards predicated upon abstract or generic ideas does not represent sound public policy and should not be pursued by the Agency.

D. Conclusion

In summary, this Petition selectively and inaccurately uses the literature and statements from individuals which amount to hearsay with no supporting facts to justify their position that the current standards for environmental enhancement to promote the psychological well-being of nonhuman primates should be revised. The Petition makes sweeping statements alleging that the current standards are unenforceable and as such have not led to improvements in how NHPs are currently housed. However, this is patently untrue. Research facilities have made significant strides in socially housing nonhuman primates and today, 88.14% of nonhuman primates at research facilities are group housed, pair housed, or have scheduled tactile contact with other nonhuman primates.

The Petition recognizes that providing an "ethologically appropriate environment" for all NHPs used in research will require establishing different standards for different species. However, attempting to produce detailed engineering standards and regulations for all species in all types of facilities performing very different types of research would take years to develop, be impossibly complicated and much more difficult to enforce. Such regulations would be prohibitively expensive and likely outdated once they were eventually developed. The current regulations require research facilities to develop facility specific environmental enrichment plans. This approach has been successful because it recognizes that the Attending Veterinarian is in the best position to design a plan to meet the psychological needs of the specific nonhuman primates at the facility. Therefore, NABR strongly recommends that the current regulations, which have proven effective, be retained.

**II. The Request for Information**

In the Summary Section of the docket, the notice states the Petition is requesting that the AWA regulations be amended to include appropriate standards to promote the psychological well-being of nonhuman primates to which researchers must adhere. The Petition does request promulgation of additional standards and definitions to promote the psychological well-being and appropriate ethological environments for primates used in research requiring that amendments be made to §3.81 of Part 3 – Standards, which hold research facilities and not researchers responsible for the psychological well-being of nonhuman primates. If the agency is not contemplating having a different set of requirements for research facilities from those that apply to exhibitors and dealers, then it is unclear why the agency later asked a question concerning the different requirements for providing an ethologically appropriate environment for research facilities, dealers and exhibitors.

In the Supplemental Information the following statement appears, “(s)ection 3.81 of the AWA regulations requires research facilities that house nonhuman primates to develop, document, and follow an appropriate plan for environmental enhancement adequate to promote the psychological well-being of nonhuman primates.” This statement is misleading because the regulations also apply to dealers and exhibitors. The Agency needs to make clear that any proposed change to existing standards would apply to all regulated entities under the AWA and reissue the request for comments so that dealers and exhibitors will also have an opportunity to comment. As worded, these entities are likely unaware that the proposed changes would affect them and thus should be afforded the opportunity to comment.

The Supplemental information also contains the following statement, “...the petition asks that we amend §3.81 to require that research facilities construct and maintain an ethologically appropriate environment for nonhuman primates housed at the facilities...” when what the petition actually requests is “...*species appropriate standards as the “minimum requirements” for a “physical environment adequate to promote the psychological well-being” of all primates used in research*” which they indicate includes, “.environmental enhancement, access to the outdoors, and opportunities for choice and self-determination.” Providing access to the outdoors would undoubtedly require construction of new facilities or major renovation of existing facilities in most institutions currently housing nonhuman primates. Before those facilities can substantially comment on necessary costs, the term “ethologically appropriate environment” must be clearly defined in the scientific literature by those with expertise in the maintenance and care of nonhuman primates outside of the natural environment.

### **III. Response to the USDA Questions**

- A. 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?

In order to address this question, the Agency needs to first clarify why it would consider developing regulations that establish a standard of care only for those animals maintained in research facilities, as opposed to nonhuman primates in the possession of dealers and exhibitors.

Section 2143 of the Animal Welfare Act (AWA) requires the Secretary to promulgate standards for humane handling, care, treatment and transportation of animals by dealers, research facilities and exhibitors. We question whether Congress gave the Secretary the authority to promulgate different standards for the welfare of animals held by different regulated entities. As stated above the potential costs of such an undertaking are unknown, but would be considerable. Costs cannot be evaluated until there is a clear evidence-based definition of an “ethologically appropriate environment;” a relatively new concept that would presumably be used as the basis for establishing standards. As such, it is impossible to provide meaningful input on the potential cost of constructing and maintaining facilities which would meet those standards.

