



March 6, 2023

**Submitted electronically via Federal eRulemaking Portal at [www.regulations.gov](http://www.regulations.gov)**

Regulatory Analysis and Development

PPD, APHIS, Station 3A-03.10,

4700 River Road, Unit 118,

Riverdale, MD 20737-1238

**RE: Docket No. APHIS-2022-0022 – Comments Submitted in Response to Advance Notice of Proposed Rulemaking Entitled *Wild and Exotic Animal Handling, Training of Personnel Involved with Public Handling of Wild and Exotic Animals, and Environmental Enrichment for Species* ([88 FR 1151](#))**

To Whom it May Concern:

COGR (Council on Governmental Relations) is an association of over 200 public and private U.S. research universities and affiliated academic medical centers and research institutes. COGR concerns itself with the impact of federal regulations, policies, and practices on the performance of research conducted at its member institutions. COGR's member institutions are leaders in the conduct of basic and applied research involving animals, which results in important scientific advances that benefit the health and well-being of animals and humans. One area of significant interest and expertise among COGR member institutions is ensuring that research using animals is conducted in a manner that ensures proper protections for animal health, safety, and welfare, while reducing unnecessary burden on researchers and research institutions.

COGR appreciates the opportunity afforded by the U.S. Department of Agriculture Animal and Plant Health Inspection Service (USDA APHIS) to comment on the above-captioned advance notice of proposed rulemaking published on January 9, 2023 (ANPRM). The ANPRM addresses an unusual combination of matters: (a) handling of wild and exotic animals during public exhibition by Class C (exhibitor) Licensees, including training requirements for handlers and (b) environmental enrichment for animal species subject to the Animal Welfare Act (AWA) held by any USDA APHIS licensee or registrant, including research facilities under [9 CFR Part 2, Subpart C](#). We deeply appreciate the importance of ensuring that exhibitors of wild and exotic animals properly handle these animals, particularly during public exhibitions. However, given that our member institutions' expertise concerns research, we are confining our comments to the "Environmental Enrichment for Animals" portion of the NPRM, which will directly impact

registered research institutions. Our comments are organized as follows: (a) general comments on environmental enrichment for all species of animals encompassed by the AWA; and (b) comments in response to the specific questions listed in the ANPRM.

### **General Comments**

COGR's member institutions take very seriously their obligations to protect the health, safety, and welfare of the research animals in their care. Research animals are an essential component of scientific efforts to understand and improve human and animal health and well-being, and we appreciate the importance of actions taken to promote the psychological and social well-being of animals. Indeed, many research institutions already include within their animal care and use programs environmental enrichment for multiple species that are not encompassed under current AWA enrichment requirements. Accordingly, we support USDA APHIS' efforts to develop enrichment standards for additional animal species, but urge USDA APHIS to ensure that any adopted standards meet the following core criteria:

- Standards are based on robust scientific evidence that demonstrates actual benefit to the animal species they encompass and avoid anthropomorphic approaches.
- Standards supply Institutional Animal Care and Use Committees (IACUCs) with sufficient latitude to permit exceptions to enrichment requirements when necessary to conduct specific scientific protocols (e.g., protocols involving stress models) or when it is deemed more appropriate for the welfare of specific animals.
- Standards are structured as performance standards that provide institutional animal care and use programs with sufficient implementation flexibility.

Employing these criteria is essential to developing environmental enrichment standards that provide substantive benefit to the animals involved in research activities, and our specific comments include further discussion of their importance.

Additionally, we also note that enrichment strategies are not necessarily risk free. For example, increasing animals' social contact may lead to an increase in both positive and non-positive animal interactions (e.g., socially aggressive behavior) that may result in injury, just as in the animal's native habitat. Any enrichment standards that USDA APHIS promulgates must take account of such risks, and the agency should not automatically label enrichment-related incidents as being non-compliant with the AWA.

### **Specific Comments**

Below, we include our comments in response to the specific questions listed in the ANPRM. In some cases, a single response addresses multiple questions.

#### **Response to Questions Regarding Specific Types of Environmental Enrichments**

- *What, if any, general environmental enrichments should be required for all species?*
- *What environmental enrichments addressing psychological needs should be required for social species (in general or for particular species)?*
- *What environmental enrichments addressing natural feeding, foraging, and food acquisition behaviors should be required for animals in general, for certain taxa of animals, or for particular species?*
- *What environmental enrichments addressing enclosure space, lighting, and design to allow for species-typical behaviors should be required for animals in general, for certain taxa of animals, or for particular species?*
- *Are there other components or types of environmental enrichments we should consider when developing environmental enrichment requirements for certain taxa of animals or for particular species?*

There are numerous social species of animals, each with unique characteristics that shape the type of environmental enrichment efforts that beneficially address the animals' psychological and physical needs (e.g., lighting, space, feeding). We appreciate that enrichment standards will need to address the items noted in the foregoing questions, however, we firmly believe that all standards should be data-driven, as opposed to being supported only anecdotally or being the product of over-generalization across multiple species. Accordingly, we encourage USDA APHIS to first seek input on the following two fundamental questions, which must be addressed to properly evaluate any input on specific enrichment standards, or components thereof:

- What type and level of scientific data should be required to support any enrichment standard?
- What type and level of scientific data is required to support applying an enrichment standard across one or more genera of animals as opposed to tailoring the standard to a specific species of animal?