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

Since the following language appears in the supplemental information, “an environment that is appropriate with respect to the patterns of behavior exhibited by the nonhuman primates in their natural state,” it is unclear why this question was presented by the agency. Providing an environment that would mimic the environment found in the natural state would make it nearly impossible to provide the type of environmental control necessary to minimize the impact of non-experimental variability on animals used in research. Controlling the environment is a key element of reducing the number of animals used, as discussed in Russell and Burch’s book where the authors coined the phrase “dramatype” to describe it.<sup>6</sup>

As the Petitioners acknowledge, the IOM report introduced the concept of an “ethologically appropriate environment.” The NIH Working Group proposed definitions for the components of such an environment for chimpanzees, and in spite of the concerns and comments from some the leading experts on the care and housing of chimpanzees, the NIH accepted all but one the proposed definitions and significantly altered the other. Hypothetically, before this concept could be applied to all species of nonhuman primates currently regulated by the Agency, the patterns of behavior exhibited by each of those species in their natural state would have to be defined and standards developed to address those behaviors.

It should be noted the components developed by the Working Group for chimpanzees were, in many instances, reflective of how chimpanzees were currently being maintained in research facilities and by exhibitors. The same cannot be said at this point for the nonhuman primate species most commonly used in research. It should be pointed out that in the Final Report on Environment Enhancement to Promote The Psychological Well-Being of Non-Human Primates (USDA, APHIS, AC – July 15, 1999), the committee refers to “species appropriate behavior” recognizing that the very nature of the resources provided for animals maintained by the regulated entities negates the need for some “species typical behavior” because not all patterns of behavior exhibited in the wild are necessary or even desirable in captivity.

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<sup>6</sup>Russell WMS, Burch RL. 1959 (as reprinted 1992). The principles of humane experimental technique. Wheathampstead (UK): Universities Federation for Animal Welfare.



- C. 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?

Given the language in the Supplemental Information on what constitutes an “ethologically appropriate environment,” it is unclear why this question is being asked by the agency. As stated above until the phrase “ethologically appropriate environment” moves from being a concept to an evidence-based definition applicable to nonhuman primates in general, it is virtually impossible to provide meaningful comments about what conditions might represent an ethologically inappropriate environment.

- D. 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?

This question also poses somewhat of a challenge to answer in light of the fact that the notice is requesting input on changing the standards required for nonhuman primates housed in research facilities, yet it does not address nonhuman primates housed with dealers and exhibitors. As stated above, the AWA requires that the standards promulgated by the Secretary be applicable to all animals covered by the AWA regardless of whether they are housed by a research facility, dealer or exhibitor. If in fact the phrase “ethologically appropriate environment” can move from being a concept to being an evidence-based set of conditions, then where the animals are housed would not change that definition.

- E. 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?

The current language in the regulations which gives the Attending Veterinarian this responsibility was developed to implement the intent of Congress in amending the Animal Welfare Act (AWA) in 1985. In §2143(a)(B) of the AWA, Congress addressed the issue of exercise for dogs and a physical environment to promote the psychological well-being of primates and used the phrase “as determined by the attending veterinarian.” There is no need to change the language in the current Standards as it relates to who should make the determination about what component should be included in an institution’s program. It is already directed by law

## **Conclusion**

The Petition is proposing that the regulations in §3.81 be revised to provide all nonhuman primates used in research a species specific “ethologically appropriate environment.” The Petitioners justify the need for these changes based upon their assertion that current regulations provide the institution too much flexibility and are thus difficult to enforce. Petitioners argue this

has led to a situation in which the way nonhuman primates are housed has not changed appreciably since the enactment of the regulations.

To justify this allegation the petitioners use outdated information, ignore the agency's information and misrepresent the findings of other publications. Over a period of decades the Agency has developed effective means to implement and enforce the current standards and in doing so has issued citations for institutions failing to comply with those standards. Further, the number of those citations issued to research facilities continues to decline. The Agency's own survey in 2000-2001 showed that the majority of the animals were being housed socially and the 2014 survey conducted by the Association of Primate Veterinarians (APV) demonstrates that the number of animals being socially housed continues to increase to a level approaching 85% of all nonhuman primates housed in research facilities. As the number of older animals housed in those facilities, which cannot be socially housed due to aggression or illness issues, continues to decline, the overall number of animals being socially housed will continue to increase.

Since the information presented in the petition does not accurately reflect how nonhuman primates are currently being housed in research facilities, and because the Agency's own record of enforcement shows that very few facilities are not compliant with §3.81, there is no evidence to suggest that the standards in this section should be changed.