The evidentiary standards that result from analyzing these two questions should be used to frame the discussion regarding the development of enrichment standards. For instance, will data from controlled studies be required to support a standard, or is observational data adequate? Will data from animal preference testing at individual research institutions be permitted to shape practices at the local level or will there be a generalized set of requirements? Answers to these and similar questions are essential to ensure that any environmental enrichment standard is supported by robust scientific data.

- *If we choose to require a written plan, what specific requirements should the attending veterinarian consider when reviewing and/or approving the written plan?*

In the research context it is important for USDA APHIS to provide adequate flexibility to researchers, the IACUC, and the Attending Veterinarian to consider the aims and needs of the research protocol when developing and/or evaluating a written enrichment plan. In some cases, a scientific protocol may require a certain level of animal stress (e.g., inflammatory response

models), while in other protocols, certain types of enrichment may be inappropriate because they are not compatible with research interventions (e.g., group housing immediately following a research-required surgical procedure). Accordingly, specifications for written plans must include provisions for accommodating research requirements as well as specific animal (individual or group) needs and behavioral patterns. This flexibility must include latitude regarding the specificity and details of the plans. For example, a facility may develop a general written plan for a given species that it then augments with a more specific plan directed to animals in a particular research project or to the needs of an individual animal.

- ***If environmental enrichment requirements were presented as performance standards, what guidance could APHIS provide to assist licensees and registrants to meet the performance standards?***

As an initial point, USDA APHIS should ensure that any environmental enrichment standards are presented as performance-based standards. As the [\*Guide for Care and Use of Laboratory Animals\*](#) states, a performance standard describes a desired outcome, but “provides flexibility in achieving this outcome by granting discretion to those responsible for managing the animal care and use program, the researcher, and the IACUC” and can be an advantageous approach that “accommodate[s] the consideration of many variables (such as the species and previous history of the animals, facilities, staff, expertise and research goals).”<sup>1</sup> Given the tremendous variability in both animal species and research protocols to which enrichment standards will apply, the use of performance standards, as opposed to engineering standards, is critical to facilitating the incorporation of the standards within the research environment. Further, any guidance issued concerning performance standards must be tailored to the environment in which the guidance will be applied (e.g., exhibition v. research), and highlight flexibility that can be employed to address unique environmental and species characteristics. This holds particularly true for research environments where consideration must be given to how best to achieve scientific goals. Thus, guidance on enrichment standards in the research arena should afford maximum flexibility to IACUCs and attending veterinarians in their application.

- ***What direct costs may be associated with providing environment enrichment for the potentially affected animals in each category?***

Additional direct costs that research institutions will incur in providing environmental enrichment encompass a wide-range of costs including those associated with training of personnel on regulatory requirements, personnel time required to develop and implement enrichment strategies, and associated facilities, equipment, and materials. For example, if a written enrichment plan is required to be submitted to the IACUC for review along with each research protocol, costs will be associated with researcher development of the plan and IACUC and attending veterinarian review of the plan. Further, specific consultant expertise may be required to develop enrichment strategies for certain species of animals. After the plan is approved, costs associated with providing specific

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<sup>1</sup> National Research Council of the National Academies (8<sup>th</sup> ed.) (2011) at p. 6-7.

animal living space size/build-out and equipment will be incurred, along with the costs of any materials associated with the enrichment plan (e.g., special cage construction to facilitate social housing, toys or other enrichment devices, nesting material, food for encourage foraging behaviors, etc.) Importantly, staff time (both research and animal care) costs associated with monitoring and evaluating the success of the enrichment strategy, as well as making any necessary changes, also must be considered.

Unsurprisingly, research institutions are concerned about how they will absorb the associated costs (direct and indirect), and their impact on research project budgets. In developing such standards USDA APHIS should include with the publication of proposed standards realistic cost estimates based on current national labor costs associated with animal care. These cost estimates would assist the institutions in budgeting and appropriately allocating costs to the research project. Further, research institutions already provide institutional subsidies to their animal care activities. As the cost of animal care activities increases, we encourage USDA APHIS to consider solutions that recognize and address the costs associated with implementing the proposed rule.

One important facet of cost concerns is the timing of standard implementation, both in terms of how the standards are promulgated, as well as the time that institutions will be allotted for coming into compliance with the new standards. We urge USDA APHIS to issue species-specific enrichment standards over time, as opposed to issuing all standards at the same time. Such a schedule would better enable institutions, particularly those with more limited resources, to absorb the additional time and expenses involved with implementation. Additionally, each standard that is promulgated should provide institutions with at least 12 months to come into compliance with the new standard.

**Conclusion:**

COGR and its member institutions recognize and appreciate their important partnership with USDA APHIS in promoting the health, safety and welfare of animals used in research and the important role that appropriate environmental enrichment can play in this endeavor. We trust that this ANPRM is just the beginning of a dialog with the regulated community about how best to develop species-specific environmental enrichment standards, and we look forward to continuing to work with USDA APHIS in this regard.

Should you have any questions about the comments set forth in this letter, please feel free to contact Kris West, COGR's Director for Research Ethics and Compliance at [kwest@cogr.edu](mailto:kwest@cogr.edu).

Sincerely,



Wendy D. Streit  
President